CIVIL JUSTICE & NATIONAL ADVOCACY

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MEMORANDUM IN SUPPORT OF PROTECTING THE LEGAL RIGHTS OF GENERIC DRUG VICTIMS

Two recent state court decisions have restored the legal rights of patients harmed by generic drugs, whose rights were extinguished in 2011. Congress should protect those decisions.

Introduction and Summary

Since 2011, consumers who take generic drugs and are injured due to an unsafe, inaccurate or outdated label, have no recourse in court. Yet those injured by the brand-name version of the same drug have their full legal rights. This absurd and unfair result was caused by a U.S. Supreme Court decision, which could be corrected either by Congress or the Food and Drug Administration (FDA). However, as a result of industry lobbying pressure, neither Congress nor the FDA have done so, to date.

Now, high courts in two states – California and Massachusetts – have issued decisions based on state tort law, that rectify this gross injustice in ways that make legal and practical sense for residents in those states. However, there are indications that the drug industry may respond politically to these recent cases by pushing either federal legislation or a new federal rule to undermine them. These special interests may go so far as to push for a new federal liability scheme where no one – whether harmed by a generic or a brand-name drug – has any legal rights at all.[1]

We urge Congress to protect these state decisions by opposing any industry attempt to undermine them, whether by legislation or rule, or to interfere with the rights of any patient injured as a result of an unsafe, inaccurate or outdated drug label. Congress should give generic drug companies responsibility for maintaining safe and accurate labels, or consider codifying into national policy the holdings of these two state decisions.

Background on Federal Action

In 2011, in the case *PLIVA vs. Mensing*,[2] the U.S. Supreme Court immunized the generic drug industry from liability for injuries caused by a drug's unsafe warning label, even if the manufacturer knows that label to be inaccurate and out-of-date. The Court noted that FDA

[1] This is precisely what the industry lobbied the FDA to do in 2015. See, e.g., https://centerjd.org/content/comments-fda-generic-drugs-and-industry-proposal

[2] 131 U.S. 2567 (2011). See also, *Mutual Pharm. Co., Inc. v. Bartlett*, 133 U.S. 2466 (2013).

regulations specify that generic drug companies are responsible only for ensuring that their warning labels *are the same as the brand-name labels*.[3] The Court reasoned that since generic drug companies cannot independently change their warning labels, they cannot be responsible when the labels are inadequate.[4]

The result has been a two-tiered system of justice in America, succinctly described by Justice Sonia Sotomayor in her dissent in *PLIVA* when she said the decision would result in "so many absurd consequences that I cannot fathom that Congress would have intended.…" Specifically, "[a] drug consumer's right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic. If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings under our opinion in *Wyeth*. If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue."[5]

Federal legislation to correct the situation, which even the Court suggested was "bizarre,"[6] was immediately introduced but failed to gain momentum.[7] During the Obama Administration, the FDA tried to do the same with a new proposed rule establishing new safety responsibilities for generic drug companies.[8] However, the rule was never finalized and it is unlikely to be issued under the Trump Administration.

Recent State Court Decisions

Two recent state Supreme Court decisions have established a state tort remedy for patients injured by generic drugs in ways that make legal and practical sense for residents in those states.

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[3] 131 U.S. 2567, 2574 (2011).
[4] *Id.* at 2577-8.
[5] *Id.* at 2592 (Sotomayor, J. dissenting).
[6] "We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated. But 'it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre.'" *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581-2 (2011)(footnote omitted).
[7] *See, e.g.*, S. 2295, the "Patient Safety and Generic Labeling Improvement Act" (112th. Cong.) sponsored by Senator Patrick Leahy and seven other Senators, which would permit generic drug companies to change the labeling of a drug. *See also*, Office of U.S. Senator Patrick Leahy, "Leahy To Introduce Bill To Protect Consumers Who Take Generic Drugs," March 26, 2012, http://www.leahy.senate.gov/press/leahy-to-introduce-bill-to-protect-consumers-who-take-generic-drugs.
[8] On November 5, 2013, the FDA issued a proposed rule that addresses *PLIVA*. Noting that the Court found in *PLIVA* "that Federal law did not permit a generic drug manufacturer to … unilaterally strengthen warnings in its labeling or to issue additional warnings," and because "the difference between [brand-name and generic companies'] ability to independently change product labeling … leads to different outcomes on whether Federal labeling requirements preempt State law failure-to-warn claims," the proposed FDA rule would enable generic drug companies "to update product labeling promptly to reflect certain types of newly acquired information related to drug safety, irrespective of whether the revised labeling differs from" that of the brand-named drug. Under the rule, "when new information becomes available that causes information in labeling to be inaccurate" a generic company "must take steps to change the content of its labeling…." "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products," Federal Register Doc. 2013-26799, November 13, 2013, at 67986-8, http://www.gpo.gov/fdsys/pkg/FR-2013-11-13/pdf/2013-26799.pdf

In December 2017, in the case *TH v. Novartis*,[9] the California Supreme Court ruled that a brand-name drug company may be liable for injuries caused by an unsafe generic drug warning label. The ruling was grounded in the FDA's regulatory scheme, which provides that only a brand-name company – and not a generic company – has the power and authority to change a drug safety label.[10] As explained by Leslie Brueckner, counsel for the plaintiffs, "[w]riting for a unanimous Court on this point, Justice Cuellar held that, because generic manufacturers are 'required to follow the brand-name manufacturer's label to the letter,' a brand-name manufacturer 'owes a duty of reasonable care in ensuring that the label includes appropriate warnings, regardless of whether the end user has been dispensed the brand-name drug or the its generic equivalent.'"[11] In addition, the decision "gives consumers of generic drugs the right to seek justice for their injuries. It will also protect public health and safety, by giving brand-name manufacturers a strong incentive to update their labels when new risks emerge after their drugs go generic."[12]

Similarly, in *Rafferty v. Merck & Co Inc.*,[13] the Massachusetts Supreme Court ruled in March 2018 that brand-name drug companies can be sued for recklessness if they fail to update warning labels for their drugs that cheaper, generic versions must adopt as well. The court defended its decision against opponents, such as the U.S. Chamber of Commerce, reasoning that where a brand-name drug manufacturer provides an inadequate warning for its own product, it knows or should know that it puts at risk not only the users of its own product, but also the users of the generic product.

Noted Leslie Brueckner after the *Novartis* ruling, these cases not only provide important remedies for the vast majority of drug consumers whose rights were eliminated in 2011, but also they will "make America a much safer place." That's because the brand-name companies, and only the brand name companies, write the safety information that appears on both the brand-name and generic drug labels. If this information is outdated or incorrect, people will be hurt or killed. It is the "risk of tort liability [that] creates an incentive for drug companies to change their labels when new risks emerge.… [W]hen drug companies know they can't be sued for negligent misrepresentation, all bets are off. Unless there's a risk of liability in the courts, there's little incentive for drug companies like Novartis to change their labels to warn of newly discovered risks. Today's decision creates that much-needed incentive and, as a result, drugs will be much safer for everyone."[14]

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[9] http://www.courts.ca.gov/opinions/documents/S233898.PDF

[10] The court also ruled that if the brand-name drug manufacturer's failure to update its label foreseeably and proximately caused physical injury, the brand-name manufacturer's liability does not automatically terminate when the manufacturer transfers its rights in the drug to another enterprise, in this case a "fly-by-night" company.

[11] https://www.publicjustice.net/public-justice-wins-huge-ruling-behalf-generic-drug-victims-california-supreme-court/

[12] Ibid.

[13] https://law.justia.com/cases/massachusetts/supreme-court/2018/sjc-12347.html

[14] https://www.publicjustice.net/public-justice-wins-huge-ruling-behalf-generic-drug-victims-california-supreme-court/

Stakeholder Reaction

Not surprisingly, the drug industry, which generally seeks minimal responsibility and liability exposure, reacted negatively to these decisions. On February 9, 2018 – less than two months after the *Novartis* ruling - the conservative Congressional Civil Justice Academy at George Mason University's law school, signaled the industry's possible political response by holding a Senate event,[15] featuring Leslie Brueckner and attorney Phil Goldberg of Shook Hardy & Bacon, which represents the drug industry in its "tort reform" lobbying practice.[16]

Goldberg suggested, among other things, that the federal government (the FDA) should take care of all drug safety problems, and that state tort rights for injured drug consumers should essentially be eliminated, providing the entire pharmaceutical industry with immunity. This is similar to the drug industry's 2015 response to the Obama Administration FDA proposed rule, when it argued that brand and generic companies should be permitted to escape responsibility for independently fixing labels even if they know the labels are inaccurate or out-of-date, placing exclusive safety responsibility on the FDA. That would mean no injured person – whether harmed by a generic or a brand-name drug label – would have any legal rights to hold a company accountable in court, or obtain compensation for injuries.[17] That position was strongly opposed by a large number of consumer, patient safety and legal organizations not to mention members of the public and individual victims who have suffered as a result of unsafe drugs.[18]

Goldberg and the industry's position also stands in stark contrast to other U.S. Supreme Court rulings, including the 2009 case *Wyeth v. Levine* where the Court ruled that brand-name drug companies should not be immune from liability for injuring or killing patients.[19] The Court explained that the "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 post-marketing phase as new risks emerge,"[20] and the "FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation."[21] Further, in terms of state tort law, the Court said that "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly"[22] and that such suits "serve a distinct compensatory function that may motivate injured persons to come forward with information."[23]

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[15] http://masonlec.org/events/inventing-new-liability-who-should-we-blame-when-generic-drugs-harm-patients/
[16] https://www.shb.com/services/practices/public-policy
[17] *See, e.g.,* https://centerjd.org/content/comments-fda-generic-drugs-and-industry-proposal
[18] *See, e.g.,* https://www.regulations.gov/contentStreamer?documentId=FDA-2013-N-0500-0116&attachmentNumber=1&contentType=pdf; https://www.regulations.gov/contentStreamer?documentId=FDA-2013-N-0500-0115&attachmentNumber=1&contentType=pdf; https://www.regulations.gov/contentStreamer?documentId=FDA-2013-N-0500-0128&attachmentNumber=1&contentType=pdf; https://centerjd.org/content/comments-fda-generic-drugs-and-industry-proposal; https://www.regulations.gov/document?D=FDA-2013-N-0500-0131
[19] *Wyeth v. Levine*, 555 U.S. 555 (2009).
[20] *Id.* at 578-9 (footnote omitted).
[21] *Id.* at 579 (footnote omitted).
[22] *Id.* at 579.
[23] *Ibid.*

What Congress Should Do

There are several approaches Congress should consider to protect the state tort rights of generic drug consumers. First, it should reconsider the "Patient Safety and Generic Labeling Improvement Act" sponsored in 2012 by Senator Patrick Leahy, which would permit generic drug companies to change the labeling of a drug.[24] This would allow harmed consumers to hold generic drug companies accountable for failures to make safety changes. Second, it should oppose on any legislation, or movement by the FDA, to allow the brand and generic companies to escape responsibility to independently fix labels they later find are unsafe, inaccurate or out-of-date. Finally, Congress could consider affirmative legislation to codify the two the recent state Supreme Court holdings, by ensuring the state tort rights are not preempted by federal law.[25]

For more information, please contact student Allyson Balcolm or Joanne Doroshow, Adjunct Professor and Executive Director of the Center for Justice & Democracy at New York Law School, joanned@centerjd.org.

[24] *See*, Office of U.S. Senator Patrick Leahy, "Leahy To Introduce Bill To Protect Consumers Who Take Generic Drugs," March 26, 2012, http://www.leahy.senate.gov/press/leahy-to-introduce-bill-to-protect-consumers-who-take-generic-drugs.

[25] Legislation might specify, for example, that until the FDA withdraws approval of a "new drug application" (NDA), nothing shall preempt liability of the NDA holder for a claim under common law or under a State statute authorizing a civil remedy for damages or other monetary relief, provided the basis for the claim (the injuries) arose during the life of the NDA.