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 STEWART 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) (THE HONORABLE WILLIAM T. HART, J.)

BRIEF OF 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 AS AMICI CURIAE SUPPORTING DEFENDANT-APPELLANT

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APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 17-3030

Short Caption: Dolin v. GlaxoSmithKline LLC

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party or amicus curiae, or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statement be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

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(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P 26.1 by completing item #3):

Chamber of Commerce of the United States of America; American Tort Reform Association;

Product Liability Advisory Council, Inc.; National Association of Manufacturers;

Illinois Chamber of Commerce

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Williams & Connolly LLP

(3) If the party or amicus is a corporation:

i) Identify all its parent corporations, if any; and

None

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

None

Attorney's Signature: s/ Kannon K. Shanmugam Date: 1/29/2018

Attorney's Printed Name: Kannon K. Shanmugam

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/ Amy Mason Saharia Date: 1/29/2018

Attorney's Printed Name: Amy Mason Saharia

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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INTEREST OF AMICI CURIAE

The Chamber of Commerce of the United States of America ("the Chamber") is the largest organization of businesses in the world. It has 300,000 direct members and represents the interests of more than 3 million companies and professional organizations of all sizes, in every industry, and across all regions of the country. One of the Chamber's most important responsibilities is representing its members before the courts, legislatures, and executive branches of the federal government and of the States. The Chamber regularly files briefs as amicus curiae in litigation that touches on issues of vital concern to the Nation's business community. The Chamber has filed amicus briefs in numerous federal- and state-court proceedings in which plaintiffs have advanced the same novel theory of innovator liability that plaintiff advances here.[1]

The American Tort Reform Association (ATRA) is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil

[1] Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), amici state that no party or counsel for a party other than amici, their members, or their counsel authored this brief in whole or in part or made a monetary contribution intended to fund the preparation or submission of this brief.

litigation. For more than a decade, ATRA has filed amicus briefs in cases involving important liability issues.

The Product Liability Advisory Council, Inc. (PLAC), is a nonprofit association with 94 corporate members representing a broad cross-section of American and international products manufacturers. Those companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with an emphasis on the law governing the liability of product manufacturers. PLAC's perspective is derived from the experiences of a corporate voting membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred of the leading product liability defense attorneys in the country are sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed over 1,100 briefs as amicus curiae in both federal and state courts, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability.

The National Association of Manufacturers (NAM) is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs more than 12 million men and women, contributes $2.17 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for more than three-quarters of all private-sector research and

development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

The Illinois Chamber of Commerce (Illinois Chamber) is an association that zealously advocates on behalf of Illinois businesses to achieve a competitive business environment that will enhance job creation, job retention, and sustained economic growth. The Illinois Chamber is often referred to as the unifying voice of the business community in Illinois. The association consists of pharmaceutical manufacturers, other manufacturers, railroads, insurers, retailer and banks, in addition to a host of other industrial and commercial concerns. Just as the Chamber provides its members with benefits, these businesses, in turn, provide the State of Illinois with jobs, income, profits, and taxes that allow the State of Illinois and its residents to flourish.

The Chamber, ATRA, PLAC, NAM, the Illinois Chamber, and their members have a strong interest in this case. Although this case arises in the pharmaceutical context, the Court's resolution of the case could have a widespread, serious impact on product developers in all fields, which have until now relied on their understanding of long-settled principles of tort liability. Amici are uniquely positioned to explain the prevailing rule nationwide for imposing liability on a manufacturer only for harm traceable to the manufacturer's own product, and to address the significant policy consequences that might arise

from expanding that rule by holding a manufacturer responsible for harms inflicted by its competitors' products.

INTRODUCTION

It is a fundamental and well-settled principle of tort law, both in Illinois and across the Nation, that liability for harm caused by products is limited to the persons who actually made or sold the injurious products. A manufacturer thus has no duty to warn consumers or prescribers about products made and sold by a competitor, and it cannot be held liable for injuries caused by its competitor's products when the manufacturer does not control the manufacture of and has made no representations about those products, as opposed to its own.

That longstanding principle of tort liability applies with equal force in the context of the pharmaceutical industry, as courts around the country have confirmed. More than a hundred state and federal courts to have considered the question presented have concluded that pharmaceutical manufacturers, like all other manufacturers, may be held liable only for harm caused by their own products. There is no reason to believe that the Illinois Supreme Court would carve out an exception for the pharmaceutical industry, thereby eroding basic tort doctrines and disturbing settled expectations about the scope of tort liability.

Creating an exception to ordinarily applicable tort principles in the pharmaceutical context would lead to undesirable policy outcomes. Saddling innovator manufacturers with the liability costs of their generic competitors would increase the cost of innovation, and investment in developing and marketing innovative products would inevitably decrease—harming the economy and, uniquely in this field, public health. This Court should not recognize a novel principle of state law that would risk such profound problems for industrial and pharmaceutical innovation.

ARGUMENT

I. FUNDAMENTAL PRINCIPLES OF TORT LAW PRECLUDE THE IMPOSITION OF LIABILITY ON A MANUFACTURER FOR HARM CAUSED BY PRODUCTS MANUFACTURED BY ANOTHER

The American business community organizes its activities across the country in reliance on certain fundamental principles of tort law. One of those principles is the venerable rule that a manufacturer can be held liable only for harms caused by products it actually made or sold. That principle, and others like it, provide a backstop on which manufacturers and other businesses depend. No matter the theory of liability, under any set of facts, liability does not exist unless a specific product links the allegedly culpable manufacturer to a particular injury. No such link exists when a plaintiff is injured by a product the defendant manufacturer did not make and when the defendant did not

make any representations about that product. To impose liability without such a link would upend the settled expectations of businesses throughout the country and introduce serious uncertainty and instability into tort law.

A. As the Illinois Supreme Court has explained, "[b]oth negligence and strict liability require proof that defendant breached a duty owed to a particular plaintiff." *Smith* v. *Eli Lilly & Co.*, 560 N.E.2d 324, 343 (1990). And no matter the plaintiff's theory—whether strict liability or negligence, design defect or failure to warn—a manufacturer's duty is limited to avoiding harm that "could result from a particular use of *his product*." *Hayes* v. *Kay Chemical Co.*, 482 N.E.2d 611, 612 (Ill. App. Ct. 1985) (emphasis added). As Illinois courts have recognized, this duty can extend beyond "users" of a product to those who are incidentally injured by that product. *Id.* But in Illinois, as elsewhere, that duty does not extend beyond those who are actually injured by a product the defendant himself made or sold. As an Illinois appellate court put it in the context of determining a manufacturer's duty to warn of the relative riskiness of its product, a defendant "is under no duty to provide information on other products in the marketplace." *Pluto* v. *Searle Laboratories*, 690 N.E.2d 619, 621 (Ill. App. Ct. 1997).

In *Smith*, *supra*, the Illinois Supreme Court underscored that these universal principles apply with equal force in the context of pharmaceutical manufacturing: in order to hold a pharmaceutical manufacturer liable, a plaintiff

must show that the manufacturer "breached a duty owed to [that] *particular* plaintiff." *Smith*, 560 N.E.2d at 343 (emphasis added). As the court explained, although "[e]ach [pharmaceutical] manufacturer owes a duty to plaintiffs who will use its drug or be injured by it," that duty "is *not* so broad as to extend to anyone who uses the *type* of drug manufactured by a defendant." *Id.* (emphasis added). "Abrogation of these concepts would . . . result in violating the principle that manufacturers are not insurers of their industry," *id.* at 344, and would "alter . . . tort law significantly while only providing a markedly flawed alternative with unclear future ramifications," *id.* at 342. *Smith* indicates how the Illinois Supreme Court would decide the question presented in this case, where—as in *Smith*—the plaintiff attempts to hold a manufacturer liable for products manufactured by its competitors.

The correct analysis, moreover, does not turn on the plaintiff's theory of liability. Whether a plaintiff frames her claim in terms of fraud, strict liability, or something in between, tort law does not permit liability unless the plaintiff can identify an instrumentality linking the defendant's own conduct to the plaintiff's harm. *See Smith*, 560 N.E.2d at 343. In particular, no defendant can be liable for negligence without violating a duty it owes "to the plaintiff." *Kirk* v. *Michael Reese Hospital & Medical Center*, 513 N.E.2d 387, 395-396 (Ill. 1987).

B. The law of Illinois is no outlier in this regard. To the contrary, the vast majority of States agree that a manufacturer is responsible to warn only those who use its own products, not those who use products made and sold by its competitors. "[G]eneral tort principles" do not "impose liability with respect to a defendant that did not sell, distribute, manufacture, or otherwise have contact with the allegedly harmful product." *Schrock* v. *Wyeth, Inc.*, 727 F.3d 1273, 1284 (10th Cir. 2013). Absent a common instrumentality connecting the defendant to the plaintiff, the defendant would pay for harms it did not cause, severing the essential connection that justifies imposing liability in the first place.

The rule that a manufacturer is responsible to warn only those who use its own products is codified in Section 388 of the Second Restatement of Torts and its comments, on which the Illinois courts have relied to delineate the scope of the duty to warn. *See Carrizales* v. *Rheem Manufacturing Co.*, 589 N.E.2d 569, 577 (Ill. App. Ct. 1991). Section 388 provides that those who supply chattels have a duty to warn "those whom the supplier expects to use the chattel . . . or to be endangered by its probable use." Restatement (Second) of Torts § 388 (1965). And comment (e) to that section adds that liability "exists only if physical harm is caused by the use of the chattel by those for whose use the chattel is supplied." *Id.* cmt. e.

Plaintiff argued below, and the district court agreed, that this case is somehow different because the alleged harm arose not from appellant's product but from its representations *about* its product. But that attempted distinction is unavailing. In Illinois, as in other States, a manufacturer has a duty to warn only as to "a dangerous propensity of *its product*" when "it knows or should know that harm might or could occur if no warning is given." *Modelski* v. *Navistar International Transportation Corp.*, 707 N.E.2d 239, 246 (Ill. App. Ct. 1999) (emphasis added). Here, the warnings appellant issued were directed only at the users and prescribers of its own product; appellant had no duty to warn the decedent or his doctor because the decedent did not use any product appellant made.

To be sure, there are a few outlying decisions from other States that have recognized a novel duty for manufacturers to warn consumers who were injured by the products of the manufacturers' competitors. But those decisions arise in States that have adopted tort principles different from those in Illinois, and courts have applied those divergent principles to reach conclusions that Illinois law forbids. For example, the California Supreme Court's recent decision in *T.H.* v. *Novartis Pharmaceutical Corp.*, 407 P.3d 18 (2017), relies heavily on idiosyncratic features of California tort law. *See id.* at 47 (noting that "it is California law that we must construe and apply in this case"

and adding that, "[d]espite the impressive case authority [the defendant manufacturer] has collected on its behalf, none of it purports to interpret California law"). Most relevant for present purposes, the court emphasized that California tort law treats "the foreseeability of physical harm" as the "most important" factor in imposing a duty of care, and it distinguished leading cases that reached the opposite result on the basis that "California law places greater weight on the element of foreseeability" than does the law of other States. *Id.* at 29, 37 (citation omitted).

By contrast, the Illinois Supreme Court has held that "foreseeability alone provides an inadequate foundation upon which to base the existence of a legal duty." *Ward* v. *K Mart Corp.*, 554 N.E.2d 223, 226 (1990). And while California allows plaintiffs to hold defendants liable regardless of what kind of relationship existed between the parties, *see Novartis*, 407 P.3d at 37-38, the Illinois Supreme Court has conditioned the existence of a duty of care on "whether the defendant and the plaintiff stood in such a relationship to one another that the law imposed upon the defendant an obligation of reasonable conduct for the benefit of *the plaintiff*." *Kirk*, 513 N.E.2d at 396 (emphasis added). Here, appellant owed no duty to the decedent because it never sold him its products or made any representations to his doctor about the safety of the competing products allegedly at fault.

In sum, it is immaterial whether a plaintiff injured by a product asserts a claim sounding in fraud, negligence, or strict liability. If the defendant manufacturer did not produce that product or make representations about it, the manufacturer cannot be liable. Nor does the outcome change if the plaintiff argues that he was harmed by the defendant's statements about its own product (a product the plaintiff never used), as opposed to statements about the product that actually inflicted the plaintiff's injury. Under fundamental rules governing tort disputes—rules that Illinois has incorporated and applied—only the producer or seller of a product, or one who makes representations about that product, are responsible as a matter of state tort law for harm the product inflicts.

II. THERE IS NO VALID JUSTIFICATION FOR CREATING AN EXCEPTION TO FUNDAMENTAL PRINCIPLES OF TORT LAW IN THE CONTEXT OF THE PHARMACEUTICAL INDUSTRY

The foregoing basic principles of tort law apply across all industries, and there is no reason to believe that the Illinois Supreme Court would carve out an exception to those principles solely for pharmaceutical manufacturers. Courts across the Nation have overwhelmingly held that pharmaceutical manufacturers are not liable for injuries caused by their competitors' products. In the absence of an instrumentality linking a defendant's product or statements to the plaintiff's injuries, those courts—including every federal court of appeals to have considered the question and state courts in more than a dozen

jurisdictions—have concluded that the defendant cannot be held liable. As those courts have held, under the well-established principles that govern every tort case, the answer is clear: a manufacturer may be called to account only for the harms its own products inflict, regardless of the theory of liability on which a plaintiff's claim is based.

A. By way of background, a pharmaceutical manufacturer seeking regulatory approval from the Food and Drug Administration (FDA) for a new drug must submit a new drug application (NDA), showing that the drug is safe for use and effective for its indications and that the proposed label accurately and sufficiently describes the risks of its use. *See* 21 U.S.C. § 355(b)(1), (d). Once granted, an NDA brings with it certain responsibilities, including the obligation to submit annual reports demonstrating the safety, effectiveness, and appropriate labeling of approved drugs. *See* 21 C.F.R. §§ 314.80, 314.81. Pharmaceutical manufacturers that hold NDAs may also submit supplemental applications to change the label and accompanying warnings of a drug, and they are required to do so if they learn of a risk not already adequately identified. *See* 21 C.F.R. §§ 314.70, 314.71.

Congress also has created a streamlined process for approval of generic versions of brand-name drugs once the patent exclusivity accorded to new pharmaceutical products expires. *See* Drug Price Competition and Patent

Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Hatch-Waxman Act) (codified as amended at 21 U.S.C. § 355(j)). A generic pharmaceutical manufacturer can submit an abbreviated new drug application (ANDA), which requires only that the manufacturer show that its product is "bioequivalent" to the brand-name drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv). That process allows the generic manufacturer to rely on the safety and effectiveness studies conducted by the original brand-name manufacturer at its own expense. *See id.*

After ANDA approval, a generic manufacturer is required to maintain a label and accompanying warnings for its product that are "the same" as those used for the brand-name drug with which the generic version competes. *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 613 (2011) (citing 21 U.S.C. §§ 355(j)(2)(A)(v), 355(j)(4)(G), and 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7)). While generic pharmaceutical manufacturers are not authorized independently to update the labels for their products, *PLIVA*, 564 U.S. at 613, they otherwise have similar responsibilities to those of NDA holders: they are required to monitor the market and to submit annual reports and supplemental applications (when appropriate) to FDA. *See* 21 C.F.R. §§ 314.70, 314.71, 314.80, 314.81, 314.97, 314.98; 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992). According to FDA, "[g]eneric drug manufacturers that become aware of safety problems must ask

the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug." *PLIVA*, 564 U.S. at 616.

B. Since 1996, at least 134 federal- and state-court decisions have concluded that pharmaceutical manufacturers cannot be held liable for products made and sold by others. Those decisions rely on three basic lines of reasoning. *First*, general principles of tort law impose liability on manufacturers only for injuries caused by their own products and do not impose a duty on manufacturers to warn consumers about the risks associated with other manufacturers' products. *Second*, the labels and warnings issued by brand-name manufacturers are representations only about the safety of their own products, not about the safety of their competitors' products. *Third*, policy considerations—and in particular, the need to promote innovation—strongly counsel against creating a special rule holding pharmaceutical manufacturers liable for injuries resulting from their competitors' products.

The first federal court of appeals to confront this question was the Fourth Circuit, in a 1994 case that considered whether a plaintiff injured by the generic version of a drug could recover from the manufacturer of the drug's brand-name analogue. *See Foster* v. *American Home Products Corp.*, 29 F.3d 165, 168-169 (4th Cir. 1994). The Fourth Circuit held that the brand-name manufacturer could not be held liable under Maryland law. *See id.* at

169. The court reasoned that each manufacturer was responsible for preventing the consumers of its own products from being injured, and was correspondingly liable only for its own products' harms; it "stretch[ed] the concept of foreseeability too far" to impose a duty on brand-name manufacturers to warn those who never used their products of the risk of harm posed by products their competitors made and sold. *See id.* at 169-171.

Since *Foster*, six other federal courts of appeals have followed suit and held that brand-name pharmaceutical manufacturers cannot face liability for injuries caused by their competitors' products. For example, the Eighth Circuit held that a plaintiff could not adequately show that the brand-name manufacturers "owed her a duty of care necessary to trigger liability" under Minnesota law, in part because their statements about their products were representations made to "their customers, not the customers of their competitors." *Mensing* v. *Wyeth, Inc.*, 588 F.3d 603, 613 n.9, 614 (2009), *rev'd on other grounds*, 564 U.S. 604 (2011), *opinion reinstated in relevant part*, 658 F.3d 867 (8th Cir. 2011).

The Sixth Circuit followed suit, applying Kentucky law to "reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company." *Smith* v. *Wyeth, Inc.*, 657 F.3d 420, 424 (2011). Several years later, the Sixth Circuit revisited the issue in a multidistrict litigation, examining the law of

some 22 States (including Illinois) and concluding in each case either that a manufacturer owed no duty to a plaintiff injured by a drug produced by its competitor, or that the plaintiff's suit was otherwise barred under state-specific product-liability statutes or rules. *See In re Darvocet, Darvon & Propoxyphene Products Liability Litigation*, 756 F.3d 917, 937-939, 941-954 (2014) (disagreeing with the district court's decision in this case).

The Fifth, Ninth, Tenth, and Eleventh Circuits have also held that a plaintiff has a claim only against the manufacturer of the pharmaceutical product that caused the injury, no matter the theory of liability. *See Lashley* v. *Pfizer, Inc.*, 750 F.3d 470, 476 (5th Cir. 2014) (per curiam) (concluding that, "because [a]ppellants did not ingest the brand manufacturers' products, these defendants have no common-law duty to them"); *Moretti* v. *Wyeth, Inc.*, 579 Fed. Appx. 563, 565 (9th Cir. 2014) (holding that "Nevada law [does not] recognize[ ] a claim against the [b]rand [d]efendants for misrepresentation"), *cert. denied*, 135 S. Ct. 1398 (2015); *Guarino* v. *Wyeth, LLC*, 719 F.3d 1245, 1253 (11th Cir. 2013) (concluding that "Florida law does not recognize a [misrepresentation] claim against the brand manufacturer of a prescription drug when the plaintiff is known to have consumed only the generic form"); *Schrock*, 727 F.3d at 1283-1286 (noting that "[n]o authority is cited to suggest that a manufacturer may be held liable under Oklahoma law for concealing a defect in a product that is never purchased or used by the plaintiff").

In all of these cases, the courts, while applying the law of different States, reached the same conclusion. Although there are variations in tort law from State to State, the law of each State grows out of and incorporates certain common principles. One of those principles is that a defendant can be held liable only for harm fairly traceable to its own acts or omissions. In the product-liability context, an individual manufacturer can thus be called to account only for harms caused by its own products. Courts have consistently concluded that manufacturers cannot be held responsible for failing to warn against or prevent harm caused by products they did not make, from which they did not profit, and about which they made no statements at all.

As in other similar cases, plaintiff argues that, in the wake of *PLIVA* and *Wyeth* v. *Levine*, 555 U.S. 555 (2009), the law treats brand-name and generic pharmaceutical manufacturers differently: under *Wyeth*, consumers injured by brand-name pharmaceutical drugs may sue brand-name manufacturers for their harms, while under *PLIVA*, generic manufacturers are not liable for injuries their products inflict. Br. 26-29. But the mere fact of that disparate treatment under *federal* preemption law does not justify reshaping the accepted principles of *state* tort liability and discarding principles that guide the decisionmaking of manufacturers in all industries. The *PLIVA* Court acknowledged that "federal drug regulation" dealt individuals such as plaintiff an "unfortunate hand," but it nonetheless refused to "distort the Supremacy

Clause" to create a remedy. 564 U.S. at 625-626. So too here, this Court should not "distort" Illinois tort principles to provide a remedy. "Congress and the FDA retain the authority to change the law and regulations" so as to hold generic manufacturers liable for harm caused by their products, *id.* at 626, and resolving any inconsistencies in federal law is the proper province of those federal actors—all the more so in a case like this, where the choice of liability rule implicates "health care policy for the [entire] country." Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 Fordham L. Rev. 1835, 1875 (2013) (Schwartz).[2] If federal drug regulations treat similarly situated consumers differently, it is up to Congress or FDA to change the law.

It would create more problems than it would solve if longstanding principles of tort law were modified to address apparent (and potentially temporary) anomalies in federal preemption law. That is especially true because the question of whether to expand tort liability to those that did not manufacture the injury-causing product "involves policy choices . . . more appropriately

[2] FDA has twice issued proposed rules that would permit generic pharmaceutical manufacturers to amend their labels in certain circumstances, which could restore generic pharmaceutical manufacturer liability for harms caused by their own products. *See* 80 Fed. Reg. 8577-01 (Feb. 18, 2015); 78 Fed. Reg. 67985-02 (Nov. 13, 2013).

[made] within the legislative domain." *Huck* v. *Wyeth, Inc.*, 850 N.W.2d 353, 376 (Iowa 2014) (internal quotation marks omitted), *cert. denied*, 135 S. Ct. 1699 (2015). And any exception this Court might carve into fundamental tort principles, even if intended to apply only to the pharmaceutical industry, would introduce uncertainty across all industries in the calculation of what tort liability an innovator should expect to face. The Court should reject the invitation to create a far-reaching solution to a potentially temporary problem when that solution risks significant costs to the public and the economy by discouraging innovation.

III. CREATING AN EXCEPTION TO FUNDAMENTAL PRINCIPLES OF TORT LAW IN THE CONTEXT OF THE PHARMACEUTICAL INDUSTRY WOULD HAVE SERIOUS ADVERSE POLICY CONSEQUENCES

Courts across the Nation have recognized that public-policy considerations strongly support the conclusion that a manufacturer should not be liable for harm caused by its competitors' products. Shifting liability onto innovative manufacturers in any industry comes at too high a cost and risks too much. As the Illinois Supreme Court has explained, courts should not "adopt a theory which would alter [Illinois] tort law significantly while only providing a markedly flawed alternative with unclear future ramifications." *Smith*, 560 N.E.2d at 342.

The original developer of a product incurs significant costs. And no matter how costly its development, a new product may never even be sold, much less prove successful, if regulatory or marketplace obstacles prove insuperable. Even if the developer manages to steer a product to the marketplace and market it successfully, it has no guarantee that its profits will ever cover its investment. And of course, the developer must also consider, and price in, the potential cost of liability to consumers for the product. The challenges a developer faces are all the more significant given the competition of alternatives, which can crowd the original developer out of the market entirely—even more so when competitors can entirely forgo the cost of development, regulatory approval, and marketing.

As many courts have recognized, those challenges are uniquely acute for pharmaceutical manufacturers. *See, e.g.*, *Foster*, 29 F.3d at 170; *Huck*, 850 N.W.2d at 376. Developing and obtaining approval for groundbreaking pharmaceutical products can require enormous investment over decades. And federal law and regulations 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. That being said, similar problems "may arise with other types of consumer goods, ranging from nonprescription drugs and foods to household chemicals and appliances; in other words, crossover tort litigation could occur in any market served by brand-

name companies that actively promote their wares but face competition from largely identical but lower-priced store brands" or other competing alternatives. Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product*, 45 Tort Trial & Ins. Prac. L.J. 673, 694 (Spring-Summer 2010).

Whatever the challenges of developing new products, developers have always been able to rely on the settled understanding that their exposure to risk is limited to the products they manufacture or sell themselves. That settled understanding allows manufacturers to anticipate their potential liability based on their sales; to set the price of their products at a level adequate to cover those projected costs; and to negotiate with insurers to cover that projected liability. Developers depend on that understanding when they make decisions about how to develop new products. And relying on that understanding, American industry has achieved dazzling success in innovation in all fields—with appropriate opportunity for those injured by innovative products to recover from those that produced them, and with appropriate incentives for those that produce innovative products to ensure that their products are safe and bear adequate warnings. *See Huck*, 850 N.W.2d at 379-380.

Shifting the cost of harm to consumers onto manufacturers whose products the consumers did not even use risks permanently disrupting developers' ability to plan for the future and to project the size of their risk. Developers

of new products would face liability arising from product sales made not by them but by competitors that took advantage of the innovators' initial investment in research, regulatory approval, and marketing. Such a shift would effectively force innovators in all industries to serve as insurers for the tort liability arising from all sales of their own and their competitors' products, increasing their cost but not the cost of competing alternatives. As the Illinois Supreme Court has already explained, however, "manufacturers are not insurers of their industry." *Smith*, 560 N.E.2d at 344. And imposing such a burden on innovator manufacturers here would be particularly unjust where the competitors were able to bring their products to market without paying for development, regulatory approval, or marketing. *See, e.g.*, Sarah C. Duncan, Note, *Allocating Liability for Deficient Warnings on Generic Drugs: A Prescription for Change*, 13 Vand. J. Ent. & Tech. L. 185, 215 (2010); Schwartz 1861.

What is more, the assignment of 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, unavoidable uncertainty into the calculus of product development. A manufacturer naturally takes into account tort liability to consumers of its own products in developing and pricing its products. As the Second Restatement of Torts recognizes, product-liability costs are to "be treated as

a cost of production against which liability insurance can be obtained." Restatement (Second) of Torts § 402A cmt. c. But the new rule plaintiff asks this Court to adopt would not merely multiply the size of tort liability; it would also render it unpredictable. An innovator would need to predict, years in advance, the number of generic competitors it would face, the sales of those competitors, and other similar considerations. The loss of predictability in projecting risk is even costlier than the dollar value of tort judgments in favor of the class of consumers injured by competitors' products. *See* Schwartz 1870. And manufacturers would also face significant planning and compliance costs from the need to balance any new rule, applicable in Illinois, with the long-settled rule that would still apply throughout most of the rest of the Nation.

Not only would the risks facing innovator manufacturers be unpredictable; they may also be uninsurable. Product-liability insurance covers a manufacturer's own products; it is questionable whether insurers would provide insurance to cover another manufacturer's products. As one Illinois court put it, "it is one thing to assume that a manufacturer can acquire insurance against potential liability for its own products and another to assume it can acquire such insurance for the products made by a different manufacturer." *Nguyen* v. *Johnson Machine & Press Corp.*, 433 N.E.2d 1104, 1111 (Ill. Ct. App. 1982).

As the Illinois Supreme Court has observed, any tort-law innovation that "broaden[s] manufacturers' liability exposure," especially one requiring them

to "insure against losses arising from the products of others in the industry as well as their own," will inevitably "contribute to diminishing participants in the market as well as research and availability" of new products. *Smith*, 560 N.E.2d at 341-342. *First*, the cost of innovative products would necessarily rise to fund the increased scope of liability that would follow once competing versions entered the market. In the pharmaceutical context—where generic versions of a drug quickly dominate the market when introduced—the innovator would have to price the costs of marketwide tort liability into a fraction of the products sold in the market. That would make brand-name products prohibitively expensive, which would have a negative effect on public health. *See, e.g.*, *Darvocet*, 756 F.3d at 944, 945, 947, 948-949; Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 Tenn. L. Rev. 1357, 1360 & nn.17-18 (1994) (T. Schwartz). Over time, as the innovator sells fewer and fewer products in the face of generic competition, it could well leave the market altogether.

Second, and relatedly, confronted with ballooning and unpredictable liability costs, rational manufacturers would necessarily devote fewer resources to innovation and release fewer innovative new products. *See*, *e.g.*, *Darvocet*, 756 F.3d at 944, 945, 947, 948-949; T. Schwartz 1360 & nn.17-18. Manufacturers would have less incentive to launch new products because their profits

from those products would be decreased (or wiped out altogether) by the murky and expanded scope of their tort exposure.

Innovative developers would have to guess not merely at the size of their own liability, but also at the cost of insuring the sales of the product for an unknown period into the future. Any company contemplating investing in innovative research and development would have to weigh the benefits of new products against enormous risks it could neither calculate nor control. This unpredictability would also affect the ability of manufacturers to arrive at meaningful valuations of their product lines and businesses as a whole, hampering their access to credit and insurance and their ability to sell and license their own products.

The results of a more expansive liability regime are highly unpredictable. Perhaps only blockbuster products, promising large and lasting profits, would prove worth the candle. Or perhaps manufacturers would eliminate products or whole product lines altogether in an effort to control their potential liability. No matter the specific strategy adopted by individual manufacturers, the aggregate consequence is clear and unavoidable: consumers would see fewer new products brought to market. *See* Schwartz 1871.

For most types of products, that decline might simply represent overall losses to the economy. For the pharmaceutical industry, however, the prospect is much more serious: the economic and social burden of an expansion

of liability would include harm to public health. *See* H. William Smith III, Note, *Vaccinating AIDS Vaccine Manufacturers Against Product Liability*, 42 Case W. Res. L. Rev. 207, 218 & n.80 (1992) (discussing the efforts of courts in other States to shape the liability of pharmaceutical manufacturers to avoid the risk of "deter[ring] the marketing of new products for fear of large adverse monetary judgments").

The foregoing policy considerations have long informed the fundamental rule that tort liability can attach only where a common instrumentality links the injured person to the alleged wrongdoer. A more expansive liability regime would disturb the existing equilibrium between the undoubted obligation to redress injuries and the need to allocate liability in a way that maximizes innovation and overall well-being. Nothing suggests that the Illinois Supreme Court would disregard those policy considerations by creating an exception to well-settled tort principles for pharmaceutical manufacturers.

Nor is there any valid reason to believe that such an exception could remain cabined to the pharmaceutical industry. As another state court of last resort has noted, creating such an exception would leave courts on a "slippery slope." *Huck*, 850 N.W.2d at 380. Competitors copy innovative designs across many industries, whether by reverse engineering or otherwise. Under plaintiff's theory of innovator liability, would an innovator be liable to users of a product reverse-engineered by a competitor? For example, "[i]f a car seat

manufacturer recognized as the industry leader designed a popular car seat, could it be sued for injuries sustained by a consumer using a competitor's seat that copied the design?" *Id.*; *see also* Schwartz 1869-1870 (noting that "there is no principle limiting competitor liability to prescription drugs"). At a minimum, a new rule of tort liability for the pharmaceutical industry would destabilize the assumptions made by manufacturers in other industries about how far tort liability can run, and prudent manufacturers in all industries would have to consider the possibility that such a rule would be applied to their products as well.

The dramatic change to tort law that plaintiff seeks in this case threatens serious and unmistakable consequences. Plaintiff's proposed rule would disrupt the process of developing new products in all industries, including the development of life-saving pharmaceuticals. This Court should reject that rule and reaffirm the principle, already recognized by Illinois courts, that a manufacturer may be held liable only for harm caused by its own product.

CONCLUSION

The judgment of the district court should be reversed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE
WITH TYPEFACE AND WORD-COUNT LIMITATIONS

I hereby certify that:

1. This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) and 7th Cir. R. 32(c) because it contains 6204 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f); and

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JANUARY 29, 2018

CERTIFICATE OF SERVICE

I, Kannon K. Shanmugam, counsel for amici curiae and a member of the Bar of this Court, certify that, on January 29, 2018, a copy of the attached Brief of Amici Curiae in Support of Defendant-Appellant was filed with the Clerk and served on the parties through the Court's electronic filing system. I further certify that all parties required to be served have been served.

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