NO. 12-142

IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

ON WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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INTEREST OF THE AMICUS CURIAE[1]

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit corporation comprised of a broad range of American and international manufacturers; in addition, several hundred leading product liability defense lawyers are non-voting members.[2] PLAC seeks to develop and reform the law, with emphasis on product liability, so that it is fair and reasonable. To that end, PLAC submits amicus briefs in cases raising important legal issues to present the perspective of product manufacturers. PLAC's briefs have been accepted in over 975 cases, including in this Court.[3]

The jury verdict and district court judgment below found that a generic prescription drug manufactured by defendant was defectively designed under New Hampshire product liability law, and hence unlawfully marketed in the state, because the drug's risks exceeded its benefits. The court so found even though, pursuant to the Federal Food, Drug and

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[1] Pursuant to Supreme Court Rule 37.3(a), PLAC notes that all parties have consented to the filing of amicus briefs by letters of general consent filed with the Clerk. Pursuant to Supreme Court Rule 37.6, PLAC states that this brief was not authored, in whole or in part, by counsel for a party, and that no monetary contribution intended to fund the preparation or submission of this brief was made by any person or entity other than PLAC or its counsel.

[2] The corporate members of PLAC are listed in the Appendix to this brief.

[3] For example, PLAC submitted amicus briefs in *Wyeth v. Levine*, 555 U.S. 555 (2009), *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) and *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

Cosmetic Act ("FDCA"), the United States Food and Drug Administration ("FDA") had *approved* the drug for marketing in interstate commerce, finding the drug to be both "effective" and "safe," the latter because *the drug's benefits exceeded its risks*.

Because the FDCA forbids the marketing of new drugs unless they are approved by the FDA, and requires generic drugs to be the "same" in active ingredients and biological effect as the branded drug on which their approval is based, defendant would have been prohibited by the FDCA from changing its drug's design to meet New Hampshire law's requirements. The court of appeals rejected defendant's contention that this direct conflict with the FDCA preempted plaintiff's design defect claim, noting that defendant could lawfully have elected not to sell its drug in New Hampshire at all.

The court's radical conclusion is of great concern to PLAC members and their employees, shareholders and customers. Many PLAC members—which include manufacturers of branded and generic pharmaceuticals, medical and surgical devices, airplanes, automobiles, trucks, motorcycles, cigarettes and other tobacco products and alcoholic beverages, as well as oil and gas companies—are highly regulated by the federal government. Typically the applicable regulatory scheme involves a delicate balancing by an expert agency of the benefits of a product or activity against its costs and risks, and establishes federal requirements for selling or conducting the product or activity in interstate commerce. The notion that an individual state could *ban* a product or activity that is sold or conducted in a federally mandated fashion is contrary to prior decisions of this Court, would effectively eviscerate the

Supremacy Clause and would deprive consumers of innumerable beneficial products and services.

Moreover, the FDCA, like all federal statutory schemes, is motivated by certain Congressional objectives, in this case both to ensure that beneficial prescription drugs are freely available to patients and their physicians, and to lower the cost of healthcare by promoting the availability of inexpensive generic drugs. The product ban effected by the court of appeals' decision would deprive PLAC members' employees of the particular drug at issue here, and also subject PLAC's members or their employees to higher healthcare costs, which are likely in part also to be borne by shareholders and customers. State law bans of products or services governed by other federal regulatory schemes would equally frustrate important federal purposes.

STATEMENT OF THE CASE

The judgment below arises out of side effects suffered by plaintiff Karen L. Bartlett from use of the prescription drug sulindac. Sulindac was manufactured by defendant Mutual Pharmaceutical Company, Inc. ("Mutual") and is the generic form of the branded drug Clinoril®.[4]

[4] Chemically, sulindac is (Z)-5-fluoro-2-methyl-1-[[p-(methylsulfinyl)phenyl]methylene]-1H-indene-3-acetic acid. FDA, *Clinoril Labeling Revision* (Dec. 23, 2010) at 1, http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/017911s074lbl.pdf.

Prior to 1978, pursuant to the FDCA, Clinoril's sponsor submitted a "New Drug Application" ("NDA") to the FDA for approval to market Clinoril in interstate commerce. The NDA was required to contain extensive information about the drug's composition and manufacture, results of all pre-clinical and clinical studies and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product . . . received by the applicant from any source." 21 C.F.R. § 314.50(d)(5)(iv); 21 U.S.C. § 355(b)(1)(A). The application was also required to include a specific "discussion of why *the benefits exceed the risks* under the conditions stated in the labeling." 21 C.F.R. § 314.50(d)(5)(viii) (emphasis added); *see also* 21 C.F.R. § 314.50(c)(2)(ix).

The FDA approved Clinoril's NDA in 1978. *Drugs@FDA Database – CLINORIL Approval History* (FDA), http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails. By that approval, the agency determined that the drug was "*safe* for use under the conditions prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. § 355(d) (emphasis added).

The FDA's conclusion that Clinoril was "safe" did not mean that it was 100% safe. To the contrary, "[n]o drug is absolutely safe; all drugs have side effects." *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (FDA) ("Review Process"), http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last visited January 5, 2013); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 142 (2000) (noting that highly toxic drugs used in the treatment of various cancers are safe within the meaning of the FDCA "because,

for certain patients, the therapeutic benefits outweighs the risk of harm").[5]

Rather, by its safety determination the FDA concluded that the drug's *health benefits exceeded its risks*. 60 Fed. Reg. 39180 (1995) ("In evaluating . . . safety . . . FDA weighs the product's demonstrated effectiveness against its risks[,]. . . tak[ing] into account information such as the seriousness and outcome of the disease, the presence and adequacy of existing treatments, and adverse reaction and other safety data"); 71 Fed. Reg. 3934 (2006) ("the agency makes approval decisions based . . . on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling"); *United States v. Rutherford,* 442 U.S. 544, 555 (1979) (FDA considers drug safe when "expected therapeutic gain justifies the risk entailed by its use"); *Brown & Williamson*, 529 U.S. at 140 (same, citing *Rutherford*); *Review Process*, *supra* ("'Safe' in this sense means that the benefits of the drug appear to outweigh the known risks").

In 1987, pursuant to the Hatch-Waxman amendments to the FDCA, Mutual submitted an abbreviated NDA ("ANDA") to market sulindac as a generic form of Clinoril. *Drugs@FDA - Approval History of Mutual's 200 mg sulindac* (FDA) ("Mutual Approval History"), http://www.accessdata.fda.gov/

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[5] By definition, a prescription drug, due to its "toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for use *except* under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A) (emphasis added).

scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails. The ANDA was required to demonstrate that sulindac was the "same as" Clinoril in active ingredients, route of administration, dosage form, strength and conditions of use recommended in the label, 21 U.S.C. § 355(j)(2)(A), and by appropriate testing that sulindac was bio- and therapeutically equivalent to Clinoril, *id*. In 1991, FDA approved Mutual's ANDA. *Mutual Approval History*, *supra.*

Following Clinoril's and sulindac's respective approvals, their manufacturers were required to report to FDA all adverse events associated with the drugs' use, 21 C.F.R. § 314.80, and periodically submit any new information that might affect FDA's previous conclusions about the drugs' safety, effectiveness or labeling, 21 C.F.R. § 314.81. *See also* 21 U.S.C. § 355(k); Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, § 901, 121 Stat. 922 (enhancing FDA authority to require post-market clinical trials and surveillance). Although FDA is required to withdraw a drug's approval if it finds that "clinical or other experience, tests, or other scientific data show that such drug is unsafe for use," 21 U.S.C. § 355(e); *see also Brown & Williamson Tobacco Corp.*, 529 U.S. at 134, FDA had commenced no such proceeding for Clinoril or sulindac as of the time plaintiff was prescribed the drug in 2004, *see CLINORIL Approval History, supra; Mutual Approval History, supra.*[6]

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[6] Over time, FDA has approved many NSAIDs, including Motrin, Naprosyn, Celebrex, Toradol, Daypro and Relafen. *Clinoril® Medication Guide* at 2-3. As the agency has done this, it has not generally withdrawn approval for prior NSAIDs, as patients respond differently to different compounds and FDA believes patients should have a choice of therapies. However, if

At that time, sulindac was indicated by its FDA-approved label (under the FDCA, the "same" as Clinoril's label) for acute or long-term use in treating osteoarthritis, rheumatoid arthritis, acute gouty arthritis, ankylosing spondylitis and acute painful shoulder (acute subacromial bursitis/supraspinatus tendinitis). *Clinoril Labeling Revision, supra.* Physicians were, however, free to prescribe the drug for "off-label" uses in the exercise of their clinical judgment. *E.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 & n.5 (2001) (noting "off-label" use of prescription drugs and devices is lawful under FDCA and widely accepted).[7]

Plaintiff's physician prescribed sulindac to treat her shoulder pain. *Bartlett v. Mut. Pharm. Co.*, 760 F. Supp. 2d 220, 228 (D.N.H. 2011) As a result,

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significantly safer NSAIDs become available, FDA may require a heightened benefit to justify marketing: for example, the agency expressed the view in 2005 that Bextra should be withdrawn because it presented greater risks than other NSAIDs with comparable efficacy, and the manufacturer withdrew it. See *Alert for Healthcare Professionals, Valdecoxib (marketed as Bextra)* (FDA April 7, 2005), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124649.htm.

[7] Sulindac is one of many drugs classified as non-steroidal anti-inflammatory drugs ("NSAIDs"). *See* FDA, *Clinoril® (Sulindac) Medication Guide* (July 2010) at 1, http://www.fda.gov/downloads/Drugs/DrugSafety/ucm088573.pdf. Due to the prevalence of the painful conditions that these drugs treat, they are widely prescribed. Daniel H. Soloman, MD, MPH, "Nonselective NSAIDs: Overview of Adverse Effects," http://www.uptodate.com/contents/nonselective-nsaids-overview-of-adverse-effects (last visited on January 5, 2013) ("this class of drugs [is] one of the most commonly used in the world").

she suffered a severe dermatological side effect diagnosed as toxic epidermal necrolysis ("TEN") or Stevens-Johnson syndrome ("SJS").[8]

At trial, the jury found for plaintiff on her claim that sulindac was defectively designed. *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 44 (1st Cir. 2012). The verdict was premised on plaintiff's claim, and the jury's finding, that the drug was unreasonably dangerous because its risks, particularly of TEN/SJS, outweighed its benefits. *Id.* at 34-35.

On appeal, the First Circuit rejected Mutual's argument that plaintiff's design defect claim was preempted by the FDCA. The court concluded that this Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), established a general no-preemption rule under the FDCA that applied to design defect claims involving prescription drugs as well as the failure-to-warn claims at issue in that case. *Bartlett*, 678 F.3d at 38. The court also concluded that this Court's holding in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), that failure-to-warn claims involving generic drugs *were* preempted by the FDCA because the act required such drugs to use the "same" labeling as their branded equivalents, carved out a limited ex-

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[8] TEN/SJS is a serious and potentially fatal condition characterized by necrosis of the skin and mucous membranes. *See Dorland's Illustrated Medical Dictionary* 1872 (31st ed. 2007). TEN is diagnosed when 30 percent or more of the outer skin layer on a patient's total body surface area has deteriorated, been burned off or turned into an open wound. *Bartlett*, 678 F.3d at 34. The risk of TEN/SJS was described in sulindac's labeling at the time Ms. Bartlett was prescribed the drug. *Bartlett*, 760 F. Supp. 2d at 229 (noting that "sulindac's label expressly mentioned SJS/TEN in its list of potential adverse reactions").

ception to *Levine* that did not extend to design defect claims. *Id.* at 38. Although the court acknowledged that the FDCA prohibited Mutual from altering the design of its drug, the court concluded that Mutual could have avoided a conflict between federal and state law by choosing not to sell sulindac at all. *Id.* at 37.

SUMMARY OF THE ARGUMENT

Under the Supremacy Clause of art. VI, sec. 2 of the United States Constitution, a federal statute preempts state law where either compliance with both federal and state law is impossible, or where state law stands as an obstacle to accomplishing the full purposes and objectives of the federal statute. Plaintiff's design defect claim was preempted under *both* standards.

First, plaintiff's claim was preempted because it was impossible for Mutual to comply with both the FDCA and New Hampshire product liability law. New Hampshire law held sulindac's design to be defective, and thus required Mutual to change the design. Had Mutual done that, however, it would have violated the FDCA in two respects. The altered product would have been a new drug under the statute, so that Mutual could not lawfully have sold the drug because it lacked an approved NDA to do so. Moreover, as the manufacturer of a generic drug, Mutual could not lawfully change sulindac's design to differ from that of Clinoril, the branded drug on which sulindac's ANDA was based. Because Mutual thus could not "independently do under federal law what state law requires," plaintiff's claim was preempted under the standard set forth by this Court in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579 (2011).

The court of appeals suggested *Mensing* was not controlling because it applied only to generic drug failure-to-warn, not design defect, claims, and that otherwise this Court had established a broad rule against the preemption of pharmaceutical product liability claims in *Wyeth v. Levine*, 555 U.S. 555 (2009). *Wyeth* did no such thing, however; to the contrary, as the Court made clear by citing *Wyeth* for the very standard the Court used to decide *Mensing*, both cases were resolved by applying precisely the same preemption principles.

The court further suggested that, even though the FDCA forbade Mutual to change sulindac's design, there was no conflict between the statute and state law because Mutual could simply have elected not to sell the drug in New Hampshire at all. This Court, however, has never held, or even suggested, that there is no actual conflict between federal and state requirements concerning a product if its supplier may lawfully forebear from selling it. If this argument were valid, the Court would not have found preemption in various product-related cases in which it has previously done so, including both "impossibility" and express preemption cases. In any event, the Court in *Mensing* rejected an argument to avoid preemption that could "often" be made in conflict preemption cases, because "[w]e do not read the Supremacy Clause to permit an approach to preemption that renders conflict preemption all but meaningless." 131 S. Ct. at 2579. *A fortiori*, therefore, the court of appeals' argument is invalid, as it would apply in literally every case where federal law establishes requirements for a product and thus render the Supremacy Clause *entirely* meaningless.

Second, plaintiff's claim was preempted because New Hampshire's prohibition of the sale of

sulindac would stand as an obstacle to the accomplishment of *two* core FDCA objectives. One important FDCA objective is to assure that drugs that are "safe" and "effective" are made available (as promptly as possible) to patients and their physicians, and the FDA's finding that a drug is "safe" means it is a *net benefit to public health* because its therapeutic benefits exceed its risks. A second FDCA objective, at least since the 1984 Hatch-Waxman Amendments, is to lower the cost of health care by making less-expensive generic drugs available to compete with branded drugs.

The judgment below, however, would frustrate accomplishment of both objectives. Under the judgment, New Hampshire patients and physicians would not only be deprived of a drug that provides a net health benefit, thus *harming* public health, they would be deprived of such a drug that is low in cost. Plaintiff's state law claim is thus preempted under the Court's well-established "obstacle" preemption jurisprudence, including *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (preempting state law claim of fraud by not providing FDA with information purportedly required by FDCA, as this would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives").

Indeed, permitting a jury to ban a prescription drug by a risk-benefit finding that is directly contrary to that made by the FDA is an even starker conflict with federal law than in *Buckman*. Such a result is particularly inappropriate because the agency employs expert professionals to make the assessment based on all available scientific information about the drug's benefits and risks, while the jury is comprised of lay persons, hears only the evidence

counsel selects and focuses solely on the particular patient and adverse event at issue.

ARGUMENT

I. PLAINTIFF'S DESIGN DEFECT CLAIM CONFLICTS WITH THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND HENCE IS PREEMPTED

The Supremacy Clause of art. VI, sec. 2 of the United States Constitution provides that the "Constitution and the Laws of the United States which shall be made in Pursuance thereof; . . . shall be the Supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." As this Court has held, "under the Supremacy Clause, from which our pre-emption doctrine is derived, 'any state law, however clearly within a State's acknowledged power, which *interferes with or is contrary to* federal law, must yield.'" *Gade v. National Solid Waste Management Association*, 505 U.S. 88, 108 (1992) (citations omitted) (emphasis added).

When a federal statute is involved, preemption of conflicting state law "is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Gade*, 505 U.S. at 98 (citations omitted). State law conflicts where either "compliance with both federal and state [law] is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full pur-

poses and objectives of Congress." *Id.* [9] Here, plaintiff's design defect claim is preempted under *both* standards.

A. It Was Impossible for Mutual to Comply with Both the FDCA and New Hampshire Product Liability Law Regarding Sulindac's Design

1. New Hampshire Law Required Mutual to Alter Sulindac's Design, While the FDCA Forbade That

Plaintiff's claim was preempted because it was impossible for Mutual to comply with both the FDCA and New Hampshire product liability law regarding sulindac's design. As this Court held in *Mensing*, the test for "impossibility" preemption "is whether the private party could independently do under federal law what state law requires of it." 131 S. Ct. at 2579. Here Mutual could *not*.

Under the jury's verdict, sulindac was defectively designed, so Mutual could not lawfully sell the drug without changing its design. Were Mutual to

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[9] This Court has suggested that there may be a presumption against preemption at least in certain circumstances, but any such presumption "is *not* triggered when the State regulates in an area where there has been a history of significant federal presence." *United States v. Locke*, 529 U.S. 89, 108 (2000) (emphasis added). Pharmaceutical safety is precisely such an area, as federal regulation has been ongoing since 1848. Ch. 70, 9 Stat. 237 (1848); *see Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach,* 495 F.3d 695, 704-705 (D.C. Cir. 2007), *cert. denied* 128 S. Ct. 1069 (Jan. 14, 2008).

have done that, however, sale of the drug would have been unlawful under the FDCA in two separate respects.

First, had Mutual altered sulindac's design, the product would have been a new drug under the FDCA. 21 U.S.C. § 321(p)(1) (defining new drug to be any drug "the composition of which . . . is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof"); 21 C.F.R. § 310.3(h) (giving examples where FDA considers drug to be new, including because of "newness for drug use of any substance which composes such drug, in whole or in part"); *see Sprague v. Upjohn Co.*, 1995 WL 376934, at *2 (D. Mass. May 10, 1994) ("Halcion is a prescription drug, for which the only active . . . ingredient is the chemical compound [t]riazolam. . . . To alter the chemistry of the [t]riazolam molecule, would be to create a new compound."). Under those circumstances, Mutual could not lawfully have sold the drug, as it would have lacked an approved NDA to do so. 21 U.S.C. § 355(a) (unlawful to sell new drug without approved NDA).

Second, as the manufacturer of a generic drug, Mutual could not lawfully change sulindac's design so as to differ from that of the branded drug, Clinoril, on which sulindac's ANDA was based. To the contrary, the FDCA expressly requires that a generic drug be compositionally the "same as" the predicate branded drug in "active ingredients," and functionally "bioequivalent to" it. 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.127(a)(3) (dissimilar "active ingredients" will cause rejection of applica-

tion for approval of generic drugs); 21 C.F.R. § 314.127(a)(7).

For these reasons, plaintiff's design defect claim was preempted by the FDCA. Indeed, this conclusion is directly compelled by this Court's rationale in *Mensing*. In that case, plaintiffs had developed tardive dyskinesia after taking generic metoclopramide, and brought failure-to-warn claims under state law alleging that manufacturers of the generic drugs should have employed stronger warnings. *Mensing*, 131 S. Ct. at 2573. Defendants argued the claims were preempted by the FDCA's requirement that generic drugs' labeling be the "same" as that of the predicate branded drug. *Id.* In response, plaintiffs argued defendants could have (i) utilized FDA's "changes-being effected" ("CBE") regulations to unilaterally strengthen their warnings while simultaneously seeking FDA approval of the strengthening, (ii) used "Dear Doctor" letters to send additional warnings to healthcare professionals or (iii) at least asked FDA to require the branded manufacturer to strengthen *its* warnings, allowing (indeed requiring) defendant to follow suit. *Id.* at 2575-2578.

Analyzing the relevant statutory and regulatory language (including FDA's own interpretations), however, the Court held that the first two options were forbidden by the FDCA, under which all labeling of a generic drug, including the content of any "Dear Doctor" letter, must be "the same *at all times* as the corresponding brand-name drug labels," *i.e.,* there was "an ongoing federal duty of 'sameness.'" *Id.* at 2575, 2577-2578 (emphasis added).

As to the third option, the Court held the option would not allow defendant to "*independently* do

under federal law what state law requires," which was required to avoid preemption. *Id.* at 2579 (emphasis added). While seeking FDA assistance *might* eventually result in a stronger warning, allowing such a mere possibility to avoid preemption "would make most conflicts between state and federal law illusory[,]" because "[w]e can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it." *Id.* "If these conjectures suffice to prevent federal and state law from conflicting . . . , it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force. We do *not* read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless." *Id.* (emphasis added).

In short, because under the FDCA the defendant in *Mensing* could not independently have changed its warnings to satisfy its state law duty, plaintiff's claim was preempted. *Id.* at 2577-2578. In the present case, for the *two* FDCA reasons noted above, defendant Mutual could not lawfully have changed sulindac's design, a fact that the court of appeals itself acknowledged. *Bartlett*, 678 F.3d at 37 ("Mutual cannot legally make sulindac in another composition"). Having made this acknowledgment, the court erred in failing to hold plaintiff's claims preempted.[10]

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[10] Other courts have correctly followed *Mensing* to hold design defect claims against generic pharmaceutical manufacturers to be preempted. *E.g., Bartoli v. APP Pharms., Inc. (In re Pamidronate Prods. Liab. Litig.)*, 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012) ("the federal duty of 'sameness'" also applies in the context of generic drug design, and federal law preempts

state laws imposing a duty to change a drug's design on generic drug manufacturers"); *Frazier v. MYLAN Inc.*, 2012 U.S. Dist. LEXIS 183187, at *16-*19 (N.D. Ga. Dec. 18, 2012) (rejecting *Bartlett* and holding design defect claims preempted because "Mylan was not free to unilaterally pursue a safer alternative design of phenytoin to comply with state law while also being in compliance with federal law"); *Johnson v. Teva Pharms. USA, Inc.*, 2012 U.S. Dist. LEXIS 71384, at *12-*13 (W.D. La. May 21, 2012) (design defect claims preempted under *Mensing* because plaintiff "cannot show that an alternative drug design was available to the Generic Defendants"); *Lashley v. Pfizer, Inc.*, 2012 U.S. Dist. LEXIS 144060, at *6 (S.D. Miss. Oct. 1, 2012) (denying reconsideration of preemption of plaintiff's design defect claim because *Bartlett* "unpersuasive and not a proper basis for relief"); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 2011 U.S. Dist. LEXIS 135006, at *32 (D.N.J. Nov. 21, 2011) (applying *Mensing* to preempt defective design claim "because FDA requires generic Fosomax to have the same active ingredient as Fosamax"). Outside the pharmaceutical context, other "impossibility" preemption decisions of this Court also demonstrate the court of appeals' error in this case. *See, e.g., McDermott v. Wisconsin*, 228 U.S. 115, 133-134 (1913) (state law claim requiring food vendor to use state-specific label preempted because would cause product to be misbranded under federal Pure Food and Drug Act of 1906); *Hisquierdo v. Hisquierdo*, 439 U.S. 572, 590 (1979) (state community property law that expressly divided railroad retirement income in the case of divorce preempted because federal Railroad Retirement Act prohibited assignment of railroad retirement income); *Am. Tel. & Tel. Co. v. Centraloffice Tel.*, 524 U.S. 214 (1998) (state law breach of contract claims for failing to provide service options not in federally filed tariff preempted because claims "directly conflict" with Federal Communications Act limiting contract to terms of tariff).

2. If Accepted, the Court of Appeals' "Forebear from Selling" Argument Would Render the Supremacy Clause Meaningless

The court of appeals' initial justification for avoiding *Mensing*'s rationale was to assert that *Wyeth* established a broad no-preemption rule for pharmaceutical product liability claims, while *Mensing* established only a narrow exception for generic drug failure-to-warn claims into which this case did not fall. *Bartlett*, 678 F.3d at 37. But *Wyeth* established no such sweeping "rule"; rather, it applied to its facts precisely the same well-established "impossibility" preemption principles that the Court later applied in *Mensing*. *Wyeth*, 129 S. Ct. at 568-573.

Indeed, in *Mensing* the Court made explicit that it was applying the same standard in both cases, as the Court cited *Wyeth* itself for the governing principle that "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." 131 S. Ct. at 2579 (citing "*Wyeth*, 555 U.S. at 573"). The only reason for *Wyeth*'s no-preemption holding was that the FDA's CBE regulations *allowed* the branded manufacturer in that case unilaterally to strengthen its warnings (so long as it simultaneously applied for FDA approval) as required by state law. *Wyeth*, 129 S. Ct. at 1196-99 (citing 21 C.F.R. § 314.70(c)(6)(iii)(A), 21 C.F.R. § 314.70(c)(6)(iii)(C) (2004)). That holding is inapplicable here where the

relevant FDCA provisions and regulations forbade defendant unilaterally to change its drug's design.[11]

The court of appeals' ultimate rationale for finding no preemption in this case, however, was that there was simply no federal-state law conflict because "the decision to make the drug and market it in New Hampshire is wholly [Mutual's]," and Mutual "can choose not to make [or sell in New Hampshire] the drug at all." *Bartlett*, 678 F.3d at 37-38.[12] Certainly, this Court has never held—nor,

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[11] The Court in *Wyeth* foreshadowed how it would resolve the preemption issue in a pharmaceutical product liability case in which the defendant could *not* do under the FDCA what state product liability law required, noting that if there was "clear evidence" FDA would not have approved labeling changes required by state law, the Court *would* "conclude that it was impossible for [defendant] to comply with both federal and state requirements," *i.e.,* find preemption. 129 S. Ct. at 1198. Even before *Mensing*, therefore, lower courts had applied *Wyeth* to reach precisely this result when presented with a proper record. *E.g., Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010) (preempting claims that manufacturer should have adopted stronger warning: "The FDA decided not to require such a warning because it would confuse rather than inform; and a court cannot order a drug company to place on a label a warning if there is 'clear evidence' that the FDA would not approve it") (citing *Wyeth*); *Dobbs v. Wyeth Pharms.*, 797 F. Supp. 2d 1264, 1277 (W.D. Okla. 2011) (finding impossibility preemption of failure-to-warn claim based on clear evidence FDA would have rejected enhanced suicide warning).

[12] At some literal or theoretical level, such a course of action would not conflict with federal law because the FDCA does not affirmatively *require* Mutual to make sulindac or sell it in New Hampshire, so it would not be "impossible" for Mutual to comply with both federal and state law. But by prescribing the requirements for the sale of any drug in interstate commerce, the FDCA necessarily assumes that the drug *will*

to amicus' knowledge, has the Court even *suggested*—that there is not an actual conflict between federal and state requirements concerning a product if its supplier may lawfully forebear from selling it.

Moreover, if this obvious and literalist argument were valid, the Court would not have found "impossibility" preemption in any of the product-related cases in which the Court *has* found such preemption. *E.g., McDermott v. Wisconsin*, 228 U.S. 115, 133-134 (1913) (where state law required labeling of maple syrup in manner that federal law prohibited, retail merchants could not comply with both federal and state law and hence state law was preempted); *Mensing,* 131 S. Ct. at 2577 (where state product liability law required warnings for generic drug which federal law prohibited, manufacturer could not comply with both federal and state law and hence state law claim was preempted).

Indeed, if accepted, the argument would also reverse the holdings of various *express* preemption cases involving products that are subject to federal requirements. *See, e.g., Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-524 (1992) (state law claim requiring additional health warnings on cigarette packages preempted by Federal Cigarette Labeling and Advertising Act imposing federal warning requirements and expressly preempting any state law "requirement or prohibition based on smoking and

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indeed be so sold; moreover, this is so with respect to any other product or activity the sale or conduct of which is subject to federal requirements. In any event, as discussed in the text, this Court has made clear that such a sweeping literalist argument cannot be permitted effectively to nullify the Supremacy Clause.

health . . . with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act"); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) (state law negligence and strict liability claims preempted by FDCA's Medical Device Amendments imposing requirements on approved medical devices and expressly preempting states from imposing "any requirement . . . different from, or in addition to any requirement under [FDCA]").

In any event, the invalidity of the "forebear from sale" argument under the Supremacy Clause follows *a fortiori* from *Mensing*. There the Court held that the argument that defendant *might* ultimately be able with government or third-party assistance to accomplish lawfully under federal law what state law required did not defeat preemption. As the Court noted, such an argument could "often" be made in conflict preemption cases, and "[w]e do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless." 131 S. Ct. at 2579.

In contrast to the "possibility" argument, the "forebear from sale" argument adopted by the court of appeals would avoid preemption in literally *every* case involving conflicting federal and state requirements concerning the sale of a product, or the conduct of other activities, in commerce. The argument would thus render conflict preemption not merely "all but meaningless," but entirely so. The lower court's acceptance of the argument was error.[13]

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[13] Various other courts have so realized. *E.g., In re Darvocet, Darvon & Propoxyphene Products Liability Litigation*, 2012 WL 718618, at *3 (E.D. Ky. March 5, 2011) ("[T]he

B. New Hampshire's Prohibition of the Sale of Sulindac Frustrated Two FDCA Objectives—Making Beneficial Drugs Available to Patients and Their Physicians, and Lowering the Cost of Prescription Drugs

If for some reason—contrary to the arguments set forth above—the Court were to find no "impossibility" preemption because Mutual could have cho-

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idea that [the manufacturer] should have simply stopped selling [the drug] is an oversimplified solution that could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct altogether."); *Jacobsen v. Wyeth*, LLC, 2012 U.S. Dist. LEXIS 116887, at *33 (E.D. La. Aug. 20, 2012) ("If state law could require a generic drug manufacturer to wholly withdraw from the market based on the unreasonable danger of the product (which is all a successful failure to withdraw from the market claim could be), it necessarily must repudiate the label approved by the FDA.")(citation omitted); *Aucoin v. Amneal Pharms., LLC*, CCH Prod. Liab. Rep. P18,891, at *30 (E.D. La. July 20, 2012) (same); *Eckhardt v. Qualitest Pharms., Inc.*, 858 F. Supp. 2d 792, 801 (S.D. Tex. 2012) ("a state law requirement that the drug be completely withdrawn from the market, based solely on a theory that the federally mandated label was inadequate, would also impermissibly conflict with federal law and be preempted"); *In re Fosamax*, 2011 U.S. Dist. LEXIS 135006 at *36 n.5 (D.N.J. Nov. 21, 2011) ("To accept Plaintiffs' argument that Generic Defendants could have simply stopped marketing alendronate sodium, this Court would have to directly contravene binding law."); *Coney v. Mylan Pharms. Inc.*, CCH Prod. Liab. Rep. P18,778, at *12-*13 (S.D. Ga. Jan. 19, 2012) (rejecting argument that Mylan could have simply chosen to take phenytoin off the market because "[f]inding that state law prohibits Mylan from doing what federal law explicitly requires Mylan to do would be tantamount to conferring supremacy upon the state law").

sen not to sell sulindac in New Hampshire, the Court would still be required to find "obstacle" preemption. Under these circumstances, New Hampshire's prohibition of the sale of sulindac would stand as an obstacle to the accomplishment of *two* core Congressional objectives under the FDCA—ensuring that beneficial drugs are available to patients and their physicians, and lowering the cost of prescription drugs.

One primary statutory objective of the FDCA is to assure that safe and effective drugs are made available to patients and their physicians, and indeed that this occurs *promptly*. Hence the statute commands that the FDA "shall" approve an NDA or ANDA within 180 days unless the agency finds the drug has not been shown to meet the statutory conditions for approval, including safety and efficacy for a new drug or sameness for a generic one. 21 U.S.C. § 355(c)(1) (NDA), 21 U.S.C. § 355(j)(5)(a) (ANDA); *see also* 21 U.S.C. § 393(b)(1) (commanding FDA to "promptly and efficiently review[] clinical research and tak[e] appropriate action on the marketing of regulated products in a timely manner").

Moreover, as noted earlier, the FDA's finding that a drug has been shown to be "safe" means that the drug is a *net benefit to public health*, *i.e.,* that its benefits in the form of disease prevention, cure or mitigation exceed its risks in the form of adverse effects. 60 Fed. Reg. 39180; 71 Fed. Reg. 3934; *Rutherford,* 442 U.S. at 555; *Brown & Williamson*, 529 U.S. at 140, 142.[14]

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[14] Congress has explicitly recognized that the FDA's role in approving drugs for sale in commerce is a matter of "public health." *See, e.g.,* 21 U.S.C. § 393(b)(2)(B) (defining

In addition, and as this Court has already recognized, a second core objective of the FDCA, at least since enactment of the 1984 Hatch-Waxman Amendments,[15] is to lower the cost of health care by making less-expensive generic drugs available to compete with branded drugs. H.R. Rep. No. 98-857, pt. 1, p. 14 (1984) (describing amendments' purpose as to "make available more low cost generic drugs by establishing a generic drug approval procedure"); *Mensing*, 131 S. Ct. at 2574, 2582 (noting that ANDA process "allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug," and hence "allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public").[16]

In the present case, the judgment below—to the effect that generic sulindac cannot lawfully be

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FDA's mission as, in part, to "protect the public health by ensuring that . . . drugs are safe and effective"), 21 U.S.C. § 393(b)(1) (commanding FDA to "promote the public health" by taking prompt action on drug marketing).

[15] The amendments are more formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

[16] Other courts, including the court of appeals itself, have recognized this essential Congressional purpose. *Accord In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (purpose of Hatch-Waxman Amendments is "to get generic drugs into the hands of patients at reasonable prices—fast"); *Bartlett*, 678 F.3d at 37 ("There is no doubt that Congress wanted to reduce medical costs by spurring generic copycat drugs, and accordingly generic manufacturers do not, after patent protection lapses, need separate FDA approval to manufacture approved drugs or employ their approved label.").

sold in New Hampshire because the drug is unreasonably dangerous in design—interferes with the accomplishment of *both* of these core FDCA objectives. That is, by this judgment New Hampshire patients and physicians are not only deprived of a drug the FDA has found to be safe and effective, they are deprived of such a drug that is low in cost.

For these dual reasons, therefore, plaintiff's state law claim conflicts with the FDCA and is impliedly preempted. *See, e.g., Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 879, 881 (2000) (state law design defect claim mandating use of airbag in automobile impliedly preempted by National Traffic and Motor Vehicle Safety Act, as claim was obstacle to purpose of regulations under statute which deliberately permitted marketplace to experiment with different passive restraint devices because "a mix of devices would help develop data on comparative effectiveness, would allow the industry time to overcome the safety problems and the high production costs associated with airbags, and would facilitate the development of alternative, cheaper, and safer passive restraint systems"); *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494-497 (1987) (state law nuisance claim regarding interstate pollution impliedly preempted by Clean Water Act because would "upset the balance of public and private interests so carefully addressed" by the statute); *Perez v. Campbell*, 402 U.S. 637, 653 (1971) (state law suspending drivers' licenses of individuals who failed to pay judgments arising from automobile accidents preempted as obstacle to federal bankruptcy statute's mandate of establishing uniform national standards for discharge of debts); *Nash v. Florida Industrial Commission*, 389 U.S. 235, 239-240 (1967) ("coercive" state law denying unemployment benefits

to individuals filing unfair labor practice charges with National Labor Relations Board preempted by National Labor Relations Act because law "frustrat[ed] the purpose of Congress to leave people free to make charges of unfair labor practices" under the statute).[17]

Indeed, the conflict with federal objectives here is similar to, but considerably more acute than, the conflict that led this Court to find implied preemption in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). There plaintiff sought to recover on a state law claim that defendant had committed fraud on the FDA—by withholding information about a medical device's actual intended uses—in seeking clearance to market the device as "substantially equivalent" to already marketed devices. *Id.* at 346-347. The Court noted that under the medical device provisions of the FDCA, "the FDA pursues difficult (and often competing) objectives," *id.* at 349, including ensuring that devices are "reasonably safe and effective," getting them "on the market within a relatively short period" and making

[17] Notably, this is not a case where federal law sets only a "minimum" standard for protecting public health, so that a "higher" standard under state law arguably would not frustrate the federal objectives. Rather, federal law has set an *optimal* standard, namely, that sulindac should be available because it provides a net public health benefit (and a low-cost one), so that a state law ban would create a public health *detriment* (and eliminate the low-cost product), achieving the precise opposite of the federal objectives. In addition, frustration of the federal objectives could not be avoided, even in a theoretical and literalist fashion, by Mutual's forbearing from selling sulindac. Rather, such forbearance would be directly to the contrary of the federal objectives of assuring the availability of beneficial, and low-cost, drugs to patients and physicians.

them available to patients and physicians, including for "'off-label' usage," *id*. at 350. The agency had authority to punish and deter fraud on itself, and "this authority is used by the Agency to achieve a somewhat delicate balance of [these] statutory objectives." *Id*. at 348.

Under these circumstances, the Court held that the state law claim would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives." *Id*. at 350. For example, permitting such claims "may" deter manufacturers from applying for approval of beneficial new devices, which "could" deprive patients of those devices both for approvable purposes as well as generally accepted off-label uses. *Id*. at 350-351. Alternatively, permitting the claims might cause applicants to include a deluge of information in applications, which in turn "could" cause delays in getting devices to market, thus "delay[ing] health care professionals' ability to prescribe appropriate off-label uses." *Id*. at 351.

In the present case, the FDA similarly engages in a "somewhat delicate balance of statutory objectives," *id*. at 348, including balancing risks against benefits in approving a drug for marketing. In so doing, the agency expressly found that sulindac as designed provides a net public benefit, because its benefits exceed its risks, so the drug *should* be available to patients and their physicians. The contrary New Hampshire rule not merely "may" or "could" achieve contrary results, *id*. at 350-351, it would indisputably do so, and the rule would not merely "*delay* health care professionals' ability to prescribe," *id*. at 351 (emphasis added), but definitively eliminate it.

Finally, permitting a lay jury applying state law to ban a prescription drug FDA has determined to be a public health benefit is *particularly* inappropriate given the disparate information and expertise available to the respective decision-makers. In approving Clinoril and then sulindac, the FDA had the benefit of a comprehensive NDA containing preclinical and clinical studies as well as all other available data relating to safety and effectiveness, 21 C.F.R. § 314.50, extensive post-marketing reports, 21 C.F.R. § 314.80(c)(2), 21 C.F.R. § 314.81(b)(2)(i), neutral outside expert advisory committees, 21 C.F.R. § 14.171, plus internal physician and scientist reviewers, and made a *prospective* determination of the benefit-risk ratio considering *all* potential users of the drug.

By contrast, and as this Court has noted in the similar context of medical device preemption, a jury making a risk-benefit decision in a tort lawsuit hears only the small subset of the available data that counsel elect to place before it, typically focuses only on the particular risk at issue in the case, generally has no expert members, hears only from partisan experts hired by the parties and decides the issue only in retrospect and in the context of a single patient who has suffered a particular side effect.[18] *See Riegel*, 552 U.S. at 324-326 (finding claims against medical device manufacturer expressly preempted; permitting claims would "disrupt the [FDCA's] regulatory scheme" because a jury inevitably focuses on risk to injured plaintiff and "is not concerned with [product's] benefits," while FDA's

[18] In this case, for example, the evidence focused almost exclusively on the risk of TEN/SJS.

risk-benefit determination considers interests of *all* potential users, including "those who would suffer *without* [the product]") (emphasis added).[19]

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[19] For all the above reasons, the lower courts have held state-law attempts to regulate the availability of prescription or over-the-counter drugs, and indeed to countermand the risk-benefit decisions of other federal agencies, to be impliedly preempted. *E.g., Autin v. Solvay Pharms., Inc.*, 05-2213, 2006 U.S. Dist. LEXIS 19507, at *11 (W.D. Tenn. Mar. 31, 2006) (negligence, warranty and other state law claims for selling non-FDA-approved drug without affirmative FDA finding drug was "generally recognized as safe and effective"—which, under FDCA, drug must be to be sold without approval—preempted because "court cannot usurp the FDA's power to evaluate the effectiveness of a drug or to approve a drug"); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011), *reconsideration denied*, 825 F. Supp.2d 661 (D. Md. 2012) (state law duty compelling generic manufacturers to stop production of drug that under federal law they have authority to produce "would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce"); *Robinson*, 651 F.3d at 869 (claims for selling over-the-counter drug without stronger warnings of prescription version preempted; "The decision whether to permit a drug to be sold over the counter rather than just by prescription is for the FDA. . . . The agency bases its decision on whether the drug is safe and effective for use without a doctor's permission . . . and it has decided not to require [that drug] be sold by prescription only."); *see also Farina v. Nokia, Inc.*, 625 F.3d 97, 126 (3d. Cir. 2010) (claims against cell phone manufacturers for injuries from radio frequency emissions preempted because in regulating emissions Federal Communications Commission weighs safety against efficiency and national uniformity; "[a]llowing juries to perform their own risk-utility analysis and second-guess the FCC's conclusion would disrupt the expert balancing underlying the federal scheme").

CONCLUSION

For all the foregoing reasons, amicus urges the Court to reverse the decision below.

Respectfully submitted,

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APPENDIX

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Corporate Members of the
Product Liability Advisory Council

as of 1/15/2013
Total: 99

3M
Altec, Inc.
Altria Client Services Inc.
Ansell Healthcare Products LLC
Astec Industries
Bayer Corporation
BIC Corporation
Biro Manufacturing Company, Inc.
BMW of North America, LLC
Boehringer Ingelheim Corporation
The Boeing Company
Bombardier Recreational Products, Inc.
BP America Inc.
Bridgestone Americas, Inc.
Brown-Forman Corporation
Caterpillar Inc.
CC Industries, Inc.
Chrysler Group LLC
Cirrus Design Corporation
Continental Tire the Americas LLC
Cooper Tire & Rubber Company
Crown Cork & Seal Company, Inc.
Crown Equipment Corporation
Daimler Trucks North America LLC
Deere & Company

The Dow Chemical Company
E.I. duPont de Nemours and Company
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, LLC
Exxon Mobil Corporation
FMC Corporation
Ford Motor Company
General Electric Company
General Motors LLC
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Harley-Davidson Motor Company
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Hyundai Motor America
Illinois Tool Works Inc.
Isuzu North America Corporation
Jaguar Land Rover North America, LLC
Jarden Corporation
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Merck & Co., Inc.
Meritor WABCO
Michelin North America, Inc.
Microsoft Corporation
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Mitsubishi Motors North America, Inc.
Mueller Water Products
Mutual Pharmaceutical Company, Inc.
Navistar, Inc.
Nissan North America, Inc.
Novartis Pharmaceuticals Corporation
PACCAR Inc.
Panasonic Corporation of North America
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The Sherwin-Williams Company
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St. Jude Medical, Inc.

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Teva Pharmaceuticals USA, Inc.
TK Holdings Inc.
The Toro Company
Toyota Motor Sales, USA, Inc.
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen Group of America, Inc.
Volvo Cars of North America, Inc.
Wal-Mart Stores, Inc.
Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.