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
The Hon. William T. Hart
Case No. 12-cv-6403

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANT-APPELLANT, URGING REVERSAL

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Appellate Court No: 17-3030

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IDENTITY AND INTEREST OF *AMICUS CURIAE*[1]

Washington Legal Foundation (WLF) is a nonprofit, public-interest law firm and policy center with supporters in all 50 States, including Illinois. WLF devotes much of its resources to defending and promoting free enterprise, individual rights, a limited government, and the rule of law. To that end, WLF often appears as *amicus curiae* before this and other federal and state courts in cases deciding the proper scope of liability for prescription drug manufacturers. *See, e.g.*, *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574 (7th Cir. 2017); *In re Zoloft Prods. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017); *In re Cipro Cases I & II*, 61 Cal. 4th 116 (2015).

In addition, WLF's Legal Studies Division, the publishing arm of WLF, regularly publishes articles about pharmaceutical liability—including the novel theory of "innovator liability" at issue in this appeal. *See, e.g.*, John J. Park, Jr., *Law Rejecting "Innovator Liability" Theory Restores Civil Justice Sanity to Alabama*, WLF Legal Opinion Letter (June 19, 2015); Victor E. Schwartz & Phil Goldberg, *Iowa High Court Exposes Pharma "Innovator Liability" for What It Is: Deep-Pocket Jurisprudence*, WLF Legal Opinion Letter (Sept. 12, 2014).

[1] Under Fed. R. App. P. 29(a)(4)(E), *amicus* WLF states that no party's counsel authored this brief in whole or in part, and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief.

WLF believes that public health and the American economy both suffer when longstanding common-law tort principles are distorted to create a basis for imposing massive liability on prescription drug manufacturers for injuries caused by drugs they neither sold nor manufactured. That liability is especially misguided when, as here, it would upset the careful regulatory-policy balance that Congress has watchfully maintained for decades between innovator and generic drug manufacturers in the pharmaceutical field. WLF fears that allowing non-expert judges and juries to second-guess that delicate policy balance, as the district court did below, undermines the very public-health and safety goals that WLF seeks to further.

STATEMENT OF THE CASE

The relevant facts are set out in detail in Appellant's opening brief. WLF wishes to highlight several facts of particular relevance to the innovator liability issue on which this brief focuses.

The Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, regulates the sale and distribution of all prescription drugs to the public. Section 352(f) provides that every approved drug must bear "adequate directions for use." *Id.* § 352(f). FDA does not approve the marketing of a new drug unless it is satisfied that, among other things, the drug is safe, effective, and adequately labeled for its intended use. *Id.* § 355(d).

In 1984, Congress amended the FDCA by adopting the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Hatch-Waxman Act), which streamlined the approval of generic versions of previously-approved branded drugs whose exclusive patent protection expired. Hatch-Waxman created the Abbreviated New Drug Application (ANDA) process to facilitate quicker market entry by lower-priced drugs following expiration of the original New Drug Application (NDA) applicant's exclusive marketing period. Under that process, companies seeking to market a generic version of a previously-approved drug can rely solely on the safety and effectiveness data in the original NDA filing. 21 U.S.C. § 355(j).

The only significant scientific information required in an ANDA is evidence that the applicant's generic drug is "bioequivalent" to the original branded drug. *Id.* § 355(j)(2)(A)(iv). If the ANDA establishes bioequivalence, Congress assumed that the generic drug shares the branded drug's safety and effectiveness. That assumption significantly reduces the cost of developing, manufacturing, and marketing generic drugs. As amended by Hatch-Waxman, the FDCA provides that FDA may not approve the ANDA unless the application establishes that the labeling "is the same." *Id.* § 355(j)(4)(G).

FDA regulations require a generic drug to maintain the same labeling as the branded drug throughout the lifecycle of the generic drug. *See* 21 C.F.R.

§ 314.150(b)(10). Because it is impossible for generic manufacturers "to comply with both their state-law duty to change the label and their federal law duty to keep the label the same," the U.S. Supreme Court has determined that Congress intended to preempt all failure-to-warn claims under state law against generic manufacturers. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011). Although a generic manufacturer cannot unilaterally alter its label, if it "believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and [branded] drugs should be revised." 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992).

This appeal arises from Wendy Dolin's negligence suit alleging that her late husband's 2010 suicide was caused by ingesting paroxetine, a selective serotonin reuptake inhibitor (SSRI) widely used to treat depression and anxiety disorders. R.1-1. Although from 1992 to 2014 GlaxoSmithKline (GSK) manufactured and marketed Paxil—a branded version of paroxetine approved by the FDA as safe and effective—it is undisputed that Mr. Dolin *never* took Paxil. A2. Instead, Mr. Dolin took only a generic version of paroxetine manufactured and marketed by Mylan Pharmaceuticals, a generic competitor of GSK. *Id.*

The district court dismissed Mrs. Dolin's claims against Mylan on preemption grounds. A24-A25. But Mrs. Dolin also sued GSK on the theory that because generic paroxetine bears labeling identical to Paxil's, GSK should be

liable under Illinois law for failing adequately to warn her husband's doctor about the risk of suicidal behaviors allegedly associated with Mylan's drug. GSK sought summary judgment, arguing that Illinois tort law would not support liability because GSK neither manufactured nor sold the paroxetine that Mr. Dolin ingested. A2-A3. The district court denied summary judgment, reasoning that because "it was entirely foreseeable that negligence on the part of GSK with respect to paroxetine's design and warning label could result in injury to a consumer ingesting a subsequent generic version of the drug," Illinois law recognizes a duty running from branded manufacturers to the customers of their generic competitors. A10.

Plaintiff advanced to trial on a single negligence claim. At the close of evidence, GSK unsuccessfully sought judgment as a matter of law, in part by incorporating earlier arguments against innovator liability from its summary judgment motions. The jury returned a verdict of $3 million in Plaintiff's favor. R.569. GSK renewed, again unsuccessfully, its motion for judgment as a matter of law, and the district court entered final judgment. R.588. This appealed followed.

SUMMARY OF ARGUMENT

In a highly controversial decision, the district court held that Illinois law permits a negligence claim against a branded drug manufacturer when the drug that injured the plaintiff was manufactured and sold by the defendant's generic

competitor. The essence of the district court's theory of liability was that "it was entirely foreseeable that negligence on the part of GSK with respect to paroxetine's design and warning label could result in injury to a consumer ingesting a subsequent generic version of the drug." A10.

But Illinois imposes no legal duty based on mere "foreseeability," and the district court's unbounded theory of liability expands Illinois tort law well beyond its basic moorings. Under Illinois law, as nearly everywhere else, a manufacturer owes no duty of care to the customers of its competitors. Instead, Illinois law recognizes a duty of manufacturers to warn consumers of the dangerous propensities of *only their own* products. Simply put, companies are not their competitors' keepers, nor are they insurers against harm from products they never manufactured or sold.

Contrary to the district court's view, mere "foreseeability" cannot justify a new duty where none existed before. By conflating the existence of a legal duty with the foreseeability of injury, the district court's novel theory of liability also marks a sharp and unwarranted break from longstanding principles of tort law. Under those well-established precepts, foreseeability determines the *scope* of a duty; it does not determine whether a duty *exists*.

Whether a duty exists is a quintessential question of law; what constitutes the scope of that duty is mainly a question of fact for the jury. If no duty exists in

the first place, then no need arises to determine the scope of duty by considering whether the injury was foreseeable. For these reasons, among many others, the district court's "foreseeability-ergo-negligence" approach to tort duty has been roundly rejected.

In any event, this Court should reject Plaintiff's call to alter the careful policy balance that Congress has watchfully maintained in the pharmaceutical market for decades. It is not for the judiciary to fashion a remedy for plaintiffs by distorting existing law, particularly in the context of a comprehensive federal regulatory scheme. Only Congress has the institutional capacity to fully accommodate the many competing interests implicated in regulating prescription drugs.

Allowing non-expert judges and juries to second-guess that careful balance, as happened here, severely undermines Congress's preferred policy aims. This Court should therefore reject the district court's novel legal theory, which would shift liability to branded manufacturers any time a generic competitor's drug causes an injury. The deeply flawed judgment below should be reversed.

ARGUMENT

I. MERE "FORESEEABILITY" IS A LEGALLY INSUFFICIENT BASIS FOR ESTABLISHING A DUTY OF CARE

The district court's recognition of innovator liability hinged almost entirely on the "foreseeability" that an inadequacy in the labeling of a branded drug may

ultimately result in injury to consumers of the generic version of that drug. But that is not the law. By conflating a preexisting legal duty with the "foreseeability" of a potential injury resulting from a breach of that duty, the district court's *sui generis* approach to negligence—if adopted by this Court—would not only upend long-settled tenets of Illinois negligence law but would also run roughshod over universally held bedrock principles of tort law. As explained below, this Court should reject the district court's misguided attempt to make "foreseeability" the first and last word when establishing negligence under Illinois law.

A. The District Court's Overreliance on "Foreseeability" as the Basis for Imposing a Common-Law Duty on GSK Contravenes Illinois Tort Law

Plaintiff advanced to trial on a single claim, negligent failure to warn. In evaluating that claim on summary judgment, the district court placed undue emphasis on whether the risk of harm was "foreseeable." Noting that "Plaintiff has alleged that GSK was at least negligent in connection with paroxetine's design and warning label," the district court then remarked that "the foreseeability of Plaintiff's injury as a result of such negligence should not be controversial." A10. The district court then bottomed liability on its view that "it was entirely foreseeable that negligence on the part of GSK with respect to paroxetine's design and warning label could result in injury to a consumer ingesting a subsequent generic version of the drug." *Id.* But to speak of "negligence" before establishing

the existence of a duty the defendant owes to the plaintiff is to put the cart before the horse.

To prevail on a claim of negligence under Illinois law, "the plaintiff must plead and prove the existence of a duty owed by the defendant to the plaintiff, a breach of that duty, and injury proximately resulting from the breach." *Carney v. Union Pac. R. Co.*, 412 Ill. Dec. 833, 839, 77 N.E. 3d 1, 7 (2016). Yet "because so many actions grounded upon negligence involve familiar patterns of conduct, it is easy to forget that implicit in an allegation of negligence is the assertion of a failure to comply with the standard of care that the law requires—the assertion of a duty and its breach." *Lance v. Senior*, 36 Ill. 2d 516, 518, 224 N.E. 2d 231, 233 (1967). In denying GSK's motion for summary judgment on innovator liability, the district court evaded this crucial inquiry.

Above all, the threshold question in *every* negligence action is whether the defendant owed the plaintiff a duty of care. If the answer to this question is no, the analysis ends because no tort has occurred. "In the absence of a showing from which the court could infer the existence of a duty, no recovery by the plaintiff is possible as a matter of law." *Bruns v. City of Centralia*, 386 Ill. Dec. 765, 770, 21 N.E. 3d 684, 689 (2014); s*ee Gregory v. Beazer East*, 322 Ill. Dec. 926, 935, 892 N.E. 2d 563, 572 (2008) ("[U]nless the plaintiff can demonstrate that a duty is owed … there can be no negligence imposed on the defendant."). Here, the district

court's dogged reliance on mere "foreseeability" cannot possibly satisfy the threshold requirement of duty, so the judgment below should be reversed.

Whether a defendant owes the plaintiff a legal duty in any given case "is a question of law for the court to decide." *Choate v. Ind. Harbor Belt R.R. Co.*, 366 Ill. Dec. 258, 264, 980 N.E. 2d 58, 64 (2012). By contrast, "[q]uestions of foreseeability are ordinarily for a jury to resolve." *Kirk v. Michael Reese Hosp. and Med. Ctr.*, 111 Ill. Dec. 944, 950, 513 N.E. 2d 387, 393 (1987). This approach strikes "a sound balance between inviting trial courts to invade the jury's province on what is essentially a factual matter, and permitting a sympathetic jury to find an event foreseeable in even the most bizarre cases." *Nelson by Tatum v. Commonwealth Edison Co.*, 80 Ill. Dec. 401, 407, 465 N.E. 2d 513, 519 (Ill. App. 1984). Stated differently, the *legal* question of whether a duty exists at all is both prior to and distinct from the *factual* question of whether the plaintiff's injury was a foreseeable result of that duty's breach. The district court inexplicably ignored this vital distinction.

Contrary to the district court's reasoning, "it appears from close examination and analysis of the determination of duty in Illinois cases that 'foreseeability of harm' in actuality plays little part in a resolution of the duty issue." *Zimmerman v. Netemeyer*, 78 Ill. Dec. 383, 387, 463 N.E. 2d 502, 506 (Ill. App. 1984). By extension, "[i]n determining whether the law imposes a duty, foreseeability of

possible harm alone is not the test, for in retrospect almost every occurrence may appear to be foreseeable." *Barnes v. Washington*, 56 Ill. 2d 22, 29, 305 N.E. 2d 535, 538 (1973); *see Cunis v. Brennan*, 56 Ill. 2d 372, 375, 308 N.E. 2d 617, 618 (1974) ("[T]he existence of a legal duty is not to be bottomed on the factor of foreseeability alone."); *Mieher v. Brown*, 54 Ill. 2d 539, 344, 301 N.E. 2d 307, 309 (1973) ("In a sense, in retrospect almost nothing is entirely unforeseeable."); *Lance*, 36 Ill. 2d at 518, 224 N.E. 2d at 233 ("After the event, hindsight makes every occurrence foreseeable, but whether the law imposes a duty does not depend on foreseeability alone.").

Even when relevant to determining the scope of a preexisting duty, foreseeability "is not intended to bring within the scope of the defendant's liability every injury that might possibly occur." *Winnett v. Winnett*, 57 Ill. 2d 7, 12, 310 N.E. 2d 1, 4-5 (1974). Instead, the duty inquiry under Illinois law focuses mainly on "whether defendant and 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 plaintiff." *Bruns*, 386 Ill. Dec. at 770, 21 N.E. 3d at 689. Under this approach, the "the magnitude of the burden of guarding against it and the consequences of placing the burden upon the defendant, must also be taken into account." *Lance*, 36 Ill. 2d at 518, 224 N.E. 2d at 233. Yet as the Sixth Circuit has recognized, the district court below gave short shrift to these important

considerations. *See In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 944-45 (6th Cir. 2014) (applying Illinois law) ("[T]he *Dolin* court failed to properly account for the magnitude of brand manufacturers' burden of guarding against the injury; and the consequences of placing that burden on the brand manufacturers.").

As GSK persuasively shows in its opening brief, such considerations weigh strongly against imposing a new duty on branded drug manufacturers that runs to consumers of their generic competitors. Nor would it be fair to do so. *See, e.g.*, *Huck v. Wyeth, Inc.*, 850 N.W. 2d 353, 376 (Iowa 2014) (explaining that "it would be 'especially unfair to find brand manufactures have a duty to those who take generic drugs 'when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its label and riding on the coattails of its advertising") (quoting *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994)). The district court's contrary holding simply "stretches foreseeability too far." *In re Darvocet*, 756 F.3d at 947.

The duty to warn about the risks posed by generic drugs rests with generic manufacturers. Although federal law may sometime preempt the *remedy* that injured plaintiffs may seek under state law against generic manufacturers, such preemption does not alter the *duty* such manufacturers owe to prescribers of their own products. Despite the federal preemption of certain tort remedies, generic

manufacturers still have an independent, non-delegable duty under federal law to monitor drug safety and to seek labeling changes when necessary. Indeed, if a generic manufacturer "believes that new safety information should be added" to its drug labeling, it must "provide adequate supporting information to FDA, and the FDA will determine whether the labeling for" that drug should be revised. 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992). Because this duty exists regardless of the availability of any remedy for breaching it, shifting that duty to a branded manufacturer who neither manufactured nor sold the drug that injured the plaintiff makes no sense.

In any event, it is axiomatic that a manufacturer under Illinois law owes a duty of care to *only* "those who will use its product or who might be injured by it." *Lewis v. Lead Indus. Ass'n, Inc.*, 276 Ill. Dec. 110, 116, 793 N.E. 2d 869, 875 (Ill. App. 2003). That duty "is not so broad as to extend to anyone who uses or might be injured by a like-kind product supplied by another." *Id*. Most relevant here, a drug manufacturer "is under no duty to provide information on other products in the marketplace." *Pluto v. Searle Labs.*, 228 Ill. Dec. 860, 862, 690 N.E. 2d 619, 621 (Ill. App. 1997). Such as requirement "would only lead to greater liability on behalf of drug manufacturers that were required to vouch for the efficacy of a competitor's product." *Id.* It would also "raise serious implications regarding the free flow of commerce in that industry." *Id.*

This limitation on duty holds true even if *all* manufacturers of a given drug were similarly negligent. *Smith v. Eli Lily & Co.*, 148 Ill. Dec. 22, 41-42, 560 N.E. 2d 324, 343-344 (1990) ("Such a solution is an unreasonable over-reaction in attempting to achieve what is perceived as a socially satisfying result.)"; *cf. Kirk*, 111 Ill. Dec. at 950, 513 N.E. 2d at 393 ("Certainly, if the manufacturer of a prescription drug has no duty to directly warn the user of a drug of possible adverse effects, it has no duty to warn a nonuser."). As the Illinois Supreme Court has cautioned, bedrock tort principles "should not be ignored merely because the defendants are members of the drug industry." *Smith*, 148 Ill. Dec. at 42, 560 N.E. 2d at 344.

Consistent with these authorities, "[i]t would be unfair to impose liability on a manufacturer for a defect in a product unless the manufacturer had the opportunity to avoid liability by stopping the assembly line that produced the particular product." *Gillenwater v. Honeywell, Inc.*, 375 Ill. Dec. 123, 144, 996 N.E. 2d 1179, 1200 (Ill. Ct. App. 2013) (rejecting claim that a manufacturer can be held liable for a product that it did not manufacture because "a manufacturer is responsible only for the defects in the products it manufactured" and holding that "[a] manufacturer owes a duty to plaintiffs who will use its product or be injured by it, but the manufacturer does not owe a duty to anyone who uses a product similar to, but not manufactured by, the manufacturer").

Plaintiff premises her novel theory of duty on the federal regulatory requirement that generic manufacturers use the same drug label as branded manufacturers. But such a theory rests not on "the foreseeable result of the brand manufacturer's own conduct, but [on] the laws over which the brand manufacturers have no control." *In re Darvocet*, 756 F.3d at 944. That is why "an overwhelming majority of courts, in at least fifty-five decisions from twenty-two states, have rejected the contention that a name brand manufacturer's statement regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug." *Id.* at 938 (citations and quotation marks omitted). Illinois is among them. *See, e.g., Guvenoz v. Target Corp.*, 391 Ill. Dec. 134, 146, 30 N.E. 2d 404, 416 (Ill. App. 2015) (noting that the "overwhelming majority of courts have held that generic consumers may not sue the name-brand manufacturer" and that, under "existing jurisprudence," plaintiffs "cannot obtain relief from brand-name drug manufacturers whose products they did not ingest"). Given such a clear consensus, this Court should reject the district court's attempt to radically transform Illinois tort law.

B. The District Court's Expansive "Foreseeability" Test Violates Universal Principles of Tort Law

"It needs no argument to show that duty does not always coincide with foreseeable risk." William Prosser, *Palsgraf Revisited*, 52 Mich. L. Rev. 1, 16 (1953). Under long-settled principles of black-letter tort law, "foreseeability should

not be confused with duty. If there is no duty, the principle of foreseeability to determine the scope of duty is inapplicable. And foreseeability should not be employed as the sole means to create a duty where none existed before." 57A Am. Jur. 2d *Negligence* § 136 at 198 (1989). Yet that is precisely the sort of slapdash approach to tort liability that the district court undertook below—despite the overwhelming weight of authority to the contrary. Given that consensus, this Court should reject the district court's deeply flawed "foreseeability" test and clarify that foreseeability alone is never an adequate basis for imposing a new legal duty.

Under Plaintiff's untethered theory of liability, because nearly everything is arguably "foreseeable," almost everyone owes a duty of care to everyone else. Yet prominent tort scholars have long understood that "foreseeability" is a gossamer, flimsy basis for imposing tort liability: "however valuable the foreseeability formula may be in aiding a jury or judge to reach a decision on the negligence issue, it is altogether inadequate for use by the judge as a basis for determining the duty issue." Leon Green, *Foreseeability in Negligence Law*, 61 Colum. L. Rev. 1401, 1417-18 (1961). Indeed, "[i]f the foreseeability formula were the only basis of determining both duty and its violation, such activities as some types of athletics, medical services, construction enterprises, manufacture and use of chemicals and explosives, serving of intoxicating liquors, operation of automobiles and airplanes, and many others would be greatly restricted." *Id.* at 1418.

If adopted on appeal, the district court's novel theory of duty would far exceed the settled bounds of tort liability established over many decades. While "[i]t is always tempting to impose new duties and, concomitantly, liabilities, regardless of the economic and social burden," a clear line must still "be drawn between the competing policy considerations of providing a remedy to everyone who is injured and of extending exposure to tort liability almost without limit." 57A Am. Jur. 2d *Negligence* § 87 at 143 (1989). Contrary to Plaintiff's unsupported view, it is the relationship between the parties that lies at the core of the legal concept of duty, which is primarily concerned with whether that relationship "imposes upon one a legal obligation for the benefit of the other." William Prosser, *Handbook of the Law of Torts* § 53 at 324 (4th ed. 1971).

It should therefore come as little surprise that Plaintiff's "foreseeability-ergo-negligence" approach to imposing tort liability has found very little purchase among state or federal courts. As the U.S. Supreme Court has cogently explained, "[c]onditioning liability on foreseeability … is hardly a condition at all." *Conrail v. Gottshail*, 512 U.S. 532, 553 (1994). After all, "[i]f one takes a broad enough view, all consequences of a negligent act, no matter how far removed in time or space, may be foreseen." *Id.* That remains the overwhelming majority view. *See, e.g.*, *Samson v. Saginaw Prof'l Bldg., Inc.*, 393 Mich. 393, 406, 224 N.W. 2d 843, 849 (1975) ("[T]he mere fact that an event may be foreseeable does not impose a duty

upon the defendant to take some kind of action accordingly."); *D'Ambra v. United States*, 114 R.I. 643, 650, 339 A.2d 524, 528 (1975) ("Given the wide disparity, however, between what courts have found to be 'foreseeable' …, any strong reliance on [foreseeability] … would seem to be misplaced."); *Tobin v. Grossman*, 24 N.Y. 2d 609, 619, 249 N.E.2d 419, 424 (1969) ("Every inquiry has ramifying consequences, like the ripplings of the waters, without end. The problem for the law is to limit the legal consequences of wrongs to a controllable degree.").

Indeed, under the modern approach of the American Law Institute (ALI) *Restatement (Third) of Torts*, the foreseeability of harm does not factor into the existence of a duty owed at all but goes only to whether that duty has been breached. *See* American Law Institute, *Restatement (Third) of Torts: Liab. For Physical & Emotional Harm* § 7 (2010). As the drafters explained, the "extent of foreseeable risk depends on the specific facts of the case and cannot be usefully assessed for a category of cases; small changes in the facts may make a dramatic change in how much risk is foreseeable." *Id.* § 7, cmt. j.

The ALI approach thus defers the foreseeability question to the second stage of the negligence analysis (*i.e.*, breach). At the threshold stage of the analysis (*i.e.*, the existence of a duty), the court makes a purely legal determination, based on the weighing of public-policy factors. *Id.* By viewing duty as wholly distinct from foreseeability of harm, the ALI approach "has the benefit of providing clearer rules

of behavior for actors who may be subject to tort liability and who structure their behavior in response to that potential liability." *Id.*, § 7, cmt. i. The ALI intended its elimination of foreseeability from the duty analysis "to facilitate more transparent explanations of the reasons for a no-duty ruling and to protect the traditional function of the jury as factfinder." *Id.* § 7, cmt. j.

Sweeping aside fundamental canons of tort law, the district court effectively collapsed duty, breach, and causation into one overriding consideration: foreseeability. But no principled basis exists for undertaking so seismic a shift in tort law. "While it may seem that there should be a remedy for every wrong, this is an ideal limited perforce by the realities of this world." *Tobin*, 24 N.Y. 2d at 619, 249 N.E.2d at 424. If this Court adopts the district court's all-purpose view of foreseeability, the threshold concept of duty "would be so extended that many cases now disposed of on the duty issue would reach a jury on the fact issue of negligence." Green, *supra*, at 1418.

II. THIS COURT SHOULD REJECT PLAINTIFF'S INVITATION TO SECOND-GUESS CONGRESS'S CAREFULLY CRAFTED POLICY BALANCE BY INVENTING A NEW TORT DUTY FOR BRANDED MANUFACTURERS

GSK has shown convincingly why Plaintiff's negligence claim is twice preempted under federal law. WLF will not repeat those arguments here. Because the Supremacy Clause requires state law to give way whenever federal policymakers have spoken, this Court must also accept Congress's decision to

preempt various tort law remedies against generic manufacturers. In doing so, however, the Court should also resist the impulse to "turn somersaults to create" a novel legal theory of liability for branded drug manufacturers that would stand as an obstacle to the comprehensive regulatory regime Congress has implemented. *Riegel v. Medtronic*, 552 U.S. 312, 325 (2008). It is for Congress, not this Court, to undertake any necessary policy changes in this complex and highly regulated area.

Congress enacted the Hatch-Waxman Act to strike a balance between two competing policy objectives: "to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230 (4th Cir. 2002) (citations and quotation marks omitted). On one hand, Congress sought to facilitate generics so that prescription drugs would remain affordable for patients who need them. On the other hand, Congress wanted to ensure that the patent system provided substantial financial rewards to those whose investments in research and development yielded new life-saving medications, thereby incentivizing continued R&D expenditures.

As Congress's compromise solution, the Hatch-Waxman Act struck a careful balance among the competing interests of federal regulators, consumers, innovator drug manufacturers, and generic drug manufacturers. It granted certain

patent rights to innovator drug manufacturers while simultaneously taking steps to cabin prescription drug prices by streamlining the approval process for generic drugs. In carefully crafting a balance among several competing interests, Congress sent an unmistakable message that the measures it adopted provided the appropriate level of incentives and constraints for both branded and generic drug manufacturers while ensuring the safety and effectiveness of all prescription drugs. Of course, when Congress harmonized these competing incentives and constraints, it held the perfectly reasonable assumption that branded manufacturers would *not* be held liable for injuries caused by drugs they neither sold nor manufactured.

Allowing non-expert judges and juries to second-guess that delicate policy balance would severely undermine the assumptions undergirding Congress's carefully calibrated regulatory scheme. *See, e.g., United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 497 (2001) (explaining that courts can neither "override Congress's policy choice, articulated in a statute" nor "reject the balance that Congress has struck in a statute"). As this Court has repeatedly explained, "[o]nly Congress may change the law in response to policy arguments, courts may not do so." *Envtl. Def. Fund, Inc. v. City of Chicago*, 985 F.2d 303, 304 (7th Cir. 1993). Yet Plaintiff urges the Court to disregard these venerable separation-of-powers principles by carving out a remedy where none exists.

Likewise, "[f]ederalism proscribes unwarranted federal judicial meddling in state matters," so "when this court sits in diversity, federalism requires us to enforce the substantive law of the forum state, even when we conclude we see a more enlightened path." *Am. Home Assurance Co. v. Stone*, 61 F.3d 1321, 1328-29 (7th Cir. 1995) (citation and quotation marks omitted). "When given a choice between an interpretation of Illinois law which reasonably restricts liability, and one which greatly expands liability," this Court will "choose the narrower and more reasonable path (at least until the Illinois Supreme Court tells [it] differently)." *Todd v. Societe Bic, S.A.*, 21 F.3d 1402, 1412 (7th Cir. 1994) (en banc). Simply put, "this court is not an appropriate forum for pronouncing an Illinois public policy where the state constitution, statutes or judicial opinions give no clear indication that such policy is 'well defined and dominant' in Illinois." *Id.* at 1329 (citations omitted).

Contrary to Plaintiff's view, "the judiciary may not sit as a superlegislature to judge the wisdom or desirability of legitimate policy determinations." *New Orleans v. Dukes*, 427 U.S. 297, 303 (1976). Only Congress has the institutional capacity to accommodate fully the many competing interests implicated in regulating prescription drugs. Unlike Congress, federal courts sitting in adversary proceedings are confined to rendering opinions based on the limited evidentiary record before them. Courts cannot commission independent studies, hire policy

experts, or conduct public hearings to gather information from relevant constituencies. Nor can they balance the competing interests of stakeholders by making compromises with the benefit of comprehensive, legislative fact-finding.

In *PLIVA, Inc. v. Mensing*, the U.S. Supreme Court rejected a similar invitation to "distort" existing law in order to allow generic drug consumers to seek common-law remedies under state law. 564 U.S. at 623-26. In words that apply with equal force here, *Mensing* explained that "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre." *Id*. at 625-26 (citation and quotation marks omitted). Refusing to "distort the Supremacy Clause in order to" invent a legal remedy for every injured plaintiff, the Court in *Mensing* reiterated that "[a]s always, Congress and the FDA retain the authority to change the law and regulations if they so desire." *Id.* at 626.

Similarly, although acknowledging that "[r]espondent's situation is tragic and evokes deep sympathy," the Court in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2480 (2013), still concluded that "a straightforward application of pre-emption law requires that the judgment below be reversed." Resisting the call to sweep aside settled law to achieve a particular policy outcome, the Court reiterated that "sympathy for [a party] does not relieve us of the responsibility of following the law." *Id.* at 247. So too here.

The appropriate role of the judiciary is to interpret the law, not to rewrite it.

Of course, the corollary to that rule is that the political branches may do so when necessary. As this Court has emphasized, any "argument about what makes for good public policy should be directed to Congress; the judiciary's job is to enforce the law Congress enacted, not write a different one that judges think superior." *Bethea v. Robert J. Adams & Assoc.*, 352 F.3d 1125, 1127-28 (7th Cir. 2003). The judiciary, however, is ill-suited to address complex regulatory concerns that are best left to the political branches. Without this venerable constraint on judicial policy-making,

> Judges are nothing more than politicians in robes, free to tackle the social problems of the day based on avant-garde [tort] theory or, worse yet, their own personal preferences. While such jurists may often be well meaning, their approach is inconsistent with our government's history, structure, and framework, and it threatens the ideal of self-rule that we should so dearly cherish.

Hon. Diarmuid F. O'Scannlain, *Politicians in Robes: The Separation of Powers & the Problem of Judicial Legislation*, 101 Va. L. Rev. Online 31, 33 (2015).

The principle that the judiciary should not distort existing law to invent a new remedy for a sympathetic plaintiff applies directly to this case. Rather than having to persuade a majority of both houses of the United States Congress, the President, and the public constituencies they represent to rewrite existing law, Plaintiff and her counsel naturally would prefer to persuade only two out of three members of this panel. But because "courts are not institutionally qualified to balance the complex, interrelated, and divergent policy considerations in

determining labeling and liability obligations of brand and generic pharmaceuticals," *Huck*, 850 N.W. 2d at 377, this Court should resist any temptation to fashion a "fix" for Plaintiff here. Instead, any change in the law to address the "unfortunate hand that federal drug regulation has dealt," *Mensing*, 564 U.S. at 625, must be taken up by Congress, not this Court.

* * *

The interests of fairness, predictability, and stare decisis were all injured in this case. WLF joins with Appellant in urging the Court to reverse the deeply misguided judgment below.

CONCLUSION

For all these reasons, *amicus curiae* Washington Legal Foundation urges the Court to reverse the judgment below.

Date: January 29, 2017

Respectfully submitted,

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COMBINED CERTIFICATIONS

I hereby certify that:

1. This brief complies with the type-volume limitations of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B) because this brief contains 5,883 words, excluding those parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced serif typeface using Microsoft Word 2010 in 14-point Times New Roman font.

Dated: January 29, 2018

/s/ Cory L. Andrews
Cory L. Andrews

CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of January, 2018, a true and correct copy of the foregoing **BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANT-APPELLANT, URGING REVERSAL** was filed with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit via the appellate CM/ECF system, which will electronically serve all counsel of record under Fed. R. App. P. 25(c)(2).

/s/ Cory L. Andrews
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