Nos. 09-993, -1039, -1501

IN THE
Supreme Court of the United States

PLIVA, INC. ET AL., *Petitioners*,
v.
GLADYS MENSING, *Respondent*.

ACTAVIS ELIZABETH, LLC, *Petitioner,*
v.
GLADYS MENSING, *Respondent.*

ACTAVIS, INC., *Petitioner,*
v.
JULIE DEMAHY, *Respondent.*

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH AND EIGHTH CIRCUITS

BRIEF OF REP. HENRY A. WAXMAN AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS URGING AFFIRMANCE

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Dated: March 2, 2011

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INTEREST OF *AMICUS CURIAE*

Amicus curiae Rep. Henry A. Waxman is a Member of Congress with an important interest in this case.[1] Rep. Waxman is ranking Member of the House Committee on Energy and Commerce, which has principal responsibility for legislation and oversight in the areas of public health, consumer protection, and food and drug safety. Rep. Waxman is a committed advocate for consumer protection and was a co-author and leading sponsor of the statute at issue in this case, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Hatch-Waxman Amendments).

Rep. Waxman is proud of the benefits generated by the Hatch-Waxman Amendments for American consumers. In 1984, just 19 percent of the prescription drugs in the United States were generic.[2]

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[1] This brief has been filed with the written consent of the parties, which is on file with the Clerk of Court. Pursuant to Rule 37.6, *amicus* affirms that no counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *amicus* or his counsel, make a monetary contribution to the preparation or submission of this brief.

[2] Congressional Budget Office, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 1 (July 1998) (CBO Report).

Today, generic drugs account for 70 percent of the prescriptions filled in this country.[3] Generic drugs have played an important role in holding down national spending on prescription pharmaceuticals and have saved consumers many billions of dollars.[4] Research shows that, on average, the cost of a generic drug is 80 to 85% lower than the brand-name product.[5]

Amicus has an important perspective on the question presented. He is a strong supporter of the generic drug industry. This ongoing commitment does not, however, detract from his belief that in enacting the Hatch-Waxman Amendments, Congress did not intend to categorically preempt state-law failure-to-warn claims.

At bottom, this case presents a question of congressional intent. This Court has explained that "[t]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485 (1996) (citation and internal quotation marks omitted); *see also Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 516 (1992) (same). *Amicus* is uniquely situated to address the question of congressional intent at the center of this case.

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[3] Susan Okie, "Multinational Medicines-Ensuring Drug Quality in an Era of Global Manufacturing," 361 NEW ENG. J. MED. 737, 738 (2009).

[4] CBO Report at 1.

[5] Food and Drug Administration, "Facts and Myths About Generic Drugs," available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm.

Although *amicus* submits this brief in his individual capacity, his views are informed by his experiences as a Member of Congress.

SUMMARY OF ARGUMENT

The Hatch-Waxman Amendments do not categorically preempt state-law failure-to-warn claims. Such claims are generally consistent with the purposes of the Amendments -- to benefit consumers by bringing safe and effective low-cost generic drugs to market. Nothing in the legislative history of the Amendments manifests any congressional intent to abolish all state-law failure-to-warn remedies for injured consumers. Had Congress intended to take that momentous step, it would have issued a clear statement that state law was preempted. At its core, "[p]re-emption fundamentally is a question of congressional intent." *English v. General Elec. Co.*, 496 U.S. 72, 78 (1990). Congress did not intend to preempt all failure-to-warn claims involving generic drugs.

Nor would it be "physically impossible" for generic drug manufacturers to comply with federal law and their state-law duties. Although a generic drug label must be the same as its brand-name counterpart, there are other bases for imposing failure-to-warn liability on generic manufacturers. For example, generic drug makers have the same responsibility as brand-name manufacturers to inform the FDA of any new information about risks that may require a change in the labeling of their drugs. They can also request that the FDA send a "Dear Health Care Professional" letter or coordinate a campaign of such letters, in order to advise physicians and others of

newly available information. If generic manufacturers fail to take such steps, requiring them to pay damages under state law in a failure-to-warn case creates no inconsistency with federal law.

Categorical preemption of failure-to-warn claims would deprive consumers of generic drugs of a remedy available to consumers of brand-name drugs under *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), in which this Court held that state-law failure-to-warn claims against brand-name manufacturers are not preempted. Although there are important differences in the regulatory treatment of brand-name and generic drugs, this Court's reasoning in *Levine* militates against categorical preemption here. In particular, this Court's recognition of the longstanding coexistence of state tort remedies and federal regulation of prescription drugs demonstrates that the two systems are in general complementary.

Moreover, petitioners' position in this case would create the peculiar situation in which a plaintiff whose doctor prescribes a generic drug would be deprived of a remedy for a failure-to-warn claim, while under *Levine*, the same plaintiff would be able to bring a state-law claim if he or she had demanded a brand-name drug instead, or if the doctor had chosen to prescribe a brand-name drug without asking the patient. Congress did not intend that use of generic drugs would come at the price of losing a traditional compensatory tort remedy under state law. Given the fact that generic drugs now account for seven out of ten prescriptions filled in the United States, carving out an exception to *Levine* for generic drugs would dramatically weaken the force and reduce the scope of that decision and, at the same

time, leave millions of consumers without any ability to seek a remedy for their injuries.

ARGUMENT

This Court has made clear that a state tort claim is preempted if it is impossible for a defendant to satisfy both its state-law obligation and federal regulatory requirements. *Levine*, 129 S. Ct. at 1196. In addition, "[u]nder ordinary conflict preemption principles a state law that 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives' of a federal law is pre-empted." *Williamson v. Mazda Motor of America, Inc.*, No. 08-1314, slip op. at 5 (Feb. 23, 2011) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

In this case, holding a generic manufacturer liable on a failure-to-warn theory would not impermissibly frustrate the purposes of the Amendments. Nor is there a conflict between a generic manufacturer's duties under state law and the requirements of the Hatch-Waxman Amendments that would warrant a categorical preemption of failure-to-warn claims against generic drug manufacturers.

I. State-Law Failure-To-Warn Claims Are Consistent With The Purposes Of The Hatch-Waxman Amendments.

The Food, Drug and Cosmetics Act (FDCA) requires that manufacturers obtain premarket regulatory approval for all prescription pharmaceuticals before they are introduced into commerce. 21 U.S.C. § 355(a). Manufacturers of new drugs must submit a new drug application (NDA) to

the FDA. *Id.* at § 355(b). The FDA has codified the NDA regulations at 21 C.F.R. Part 314. An NDA must contain, *inter alia*, scientific data demonstrating the drug's effectiveness and safety for its intended use; a statement of the drug's components; and examples of proposed labeling for the drug. *See* 21 U.S.C. § 355; 21 C.F.R. § 314.105(b). "Before approving an NDA ... [the] FDA undertakes a detailed review of the proposed labeling, allowing only information for which there is a scientific basis to be included in the FDA-approved labeling." 73 Fed.Reg. 49603, 49604 (2008). The FDA will reject the proposed labeling if "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular." *See* 21 U.S.C. § 355; 21 C.F.R. § 314.105(b).

In 1984, Congress enacted the Hatch-Waxman Amendments to the FDCA, which established the federal regulatory framework governing generics.[6] The House Energy and Commerce Committee Report cited "the policy objective" of the bill as "getting *safe* and *effective* generic substitutes on the market as quickly as possible after the expiration of the patent." H. Rep. No. 98-857, pt. 2, 98th Cong. 2d sess. 9 (1984) (emphasis added). The sponsors of the Amendments also stressed the pro-consumer nature of the bill. Rep. Waxman explained:

> The public will benefit twice; by the further incentive for research and development for new, innovative drugs and by the immediate

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[6] *See* Gerald J. Mossinghoff, "Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process," 54 FOOD & DRUG L.J. 187 (1999).

> reduction in drug prices when a generic is on the market as a competitor.

130 Cong. Rec. 24430 (Sept. 6, 1984) (statement of Rep. Waxman). Sen. Hatch added:

> This is a good bill. *Without compromising the public safety or welfare in the least* it will significantly lower the price of off-patent drugs, by many times in some cases, through increased generic competition.

Id. at 15847 (June 12, 1984) (statement of Sen. Hatch) (emphasis added).

Under the Amendments, once a brand-name drug has been approved by FDA, any drug company may seek permission to market a generic version through a significantly simplified process, known as the abbreviated new drug application procedure, or ANDA. *See* 57 Fed.Reg. 17950, 17951 (1992). ANDA drugs must be the "same as" a name brand drug that has already been approved by the FDA as to active ingredients, route of administration, dosage form, strength, and conditions of use recommended in the labeling. 21 U.S.C. § 355(j)(2)(A)(iii). Generic drug manufacturers need not repeat the clinical work of their brand counter-parts, but instead must establish only the generic drug's bioequivalence with the name brand drug. *Id.* at § 355(j)(2)(A)(iv). The ANDA must also show that the "labeling proposed for the [generic] drug is the same as the labeling approved for" the brand-name drug. *Id.* at § 355(j)(2)(A)(v).[7]

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[7] The FDA permits certain minor differences in labeling between brand-name drugs and generics that are not at issue here. 21 CF.R. § 314.94(a)(8)(iv).

The ANDA process set forth in the Hatch-Waxman Amendments was premised on the idea that a generic pharmaceutical would be shown to be the *same as* the brand-name drug in every significant way — including the labeling. As the House Energy and Commerce Committee Report explained, "[g]eneric copies of any drugs may be approved if the generic is the same as the original drug or so similar that FDA has determined the differences do not require safety and effectiveness testing." H. Rep. No. 98-857, pt. 1, 98th Cong. 2d sess. 14-15 (1984). "[T]he focus of the bill is to provide the [FDA] with sufficient information to assure that the generic drug is the same as the listed drug that has previously been determined to be safe and effective." *Id.* at 21. "[A]n ANDA must contain adequate information to show that the proposed labeling for the generic drug is the same as that of the listed drug." *Id.* at 22.

The 27 years since the enactment of the Hatch-Waxman Amendments have proven the law to be a resounding and spectacular success. Generic medicines are now considered to be a critical component of quality health care and promoting the public health. They advance competition, which lowers drug prices. Lower drug prices reduce the nation's overall health care bill. Indeed, today, a remarkable 70 percent of prescriptions are filled with generic medicines – saving consumers and the federal and state governments tens of billions of dollars annually.[8] Most importantly, lower drug prices

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[8] Generic Pharmaceutical Association, ANNUAL REPORT: GENERICS. A STEADY COURSE IN A SEA OF CHANGE 2

translate into access to life-saving and life-enhancing drugs for many patients who might not otherwise be able to afford their medications.

The success of the Hatch-Waxman Amendments rests primarily with the law's core principle — the assurance of "sameness" between brand and generic drugs, which provides confidence to consumers that generics will be every bit as safe and effective as brand-name drugs. A key component of this "sameness" principle is that manufacturers of generic drugs will be held to the same high standards as brand-name drugs and that any violation of these standards can be addressed with an identical set of legal tools.

As a practical matter, Congress could not have intended it any other way. Consumers' legal rights would have to be protected in the same way regardless of which kind of drug they take. If not, their ability to seek redress in court would depend upon the type of medication that was prescribed, a choice many consumers are not given by either their health plan or their circumstances in life. Congress did not intend for consumers' rights to be categorically eliminated simply because they purchased a generic rather than a brand-name drug.

As a matter of policy, Congress also did not intend such an outcome. Nothing in the legislative history of the Amendments manifests any congressional intent to leave consumers of generics without any remedy in the event of injury.

(2010) (available at http://www.gphaonline.org/sites/default/files/ AnnualReport2010.pdf).

The fact that there is no express preemption provision in the Hatch-Waxman Amendments mirrors the primacy of this "sameness" principle. Congress recognized that the success of these Amendments would depend upon the extent to which consumers are confident that brand-name and generic drugs are the same and are treated the same. To take away an injured consumer's right to a state-law tort remedy simply because she happened unwittingly to take a generic rather than a brand-name drug would constitute an undoing of the very underpinning — the principle of sameness — on which the Amendments were built. This, in turn, would threaten the overall prospects for success of the legislation.

II. There Is No Conflict Between The Hatch-Waxman Amendments And State Law That Would Warrant a Categorical Preemption of Claims Against Generic Drug Manufacturers.

Petitioners have insisted that state-law tort liability for a generic drug manufacturer in a failure-to-warn case is categorically preempted because the manufacturer cannot comply with its labeling duties under both the Hatch-Waxman Amendments and state law. That argument sweeps too broadly. Although a generic drug label must be the same as its brand-name counterpart, there are other bases for imposing failure-to-warn liability on generic manufacturers.

For example, generic drug makers can and should — and, indeed, do — provide the FDA with any new information they obtain regarding safety hazards

associated with their products, just as brand-name manufacturers do.[9] If a generic manufacturer fails to inform the FDA of such new developments, requiring it to pay damages under state law in a failure-to-warn case creates no inconsistency with federal law and is not preempted.

This is especially true given the basic record-keeping and reporting requirements with which both brand-name and generic manufacturers must comply.

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[9] At hearings on the Hatch-Waxman Amendments, representatives of the generic drug industry stressed that they were willing to keep FDA informed of the risks of their products. *See* New Drug Application: Hearings on H.R. 3605, The Drug Price Competition Act, House Committee on Energy & Commerce, Subcommittee on Health and the Environment, 98th Cong., 1st sess. 45 (July 15, 1983) ("I, too, would like to comment on this adverse reaction issue that was brought up. I can speak as a manufacturer and for two other generic companies in whose representatives are in attendance that are sensitive to the importance of looking at adverse reactions. We are sensitive and responsible. The generic manufacturers of today will respond to those needs. As far as I know we have not been remiss in that responsibility. If it demands a higher level of knowledge on our part we are prepared to meet and respond to the need.") (testimony of Kenneth N. Larsen, chairman of the Generic Pharmaceutical Industry Association); *id*. at 50-51 ("[G]eneric companies . . . also put our money into research. Every single generic drug company that I know has a large research staff. It not only researches the drug that they are copying, or bringing into the market but it researches new drugs, researches adverse reaction.") (testimony of Mark Haddad, member of the board of directors of the Generic Pharmaceutical Industry Association).

Both brand-name and generic manufacturers are statutorily required to keep records of clinical experiences and ensure that their products remain safe and effective as labeled. 21 U.S.C. § 355(k). FDA regulations mandate that all manufacturers record and report adverse events. 21 C.F.R. § 314.80(a) and (c) (brand-name manufacturers); *id.* at § 314.98(a) (generic manufacturers). Manufacturers must submit annual reports including, *inter alia*, a "summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product" and a "description of actions the applicant has taken or intends to take as a result of this new information." *Id.* at § 314.81(b)(2)(i).

In commentary accompanying the FDA's implementation of the Hatch-Waxman Amendments, the FDA stated:

> If an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.

57 Fed.Reg. 17950, 17961 cmt. 40 (Apr. 28, 1992).

A generic manufacturer that becomes aware of safety issues can also use a "Dear Health Care Professional" (DHCP) letter to warn physicians and

others of the risks associated with the drug. *See* 21 C.F.R. § 200.5 (setting standards for such letters). A generic manufacturer can take steps to work together with the FDA to ensure that such a letter is distributed to health care professionals. The manufacturer can request that the FDA send out a letter or that the agency otherwise coordinate a DHCP letter campaign.[10]

The responsibility of both the brand-name and generic drug manufacturers to alert the FDA to new safety hazards is a critical one, so that the agency can ensure that labels accurately reflect the most up-to-date information and can also ensure consistency between the treatment of brand-name drugs and their generic equivalents. As this Court noted in *Levine*, "risk information [regarding pharmaceuticals] accumulates over time and that the same data may take on a different meaning in light of subsequent developments." 129 S. Ct. at 1197. The Court further noted that "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." *Id*. at 1202.

To be sure, generic drug manufacturers do not conduct or replicate the full clinical trials necessary for the initial approval of a brand-name drug, nor are they expected to do so, because it could well prevent

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[10] DHCP letters are considered a form of "labeling" under the FDCA, 21 U.S.C. § 321(m), and therefore are subject to FDA review and regulation to ensure that they are not false or misleading. *See id.* at § 352(a); 21 C.F.R. § 201.100(d)(1); *id.* at § 314.150(b)(3).

them from bringing a lower-cost generic version to market. *See* H. Rep. No. 98-857, pt. 1, 98th Cong. 2d sess. 16 (1984). But generic manufacturers often receive important risk information once their drug is on the market, and they should be treated the same as brand-name manufacturers with respect to their responsibility to bring relevant data to the FDA's attention.

There is no conflict between federal law and state failure-to-warn liability of generic drug manufacturers that would warrant a categorical preemption of all claims against them. It is clear that a generic and a brand-name label must be the same and that a generic firm cannot unilaterally change its label. To permit individual generic drug labels to differ significantly from their brand-name counterparts—particularly with respect to safety information—would thwart the "sameness" goal reflected in the Hatch-Waxman Amendments. However, it is not only possible for a generic manufacturer in possession of important risk information to take steps to notify FDA that a labeling change may be necessary, but it is, in fact, also encouraged and recommended by FDA. Therefore, generic manufacturers can fulfill both federal and state law in this respect; indeed, it is essential that they do so to fulfill the Hatch-Waxman goals of ensuring drug safety and consumer protection.

III. This Court's Reasoning In *Wyeth v. Levine* Is Applicable To Generic Drugs.

In *Levine,* this Court held that the FDCA did not preempt state-law failure-to-warn claims against

brand-name manufacturers. The Hatch-Waxman Amendments and their legislative history confirm that this Court's reasoning in *Levine* can be applied in certain respects to suits involving generic drug makers as well. *Levine* recognized that drug manufacturers bear a key responsibility for collecting and transmitting information regarding the safe and effective use of their products. In fact, this Court found that multiple reports of adverse drug experiences provided the substantiation necessary to justify a request for a heightened warning. 129 S. Ct. at 1197.

This Court's reasoning in *Levine* is instructive. The Court began with the fundamental assumption, equally salient here, "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." 129 S. Ct. at 1194-95. This Court noted the longstanding coexistence of state tort remedies and federal regulation of prescription drugs:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, ... Congress has not enacted such a provision for prescription drugs.... Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the

> exclusive means of ensuring drug safety and effectiveness.

Id.

In particular, the Court explained that "failure-to-warn actions ... lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Id.* at 1202. Congress "determined that widely available state rights of action provided appropriate relief for injured [drug] consumers" and that "state-law remedies further consumer protection by motivating manufacturers ... to give adequate warnings." *Id*. at 1199-1200.

This Court observed that Congress and the FDA have viewed state tort law as complementing, not obstructing, the goals of the FDCA. "In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation." *Id*. at 1202.

Congress understands that state tort law is an indispensable partner to federal safety regulation. "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to 'stand by both concepts and to tolerate whatever tension there [is] between them.'" *Bonito Boats, Inc. v. Thunder Craft Boats, Inc*., 489 U.S. 141, 166-67 (1989) (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984)).

Indeed, in the 1962 amendments to the FDCA, Congress expressly limited the preemptive effect of the statute by stating:

> Nothing in the amendments made by this Act to the Federal Food, Drug and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provisions of State law.

Drug Amendments of 1962 (Harris-Kefauver Act), Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962). The plain language of this provision makes clear that the FDCA does not preempt state law in the absence of a "direct and positive" conflict. As this Court observed in *Levine*, "[a]s it enlarged the FDA's powers to 'protect the public health' and 'assure the safety, effectiveness, and reliability of drugs,' Congress took care to preserve state law." 129 S. Ct. at 1195-96 (internal citations omitted).

The Hatch-Waxman Amendments are part of this 70-year history and similarly do not categorically preempt failure-to-warn suits against generic manufacturers. There is no express preemption provision in the Amendments; rather, it is subject to the same saving provision enacted in 1962. If Congress had wished to depart from the usual rule governing other pharmaceuticals, it could have crafted a special preemption provision for generic drugs in its 1984 amendments. Congress is well aware of how to enact such special provisions. It did

so for medical devices in 1976,[11] for vaccines in 1986,[12] and for over-the-counter medications in 1997.[13]

In holding in *Bruesewitz v. Wyeth LLC*, No. 09-152 (Feb. 22, 2011), that the Vaccine Act of 1986 bars state-law design-defect claims against vaccine manufacturers, this Court reiterated that "we have previously expressed doubt that Congress would quietly preempt product-liability claims without providing a federal substitute." No. 09-152, slip op. at 16 (citing *Lohr*). In *Bruesewitz*, this Court observed that, in enacting the 1986 Vaccine Act, Congress deliberately departed from the regime applicable to pharmaceuticals and established a "no-fault compensation program 'designed to work faster and with greater ease than the civil tort system.'" *Id.* at 3 (citation omitted). In contrast, there is no similar no-fault compensation scheme available with respect to generic drugs, and no indication that Congress sought to displace traditional state-law tort remedies.

Establishing a categorical preemption of all state law claims against generic drug manufacturers would

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[11] *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (considering the effect of the express preemption provision of the Medical Device Amendments of 1976, 21 U.S.C. § 360(k)(a)).

[12] *Bruesewitz v. Wyeth LLC*, No. 09-152 (Feb. 22, 2011) (construing 42 U.S.C. §300aa-22(b)(1), enacted as part of the National Childhood Vaccine Injury Act of 1986).

[13] In 1997, Congress preempted certain state requirements concerning over-the-counter medications but expressly preserved product liability actions. *See* 21 U.S.C. §§ 379r(e), 379s(d).

create a dangerous asymmetry because it would make the availability of a compensatory tort remedy depend upon the fortuity of whether a patient receives a prescription for a name brand or generic drug. In enacting the Hatch-Waxman Amendments, Congress did not intend to create a categorical exemption from failure-to-warn liability for generic manufacturers.

CONCLUSION

The judgments below should be affirmed

Respectfully submitted,

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