No. 17-3030

In the United States Court of Appeals For the Seventh Circuit

WENDY DOLIN, Individually and as Independent Executor of the Estate of Steward Dolin, Deceased,

Plaintiff-Appellee,

v.

GLAXOSMITHKLINE, LLC,

Defendant-Appellant.

On Appeal from the United States District Court for the Northern District of Illinois (Civ. No. 12-6403)
Honorable William T. Hart, J.

BRIEF OF THE ILLINOIS TRIAL LAWYERS ASSOCIATION AND AMERICAN ASSOCIATION FOR JUSTICE AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF-APPELLEE AND AFFIRMANCE

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Short Caption: Wendy Dolin v. GlaxoSmithKline LLC

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Attorney's Signature: /s Leslie J. Rosen Date: February 28, 2018

Attorney's Printed Name: Leslie J. Rosen

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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None

Attorney's Signature: /s/ Jeffrey White Date: February 28, 2018

Attorney's Printed Name: Jeffrey White

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IDENTITY AND INTEREST OF *AMICI CURIAE*

The American Association for Justice ("AAJ") is a voluntary national bar association founded in 1946 with members in every state, including Illinois. AAJ members primarily represent plaintiffs in personal injury suits, civil rights and employment rights cases, and in actions to protect the rights of consumers.

The Illinois Trial Lawyers Association ("ITLA") is a statewide organization whose members specialize in representing injured consumers and workers. Founded in 1952, the organization currently has over 2,000 members. The objectives of ITLA are to:

- Strive to achieve and maintain high standards of professional ethics, competency and demeanor in the bench and bar;
- Uphold the Constitution of the United States of America and the State of Illinois;
- Secure and protect the rights of those injured in their persons or civil rights;
- Defend trial by jury and the adversarial system of justice;
- Promote fair, prompt and efficient administration of justice; and
- Educate and train in the art of advocacy.

AAJ and ITLA address this Court, prompted by concern that the unduly narrow scope of the duty to avoid negligence and negligent misrepresentation under Illinois law advocated by Defendant-Appellant GlaxoSmithKline unfairly limits the remedy that Illinois law affords to those who have been wrongfully injured.[1]

[1] All parties have consented to the filing of this brief. Pursuant to Fed. R. App. P. 29(a)(4)(E), *amici* AAJ and ITLA state that no party's counsel authored this brief in whole or in part, and that no person or entity, other than *amici* and their counsel,

SUMMARY OF THE ARGUMENT

1. The primary argument raised in this appeal by GlaxoSmithKline and its supporting *amici* is an attack on a straw man they have named "innovator liability." They contend that GSK was unfairly held liable for harm caused by a medication it did not manufacture and over which it had no control. They warn that acceptance of such a novel theory will make name brand manufacturers the insurers of their entire industry, raising prices for prescription drugs and stifling innovation by pharmaceutical companies.

There is no merit to any of it. The district court espoused no such theory in this case. GSK was held accountable for its own negligence and negligent misrepresentations in the warnings it prepared for use by prescribing physicians, regardless of whether their prescriptions were ultimately filled with the name-brand medication or the bioequivalent generic version. GSK was not held liable for another manufacturer's dangerous product. It was held liable for its own dangerous misrepresentations.

What GSK and its supporters ask of this Court is Innovator Immunity – a special exemption from negligence rules that are well-settled in Illinois and elsewhere.

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made a monetary contribution intended to fund the preparation and submission of this brief.

Decisions from around the country declining to hold name-brand manufacturers liable for harm to users of generic versions do not represent the application of a fundamental tort principle rejecting "innovator liability." Most of those decisions represent the application of particular state products liability statutes which abrogate the common law of torts. The seminal federal decision relied heavily on the assumption that generic drug makers were capable of modifying their label warnings to reflect known dangers. The Supreme Court's subsequent decision to the contrary completely defeats that rationale.

There is no principle of tort law that a manufacturer cannot be liable for harm caused by another's product. Although such a manufacturer may not be subject to strict products liability, it is accountable for its own negligence and negligent misrepresentations that cause injury. Those principles are well settled under Illinois tort law.

The court below also correctly held that GSK owed a duty of due care to Mr. Dolin, as a consumer of the generic version of GSK's Paxil. It was obviously foreseeable that prescribers of paroxetine would rely on the information supplied by GSK. The court did not base its decision on foreseeability alone, but also applied the other established factors in the duty analysis under Illinois law,

2. The Illinois precedent that GSK deems "dispositive" of this case actually suggests that a name brand manufacturer may be held liable for inadequate

or misleading warnings accompanying the generic version where the defendant was in some measure responsible for creating that risk.

Under the concert-of-action theory accepted by the Illinois Supreme Court, a defendant may be held liable for the harm caused by another where the defendant and the other party acted "pursuant to a common design" or where the defendant knowingly "gives substantial assistance" to the other party's breach of duty.

In this case, GSK and Mylan, Inc. acted pursuant to the common design set out in federal law, under which the brand-name manufacturer, as New Drug Application ("NDA") holder, was allowed exclusive rights for a period of years but was responsible for testing and preparing label warnings, and the manufacturer of the generic version was relieve of those responsibilities but was required to use the exact labelling prepared by the name brand maker. Similarly, GSK provided substantial assistance to Mylan's breach of its duty to provide adequate warnings. Indeed, GSK's preparation of the warnings Mylan used was essential.

3. None of the *amici* supporting GSK in this appeal have raised valid public policy arguments in support of reversal. As detailed in Argument I, there is no merit in the U.S. Chamber of Commerce's argument that the district court adopted a novel theory of liability. The Chamber's contention that liability will unfairly impact those who have invested in creating new drugs omits the substantial profits generated by drugs like Paxil during the years when GSK was granted a

monopoly to sell paroxetine is unsupported and unsupportable. Name-brand drug makers are well aware of this trade-off. Claims that it is unfair are more properly addressed to the legislative and executive branches. In addition, the Chamber's dire predictions that drug makers might be unable to obtain liability insurance and could leave the market altogether are speculations unsupported by any solid evidence or data.

The claims by the Pharmaceutical Research and Manufacturers of America likewise lack support. Its own generalized assertions that the costs of bringing new drugs to market are "enormous" shed no light on its assertion that the added liability costs due to the decision in this case will lead drug manufacturers to cease production. The type of convincing evidence that might be expected from an association of pharmaceutical researchers and manufacturers is tellingly lacking. PhRMA's complaint that such companies are treated unfairly under the Hatch-Waxman legislation easing entry into the market by generic drugs is, once again, best addressed to legislators.

Finally, the arguments raised by *amicus* Washington Legal Foundation, that the district court decision rewrites and distorts existing tort law and alters the existing balance of policy considerations, merely repeat contentions that AAJ and ITLA addressed earlier.

ARGUMENT

I. THE DISTRICT COURT'S DECISION IS GROUNDED IN SETTLED ILLINOIS TORT LAW.

A. The District Court's decision does not adopt novel "Innovator Liability."

Appellant GlaxoSmithKline ["GSK"] and its supporting *amici* portray the district court's decision as embracing "a novel legal theory known as 'innovator liability.'" GSK Brief ["GSK Br."] 2. *See also* Brief of the Chamber of Commerce of the United States, the American Tort Reform Assn., et al. ["Chamber Br."] 1 & 5 (stating their interest as *amici* in opposing the "novel theory of innovator liability"); Brief of Pharmaceutical Research and Manufacturers of America ["PhRMA Br."] 14-20 (arguing that "innovator liability" is harmful and unfair.).

The liability judgment below does not resemble the strawman that GSK and its supporters have constructed. GSK was held accountable for its own misconduct under well-settled principles of Illinois tort law. What GSK and its allies seek from this court is Innovator Immunity – a novel special exemption from applicable liability rules.

Plaintiff sued GSK, asserting "common law negligence and negligent misrepresentation claims as well as product liability claims under theories of both negligence and strict liability." *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 710 (N.D. Ill. 2014) ["*Dolin I*"]. At trial, plaintiff introduced evidence that GSK's own research showed a substantial increase in suicidal behavior by patients

using Paxil compared to a placebo, including a substantial increase in the suicide risk for patients in Mr. Dolin's age group. *Dolin v. GlaxoSmithKline LLC*, 269 F. Supp. 3d 851, 858-61 (N.D. Ill. 2017) ["*Dolin II*"]. Mr. Dolin's prescribing physician, Dr. Sachman, testified that if he had known of the actual suicide risk associated with paroxetine, he would not have prescribed it for his patient. *Id*. at 859. The jury returned a verdict in plaintiff's favor, awarding $3 million in compensatory damages.

On appeal, GSK and supporting *amici* assert that the company is being subjected to "innovator liability," under which it is liable for damages despite the fact that "GSK had no control over Mylan's development, manufacturing, distribution, or marketing. Nor did GSK profit from Mylan's paroxetine sales." GSK Br. 6. *See also* Washington Legal Foundation Brief ("WLF Br.") 14 (noting the unfairness of imposing "liability on a manufacturer for a defect in a product unless the manufacturer had the opportunity to avoid liability…") (quoting *Gillenwater v. Honeywell, Inc.*, 996 N.E.2d 1179, 1200 (Ill. Ct. App. 2013). "That is innovator liability in a nutshell." GSK Br. 20.

The court below, however, expressly rejected that proposition. The court denied plaintiff's strict products liability claim precisely because the rationale for liability without fault cannot fairly extend to brand name manufacturers who did not

make or sell or profit from the medication that caused the injury. *Dolin I*, 62 F. Supp. 3d at 722–23.

However, the district court did rule that GSK could be held accountable for its own negligence and its own negligent misrepresentations in the warning it crafted for use with both Paxil and its generic equivalents. In sum, GSK was held liable for misrepresentations that GSK, and GSK alone, controlled.

GSK and its supporters nevertheless contend that "innovator liability" violates a "fundamental and well-settled principle of tort law . . . that liability for harm caused by products is limited to the persons who actually made or sold the injurious products." Chamber Br. 4. GSK contends that the "bedrock" principle that "a pharmaceutical company cannot be liable for failing to warn about a drug's risks absent proof the company manufactured the particular drug that caused the plaintiff's injury" is "dispositive." GSK Br. 19.

GSK seeks to bolster its position by reference to "more than 100 state and federal decisions [that] have rejected innovator liability under the laws of 29 states." GSK Br. 24. *See also* Chamber Br. 4 ("More than a hundred state and federal courts . . . have concluded that pharmaceutical manufacturers, like all other manufacturers, may be held liable only for harm caused by their own products."). Those cases are set out in *Germain v. Teva Pharms., USA, Inc.* (*In re Darvocet, Darvon, & Propoxyphene Products Liability Litigation*), 756 F.3d 917 (6th Cir. 2014).

However, as the Chamber acknowledges, many of the 22 states that have rejected misrepresentation claims have done so based on "state-specific products-liability statutes or rules," not the common law of torts. Chamber Br. 16. They are therefore not relevant to whether Illinois would uphold liability in this case. Other decisions rejected liability based on a finding that the defendant owed no duty to the plaintiff. *Id*. Illinois law would recognize such a duty in this case, as AAJ and ITLA discuss in part D, below.

GSK heavily relies on *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), as highly persuasive for the proposition that a name-brand manufacturer cannot be held liable on a negligent misrepresentation theory for injuries resulting from use of another manufacturer's generic substitute. GSK Br. 23-25. However, this reliance is misplaced. *Foster's* holding rested on the assumption that makers of generic drugs had the ability and duty to provide such warnings to their own consumers. *See* 29 F.3d at 169–70. The U.S. Supreme Court subsequently held that manufacturers of generic prescription drugs have no such legal authority. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011). For that reason, the weight of *Foster* as persuasive authority is questionable. Indeed, the Fourth Circuit has recently suggested that it may reconsider its view. *McNair v. Johnson & Johnson*, 694 F. App'x 115, 120 (4th Cir. 2017).

B. Manufacturers can be liable for harm caused by another's product.

The proposition at the heart of the "innovator liability" argument pressed by GSK and its supporting *amici* – that a manufacturer can be held liable only for harm by its own product – is plain overstatement.

Certainly, a company that happens to be a manufacturer may be liable for personal injury caused by another company's product based on legal responsibilities that are entirely separate from a manufacturer's duties under product liability law. GSK can be held liable for an injury caused by a GSK delivery truck, for injury to a business invitee who trips on a piece of equipment manufactured elsewhere, or for injury to a worker caused by a machine used at a GSK facility.

Similarly, a defendant can be liable for harm caused by another's product when the defendant has made representations or warranties concerning that product. For example, in *Brown v. Neff*, 603 N.Y.S.2d 707, 708-10 (N.Y. Sup.Ct. 1993), a passenger in a truck that overturned due to mechanical defects was permitted to pursue an action for misrepresentation against the garage owner who falsely certified that the vehicle had passed the state safety inspection. The court found that the cause of action was consistent with Restatement of Torts (Second) § 311 (1965), "Negligent Misrepresentation Involving Risk of Physical Harm." *Id*. at 709.

In another well-known case, the publisher of Good Housekeeping magazine was held liable to a consumer who slipped and fell while wearing shoes defendant

had given its "Good Housekeeping's Consumers' Guaranty Seal," based on its own testing of the product. *Hanberry v. Hearst Corp.*, 81 Cal. Rptr. 519, 521 (Ct. App. 1969). *See also Thompson v. Hardy Chevrolet-Pontiac-Buick, Inc.*, 417 S.E.2d 358, 360-61 (Ga. App. 1992) (finding a used car dealer liable for accident after salesman had assured the buyer "that the vehicle was in good mechanical condition and safe to drive when the brakes were in fact defective and dangerous," citing Restatement, § 311.). Finally, an early appellate decision in Illinois held that experts engaged in inspecting and testing the quality of steel rails could be held liable for certifying a shipment of rails as first class in quality, when they proved to be far inferior. *Nat'l Iron & Steel Co. v. Hunt*, 192 Ill. App. 215 (Ill. Ct. App. 1915).[2]

GSK was not found liable in this case because it was an innovator, made unfairly responsible for a competitor's product over which it had no control. As the court below took care to emphasize, plaintiff's negligence claims "exist outside of the product liability framework." *Dolin I*, 62 F. Supp. 3d at 720. In short, GSK was not held liable for a competitor's injury-producing product; GSK was liable for its own injury-producing misrepresentations.

[2] Pre-1935 appellate court decisions may be viewed as persuasive, but not precedential. *Bryson v. News America Publications, Inc.*, 672 N.E.2d 1207, 1217 (Ill. 1996).

C. Liability in this case was firmly grounded in the tort of negligent misrepresentation under the law of Illinois.

It is indisputable that some state courts, including the Illinois Supreme Court, would uphold the verdict in favor of Mrs. Dolin in this case. *See, e.g.*, *T.H. v. Novartis Pharmaceutical Corp.*, 407 P.3d 18 (Cal. 2017); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649 (Ala. 2014); *Kellogg v. Wyeth*, 762 F.Supp.2d 694, 709 (D. Vt. 2010) (permitting claim of negligent misrepresentation under Vermont law).

These decisions are not based on novel or "idiosyncratic" features of state law. *See* Chamber Br. 9. They are based on the well-established common-law cause of action for negligent misrepresentation. As the Alabama Supreme Court emphasized, its "opinion does not plow new ground, nor does it create a heretofore unknown field of tort law that has been referred to as 'innovator liability' . . . Instead, this opinion answers the question whether the Weekses may bring a fraudulent-misrepresentation claim under Alabama law." *Wyeth, Inc.*, 159 So. 3d at 655 n.2.

The prevailing rule is set forth in Restatement (Second) of Torts § 311 (1965), entitled "Negligent Misrepresentation Involving Risk of Physical Harm":

> (1) One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results
> (a) to the other, or
> (b) to such third persons as the actor should expect to be put in peril by the action taken.
> (2) Such negligence may consist of failure to exercise reasonable care
> (a) in ascertaining the accuracy of the information, or
> (b) in the manner in which it is communicated.

Liability is not limited to those instances where the plaintiff was injured by a product made by or purchased from the defendant, but also where the defendant's false statements are "un-related to . . . any activity from which he derives benefit." *Id*. at comment c.

Illinois, like California, has adopted Restatement § 311. *Board of Education v. A, C & S, Inc.*, 546 N.E.2d 580, 592-93 (Ill. 1989). *See also Brogan v. Mitchell Int'l, Inc.*, 692 N.E.2d 276, 278 (Ill. App. 1998); *Doe v. Dilling*, 861 N.E.2d 1052, 1068–69 (Ill. App. 2006), aff'd, 888 N.E.2d 24 (Ill. 2008) (noting that *A, C & S* recognized "that one who negligently gives false information to another may be liable for physical harm caused by actions taken in justifiable reliance on the misrepresentation"); *Alm v. Van Nostrand Reinhold Co.*, 480 N.E.2d 1263 (Ill. App. 1985).

The district court properly ruled that plaintiff made out a cause of action under Illinois law of negligent misrepresentation, as set out in *A, C & S*. *See Dolin I*, 62 F. Supp. 3d at 719-20.

D. GSK owed a duty to Mr. Dolin to accurately communicate warnings regarding the risks associated with Paroxetine and avoid misrepresentation of those risks.

As stated by the court in *A, C & S*, to establish a cause of action for negligent misrepresentation, "a plaintiff must also allege that the defendant owes a duty to the plaintiff to communicate accurate information." 546 N.E.2d at 591. Similarly, as the

district court below stated, where plaintiff relies on allegations of negligence, as distinguished from negligent products liability, "plaintiff must actually contend with the duty element, rather than benefit from the presumed duty manufacturers owe to consumers of their products." *Dolin I*, 62 F. Supp. 3d at 720. The district court concluded that GSK owed such a duty to Stewart Dolin. *Id*. at 715.

The primary argument raised by GSK on this issue is that the district court's decision was "bottomed on . . . foreseeability alone." GSK Br. 29. *See also* WLF Br. 8 ("[T]his Court should reject the district court's misguided attempt to make 'foreseeability' the first and last word when establishing negligence under Illinois law."); *id*. at 17 (referring to the district court's analysis as "foreseeability-ergo-negligence").

GSK correctly asserts that the touchstone of the court's duty analysis under Illinois law requires the court to assess "the reasonable foreseeability of the injury," "the magnitude of the burden of guarding against the injury," and "the consequences of placing that burden on the defendant." GSK Br. 29 (quoting *Simpkins v. CSX Transp., Inc.*, 965 N.E.2d 1092, 1097 (Ill. 2012).). *See also* WLF Br. 11 (In "the duty inquiry under Illinois law . . . 'the magnitude of the burden of guarding against [foreseeable harm] and the consequences of placing the burden upon the defendant, must also be taken into account.'"), but argues that the district court failed to apply that analysis. It is wrong.

That is precisely the analysis the district court applied. *Dolin I*, 62 F. Supp. 3d at 713-15 (setting forth and applying the *Simpkins* factors).

GSK does not dispute that it was foreseeable that GSK's misrepresentation of the suicide risk for Paxil would result in harm to Mr. Dolin when his prescription was filled with the bioequivalent generic version of Paxil. After all, a principal purpose of drug labeling is to guide physicians in their "prescribing decisions," Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3930 (Jan. 24, 2006), and physicians would rely on Paxil's label even if a generic might ultimately be dispensed.

GSK's only response is that it had "no say over whether, how, and to what extent a generic manufacturer enters the market. Brand manufacturers also have no control over whether state laws permit or require pharmacists to dispense generic drugs in place of brands." GSK Br. 29. GSK is simply conflating foreseeability with fault. The fact that the makers of generics are compelled by law to copy Paxil's label warnings makes it even more foreseeable that misrepresentations in those warnings will harm patients such as Mr. Dolin. That doctors would rely on GSK's label warnings for "all of the iterations of paroxetine" is "precisely the point" of the Hatch-Waxman regulatory scheme. *Dolin I*, 62 F. Supp. 3d at 715.

The Illinois Supreme Court has declared its fundamental tort principles regarding negligence duty, and they do not resemble those urged by GSK:

> It is axiomatic that every person owes to all others a duty to exercise ordinary care to guard against injury which naturally flows as a reasonably probable and foreseeable consequence of his act, and that such duty does not depend upon contract, privity of interest or the proximity of relationship, but extends to remote and unknown persons.

Nelson v. Union Wire Rope Corp., 199 N.E.2d 769, 779 (Ill. 1964) (upholding liability of insurer whose negligent safety inspection of a hoist led to deaths and injuries of workers). *See also Bogenberger v. Pi Kappa Alpha Corp.*, Inc., 2018 IL 120951, ¶ 22 (Ill. 2018) (same).

A federal court sitting in diversity must predict how the state's highest court would rule if confronted with the same question of state law. *Todd v. Societe Bic, S.A.*, 21 F.3d 1402, 1412 (7th Cir. 1994) (en banc). The better-reasoned decisions have imposed liability on brand name manufacturers for negligence and negligent misrepresentation in warnings designed to be used by prescribing physicians of users of both brand name drugs and bioequivalent generics. Illinois would so hold as well.

II. A BRAND NAME PRESCRIPTION DRUG MANUFACTURER WHO PREPARED INADEQUATE OR MISLEADING WARNINGS MAY BE LIABLE FOR HARM TO A PATIENT WHO INGESTED THE GENERIC EQUIVALENT MEDICATION UNDER SETTLED TORT PRINCIPLES OF CONCERTED ACTION.

A. Settled common-law negligence principles impose liability on a manufacturer for harm caused by the product of another in appropriate circumstances.

GSK and its supporting *amici* rely heavily on *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324 (Ill. 1990) as "dispositive" of this case. GSK Br. 19. According to GSK,

"*Smith* held that a pharmaceutical company cannot be liable for failing to warn about a drug's risks absent proof the company manufactured the particular drug that caused the plaintiff's injury," which "preclude[s] any theory of innovator liability under Illinois law." *Id.* at 19. The U.S. Chamber and its allies agree that "an individual manufacturer can thus be called to account only for harms caused by its own products." Chamber Br. 17. *Smith* does not support their position.

In fact, the "fundamental principle" discussed in *Smith* states that, in the context of products liability, "to hold a producer, manufacturer, or seller liable for injury caused by a particular product, there must first be proof that the defendant produced, manufactured, sold, or *was in some way responsible* for the product." 560 N.E.2d at 329 (quoting Annot., 51 A.L.R.3d 1344, 1349 (1973) (emphasis added). By law, GSK was responsible for providing adequate and accurate warnings to accompany both Paxil and the identical generic versions that came on the market after GSK's monopoly on paroxetine expired.

In *Smith*, plaintiff alleged that she developed cancer caused by diethylstilbestrol (DES) that was administered to her mother during pregnancy 25 years previously. *Id.* at 325. At the time of trial, plaintiff was unable to identify which of the several manufacturers of DES made the medication given to her mother. *Id.* at 326. To assist plaintiff in overcoming this obstacle, the trial court adopted the "market-share liability" theory developed in *Sindell v. Abbott Laboratories*, 607

P.2d 924 (Cal. 1980), holding all manufacturers who may have produced the medication answerable in damages in proportion to their share of the relevant market. *Id*. at 327. The Illinois Supreme Court reversed. *Id*. at 325-26. The court rejected market-share liability in Illinois, concluding that assigning liability where the actual manufacturer is unknown cannot be reconciled with the rationale and policies underlying strict products liability. *Id*. at 337-45. However, GSK and its supporters torture *Smith's* holding beyond recognition by arguing that *only* the manufacturer of a product can be liable for harm caused by that product.

Indeed, the Illinois Supreme Court has made clear that a non-manufacturer non-seller who nevertheless had some material connection to an unreasonably dangerous product may be held liable for its own negligence. In *Mechanical Rubber & Supply Co. v. Caterpillar Tractor Co*., 399 N.E.2d 722, 723-24 (Ill. 1980), Caterpillar designed, but did not manufacture or distribute, an industrial hopper which caused a worker's injury. The court pointed out that there are "many parties who conceivably have some relation with the manufacture and sale of the product" though they are "not directly related to the distributive process." *Id*. at 723. Examples include "a patent licensor, a consultant, an independent engineering firm, [or] an independent testing laboratory." *Id*. Such a party operates "outside the manufacturing distributing system contemplated by products liability theories." *Id*. at 724. Nevertheless, such a party "provides a service and subjects the party to *the*

duty to exercise reasonable care but the party is not liable on a products liability theory." *Id* at 723 (emphasis added).

The *Smith* court itself suggested that such a connection between a product and a non-manufacturer defendant might be established under the "concert of action" theory. The court explained:

> Concert of action applies when a tortious act is done in concert with another or pursuant to a common design, or a party gives substantial assistance to another knowing that the other's conduct constitutes a breach of duty. (Restatement (Second) of Torts §§ 876(a), (b), at 315 (1979).).

560 N.E.2d at 329.

The cited Restatement provisions, reflecting the weight of authority, provide:

> For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he
> (a) does a tortious act in concert with the other or pursuant to a common design with him, or
> (b) knows that the other's conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself.

Restatement (Second) of Torts § 876 (1979).

The Illinois Supreme Court reaffirmed its adherence to the concert of action theory in *Simmons v. Homatas*, 925 N.E.2d 1089, 1100 (Ill. 2010), stating that § 876 is based on "a duty to refrain from assisting and encouraging . . . tortious conduct." *See also A.I. Credit Corp. v. Hartford Computer Grp., Inc.*, 847 F. Supp. 588, 599–

600 (N.D. Ill. 1994) (citing *Sanke v. Bechina*, 576 N.E.2d 1212, 1213 (Ill. App. Ct. 1991), appeal denied, 584 N.E.2d 140 (Ill. 1991).).

Smith, and many other courts, declined to uphold DES claims under the concert of action theory based on the absence of evidence of a common design or plan. *See Smith*, 560 N.E.2d at 330, 340-41. As District Judge Shira A. Scheindlin noted, *Smith's* "rejection was based on the evidence and did not foreclose [concert of action] as an actionable theory of recovery." *In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig.*, 379 F. Supp. 2d 348, 393 (S.D.N.Y. 2005). Plaintiffs in that case were municipalities and other water providers who sued producers and suppliers of the gasoline additive methyl tertiary butyl ether ("MTBE"), alleging contamination of their groundwater. *Id*. at 361 Denying defense motions to dismiss, District Judge Scheindlin determined that Illinois law recognizes the concert of action theory. *In re Methyl Tertiary Butyl Ether ("MTBE") Prod. Liab. Litig.*, 175 F. Supp. 2d 593, 620 (S.D.N.Y. 2001) (citing *Smith*).

B. Judgment for plaintiff in this case is consistent with the concert of action theory.

The verdict for plaintiff in this case is well supported under the concert of action principles accepted by the Illinois Supreme Court.

First, Restatement (Second) of Torts § 876(a) permits liability where the name brand manufacturer has committed a tortious act "in concert with the [generic manufacturer] or pursuant to a common design." *See also Smith*, 560 N.E.2d at 329

(similar). Although GSK asserts that "Plaintiff never alleged that GSK conspired with Mylan," GSK Br. 22, concert of action – as distinguished from civil conspiracy – does not require express agreement. Tacit agreement can be inferred from pursuit of a common plan.

That plan is set forth explicitly in the Hatch-Waxman amendments to the FDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) § 101 and § 102 (setting forth the provisions for abbreviated new drug approval process and patent-term extension provisions for brand name manufacturers). GSK as brand name manufacturer was granted a monopoly to sell Paxil for an extended term of years, but was made responsible for testing its safety and effectiveness and for preparing label warnings for Paxil and any generic bioequivalents that may come on the market. GSK did so. Mylan played its part in the plan, entering the market after GSK's exclusivity rights expired, certifying that its generic version was bioequivalent to Paxil, and using the exact label and warnings prepared by GSK. The result of their coordinated efforts was that Mr. Dolin's doctor received and relied on inadequate and misleading information regarding the suicidal risk of paroxetine, in all its versions, for his patient. Mylan could not have provided that information itself; it was required to accompany its paroxetine with the exact labelling prepared by GSK.

Second, plaintiff's evidence would support a finding that GSK "[knew] that [Mylan's] conduct constitute[d] a breach of duty and [gave] substantial assistance or

encouragement." Restatement (Second) of Torts § 876(b). Mylan's distribution of its prescription medication with inadequate or misleading warnings constituted a breach of its duty under state products liability law. *See* WLF Br. 12 ("The duty to warn about the risks posed by generic drugs rests with generic manufacturers," though federal law may "preempt the remedy that injured plaintiffs may seek" for violation of that duty.). Mylan could not have committed that tort but for the warnings prepared by GSK, which Mylan was required by law to use. Plaintiff's evidence supported a jury finding that GSK knew its warning regarding suicidal risks to adult users of paroxetine was inadequate or misleading and that the mandated use of that label warning by Mylan would result in Mylan's breach of its strict liability duty to accompany its product with adequate warnings. GSK's assistance to Mylan was not only substantial, it was essential.

III. NONE OF THE *AMICI* HAVE RAISED VALID PUBLIC POLICY ARGUMENTS IN SUPPORT OF REVERSAL.

A. The Chamber of Commerce has raised no significant public policy claims.

The Chamber of Commerce of the United States of America, The American Tort Reform Association, The Product Liability Advisory Council, Inc., The National Association of Manufacturers and the Illinois Chamber of Commerce ("The Chamber") present no persuasive public policy arguments to support their view that the Supreme Court of Illinois would shield GSK and other brand-name

pharmaceutical manufacturers from liability for harm caused by their own negligence in warning physicians of the risks associated with their medications.

First, the Chamber has the gall to suggest that the district court disregarded policy considerations which would have led the Illinois Supreme Court to favor GSK in this case. Chamber Br. 26. It was GSK, after all, that deprived the Illinois Supreme Court of the opportunity to speak to this issue by removing the case from the Circuit Court of Cook County to the federal court.

Next, there is no merit to the Chamber's lament that that companies that make the "enormous investment" in "[d]eveloping and obtaining approval for groundbreaking pharmaceutical products" are treated unfairly by "federal law and regulations [that] are solicitous toward competing generic versions, which, after the brand-name manufacturer's period of exclusivity expires, almost invariably capture most of the product's market." Chamber Br. 20.

The Chamber fails to tell the court anything about defendant's profits from Paxil during the period it enjoyed a legal monopoly on paroxetine thanks to the same federal law and regulations. In fact, in a July 3, 2012 article regarding defendant's agreement to plead guilty to criminal charges and pay a $3 billion fine for, inter alia, promoting Paxil for unapproved uses and failing to report safety data about its top-selling diabetes drug, the New York Times reported that from the late 1990s to the mid-2000s, defendant "brought in $11.6 billion for Paxil sales." Katie Thomas and

Michael S. Schmidt, *Glaxo Agrees to Pay $3 Billion in Fraud Settlement*, THE NEW YORK TIMES (July 2, 2012), *available at* http://nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html [hereinafter "Fraud settlement"].

Moreover, the Chamber's argument that federal law unfairly burdens brand-name manufacturers with "significant costs" while allowing generics to "invariably capture most of the product's market" is an argument to be presented to the other two branches of the federal government. "It is the role of courts to provide relief to claimants, in individual or class actions, who have suffered, or will imminently suffer, actual harm; it is not the role of courts, but that of the political branches, to shape the institutions of government in such fashion as to comply with the laws and the Constitution." *Lewis v. Casey*, 518 U.S. 343, 349 (1996).

The Chamber's assertion that manufacturers should be "able to rely on the settled understanding that their exposure to risk is limited to the products they manufacturer or sell themselves" and its argument that it is unfair to "shift" risk to them for products they did not manufacture, Chamber Br. at 21-22, is unavailing. Pharmaceutical manufacturers are well-aware of their regulatory responsibilities. First, approval for a new drug requires the company to submit an NDA to the FDA, with proposed label. *Guilbeau v. Pfizer Inc.*, 880 F.3d 304, 307 (7th Cir. 2018). Second, "The FDA's approval is then conditioned on the manufacturer's use of the

label it suggests." *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 391 (7th Cir. 2010). Finally, the NDA holder "bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009). GSK's decision to move forward with Paxil was a business decision it made, fully aware of both the opportunities and responsibilities involved.

The Chamber's rhetorical assertion that assigning tort liability to manufacturers "for products they do not make would expose product developers to risk based on sales activity and regulatory compliance they could neither control nor monitor, introducing lasting, unavailable uncertainty into the calculus of product development," Chamber Br. 22, is completely lacking in substance. The Chamber cites no facts in support of its sweeping conclusion. Instead, the Chamber cites to an article containing the same unsupported assertions by Victor Schwartz, Chamber Br. at 23, long-known as "the undisputed king of tort reform." Terry Carter, *Piecemeal Tort Reform*, ABA JOURNAL (December 2001). Despite Mr. Schwartz's lengthy list of accomplishments, he is hardly a neutral author.

The Chamber's assertion that manufacturers might not be able to obtain insurance "to cover another manufacturer's products," Chamber Br. 23, might sound serious, but it is another red herring. As detailed in plaintiff's brief and in this brief

as well, the judgment for plaintiff in this case is based on defendant's own negligent conduct, for which it surely is insured.

There is likewise no merit to the Chamber's alleged concerns about manufacturers leaving the market due to uncertainty and "unpredictable liability costs." Chamber Br. 24. The Chamber's reliance on *Germain v. Teva Pharms., USA, Inc.* (*In re Darvocet, Darvon, & Propoxyphene Products Liability Litigation*), 756 F.3d 917 (6th Cir. 2014), in support of this argument, Chamber Br. 24, is misplaced. *Darvocet* does not support this assertion generally and to the extent it does, it relies on Mr. Schwartz's article.

The Chamber's argument that liability in this case would lead to less innovation and "fewer innovative new products," Chamber Br. 24, is not supported with anything but inflammatory rhetoric. A Note about vaccinations for AIDS, Chamber Br. 25, has no applicability here, in a case involving application of settled Illinois negligence law.

B. The Pharmaceutical Research and Manufacturers of America has raised no significant public policy claims.

The thrust of The Pharmaceutical Research and Manufacturers of America's primary argument is that holding manufacturers, such as GSK, liable in this case will harm innovation. PhRMA Br. 7 *et seq*.

PhRMA tells the court that "[o]n average, developing and obtaining FDA approval of a new medicine takes ten to fifteen years and costs $2.6 billion."

PhRMA Br. 7. But it provides no data at all as to what it cost GSK to develop Paxil. If GSK spent the "average" amount to bring Paxil to market, its earnings on this drug, from the late 1990s to the mid-2000s, is about $9 billion. *See* Fraud Settlement, *supra*.

PhRMA presents no figures regarding the costs of monitoring, reviewing and reporting adverse events to the FDA and conducting additional studies after approval, other than to characterize such costs as "enormous." PhMRA Br. 9. Such generalizations do not help the court assess the bold assertion that "[i]f in the aggregate the net gains are wiped out by the liability costs, then the product will no longer be made." PhRMA Br. 9.

PhRMA's discussion of the anti-nausea drug, Bendectin, contraceptive products, and vaccines, PhRMA Br. 10-11, adds nothing to the mix either. This discussion is a mere distraction from the issue at bar – whether settled Illinois negligence law authorizes the judgment entered in this case. PhRMA's next argument, that affirming this judgment "could impair the usefulness of pharmaceutical labeling and harm public health," PhRMA Br. 14, is also inflammatory and unhelpful rhetoric designed to scare. There is no sound basis for PRMA's assertion that "[f]aced with the prospect of dwindling market share and unending lawsuits, innovators may opt to warn of every conceivable risk or withdraw their branded products from the market upon generic entry." *Id*.

It is pure speculation to infer that if this judgment is affirmed drug manufacturers "may 'pile on warnings.'" PhRMA Br. 15. It is also speculative to say that "consumers and physicians may disregard lengthy labeling that is filled with speculative warnings." PhRMA Br. 15. In this case, Stewart Dolin's physician testified that he would have heeded the warning about the potential for suicide for Paxil had such a warning been there, and he would have prescribed an alternative drug. The district court's decision does not require a name-brand company to provide consumers of generic versions warnings that are any broader or more extensive than the warnings it provides to consumers of its own product. This case is not about "overwarning." PhRMA Br. 15-16.

Further still, PhRMA presents no data or evidence to support its contention that drug manufacturers will withdraw from the market if this judgment is affirmed. *See* PhRMA Br. 17. This absence of evidence is telling in a brief from an "association comprised of the leading biopharmaceutical research and technology companies," who would presumably possess current and reliable facts regarding exactly that issue. PhRMA Br. 1.

Finally, whether liability of drug name-brand drug makers is "fundamentally unfair" in view of their disfavored treatment under the Hatch-Waxman amendments, PhRMA Br. 19, is an argument to be made to Congress.

C. The Washington Legal Foundation has raised no significant public policy claims.

The Washington Legal Foundation ("WLF") adds very little to the case.

As AAJ and ITLA have discussed above, resolution of this appeal does not require this court to "distort existing law to invent a new remedy for a sympathetic plaintiff." WLF Br. 24. Nor does it require this court to "rewrite existing law" or "balance the complex, interrelated, and divergent policy considerations in determining labeling and liability obligations of brand and generic pharmaceuticals." WLF Br. 24-25.

The district court upheld GSK's liability for its own negligence and negligent misrepresentations in preparing warning labels intended for consumers of both Paxil and its generic bioequivalents under well-settled Illinois tort law. This Court should affirm on the same basis. WLF's thinking that this is not a job for the courts is simply wrong.

CONCLUSION

For the foregoing reasons AAJ and ITLA urge this Court to affirm the judgment below.

Respectfully submitted,

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Dated: February 28, 2018

CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because this brief contains 6,913 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). I further certify that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman type style.

Date: February 28, 2018

/s/ Leslie J. Rosen
LESLIE J. ROSEN

CERTIFICATE OF SERVICE

I, Leslie J. Rosen, counsel for *amici curiae* and a member of the Bar of this Court, certify that on February 28, 2018, I electronically filed the foregoing document with the Clerk of Court for the United States Court of Appeals for the Seventh Circuit by using the appellate CM/ECF system. I also certify that the foregoing document is being served on this day on all counsel of record via transmission of the Notice of Electronic Filing generated by CM/ECF. All participants in this case are registered CM/ECF users.

/s/ Leslie J. Rosen
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