No. 17-3030

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

WENDY B. DOLIN, Individually and as Independent Executor of the Estate of STEWART DOLIN, Deceased,

Plaintiff-Appellee,

v.

GLAXOSMITHKLINE, LLC, Formerly Known as SMITHKLINE BEECHAM CORPORATION,

Defendant-Appellant.

On Appeal from the United States District Court for the Northern District of Illinois
No. 12-cv-6403
The Honorable William T. Hart

BRIEF OF AMICI CURIAE AARP and AARP FOUNDATION IN SUPPORT OF PLAINTIFF-APPELLEE URGING AFFIRMANCE

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February 28, 2018

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Appellate Court No: 17-3030

Short Caption: Dolin v. GlaxoSmithKline LLC

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Attorney's Signature: s/ Mary Ellen Signorille Date: 2/26/2018

Attorney's Printed Name: Mary Ellen Signorille

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** X **No** ____

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None

Attorney's Signature: s/ William Alvarado Rivera Date: 2/28/2018

Attorney's Printed Name: William Alvarado Rivera

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ____ **No** X

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STATEMENT OF INTEREST[1]

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans 50 and older to choose how they live as they age. With nearly 38 million members and offices in every state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, AARP works to strengthen communities and advocate for what matters most to families, with a focus on health security, financial stability, and personal fulfillment. AARP's charitable affiliate, AARP Foundation, works to ensure that low-income older adults have nutritious food, affordable housing, a steady income, and strong and sustaining bonds. Among other things, AARP and AARP Foundation advocate for access to safe and affordable health care services, prescription drugs, and medical devices. *E.g.*, Brief of AARP et al. as Amici Curiae in Support of Respondent, *Wyeth v. Levine*, 555 U.S. 555 (2009) (No. 06-1249), 2008 U.S. S. Ct. Briefs LEXIS 705 (Aug. 14, 2008) (hereinafter "Wyeth Brief"); Brief of AARP as Amici Curiae in Support of Respondent, *T.H. v. Novartis*, 2016 Cal. LEXIS 9622 (Cal. Dec. 16, 2016) (No. S233898), 2016 CA S. Ct. Briefs LEXIS 3817; Brief of AARP as Amici Curiae in

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), amici state that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici, it members, or it counsel made a monetary contribution to the preparation or submission of this brief. The parties have consented to the filing of this brief.

Support of Respondent, *McNair v. Johnson & Johnson,* 2017 U.S. App. LEXIS 9367 (4th Cir. May 30, 2017) (No. 15-1806), https://www.aarp.org/content/dam/aarp/aarp_foundation/litigation/pdf-beg-02-01-2016/mcnair-v-johnson-johnson.pdf. Access to safe prescription drugs is particularly important to older adults because they have the higher rates of chronic health conditions and the highest rates of prescription drug use. National Center for Health Statistics, *Health, United States, 2015: With Special Feature on Racial and Ethnic Health Disparities* 168-69, 272-73 (May 2016), http://www.cdc.gov/nchs/data/hus/hus15.pdf.

AARP and AARP Foundation submit this brief because the jury verdict and district court's decision below correctly found that injured consumers can hold the brand name drug manufacturer accountable for the foreseeable consequences of its failure to warn consumers of known risks of the drug, when it had the duty and sole power to do so.

INTRODUCTION AND SUMMARY OF ARGUMENT

Eight years ago, in our amicus brief to the U.S. Supreme Court in *Wyeth v. Levine,* AARP expressed concern about the eradication of "the traditional role played by the tort system" as a "protector of the American public with regard to drug safety." Wyeth Brief, 2008 U.S. S. Ct. Briefs LEXIS 705, at *2. Consistent with our brief, the Court declined to hold that the federal Food, Drug and

Cosmetics Act preempted innumerable state tort claims for injuries caused by inadequate labeling of prescription drugs. *Wyeth v. Levine*, 555 U.S. 555, 581 (2009).

Three years later, the Court again considered the preemptive impact of federal law—in this case, the Hatch-Waxman Act—on state tort claims for failure to warn consumers of harms caused by generic versions of brand name prescription drugs. *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). Again, AARP expressed its concern that "a statute intended to provide consumers with increased access to *safe* generic drugs will be used to deny consumers necessary protections against *unsafe* ones." Brief of AARP et al. as Amici Curiae in Support of Respondents, *PLIVA v. Mensing*, 564 U.S. 604 (2011) (No. 09-993), 2011 U.S. S. Ct. Briefs LEXIS 281, at *3 (emphasis in original).

The Court in *PLIVA* held that, because generic drug manufacturers have a "duty of sameness" to adopt verbatim the labels written by the brand name manufacturer of the drug, it would be "impossible for [generic drug manufacturers] to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same." *PLIVA*, 564 U.S. at 618. The Court also made clear that brand name drug manufacturers face no such dilemma. The Court did *not* overturn its prior ruling in *Wyeth* because, unlike generics manufacturers, the brand name drug manufacturer has the power "to *unilaterally* strengthen its

warning" without prior approval from the Food and Drug Administration (FDA). *Id.* at 624 (emphasis added). In the post-*PLIVA* landscape, it is clear that brand name drug manufacturers, and *only* brand name drug manufacturers, can be held liable under state tort law for failing to update the labels on their own products that would "add or strengthen a contraindication, warning, precaution, or adverse reaction," and that would be copied verbatim by manufacturers of the generic version of the drug. *Wyeth*, 555 U.S. at 568 (citing 21 C.F.R. §§ 314.70 (c)(6)(iii)(A), (C)).

A brand name drug manufacturer must update its label when risks associated with a drug are either known or foreseeable to the brand-manufacturer. *See* 21 C.F.R. § 201.80(e); *see also Wyeth*, 555 U.S. at 568 (brand name drug manufacturers can update labels to add or strengthen the warnings without FDA prior authorization). Appellant, who is the brand name drug manufacturer, is fully aware that the generic drug manufacturer must use the exact same label that it writes for the brand name drug and that the label can be updated *only* by brand name drug manufacturer. *See PLIVA*, 564 U.S. at 618. As the generic version of the drug must be biologically equivalent to the brand name drug, if the brand name drug manufacturer does not update the label to warn of risks and hazards discovered after FDA approval of the label, it will result in both the brand name and generic version being misbranded and unsafe. *See* 21 U.S.C. § 352(f)

(defining "misbranded" drug). Thus, it is not only foreseeable, but inevitable that any injury caused by the generic version of the drug are tied to the brand name drug manufacturer's failure to give adequate warning of known and foreseeable risks associated with the brand name drug.

ARGUMENT

I. BRAND NAME DRUG MANUFACTURERS HAVE A DUTY TO WARN CONSUMERS OF RISKS OF WHICH THEY HAVE ACTUAL OR CONSTRUCTIVE KNOWLEDGE FOR AS LONG AS THE BRAND NAME DRUG REMAINS ON THE MARKET.

Federal law imposes a duty on drug manufacturers to update the drug's label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." 21 C.F.R. § 201.80(e). To trigger a drug manufacturer's duty to update the labels on their products, it is not necessary to show a causal connection between the drug and the hazard. *Id*. A drug is considered "misbranded" when its label fails to include "such adequate warnings…where its use may be dangerous to health…in such manner and form, as are necessary for the protection of users." 21 U.S.C. § 352(f).

Until 1985, the Food and Drug Administration (FDA) had to approve most proposed updates to prescription drug labels. Michael A. Carome, M.D. and Allison M. Zieve, *Comment on Updating ANDA Labeling After the Marketing Application for the Reference List Drug Has Been Withdrawn: Draft Guidance for Industry, Docket No. FDA-2016-D-1673*, Public Citizen, 2 (Sept. 9, 2016),

https://www.citizen.org/sites/default/files/2334-new.pdf. At that time, due in part to the urging of the pharmaceutical industry, the FDA expanded the ability of drug manufacturers to unilaterally make changes to a label that would "add or strengthen a contraindication [or] warning." New Drug and Antibiotic Regulations, 47 Fed. Reg. 46622 (Oct. 19, 1982).

As a practical matter, the safety of new drugs "cannot be known with certainty until a drug has been on the market for many years." Karen E. Lasser, et al., *Timing of New Black Box Warnings and Withdrawal for Prescription Medications*, 287 JAMA 2215, 2215 (2002). A recent study on the frequency and timing of the discovery of adverse drug reactions (ADRs) that require black-box warnings or drug withdrawal from the market concluded that "only half of newly discovered serious ADRs are detected and documented in the Physicians' Desk Reference within 7 years after drug approval." *Id*. at 2218. In some cases, ADRs to a particular drug were not detected until more than 15 years after the FDA's approval of the brand name drug's New Drug Application (NDA). *Id*. at 2217-18.

On some occasions, by the time that public awareness was raised about the risks of a drug, the combined market for the brand name and generic versions of the drugs numbered in the millions. *See, e.g.*, Sidney M. Wolfe, M.D., *Testimony on Propoxyphene (Darvon) Before FDA's Anesthetic, Analgesic and Rheumatologic Drugs and Drug Safety and Risk Management Advisory*

Committees, Public Citizen (Jan. 30, 2009), www.citizen.org/Page.aspx?pid=537 (discussing the risks and enduring market of the drug Darvon, originally approved in the 1950s). The record in this case reinforces the fact that the mere passage of time between the initial approval of the brand name drug and the approval of the generic drug does not ensure the drug's safety or that its current label contains adequate warnings.

It is vital that drug manufacturers continue to monitor the safety of their products and respond to safety risks as they are discovered because risks often do not become apparent until after FDA approval. As the U.S. Supreme Court recognized in *Wyeth*, manufacturers have "superior access to information" about their own products. *Wyeth*, 555 U.S. at 578-79 (footnote omitted). Therefore, it has been "a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label . . . [and] ensuring that its warnings remain adequate as long as the drug is on the market." *Id*. at 570-71. If the label of a prescription drug does not adequately disclose its risks, the dangers to the public remains even after the owner of that drug offloads its rights to a third party.

Although the Food and Drug Administration Amendments Act of 2007 gave the FDA additional resources for drug safety and new authority to compel manufacturers to make labeling changes, Congress continued to recognize in its passage that "the resources of the drug industry to collect and analyze post-market

safety data vastly exceed the resources of the FDA, and no matter what we do, [drug manufacturers] will always have vastly greater resources to monitor the safety of their products than the FDA does." 153 Cong. Rec. S11832 (daily ed. Sept. 20, 2007) (statement of Sen. Kennedy). Thus, the onus of updating the labels falls principally on those who produce the drugs. Indeed, under the current federal drug labeling scheme, brand name drug manufacturers provide the *only* prescribing information that doctors, pharmacists, and consumers receive about brand name drugs and their generic versions.

A. Brand name drug manufacturers should be held liable for their failure to warn of drug risks even when a generic drug is ingested because it is foreseeable that consumers may be harmed by drugs that are biologically equivalent.

Appellant argues that a brand name drug manufacturer should not be held liable for injuries caused by a drug that it did not manufacture. This argument, however, ignores that the brand name drug manufacturer's duty to warn is *already* mandated by federal law and that this duty *extends* to knowledge of risks associated with the generic versions of the drug. Here, Appellee alleged that Appellant failed to warn about the drug paroxetine's risk of suicide in adults of all ages. As the generic drug manufacturer must use the exact same label as the brand name drug manufacturer, Appellant is liable because the omission of safety information on its label caused the same omission on the label of the biologically equivalent generic drug that Appellee's husband ingested. Because the brand

name drug manufacturer knew that it had exclusive control of the information about the drug that could go out to the public and health care providers, it could foresee that its failure to update the drug's label could cause harm to consumers. Thus, Appellee's injuries were a foreseeable result of Appellant's failure to update the labels when Appellant had the power and duty to do so.

B. A ruling in favor of Appellant would leave prescription drug consumers in Illinois and across the country without a remedy if they are injured by a misbranded and unsafe generic drug.

The cost of prescription drugs has long been a concern for consumers and policymakers in the U.S. *See, e.g.*, Dennis Thompson, *What's behind the sharp rise in prescription drug prices?*, CBS News (Aug. 24, 2016), https://goo.gl/29hKRM (summarizing recent highly-publicized price increases for EpiPen, Daraprim, and Hepatitis C drugs). High drug prices are the direct result of the 20-year patent protected monopoly in which brand name drug manufacturers can raise the price of drugs without limitation and according to its demand. *See* AARP Bulletin, *Why Our Drugs Cost So Much* 3 (May 2017), https://www.aarp.org/health/drugs-supplements/info-2017/rx-prescription-drug-pricing.html; *see also* Alfred Engelberg, *How Government Policy Promotes High Drug Prices*, Health Affairs Blog (Oct. 29, 2015), https://goo.gl/FQ4BvX. Creating a faster pathway for generic drugs to enter the market and incentives for generic drug manufacturers to challenge the patents of brand name drugs, the

Hatch-Waxman Act of 1984 was one federal response to the rising costs of prescription drugs. *See* Jordan Paradise, *The Legal and Regulatory Status of Biosimilars: How Product Naming and State Substitution Laws May Impact the United States Healthcare System*, 41 Am. J. L. and Med. 49, 53-54 (2015).

As part of state efforts to stem the rise in prescription drug costs, all 50 states have passed laws that either permit or require pharmacists to substitute a prescribed brand name drug with its generic equivalent. *Id.* at 74-75 (noting that 36 states allow generic substitution in the absence of a specific brand request by the prescriber and that 14 states mandate the generic substitution). Given this nationwide statutory preference for dispensing generic drugs and the Supreme Court's rulings in *Wyeth* and *PLIVA*, a ruling in favor of Appellant would insulate both the brand name and generic drug manufacturers from any liability for failure to warn whenever a generic drug is ingested. Not only would this result be wrong as a matter of Illinois tort law, as noted in the Appellee's brief, but it would be disastrous as a matter of public policy. Thus, in exchange for efforts to reduce the cost of prescription drugs, consumers and the American healthcare system would be penalized with ineffective patient safety and tort laws.

II. STATE LAW TORT CLAIMS COMPEL DRUG MANUFACTURERS TO PROVIDE CLEAR AND ACCURATE INFORMATION DISCLOSING THE KNOWN RISKS OF A DRUG.

One of the fundamental purposes of tort law is to deter breaches of duty of care that will harm others. *Klein v. Children's Hosp. Med. Ctr.*, 46 Cal. App. 4th 889, 898 (1996). As the Supreme Court of New Jersey recently recognized, "to the extent that state tort suits uncover unknown drug hazards, they provide incentives for drug manufacturers to disclose safety risks promptly." *In Re Reglan Litig.*, 141 A.3d 724 (N.J. 2016).

A. A ruling in Appellant's favor would immunize brand name drug manufacturers from state tort claims alleging a failure to warn consumers of harms that are known or foreseeable.

An unconditional *exemption* of a tortfeasor from liability would frustrate one of the general functions of tort law. As commenters have observed, "the operating assumption of courts is not just that they will be there to…compensate an injured party, but that they will be sending a message heard clearly by those engaged in similar market practices." Andrew F. Popper, *In Defense of Deterrence*, 75 Alb. L. Rev. 181, 191 (2011). The total exemption of a tortfeasor from liability silences that message.

The rule proposed by Appellant would allow brand name drug manufacturers to evade liability, regardless of (a) whether the brand name drug manufacturer had actual or constructive knowledge of the drug's hazards at the time its exclusive right to sell/manufacture the drug ended; and (b) when the injury to a consumer taking a generic version of its drug occurred. If the Court adopts the standard proposed by Appellant, brand name drug manufacturers would have less of an incentive to aid in public safety by updating the labels on their products because they would know that their liability would be cut off simply by waiting for patent exclusivity to expire. Consequently, the consumer would have no recourse because the generic drug manufacturer, according to the holding in *PLIVA*, is also absolved of any duty to update the label.

The "foreseeability" test suggested by Appellee would permit a more flexible analysis and empower a fact-finder to decide what, if any, harms were foreseeable for a brand name drug manufacturer upon failing to update a label to advise consumers of known risks. Here, the jury evaluated evidence after five weeks of trial and found Appellant liable for its conduct.

B. Appellee's proposed rule is consistent with and complementary to existing federal drug safety law.

Appellee's theory of liability is consistent with and complementary to existing federal statutory schemes intended to ensure patient safety. As the U.S. Supreme Court noted in *Wyeth*, "failure to warn" claims similar to Appellee's

claims actually "lend force to the [Food, Drug, and Cosmetics Act's] premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling..." *Wyeth*, 555 U.S. at 579. Congress further "determined that widely available state rights of action provided appropriate relief for injured consumers" and "may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id.* at 574.

Without a doubt, the federal Hatch-Waxman Act sought to "make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (1984), as *reprinted in* 1984 U.S.C.A.A.N. 2647-2648. However, Congress did not seek to risk patient safety in fulfillment of that goal. Rather, the policy objective was to get "*safe and effective* generic substitutes on the market as quickly as possible." H.R. Rep. No. 98-857, pt. 2, at 9 (June 21, 1984), as *reprinted in* 1984 U.S.C.A.A.N. 2647, 2694 (emphasis added). Thus, the Hatch-Waxman Act was also intended to be a benefit for both consumers and drug manufacturers in which generic drugs would be approved more quickly with no decrease in safety or effectiveness. The Hatch-Waxman Act does not absolve brand name manufacturer of responsibility for the safety of the drugs that they manufacture.

III. MANUFACTURERS MUST UPDATE LABELS ABOUT KNOWN DRUG RISKS AS LABELS ARE THE PRIMARY SOURCE OF INFORMATION FOR PHYSICIANS AND CONSUMERS.

The value of clear, current information on the label of a prescription drug cannot be overstated. A recent study by Consumer Reports concluded that "most patients rely on the information printed directly on their medication containers," as opposed to lengthier instructions or warnings that may be contained within the drug's packaging. Consumer Reports, *Can You Read this Drug Label?* (June 2011), http://www.consumerreports.org/cro/2011/06/can-you-read-this-drug-label/index.htm. While many patients would prefer to receive information about a drug's potential risks directly from their physicians, as a practical matter, such conversations "occur infrequently and are often quite limited." William H. Shrank and Jerry Avorn, *Educating Patients About Their Medications: The Potential And Limitations Of Written Drug Information*, 26 Health Aff. 731 (May 2007). The instructions on drug labeling become the default source of information about a drug's safety and efficacy for many consumers.

Due to their importance in preventing medication errors, some observers have called for simplified labels that use more explicit language to support greater patient understanding of information about the drug. Michael S. Wolf, *Improving Prescription Drug Warnings to Promote Patient Comprehension*, 170 Arch. Internal Med. 50 (Jan. 11, 2010), doi:10.1001/archinternmed.2009.454 (finding

that "[s]imple, explicit language on warning labels can increase patient understanding"). On the other hand, the absence of clear, unequivocal language on the label advising patients of known risks of the drug leaves physicians and consumers without the critical information they need to make informed decisions about their care.

CONCLUSION

For the foregoing reasons and those articulated in Appellee's brief, amici AARP and AARP Foundation urge the Court to hold that Illinois tort law permits a claim of negligence against a brand name drug manufacturer when the drug ingested was produced by a generic manufacturer. A ruling to the contrary would nullify tort law protections for Illinois who use generic drugs, without regard to whether the drug is actually safe or whether they were adequately warned of its risks; but simply because they were dispensed a generic drug to reduce the high cost of prescription drugs for them, insurance companies, and the state of Illinois.

Dated: February 28, 2018

Respectfully submitted,

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This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B) because this brief contains 3,424 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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Dated: February 28, 2018

/s/Mary Ellen Signorille
Mary Ellen Signorille
Counsel for Amici Curiae AARP and AARP Foundation

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I hereby certify that on this 28th day of February, 2018, I electronically filed the foregoing Brief Amici Curiae of AARP and AARP Foundation with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ *Mary Ellen Signorille*
Mary Ellen Signorille