RECORD NO. 21-10305

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

ARTHUR CARTEE,
Plaintiff–Appellant

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

PFIZER, INC., AND

GLAXOSMITHKLINE LLC
Defendants–Appellees

On Appeal from the United States District Court
for the Southern District of Florida

PLAINTIFF-APPELLANT ARTHUR CARTEE'S OPENING BRIEF

Leslie A. Brueckner
PUBLIC JUSTICE, P.C.
475 14th Street, Suite 610
Oakland, CA 94612
Tel: (510) 622-8205

Ashley Keller
KELLER LENKNER LLC
150 N. Riverside Plaza, Suite 4270
Chicago, IL 60606
Tel: (312) 741-5222

Edward A. Wallace
Timothy E. Jackson
WEXLER WALLACE LLP
55 W. Monroe St., Suite 3300
Chicago, IL 60603
Tel: (312) 346-2222

Noah Heinz
KELLER LENKNER LLC
1300 I Street, N.W., Suite 400E
Washington, DC 20005
Tel: (202) 918-1841

March 29, 2021

Counsel for Plaintiff-Appellant Arthur Cartee

Cartee v. Boehringer Ingelheim Pharmaceuticals, Inc.
RECORD NO. 21-10305

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rule 26.1-1, counsel for Plaintiff-Appellant Arthur Cartee hereby certifies that the following is a complete list of the trial judge(s), all attorneys, persons, associations of persons, firms, partnerships, or corporations that have an interest in the outcome of the particular case on appeal, including subsidiaries, conglomerates, affiliates, and parent corporations, including any publicly held corporation that owns 10% or more of a party's stock, and other identifiable legal entities related to a party:

- Atkinson Baker & Rodriguez PC – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Baker, Douglas A. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Bayman, Andrew T. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Blaschke, Matthew J. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Boehringer Ingelheim Corporation – Parent Company of Defendant-Appellee
- Boehringer Ingelheim International GmbH – Parent Company of Boehringer Ingelheim USA Corporation
- Boehringer Ingelheim Pharmaceuticals, Inc. – Defendant-Appellee
- Boehringer Ingelheim USA Corporation – Parent Company of Defendant-Appellee
- Brueckner, Leslie – Counsel for Plaintiff-Appellant Arthur Cartee
- Carlton Fields PA – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.

- Cartee, Arthur – Plaintiff-Appellant
- Cheffo, Mark S. – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Corley, Jessica Perry – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Covington & Burling LLP – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- De Zayas, Veronica Louise – Counsel for Defendant-Appellee Pfizer Inc.
- Dechert LLP – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Devereaux, Stephen B. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Fahey, Patrick M. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Friedman, Robert B. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Gladbach, Eric Francis – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- GlaxoSmithKline LLC – Defendant- Appellee
- GlaxoSmithKline PLC (**GSK**) – Parent Company of Defendant-Appellee
- Haas, Frances M. – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Heinz, Noah – Counsel for Plaintiff-Appellant Arthur Cartee
- Hook, April N. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Jackson, Timothy E. – Counsel for Plaintiff-Appellant Arthur Cartee
- Joachim, Jordan Scott – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Keller Lenkner LLC - Counsel for Plaintiff-Appellant Arthur Cartee
- Keller, Ashley C. – Counsel for Plaintiff-Appellant Arthur Cartee
- King & Spalding LLP – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Kirkland & Ellis LLP – Counsel for Defendant-Appellee GlaxoSmithKline LLC

- Kitchens, Madison – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Krigbaum, Stephen J. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Lefkowitz, Jay P. – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Lindquist, Elizabeth Francesca – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- McCloud, Charles L. – Counsel for Defendant-Appellee Pfizer Inc.
- McGrath North Mullin & Kratz PC – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Mezzina, Paul A. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Nyemaster Goode PC – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- O'Neill, Amy L. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Petrosinelli, Joseph G. – Counsel for Defendant-Appellee Pfizer Inc.
- Pfizer, Inc. (**PFE**) – Defendant- Appellee
- Phillips Lytle LLP – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Powers, James G. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Reinhart, Honorable Bruce E. – U.S. Magistrate Judge
- Rodriguez, Justin D. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Rosenberg, Honorable Robin L. – U.S. District Court Judge
- Ruehlmann, Gregory A. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Sabnis, Cheryl A. – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.

- Sapp, Richard J. – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Sentenac, Mark Alan – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Sheppard, James Robert III – Counsel for Defendant- Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Shipman & Goodwin LLP – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Stearns Weaver Miller Weissler Alhadeff & Sitterson PA – Counsel for Defendant-Appellee Pfizer Inc.
- Thoma, Oliver Peter – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Wallace, Edward A. – Counsel for Plaintiff-Appellant Arthur Cartee
- Westby, Sarah A. – Counsel for Defendant- Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Wexler Wallace LLP – Counsel for Plaintiff-Appellant Arthur Cartee
- Williams & Connolly LLP – Counsel for Defendant-Appellee Pfizer, Inc.
- Yearick, Garth – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.
- Zousmer, Julia – Counsel for Defendant-Appellee Boehringer Ingelheim Pharmaceuticals, Inc.

Dated: March 29, 2021

Respectfully submitted,

/s/ *Ashley Keller*

Ashley Keller
KELLER LENKNER LLC
150 N. Riverside Plaza, Suite 4270
Chicago, IL 60606
Tel: (312) 741-5220

Counsel for Plaintiff-Appellant Arthur Cartee

STATEMENT REGARDING ORAL ARGUMENT

Appellant respectfully requests oral argument because this appeal turns on an application of *Erie* doctrine in an area of law that has evolved considerably since this Court's last relevant decision. Oral argument would assist the Court in clarifying and testing the parties' arguments.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Regulations

Rules

Other Authorities

JURISDICTIONAL STATEMENT

Federal subject matter jurisdiction is proper under 28 U.S.C. § 1332 because there is complete diversity between the parties. This Court has appellate jurisdiction under 28 U.S.C. § 1291 because the district court's order fully disposed of Plaintiff Cartee's claims. Mr. Cartee filed a response to Appellee's Motion to Dismiss for Lack of Jurisdiction concurrently with this brief, and adopts the arguments presented there by reference.

STATEMENT OF THE ISSUES

1. Should federal courts apply so-called "*Erie* conservatism" by presuming, in every *Erie* prediction, that state courts would rule against expanding liability on an issue with no conclusive state judicial decision on point?

2. Would the Illinois Supreme Court impose a duty on brand-name manufacturers to consumers of generic drugs to label branded drugs adequately where the brand-name manufacturers know that the generic drug must be chemically identical and must copy verbatim the branded label's warnings and precautions?

INTRODUCTION

Appellant Arthur Cartee consumed generic ranitidine, the label of which never warned him that it could cause cancer. Because federal law—and the Food and Drug Administration (FDA) regulations interpreting it—require generic manufacturers' labels to reprint verbatim the same warnings and precautions as the brand-name drug, Mr. Cartee sued the brand-name manufacturers for redress. Applying Illinois common law to the unique federal regulatory regime, Mr. Cartee and similarly situated generic consumers are foreseeable plaintiffs to whom the branded drug makers owe a duty. Some states unambiguously agree with Mr. Cartee, others unambiguously do not. But the Illinois Supreme Court has never weighed in on this question. When sitting in diversity, it is hornbook law that the district court was required to apply Illinois substantive law, rendering an *Erie* guess in the absence of controlling Illinois precedent.

Defendants contend that the overwhelming majority of states, including Illinois, reject Mr. Cartee's theory of liability. That is false. The only authority that is staunchly opposed to Mr. Cartee's claim emerges from *federal courts*. Several federal courts sitting in diversity predict—with scant analysis—that *every* state that has not expressly endorsed Mr. Cartee's theory would reject it. The district court followed that model, holding that the Illinois supreme court—and, indeed, every other court that lacked an on-point precedent—would not recognize a duty of care

brand-name manufacturers owe to consumers of generic drugs who relied on their label.

That is a puzzling conclusion in view of the actual opinion of state supreme court justices. At present, thirty-four of them have squarely considered whether generic consumers can bring failure-to-warn claims against branded manufacturers. *Twenty-five* state supreme court justices would recognize a claim under state law; only nine have rejected Mr. Cartee's theory.[1] The three opinions finding a duty were either unanimous on that point (California and Massachusetts), or had a strong six-justice majority (Alabama). The two opinions rejecting a duty were decided by a single vote; the Iowa case turned on a concurrence in the judgment, and has no majority opinion.

Why are state supreme court justices—by almost three to one—in favor of liability while so many federal courts *predict* that generic consumers would fail to state a claim? The answer is so-called "*Erie* conservatism," a doctrine as pernicious to state sovereignty as it is unfaithful to the seminal decision for which it is named.

---

[1] *See McNair v. Johnson & Johnson*, 818 S.E.2d 852, 867 (W.Va. 2018) (**2-3** against a duty); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205 (Mass. 2018) (**7-0** in favor of a duty); *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18 (2017) (**7-0** in favor of a duty); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 356 (Iowa 2014) (**3** in favor, **3** against, **1** "concur[ring] in the result only," opposing a duty "at this time"); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649 (Ala. 2014) *superseded by statute* Ala. Code § 6-5-530(a) (**6** in favor, **2** against, **1** (not counted) dissenting on the non-merits ground that fact-specific issues warranted dismissing the certified question).

Erie conservatism constitutes a *federal* common-law rule of decision that presumes states are reluctant to extend liability to previously unaddressed contexts. While any individual state judiciary is free to announce that it takes a "conservative" approach to its state's common law, federal courts have no warrant to *invent* and apply such a rule. *Erie Railroad v. Tompkins*, 304 U.S. 64 (1938) emphatically retired any notion that federal diversity jurisdiction authorizes application of a general common law. Yet no court applying *Erie* conservatism can possibly derive the doctrine from any other source.

Individual federal judges may well believe that a conservative approach to the common law best reflects considerations of sound public policy. That perfectly reasonable policy preference is not the *only* reasonable approach, and it is neither here nor there. Mr. Cartee's claim is governed by Illinois law, and the Defendants and the district court below offer precisely zero evidence that the Illinois Supreme Court ever has or would embrace a tie-goes-to-the-defendant rule.

Just the opposite is true. All of the clues in Illinois law suggest a progressive state that places greater emphasis on stretching the law to protect injured consumers rather than awaiting legislative innovation to do so. Though his case is properly in federal court as a controversy between citizens of different states, Mr. Cartee is legally entitled to a faithful application of Illinois law. The district court's decision rested on federal law and must be reversed.

STATEMENT OF THE CASE

I. FACTS[2]

In 2006, Arthur Cartee began taking generic ranitidine to treat mild heartburn.[3] Am. Short-Form Compl., *Cartee v. Boehringer Ingelheim Pharmaceuticals, Inc.*, No. 9:20-cv-80512, (S.D. Fla. Jan. 27, 2021) [ASFC], D.E. 19 at 3. As is common, his physician prescribed Zantac—the more-familiar brand-name of ranitidine—but when Mr. Cartee filled that prescription the pharmacy gave him generic ranitidine, as is permitted under Illinois law. *See* 225 Ill. Comp. Stat. Ann. 85/25. He took prescription and over-the-counter ranitidine for more than five years. ASFC 3. No one told Mr. Cartee or his doctor during that time what independent scientists and the FDA have finally uncovered: that ranitidine contains staggering amounts of N-Nitrosodimethylamine (NDMA), a potent and well-known human carcinogen. ASFC 3–4. In 2012, like hundreds of thousands of other Americans, Mr. Cartee was diagnosed with cancer because of the carcinogenic NDMA he ingested. On March 6, 2020, Mr. Cartee and his wife brought this suit in Illinois to hold Defendants liable for his injuries.

---

[2] Plaintiff's claims were rejected by the district court on a motion to dismiss; the facts relevant to this appeal are accordingly the allegations in the pleadings.

[3] The short-form complaint was filed on the member case docket. Every other docket entry cited in this brief refers to the MDL docket.

A. Zantac Was A Hugely Profitable Drug.

Zantac belongs to a class of drugs, known as H2 blockers, that help to decrease the acidity of the stomach. Master Personal Injury Complaint [MPIC], D.E. 887 ¶ 226. It was developed in the late 1970s by a predecessor to the pharmaceutical giant, GlaxoSmithKline (GSK). Having witnessed the huge success of Tagament, also an H2 blocker, GSK was determined to get a piece of the fast-growing antacid market. MPIC ¶¶ 226–30.

GSK pushed the FDA to approve Zantac and in 1983 it was off to the races. MPIC ¶ 231. The company knew that the exclusivity period following FDA-approval, before the generics rush in, is the time to maximize profits and it acted aggressively to do so. MPIC ¶ 232. The strategy worked. Zantac delivered huge profits and made pharmaceutical history as the first drug ever to generate $1 billion in annual sales. MPIC ¶ 231. The success of this "blockbuster" drug sparked a series of corporate mergers and acquisitions that propelled GSK to the top of the pharmaceutical industry.

In the 1990s, GSK joined with another industry giant, Pfizer, to expand Zantac's market reach even further. MPIC ¶ 233. Together these companies executed a plan to get FDA approval for an OTC version of the drug that patients could take without a prescription or any guidance from a doctor. Eventually, the

companies were forced by antitrust issues to transfer the marketing rights for OTC Zantac to Boehringer Ingelheim. MPIC ¶¶ 236, 239.

For decades, Zantac continued to generate huge dollars in both its branded and generic forms. As recently as 2018, it remained one of the top 10 antacid tablets sold in the United States. MPIC ¶ 252. It was just a year later that the FDA learned about Zantac's true safety profile and forced the drug companies to pull Zantac from the nation's shelves.

B. The Truth About Zantac Comes Out.

In late 2019 and early 2020, the FDA received two separate Citizen Petitions from groups of concerned, independent scientists. MPIC ¶¶ 285, 299. The first petition alerted the agency that Zantac pills may contain exceedingly high levels of NDMA. MPIC ¶ 285. The second indicated that the NDMA was coming *from the Zantac itself*—providing evidence, that over time and especially when exposed to heat, ranitidine degrades, throwing off dangerous amounts of the NDMA molecule. MPIC ¶ 299.

These Citizen Petitions got the FDA's immediate attention. And for good reason. Discovered in the early 1900s as a byproduct of rocket fuel, NDMA is a well-known and potent carcinogen. MPIC ¶ 3. EPA and the International Agency for Research on Cancer classify it as a probable human carcinogen. MPIC ¶ 254. The World Health Organization cites "conclusive evidence" that NDMA can cause

cancer. MPIC ¶ 259. Both the Department of Health and Human Services and the FDA have likewise concluded that exposure to NDMA can cause cancer in humans. MPIC ¶¶ 257–58. Today, NDMA has only one recognized use: to induce tumors in animals that are being subject to experimentation. MPIC ¶ 3.

Prompted by the Citizen Petitions, the FDA quickly took action to investigate. Its initial testing identified ranitidine products containing "unacceptable levels" of NDMA. MPIC ¶ 296. Based on those results, the FDA requested that companies recall any ranitidine confirmed to contain NDMA above acceptable levels. *Id.* As the FDA explained at the time, a recall is warranted where the agency concludes that a product is in violation of the laws it administers. MPIC ¶ 301, n.47 (citing letter of Janet Woodcock). Generally, the FDA asks companies to perform recalls voluntarily; if they resist the FDA may initiate seizure proceedings.

In 2020, the FDA performed additional testing, which revealed that the NDMA in ranitidine increases over time and can rise to dangerous levels as the product approaches its expiration date. MPIC ¶ 302. These results "eroded [the FDA's] confidence" that *any* ranitidine product could remain stable and safe through its labeled expiration date. *Id.* That loss of confidence prompted the FDA to call for the immediate withdrawal of *all* ranitidine from the market without any delay for NDMA testing. MPIC ¶ 301.

FDA was not alone in taking swift action to protect the public against any further harm from ranitidine. By 2020, more than forty-three other countries and jurisdictions had restricted or outright banned any further sales of the drug. MPIC ¶ 303. These actions were years too late for Mr. Cartee and millions of other Americans who took ranitidine, believing it to be safe. Mr. Cartee would not have taken ranitidine, and his doctor would not have prescribed it, had Defendants told the public sooner. They could have.

C. Defendants Knew or Should Have Known About Ranitidine's Dangers Decades Sooner.

The tragedy of the Zantac story is that it did not have to happen. From early on, there were glaring red flags pointing to Zantac's cancer hazard. But instead of warning the public, or raising concerns with the FDA, or even further investigating the issue themselves, the drug companies did nothing. They were too intent on protecting their profits from this blockbuster drug.

The signs started early. In 1981, for example, a group of Italian scientists published a study showing that NDMA is produced when Zantac mixes with nitrites in the stomach's gastric fluids. MPIC ¶ 310. Nitrites are chemicals contained in certain foods and particularly high in processed meats. MPIC ¶ 297. The scientists made a simple suggestion: people using Zantac, especially those using it for extended periods, should be advised to eat a diet low in nitrites or avoid taking the

medication close in time to meals. MPIC ¶ 310. Discovery has revealed other studies that were never revealed to the public or the FDA.

People using Zantac never got this advice. Instead, the drug companies spent millions on advertising campaigns showing people taking Zantac to control heartburn caused by food like tacos and pizza, which are notoriously *high* in nitrites. MPIC ¶¶ 311, 328. And they downplayed the potential hazard flagged by the Italian scientists, deeming the risk "unrealistic," since most people would use Zantac for only a short time. MPIC ¶¶ 314–15. Mr. Cartee purchased and ingested ranitidine for more than five years. *See* ASFC. He is not an outlier in the patient population. Scores of Americans used Zantac daily for years or even decades.

In 1987, GSK published a study that further downplayed Zantac's risk. The study examined the gastric contents of human patients who consumed ranitidine and reported finding uniformly safe levels of NDMA. MPIC ¶ 317. But the study, which GSK conducted itself, failed to employ the widely accepted gold-standard method for measuring NDMA, relying instead on an inferior technology. Worse, GSK discarded two-thirds of the samples—those with the highest levels of ranitidine—out of concern that those samples would contain supposedly false-positive "high concentrations of N-nitroso compounds," of which NDMA is one. With that omission, it is no wonder the study produced exactly the results GSK wanted. MPIC

¶ 320. Despite that obvious flaw, GSK claimed the study showed ranitidine did not increase nitrosamines.

Years later, researchers at Stanford took another independent look at Zantac and NDMA. The Stanford researchers concluded that taking one dose of ranitidine increased NDMA levels in healthy adults by 40,000 percent. Appearing in the journal *Carcinogenesis*, the Stanford study was widely available for review by the drug manufacturers that had long profited from ranitidine. Still, they did nothing but continue to sell their dangerous drug. MPIC ¶ 321.

D. The Plaintiffs' Suits

Mr. Cartee took over-the-counter and prescription ranitidine for more than five years from 2006 through 2012. *See* ASFC. He was diagnosed with cancer in 2012. Mr. Cartee filed suit for his injuries on March 6, 2020. Thousands of others filed similar suits, which wound up centralized before Judge Robin Rosenberg in the U.S. District Court for the Southern District of Florida. *In re Zantac (Ranitidine) Prod. Liab. Litig.*, 437 F. Supp. 3d 1368 (J.P.M.L. 2020). Judge Rosenberg issued myriad pre-trial orders, one of which required that "the Master Personal Injury Complaint [MPIC] together with the Short Form Complaint shall be deemed the operative Complaint" for each action. D.E. 1496 ¶ 5. The MPIC covered the waterfront, alleging fifteen counts against five groups of defendants.

Mr. Cartee's operative short form complaint incorporates only one of those counts and alleges a claim against only the brand-name manufacturers Pfizer, Inc., GlaxoSmithKline LLC, and Boehringer Ingelheim Pharmaceuticals, Inc. Mr. Cartee's "sole theory of liability is that Boehringer Ingelheim Pharmaceuticals, Inc., GlaxoSmithKline LLC, and Pfizer, Inc. negligently misrepresented the safety of ranitidine through their labeling of branded Zantac, that it was foreseeable that generic manufacturers of ranitidine would copy those misrepresentations, and that Plaintiff and his doctor relied on those misrepresentations in consuming and prescribing the ranitidine that caused Plaintiff's cancer and other injuries." ASFC at 3. The negligent misrepresentation claim Mr. Cartee alleged follows from two unique features of the regulatory scheme for generic drugs that are unlike products in other industries. First, federal law places the ability to change the warnings for generic drugs into the hands of *brand-name* manufacturers. Second, state law allows—encourages, even—doctors to rely on the warnings and other medical information for brand-name drugs to recommend and prescribe brand-name drugs that can then be filled by pharmacists with a *generic* version.

II. LEGAL BACKGROUND

A. Selling Pharmaceuticals Is Only Lawful with FDA Approval.

The Federal Food, Drug, and Cosmetic Act 21 U.S.C. § 301 *et seq.* (FDCA) sets the federal framework for pharmaceuticals. Selling even a perfectly safe and

effective new drug without FDA pre-approval violates federal law. 21 U.S.C. § 355(a). The manufacturer who develops a new drug—referred to as the brand-name drug—must submit a New Drug Application (NDA) to the FDA. The FDA only approves a drug once it determines based on scientific evidence and data submitted by the NDA applicant that it is safe and effective. *Id.* § 355(d); *see also Bartlett*, 570 U.S. at 476 ("for the FDA to consider a drug safe, the drug's 'probable therapeutic benefits must outweigh its risk of harm'" (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000)). Once an NDA is approved, it comes with ongoing duties to send new and emerging scientific information about the risks of the approved drug to the FDA and to unilaterally update the drug's label when the evidence warrants a different warning.[4] *See* 21 C.F.R. § 314.70. These ongoing updates are a key pillar of drug safety. "[I]t has remained a central premise of federal drug regulation that the manufacturer," not the FDA, "bears responsibility for the content of its label at all times" and "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).

[4] Studies in this area show that new safety-related information often comes many years after approval. A 2013 article authored jointly by three FDA staff members and two academics reported that "[t]he most critical safety-related label changes, boxed warnings and contraindications, occurred a median 10 and 13 years after drug approval (and the range spanned from 2 to 63 years after approval)." Jean Lester, et al., *Evaluation of FDA Safety-Related Drug Label Changes in 2010*, 22 Pharmacoepidemiology and Drug Safety 302, 304 (2013).

B. Brand-Name Manufacturers Determine the Content of Generic Drug Label Warnings.

After the brand-name manufacturer enjoys a period of highly profitable exclusivity, other drug manufacturers can file Abbreviated New Drug Applications (ANDAs) to sell a virtually identical drug called a generic. *See* 21 U.S.C. § 355(j). Generic drugs may differ in certain respects from the branded drug (for example, the expiration date), but the warnings and precautions, active ingredient, and dosage must be the same. *Id.* That means ANDA holders—the manufacturers of generic drugs—can only change their generic drug's warning label *after* a brand-name manufacturer does so. Any difference in labeling would not only violate federal law, it would also falsely imply a difference in risk, which would undermine the American system of using generic drugs as perfect substitutes for brand-name drugs.

The full implications of this regulatory regime were made clear when the Supreme Court held that certain failure-to-warn claims premised on the state-law duty to change a generic drug's warning label were *preempted*. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011). A generic drug company simply could not comply with such a state-law duty, since any change would make its generic drug warnings *different from* the brand-name drug it should match. The Supreme Court noted that to a consumer, the differing preemption result "makes little sense" since if a consumer took "the brand-name drug prescribed by their doctors" they could recover, but "because pharmacists, acting in full accord with state law, substituted

[a] generic [drug] instead, federal law pre-empts these lawsuits." *Id.* at 625. Nonetheless, that is the law, which the Supreme Court reaffirmed in a follow-on case. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 493 (2013) (noting the difference in treatment was "tragic and evokes deep sympathy" but applying preemption).

C. Some States Recognize a Duty on Brand-Name Manufacturers for Generic Drug Warnings.

Long before *Mensing*, some cases addressed whether brand-name manufacturers could be liable for injuries caused by generic drugs. The leading case was *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), which predicted Maryland would answer "no." The Fourth Circuit, relying on the FDA's position at the time, held that *generic* manufacturers, not *brand-name* manufacturers, should be liable, because they *could* modify the warnings on their products. *Id.* at 170. A deluge of federal precedent followed *Foster*. But the premise was wrong: as *Mensing* made clear, generic manufacturers *cannot* control or change the warnings on their products.

After *Mensing* and *Bartlett*, the undermined cases remained in the Federal Reporter, and courts were loath to change without new guidance. When this Court addressed the question of whether Florida would recognize a duty, it had an easy task: "[e]very court in Florida to consider the question" had rejected such a duty, which matched the federal cases. *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1251 (11th

Cir. 2013). The only state *supreme* court to address the issue had found a duty, but had just granted rehearing, vacating the decision. *Id.* at 1253 (citing *Wyeth, Inc. v. Weeks*, No. 1101397, 2013 WL 135753 (Ala. Jan. 11, 2013), *opinion withdrawn and superseded*, 159 So. 3d 649 (Ala. 2014)). That landscape has changed.

On rehearing, the Alabama Supreme Court resoundingly recognized a duty under traditional state common law applied to "a product that, unlike any other product on the market, has unprecedented federal regulation." *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 677 (Ala. 2014) ("nor are we creating a now tort of 'innovator liability' as has been suggested"). The Alabama state legislature later statutorily abrogated Alabama's common law to immunize brand-name manufacturers. *See* Ala. Code § 6-5-530(a).

The next state supreme court to address the issue was Iowa's. It ruled against recognizing a duty, but by a 3-1-3 vote in which the controlling concurrence "agree[d] with much of the dissent on the claims against the brand defendant, but decline[d] at this time to conclude the public policy considerations that ultimately drive the decision in this case, on balance, support the imposition of a duty of care." *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 381 (Iowa 2014). Iowa's law, then, is that no duty exists "at this time," as of 2014.

In light of *Mensing* and *Weeks*, the Fourth Circuit was no longer confident in its leading *Foster* precedent, because "it is no longer the case that generic

manufacturers can alter FDA-approved labels." *McNair v. Johnson & Johnson*, 694 F. App'x 115, 120 (4th Cir. 2017). It therefore certified the question of duty to the West Virginia Supreme Court. That court declined to recognize a duty in a 3-2 decision the next year. *Id.*, 818 S.E.2d 852 (W.V. 2018).

California came next. It held unanimously that brand-name manufacturers *do* have a duty to consumers of generic drugs for a number of reasons, chiefly foreseeability and the fact that "[t]he brand-name drug manufacturer is the only entity with the unilateral ability to strengthen the warning label" and so should have a duty "to prevent a known or reasonably knowable harm" only it can prevent. *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 32 (Cal. 2017)

The most recent decision came from Massachusetts. The Supreme Judicial Court *unanimously*—and contrary to the predictions of federal courts—held that brand-manufacturers had a duty to consumers of generic drugs. *Rafferty v. Merck & Co.*, 92 N.E.3d 1205 (Mass. 2018). The Massachusetts court did, however, require reckless misrepresentation, rather than mere negligence. *Id.* at 1219.

In sum, most federal cases have predicted state courts would not recognize the duty at issue here, though the vast majority of those cases came before 2017. Whether due to defendants' removal of cases or some other reason, most state court systems have never considered the question; in fact, of the five state supreme courts to address it, *three*—Alabama, Massachusetts, and West Virginia—were answering

a question certified by a federal court. But when state supreme court justices *have* answered the question, comfortably more than a filibuster-proof majority—25 out of 34—have recognized a duty.

III. THE RULINGS BELOW

Defendants moved to dismiss on an array of grounds, but only one is relevant here. Defendants argued that in performing an *Erie* guess, "federal courts sitting in diversity should not expand the scope of tort liability without a clear signal from the state courts." D.E. 1585 at 7. They next argued that, in light of that presumption, the district court should rule that any state without a supreme court decision directly supporting Plaintiffs (*i.e.*, any state other than Massachusetts and California) would not recognize a duty by brand-name manufacturers to consumers of generic ranitidine. Plaintiffs countered that *Erie* guesses cannot begin with any presumption, and that all traditional duty factors—foreseeability, placing responsibility with the actor who can prevent harm, and others—support a duty. The court requested supplemental briefing, requiring each side to address the states at issue in no more than two pages per-state. D.E. 2228.

After a hearing addressing this and other issues, the district court issued the Order relevant in this appeal. The court adopted Defendants' framework, presuming no duty would apply unless Plaintiffs cited an on-point state court decision. *See* D.E. 2516 at 14 (deferring to "principles of comity and federalism, which counsel federal

courts to 'proceed gingerly when venturing into uncharted waters of state substantive law'" (quoting *Guarino*, 719 F.3d at 1251). The court also ruled that the injury to generic consumers from brand-name manufacturers' deficient warning label *was not even foreseeable*, repeating cookie-cutter reasoning for every state based on a law review article by the general counsel of the American Tort Reform Association. *E.g.*, D.E. 2516 at 26, 34, 37, 42, 47, 48, 50, 55, 60, 67, 70, 72, 74, 77, 78 (citing 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, 1865 (2013)). These overarching reasons predominated over state-specific analysis.

For example, Plaintiffs cited *Clark v. Pfizer Inc.*, No. 1819, 2008 WL 7746430 (Pa. Com. Pl. Mar. 12, 2008) to support a duty argument in Pennsylvania. That Pennsylvania state court case asked whether "under Pennsylvania law, [brand] defendants owed any duty for which they can be held liable to purchasers of the [generic] drug because defendants had reason to anticipate those individuals would be induced to act." The state court answered yes because "[u]nder Pennsylvania law, a defendant may be liable for misrepresentation to foreseeable plaintiffs even without any direct relation between the parties." *Id.* The district court did not distinguish or even cite *Clark*. It instead relied on a pre-*Mensing federal* district court case that had been vacated on other grounds. D.E. 2516 at 63–64.

Similarly, for Missouri, Plaintiffs cited *Franzman v. Wyeth, LLC*, 451 S.W.3d 676, 691 (Mo. Ct. App. 2014), which addressed this question applying *Kentucky* law. The court spoke positively of the duty of brand-name manufacturers toward generic consumers, but held that a Kentucky statute precluded liability for brand-name manufacturers. *Id.* ("we regrettably find ourselves perpetuating this unjust result due to the breadth of the KPLA"). Missouri had no similar statute, making the question one of common law. The district court did not cite or distinguish *Franzman*, but instead cited the Schwartz law review article and *Foster* (the 1994 Fourth Circuit case) to conclude that injuries were not foreseeable. D.E. 2516 at 46–47.

The court concluded that Plaintiffs had provided insufficient state-law authority in every state except California and Massachusetts, which had already expressly held that such a duty exists. *See, e.g.*, D.E. 2516 at 35–38 (rejecting such a duty under Illinois law, finding it is not foreseeable, and citing Schwartz).

SUMMARY OF THE ARGUMENT

1. Under the rule of *Erie Railroad v. Tompkins*, federal courts must apply state law in diversity cases. Where state law is unclear, federal courts must perform an *Erie* guess, which involves predicting, based on all relevant sources available, how the state supreme court would rule. The primary purpose of *Erie* is to ensure that the substantive law applied in federal and state courts does not generate disparate results, which would be inequitable and produce forum shopping.

The district court below applied a presumption sometimes called *Erie* conservatism, which requires that when no clear state precedent applies, a federal court should rule against an expansion of liability. Employing this presumption was legal error because it is incompatible with *Erie*.

First, the presumption can only be a federal rule of decision, since it applies irrespective of state law, which defies *Erie*'s holding that there is no general federal common law. Second, *Erie* conservatism amounts to a thumb on the scale for defendants, which directly produces disparate results in federal and state court based on the substantive law applied—precisely the inequitable administration of the laws and forum shopping incentive the rule of *Erie* aimed to eradicate. Third, employing *Erie* conservatism causes federal courts to make poor predictions, consistently erring in one direction whenever evidence shows a state court would more likely than not rule a certain way, but that evidence is not sufficiently unequivocal to overcome the presumption. Fourth, though some dicta from Eleventh Circuit case law appears to support *Erie* conservatism, a close read shows that this language, in context, counsels only comity toward existing state law decisions, not a presumption against liability in the absence of state law decisions.

2. The Illinois Supreme Court would recognize a duty of brand-name manufacturers to the consumers of generic products. Mr. Cartee's claim is for negligent misrepresentation. Illinois recognizes this claim. The theory is that when

brand-name manufacturers misrepresent the safety of a branded drug, they can easily foresee that consumers of generic drugs—and their doctors—will rely on that information. That is so because generic drugs must, by law, copy the warnings and precautions of branded drugs verbatim. And physicians regularly prescribe a branded drug (obviously relying on the brand-name manufacturer's label for that prescription), which are then filled by pharmacies with a substitute generic drug. Illinois—like all states—allows, and even encourages, this substitution.

Every court in Illinois to have addressed the question has predicted that the Illinois supreme court would recognize the duty Mr. Cartee relies on. The district court, relying on the Sixth Circuit, rejected that prediction along alternative paths. One alternative was characterizing negligent misrepresentation as a product liability claim, which, the court held, failed for lack of product identification. The other was characterizing the claim under negligence, in which case, the court held, it would fail for lack of a duty. Both are incorrect.

Negligent misrepresentation is not a product liability claim, and does not require product identification. The only case that even arguably suggests the contrary was about market-share liability and turned expressly on causation issues that are absent from this case.

Under ordinary negligence, the Illinois supreme court looks to four factors in recognizing a duty. The first is foreseeability. It is not just foreseeable, but near-

certain that patients and prescribing doctors will rely on branded labeling information in choosing to prescribe or consume generic drugs. Federal law requires generic labels to copy brand-name labels, and state law works hand-in-hand with this requirement by telling pharmacies to treat them as perfect substitutes. The second is the likelihood of injury, which here is high since Zantac did not warn of its cancer risk. The third is the magnitude of the burden in guarding against injury. This burden is not the cost of *paying* damages, but the added costs of *complying* with the state-law duty. Here, brand-name manufacturers already have the legal duty to affix proper warning labels to Zantac, so extending that duty to new consumers would add no additional burden at all.

The fourth factor is the consequences of placing a burden on brand-name manufacturers. Illinois courts would not be impressed by drug manufacturers' policy arguments. Illinois courts disfavor using a lack of duty to address general goals, and the Illinois constitution affirmatively guarantees a certain remedy for personal injuries. Beyond the doctrine, the Illinois supreme court has time-and-again issued bold rulings for plaintiffs despite dire warnings of the consequences. It abolished the public-duty exception for municipalities; construed statutory damages broadly for privacy claims; and not once, but twice struck down tort reforms that would cap damages or otherwise rein in tort liability. These rulings are why the business community widely regards Illinois as one of the most pro-plaintiff

jurisdictions in the United States. Common sense and Illinois cases suggest it is more like California and Massachusetts than like Iowa and West Virginia. This federal court should predict it would join the former in recognizing a duty here.

ARGUMENT

IV. STANDARD OF REVIEW

A court of appeals "review[s] *de novo* the district court's grant of a Rule 12(b)(6) motion to dismiss for failure to state a claim, accepting the complaint's allegations as true and construing them in the light most favorable to the plaintiff." *Chaparro v. Carnival Corp.*, 693 F.3d 1333, 1335 (11th Cir. 2012).

V. FEDERAL COURTS CANNOT APPLY ANTI-LIABILITY PRESUMPTIONS WITH NO BASIS IN STATE LAW WHEN MAKING AN *ERIE* GUESS.

Defendants argued, and the lower court accepted, that in performing an *Erie* guess, "federal courts sitting in diversity should not expand the scope of tort liability without a clear signal from the state courts." D.E. 1585 at 7. This argument is commonly called "*Erie* conservatism" by the defense bar.[5] To state the obvious, no similar presumption would apply in state court, and such a presumption does not even purport to come from state law. Instead, it can only be a federal common law

[5] *See*, *e.g.*, Drug and Device Law, *Federal Courts Should Remember Federalism* (Nov. 28, 2006) https://www.druganddevicelawblog.com/2006/11/federal-courts-should-remember.html ("When a state-law action proceeds in federal court, the jurisprudential thumb is planted firmly on the scale to weigh against novel expansions of state law.").

rule of decision. Applying this presumption would plainly produce forum shopping. Though cloaked in the false garb of federalism and judicial modesty, Defendants' true principle is a barefaced rejection of *Erie*. It cannot stand.

A. Federal Courts Must Employ an *Erie* Guess.

When sitting in diversity, federal courts are required to apply the substantive law of the states. *Erie*, 304 U.S. at 78. On questions of state law, this Court is bound by the rulings of state supreme courts. Where a state's highest court has not addressed a question, "'federal courts are bound by decisions of a state's intermediate appellate courts unless there is persuasive evidence that the highest state court would rule otherwise.'" *Bravo v. United States*, 577 F.3d 1324, 1325 (11th Cir. 2009) (quoting *King v. Order of United Commercial Travelers of Am.*, 333 U.S. 153, 158 (1948)). When there is no state decision on point, a federal court must act as a state court would, predicting as best it can how the state's highest court would rule. *Id.* at 1325–26 (quoting *West v. Am. Tel. & Tel. Co.*, 311 U.S. 223, 237 (1940), and *Putman v. Erie City Mfg. Co.*, 338 F.2d 911, 917 (5th Cir. 1964)) (noting "it is the duty" of the court, which is "forced" to "ascertain" what state law is based on "all available data"); *see Turner v. Wells*, 879 F.3d 1254, 1262 (11th Cir. 2018) (same). Even with no guidance from a state's highest court, federal judges need not sink their heads in the sand, presuming that an absence of applicable precedent is evidence the state court would reject a position; after all, "[f]ederal courts, when

sitting in diversity, are no ostriches." *Lupu v. Loan City, LLC*, 903 F.3d 382, 395 (3d Cir. 2018). Like all good forecasters, a federal court must act under uncertainty rather than abdicating whenever the answer is unclear.

B. The Foundation of *Erie*

A proper prediction of state law must be guided by the foundational principles *Erie* laid down. Prior to *Erie*, federal courts discerned general law by their own lights, in the process creating yawning gaps between the results in federal court and those in state court. The regime of *Swift v. Tyson* "made rights enjoyed under the unwritten 'general law' vary according to whether enforcement was sought in the state or in the federal court; and the privilege of selecting the court in which the right should be determined was conferred upon the noncitizen." *Erie*, 304 U.S. at 74–75. *Erie* ended that paradigm definitively:

> Except in matters governed by the Federal Constitution or by acts of Congress, the law to be applied in any case is the law of the state. And whether the law of the state shall be declared by its Legislature in a statute or by its highest court in a decision is not a matter of federal concern. **There is no federal general common law**.

Id. at 78 (emphasis added).

Because there is no federal general common law, no federal rules of decision exist that could decide a diversity case differently from how it would be decided in state court. The absence of any federal rules of decision may sound merely formal, but in truth plays an important practical role in preventing any difference in result

between federal and state court deriving from substantive law. Indeed, the very "nub of the policy that underlies [*Erie*] is that for the same transaction the accident of a suit by a nonresident litigant in a federal court instead of in a state court a block away, should not lead to a substantially different result." *Van Dusen v. Barrack*, 376 U.S. 612, 638 (1964) (quoting *Guar. Trust Co. of N.Y. v. York*, 326 U.S. 99, 109 (1945)). Ensuring that any difference in results in federal and state court do not derive from the substantive law applied in the forum fulfills "the twin aims of the *Erie* rule: discouragement of forum-shopping and avoidance of inequitable administration of the laws." *Hanna v. Plumer*, 380 U.S. 460, 468 (1965). Any principle purporting to guide an *Erie* prediction that promotes forum shopping or derives from federal common law not only lacks a basis in *Erie* or federalism, but actively undermines both.

C. The District Court Applied A Federal Presumption Against Liability That Finds No Support in Illinois Law.

The district court relied heavily on a presumption that a state court would not expand liability. It received only two pages of briefing on each state's law, but ruled that *no undecided state* would recognize a duty, and emphasized that "[t]his prediction comports with the principles of comity and federalism," by which it meant *refusing to expand liability* comports with comity and federalism. D.E. 2516 at 14–15.

The principle the district court applied is *Erie* conservatism—that is, the notion that federal courts should predict a state supreme court would *reject* liability whenever no clear precedent affirmatively supports liability. *Erie* conservatism is an illicit federal common law rule of decision. Like any substantive legal presumption,[6] such a principle must be grounded in a source of law. It would be proper if grounded in state law (which the district court did not purport to do), but, of course, only if the courts of the state in question themselves apply a presumption against liability for novel causes of action—Illinois does not.[7] Any *state* presumption would apply only to *Erie* predictions concerning that state, and would derive not from federalism or judicial restraint, but simply the law of that state.

Necessarily, because it purportedly applies to *all Erie* predictions in federal court, *Erie* conservatism must derive from *federal* law rather than state law. Yet that cannot be. No statute or constitutional provision requires it. And *Erie* itself makes crystal clear that *there is no general federal common law*, with no special exception for anti-liability presumptions. When courts apply *Erie* conservatism, they are,

---

[6] The presumption cannot be procedural, since it relates wholly to the law to be applied in the case, not the rules of the forum, and it governs primary conduct rather than the litigation itself.

[7] Even in rejecting market-share liability, the court defended its progressive bona fides: "We have not in the past been hesitant to develop new tort concepts[.]" *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324, 344–45 (Ill. 1990). Its public policy recognizes "the fundamental premise of tort law—that of just compensation for any loss or injury proximately caused by the tortfeasor." *Clark v. Children's Mem'l Hosp.*, 955 N.E.2d 1065, 1073 (Ill. 2011).

whatever their protests, drawing on the law of the brooding omnipresence above each federal courthouse—the law of nowhere. *Cf. S. Pac. Co. v. Jensen*, 244 U.S. 205, 222 (1917) (Holmes, J., dissenting) ("The common law is not a brooding omnipresence in the sky, but the articulate voice of some sovereign or quasi sovereign that can be identified[.]"). The Supreme Court has made clear that federal courts may not refrain from deciding state law questions "merely because the answers to the questions of state law are difficult or uncertain or have not yet been given by the highest court of the state." *Meredith v. City of Winter Haven*, 320 U.S. 228, 234–35 (1943). This principle applies equally to the practice of using a presumption to resolve cases.

Worse still, when applied by federal courts, *Erie* conservatism inevitably induces forum shopping. That is so because it artificially pushes any prediction errors in one direction: in favor of the defendant. A state court may be equally likely to rule for the plaintiff or defendant on an unsettled question—or, in some states such as Illinois, may be much more likely to resolve uncertainties in the plaintiff's favor—but a federal court would always resolve uncertainty in the defendant's favor. Defendants are no less able to discern advantages in federal court now than they were in the era of *Swift v. Tyson*. Employing presumptions that skew results defies *Erie* rather than implementing it. *See* Abbe R. Gluck, *Intersystemic Statutory Interpretation: Methodology As "Law" and the Erie Doctrine*, 120 Yale L.J. 1898,

1937–40 (2011) (criticizing *Erie* conservatism as "discomfiting" by producing decisions "not for any substantive-law reason" and noting "serious problems: it explicitly encourages forum shopping and can lead to the stagnation of state-law development because the federal court's narrow decision is not reviewable by the state's high court").

Beyond applying a federal rule of decision and promoting forum shopping, employing a presumption against liability badly impairs the accuracy of federal court guesses. No betting man would employ the strategy of favoring one result whenever the outcome is uncertain. Consider someone trying to forecast the results of an election. Polls would be the best evidence of what would happen, much like lower court cases are the best evidence of how a state's supreme court would rule. But some elections have no polls. *Erie* conservatism is much like a forecaster who, whenever no polls exist for a race, ignores demographic information and correlations with *other* state's polling, in favor of mechanically guessing that the one party's candidates will win. Such a guess will be right *sometimes*, but will predictably misfire in a number of contests. Employing no presumption at all, and instead simply looking at all available evidence is a superior strategy both in predicting elections and state supreme court rulings.

Brand-name pharmaceutical manufacturers told federal courts for years that no state supreme court would impose a duty. Scores of federal courts agreed,

predicting time after time that no state would allow Mr. Cartee's claim. At least three federal courts ruled that Massachusetts would reject the theory. *E.g.*, *In re Darvocet, Darvon & Propoxyphene Prod. Liab. Litig.*, No. 2:11-MD-2226-DCR, 2012 WL 3610237, at *2–3 (E.D. Ky. Aug. 21, 2012), *aff'd* 756 F.3d 917 (6th Cir. 2014); *Patterson v. Novartis Pharm. Corp.*, 451 F. App'x 495, 497 (6th Cir. 2011); *In re Zofran (Ondansetron) Prod. Liab. Litig.*, 261 F. Supp. 3d 62, 78 (D. Mass. 2017). This was a bad guess—the Supreme Judicial Court of Massachusetts *unanimously recognized* a duty on brand-name manufacturers. *Rafferty*, 92 N.E.3d at 1219. Plaintiffs from Massachusetts were injured by drug company misrepresentations, then lost their case merely because they were forced into a hostile federal forum that misstated Massachusetts law. The same thing is happening to Mr. Cartee.

D. Precedent Does Not Support Application of Any Presumption.

No case in the Eleventh Circuit or Supreme Court has ever endorsed *Erie* conservatism.

1. *Guarino v. Wyeth, LLC*

In *Guarino*, 719 F.3d at 1251–53, this Court predicted that the Florida supreme court would hold that brand-name manufacturers have no duty to consumers of generic drugs. Unlike in this case, in which every court in Illinois has *found* a duty, "[e]very court in Florida to consider the question ha[d] concluded that

the brand manufacturer of a prescription drug cannot be held liable for injuries suffered by consumers who ingested only the generic form of a drug." *Id.* at 1251 (citing three federal district courts in Florida and two Florida state courts, including a court of appeals). This Court correctly explained it was "bound to follow an intermediate state appellate court unless there is persuasive evidence that the highest state court would rule otherwise," and saw "no reason to doubt this interpretation of the law." *Id.* (first quoting *McMahan v. Toto*, 311 F.3d 1077, 1080 (11th Cir. 2002)).

In light of the powerful evidence from Florida courts against the position, the Eleventh Circuit remarked that "considerations of comity and federalism counsel that we proceed gingerly when venturing into uncharted waters of state substantive law." *Id.* This statement simply means federal courts should not lightly predict a state supreme court would overturn the consensus view of *courts in that state*. That is of course correct. Comity does not require anything when there is no state court ruling a federal court would be disagreeing with. And, under *Erie*, federalism requires ensuring the forum does not drive *disparate* outcomes, which means being neither *more* nor *less* pro-liability than state courts (which only counsels opposing liability when, as in *Guarino*, state courts had already opposed it). Both comity and federalism are agnostic as between liability and immunity. Neither comity nor federalism supports *Erie* conservatism, which is the view that federal courts should

rule against expansions of liability by default except where plaintiffs have affirmatively demonstrated on-point case law in their favor.

2. *Douglas Asphalt Co. v. QORE, Inc.*

In *Douglas Asphalt Co. v. QORE, Inc.*, 657 F.3d 1146, 1153 (11th Cir. 2011), this Court affirmed summary judgment on a defamation claim under Georgia law because plaintiffs sued after the statute of limitations elapsed. The plaintiffs argued that the claim was actually not defamation, but "one for 'injurious falsehood,'" which supposedly had a longer limitations period. *Id.* This Court rejected that argument, pointing out that "the Georgia Supreme Court explicitly refused to decide whether a cause of action for injurious falsehood" exists, and "no Georgia court has since held that such a cause of action exists." *Id.* It then cited other federal cases in accord, as well as a Georgia court of appeals case which held that "[e]xpanding" a definition "under the tolling statute" in a different context, "would fundamentally alter Georgia law" and "such a change is properly the role of the legislature rather than the courts." *Carter v. Glenn*, 533 S.E.2d 109, 115 (Ga. App. 2000), *abrogated on other grounds by Dep't of Pub. Safety v. Ragsdale*, 839 S.E.2d 541 (Ga. 2020).

In this context, the court noted: "It is not the function of federal courts to expand state tort doctrine in novel directions absent state authority suggesting the propriety of doing so." 657 F.3d at 1154. This quotation is fully compatible with the ordinary view that federal courts are obligated to make their best guess of state

law, and that Georgia courts *would not* expand liability in this area. In any event, this discussion was wholly unnecessary to resolving the case, because "even if such a tort exists under Georgia law, there is nothing in Douglas's complaint to indicate that it was making—or even attempting to make—that kind of claim." *Id.* at 1154. The complaint "unambiguously" pleaded slander or label, and "never used the phrase 'injurious falsehood' or any other similar words." *Id.*

In short, this Court should predict what the Illinois supreme court would do with no federal-court-specific presumption that it would oppose liability. Any stray *dicta* in prior decisions is not to the contrary, and even if it were, is not controlling and must be cast aside.

E. The Federal Majority Position Deserves Little Weight.

In 2013, this Court felt that its prediction of Florida law was "fortified" by "the overwhelming national consensus" that brand manufacturers cannot be liable. *Guarino*, 719 F.3d at 1252. At the time, only one state supreme court had ruled on the question, but even that case had been vacated pending rehearing. *See id.* at 1253. No federal court can have any such confidence in the year 2021. Nearly all cases decided the issue before federal courts had started dismissing product liability claims against generic manufacturers *en masse*, a trend that was cemented within a day of *Guarino* with the Supreme Court's ruling in *Bartlett*, 570 U.S. 472. Even in 2017, the Fourth Circuit—home of the once-leading case rejecting a duty on brand-name

manufacturers that had been contradicted by *Mensing*—deemed the question uncertain enough to be certified to the Supreme Court of West Virginia. *McNair*, 694 F. App'x at 119–20.

Since that time, Iowa, West Virginia, California, and Massachusetts each reached the question, and the results were nothing like the consensus in federal court: they split 50/50. In terms of state jurists, the pro-liability side won 25 to 9. Lord John Maynard Keynes is quoted as saying "When the facts change, I change my mind. What do you do, sir?"[8] Notwithstanding the confident statements from *Guarino*, in light of the changed landscape, this Court must give its best prediction of how the Illinois supreme court would rule, with no thumb on the scale.[9] A bad guess is a bad guess, and earns no extra points for being "conservative."

[8] Jason Zweig, *Keynes: He Didn't Say Half of What He Said. Or Did He?*, Wall Street Journal (Feb. 11, 2019) https://www.wsj.com/articles/BL-MB-32547.

[9] Under this Court's precedent, "[w]here there is any doubt as to the application of state law, a federal court should certify the question to the state supreme court to avoid making unnecessary *Erie* 'guesses' and to offer the state court the opportunity to interpret or change existing law." *Mosher v. Speedstar Div. of AMCA Int'l, Inc.*, 52 F.3d 913, 916–17 (11th Cir. 1995). Regrettably, certification is unavailable in this case, since the Illinois supreme court accepts certified questions only from the Supreme Court of the United States and the United States Court of Appeals for the Seventh Circuit. *See* Ill. Sup. Ct. R. 20(a). Counsel is not aware of any federal rule that would allow this case to be transferred to the Seventh Circuit to be certified.

VI. THE ILLINOIS SUPREME COURT WOULD IMPOSE A DUTY ON BRAND-NAME MANUFACTURERS.

A. The Argument for a Duty

Plaintiff's claim is for negligent misrepresentation. The label for Zantac was misleading because it said nothing at all about cancer, even though Zantac degrades into a carcinogen. Under the FDA's regulatory scheme, doctors and consumers understand that generic drugs are supposed to be bioequivalent to—and have the same labeling as—the branded drug they can be substituted for. In light of this longstanding regime, doctors rely on representations by the brand-name manufacturer in writing prescriptions or recommending over-the-counter drugs. In Illinois, as in all states, the generic equivalent can be substituted by pharmacies. *See* 225 Ill. Comp. Stat. Ann. 85/25. The pleadings allege that Brand-Name Manufacturer Defendants knew that Mr. Cartee and his physicians would rely on their misrepresentations about branded Zantac in consuming or prescribing generic ranitidine. MPIC ¶ 569.

Physicians and consumers are far more likely to receive information about a drug's risks and benefits from the brand-name manufacturer. While its drug is patented, brand-name manufacturers often—and the Defendants certainly did here—expend millions of dollars to teach prescribing physicians about its drug and to promote its use to consumers. *See* MPIC ¶¶ 10–11. Brand-name manufacturers also publish their approved drug labeling in the Physicians' Desk Reference (PDR), a

primary source of information about drugs for most physicians. By contrast, generic manufacturers do little or no promotion of their products and do not publish their labeling in the PDR.

When a generic manufacturer learns of a new safety risk, it cannot simply add a warning, since the label would differ from the branded drug's. Nor can it send letters to doctors about the risk, since "such letters . . . would inaccurately imply a therapeutic difference between the brand and generic drugs." *Mensing*, 564 U.S. at 615. A brand-name manufacturer, by contrast, "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*, 555 U.S. at 571. And, using the changes-being-effected process, a brand-name manufacturer can change the labeling on its drugs to add a warning without waiting for the FDA to approve it. *Id.* at 568. The medical community would be quickly aware of such changes, and generic manufacturers would—as required—update their own labels. As one Illinois federal court explained, recognizing a duty here "simply allows [a plaintiff] to attempt to recover for deficiencies in [a drug's] label from the one entity, under federal law, that has unilateral ability to strengthen the label." *Garner v. Johnson & Johnson, Janssen Rsch. & Dev. LLC*, No. 116CV01494SLDJEH, 2017 WL 6945335, at *7 (C.D. Ill. Sept. 6, 2017).

Holding brand-name manufacturers liable for injuries caused by generic versions of their drugs is consistent with the long-standing rule that those who disseminate misinformation to the public are liable for physical harm to third parties resulting from foreseeable reliance on those misrepresentations. This principle is well-articulated in Section 311 of the Restatement (Second) of Torts, which provides:

> 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 . . . to such third persons as the actor should expect to be put in peril by the action taken.

Restatement (Second) of Torts § 311 (1)(b) (Am. Law Inst. 1965). Illinois has fully adopted section 311 of the Restatement. *Board of Education of City of Chicago v. A, C & S, Inc.*, 546 N.E.2d 580, 592 (Ill. 1989).

The Comments to Section 311 recognize it provides "broader liability" than where the representation is for pecuniary loss under Section 552. *See id.*, cmt. a. Comment b highlights that the principle described "finds particular application where it is a part of the actor's business or profession to give information upon which the safety of the recipient or a third person depends." *Id.*, cmt. b. And Comment c proposes that liability applies to advice given "gratuitously" and even where "the actor derives no benefit from giving it." *Id.*, cmt. c. Comment c also advises that such liability is "fully justified" where the actor "purports to have special

knowledge," *id.*, as is the case with any brand-name manufacturer. The California Supreme Court leaned heavily on section 311 in finding a duty. *Novartis*, 407 P.3d at 27.

The district court reasoned that Mr. Cartee's claims were either product liability or negligence claims. If they were product liability, they failed for lack of "product identification"; if negligence-based, they failed because brand-name manufacturers have no duty to consumers of generic products. D.E. 2516 at 36–38. Mr. Cartee's claim is based in negligence, which has no product identification requirement, and Illinois law does support a duty.

B. Illinois Law

Every court to have decided the issue in Illinois has held that the Illinois Supreme Court would recognize a duty. *See Garner*, 2017 WL 6945335, at *7 (Darrow, J.); *Dolin v. GlaxoSmithKline LLC*, 269 F. Supp. 3d 851, 864 (N.D. Ill. 2017) (Hart, J.) (adhering to Judge Zagel's ruling); *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 713 (N.D. Ill. 2014) (Zagel, J.), *rev'd on other grounds sub nom. Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803 (7th Cir. 2018); *see also In re Fluoroquinolone Prod. Liab. Litig.*, No. 0:15-MD-02642, 2021 WL 396819, at *9 (D. Minn. Feb. 4, 2021) (adopting *Dolin* and rejecting the opinion below). The opinion below and the Sixth Circuit have predicted the Illinois supreme court would

not recognize a duty. *See In re Darvocet. Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 944 (6th Cir. 2014).

The first opinion was by Judge James Zagel, a lifelong Illinoisan and former state police director. After setting out the regulatory context, Judge Zagel rejected GSK's argument that negligent misrepresentation claims were disguised product liability claims, and so failed for lack of product identification. 62 F. Supp. 3d at 713. The reason is persuasive. Though the Illinois legislature passed a tort reform bill in 1995 that codified product liability law in a way that would have subsumed claims like these, the Illinois Supreme Court struck it down as unconstitutional.[10] *Id.* Negligent misrepresentation claims have their own elements, and need not satisfy the requirements of product liability law (such as product identification). That ruling is correct.

1. *Product Identification*

The Illinois Supreme Court has never required product identification over and above causation. The primary case the district court relied upon in ruling otherwise—which is also what the Sixth Circuit relied upon in ruling otherwise—is

[10] *Best v. Taylor Mach. Works*, 689 N.E.2d 1057, 1104 (Ill. 1997). The Illinois Supreme Court focused primarily on the damages caps, elimination of joint and several liability, and forced disclosure of medical records, all of which were unconstitutional. Because the rest of the reforms were ruled inseverable, the supreme court did not resolve whether the lower court had been correct in ruling the product liability provisions that might otherwise be relevant here unconstitutional.

Smith v. Eli Lilly & Co., 560 N.E.2d 324, 342 (Ill. 1990). This case involved the drug diethylstilbestrol (DES), which caused birth defects that sparked lawsuits many years later. The plaintiff could not prove which defendant sold, manufactured, or designed the DES that harmed her, which meant she had no way of proving causation. Thus, "[t]he issue is whether, in a negligence and strict liability cause of action, Illinois should substitute for the element of causation in fact a theory of market share liability when identification of the manufacturer of the drug that injured the plaintiff is not possible." *Id.* at 325. The court reiterated at the end of the opinion its focus on causation: "this is too great a deviation from a tort principle which we have found to serve a vital function in the law, **causation in fact**, especially when market share liability is a flawed concept and its application will likely be only to a narrow class of defendants." *Id.* at 345 (emphasis added).

The court was persuaded that market-share liability could not work. There was no "reliable information available to establish the defendants' percentages of the market." *Id.* at 337. Market share liability would not produce an incentive for safe products because it was "40 years after" the harm and "20 years after . . . the product removed from the market," and "is only being applied to manufacturers of DES or similar products." *Id.* at 342–43.

Only after discussing the fatal flaws with market share liability did the Illinois Supreme Court briefly discuss duty. It did so because the plaintiff sought to reduce

her causation burden by defining the duty at such an abstract level that a harm to other people—or to the public in general—could, by itself, give rise to liability *to her*. The court rejected that reasoning, distinguishing a case about an unborn—indeed, not-yet-conceived—child, and noting that "negligence and strict liability require proof that defendant breached a duty owed to a particular plaintiff." *Id.* at 343. With a particular plaintiff as the focus, the causation problem returned, and the court explained that "liability may [not] be imposed based merely on a breach of duty, without causation being established." *Id.*

If Mr. Cartee sought recovery from generic manufacturers collectively simply because he could not prove which defendant harmed him, that would fall afoul of *Smith*. But that is not this case.

> Here, [Mr. Cartee] knows exactly which entity is responsible for the allegedly harmful conduct: the [brand-name] Defendants. Defendants created the label that allegedly caused [Mr. Cartee's] doctor to prescribe [ranitidine]. [Mr. Cartee] has identified the defendant and duty owed: Defendants' exclusive responsibility for the warnings that must accompany both brand-name [Zantac] and generic [ranitidine].

2021 WL 396819, at *6. The problem in *Smith* was causation, and the Illinois Supreme Court refused to allow market share to "substitute for the element of causation." *Id.* at 325. No similar causation hurdle exists here. If any Defendant here had changed the Zantac label while it held the NDA—which each held consecutively during the relevant time period—Mr. Cartee would not have been harmed. His doctor would not have prescribed ranitidine. Their tortious

misrepresentation caused his cancer. That is wholly different from *Smith*, in which the plaintiff could not prove that any particular defendants' label, design, or conduct of any sort whatever caused her injury. Product identification is no hurdle.

2. *Illinois Duty Analysis*

All agree that under Illinois law the ordinary test for duty has four prongs: "(1) the reasonable foreseeability of the injury, (2) the likelihood of the injury, (3) the magnitude of the burden of guarding against the injury, and (4) the consequences of placing that burden on the defendant." *Simpkins v. CSX Transp., Inc.*, 965 N.E.2d 1092, 1097 (Ill. 2012). All prongs are met, and Illinois has no formalistic requirements. Illinois courts "have long recognized that 'every person owes a duty of ordinary care to all others to guard against injuries which naturally flow as a reasonably probable and foreseeable consequence of an act, and such a duty does not depend upon contract, privity of interest or the proximity of relationship, but extends to remote and unknown persons.'" *Bogenberger v. Pi Kappa Alpha Corp., Inc.*, 104 N.E.3d 1110, 1118 (Ill. 2018) (quoting *Widlowski v. Durkee Foods, Div. of SCM Corp.*, 562 N.E.2d 967, 968 (Ill. 1990)).

a. Foreseeability

The injury here is not merely foreseeable but practically certain. Brand-name manufacturers know that any misrepresentations on their label will be disseminated to consumers of generic drugs, who will be harmed by them. Even the Iowa supreme

court conceded generic copying of the label "may well be foreseeable." *Huck*, 850 N.W.2d at 380. Whatever "foreseeable" means, it surely includes a misrepresentation in a public-facing warning.

The Sixth Circuit countered that "the generic consumers' injuries are not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control." *In re Darvocet,*, 756 F.3d at 944. The distinction drawn here would not be accepted in any other context. Law is inextricably intertwined with foreseeability in even the simplest cases. That a car will move forward when a light turns green, or will drive on the right side of the road is only foreseeable due to the laws over which other drivers have no control. That a doctor will prescribe prescription drugs, but not over-the-counter drugs, is similarly foreseeable only due to extant law. Whether something is foreseeable due to law, incentives, or past experience makes no difference under Illinois law. No Illinois case draws a distinction between the foreseeable result of *conduct* and the foreseeable result of *laws that channel conduct*. To the contrary, Illinois courts sensibly accept in determining foreseeability that "it is generally reasonable for one to assume that a person will not violate the criminal law." *Marshall v. Burger King Corp.*, 856 N.E.2d 1048, 1059 (Ill. 2006).

The Sixth Circuit and the district court derived their foreseeability argument from a law review article written by a tort reform advocate. *See* D.E. 2516 at 37

(citing Schwartz). Whatever his persuasiveness in other contexts, his record in predicting or stating *Illinois* law on torts is poor. He wrote an article on why the Illinois General Assembly's 1995 tort reform should be—and would be—upheld by the Illinois Supreme Court against legal challenge. *See* Victor E. Schwartz et al, *Illinois Tort Law: A Rich History of Cooperation and Respect between the Courts and the Legislature*, 28 Loy. U. Chi. L. J. 745 (1997). "Clearly," he wrote, "the Act reflects sound public policy and is consistent with Illinois legal history." *Id.* at 760. The Illinois Supreme Court addressed his article, agreeing that "the legislature has the power to change the common law" when doing so is "rationally related to a legitimate government interest," but *holding* that the "statutory cap on compensatory damages for noneconomic losses"—the very same cap he suggested is "clearly . . . sound public policy"—was "arbitrary" and so struck down as unconstitutional. *Best v. Taylor Mach. Works*, 689 N.E.2d 1057, 1077 (Ill. 1997). Mr. Schwartz's perspective on foreseeability would be no more likely to persuade.

b. Likelihood of the Injury

The likelihood of ranitidine harming consumers in the absence of a warning is high. Ranitidine degrades into a potent carcinogen, and the FDA has recalled it. Surely this suffices.

c. Magnitude of the Burden of Guarding Against Injury

The magnitude of the burden on Defendants here is minor. Imposing a duty would not lead to over-warning or any change at all since brand-name manufacturers *already* are required to have truthful labels under both federal and state law. As the California Supreme Court explained, burden "is not the cost of compensating individuals for injuries that the defendant has actually and foreseeably caused" but instead "the cost to the defendants of upholding, not violating, the duty of ordinary care." *Novartis*, 407 P.3d at 32. "Strictly speaking, then, the burden on brand-name drug manufacturers of satisfying a common law duty of care to those who are prescribed the generic version of the drug is zero." *Id.*

Illinois courts have applied nearly identical reasoning when imposing a duty on conduct that is already required by law. For example, the Illinois supreme court imposed a duty on fraternities for the benefit of drunk pledges, despite the longstanding absence of "social host liability":

> To require the NIU Chapter and officers to guard against hazing injuries is infinitesimal. Hazing is not only against the law in Illinois, it is against the university's rules as well as the Pi Kappa Alpha fraternity's rules. There can be no real burden to require the NIU Chapter and officers to comply with the law and the university's and fraternity's rules. And it seems quite reasonable to place that burden on the very people who are in charge of planning and carrying out the pledge event.

Bogenberger v. Pi Kappa Alpha Corp., Inc., 104 N.E.3d 1110, 1125 (Ill. 2018); *see also LaFever v. Kemlite Co., a Div. of Dyrotech Indus.*, 706 N.E.2d 441, 451 (Ill.

1998) ("Satisfying their duty of care as land owners, therefore, would likely require only a refinement or intensification of existing procedures, as opposed to the creation of safety measures that otherwise would not have existed."). Though the brand-name Defendants may view tort liability as a cost of doing business, Illinois law presumes they can follow the law, and that an increase in liability for failing to do so is not an additional burden on their behavior.

d. Consequences of Placing a Burden on Defendants

Finally, the consequences of placing a duty on brand-name manufacturers is not so severe that it weighs against imposing a duty. On this point, a federal court must view matters as the Illinois supreme court would, and evidence abounds that their view does not match the federal judiciary's. In the understated words of the Illinois supreme court, state law "tends to vary in the direction of greater liberality" compared to federal courts. *Greer v. Illinois Hous. Dev. Auth.*, 524 N.E.2d 561, 574 (Ill. 1988) (addressing standing).[11]

First, the doctrine. The Illinois supreme court disfavors using a lack of duty to tackle general goals:

[11] This Court may be especially interested in a recent Illinois court of appeals ruling that a bare technical violation of FACTA was sufficient to bring a class action in Illinois state court without any actual harm. *Soto v. Great Am. LLC*, 2020 IL App (2d) 180911, ¶ 35, appeal allowed, 147 N.E.3d 688 (Ill. 2020); *compare Muransky v. Godiva Chocolatier, Inc.*, 979 F.3d 917, 936 (11th Cir. 2020) (en banc) (vacating a class action settlement on the same facts for lack of standing).

> Rules declaring that no duty exists can easily be made too broad or too narrow. Because they are rules of law, not decisions about particular cases, they cover all cases in the category to which they are addressed. They are expressions of 'global' policy rather than evaluations of specific facts of the case. Consequently, no-duty rules should be invoked only when all cases they cover fall substantially within the policy that frees the defendant of liability.

Marshall v. Burger King Corp., 856 N.E.2d 1048, 1060 (Ill. 2006) (quoting 1 D. Dobbs, Torts § 227, at 579 (2001)). Beyond that, the Illinois Constitution provides that "[e]very person shall find a certain remedy in the laws for all injuries and wrongs which he receives to his person, privacy, property or reputation. He shall obtain justice by law, freely, completely, and promptly." Ill. Const. art. I, § 12. The Illinois supreme court has, on occasion, struck down laws based on this provision, explaining that the "certain remedy provision has been referred to in general as a statement of philosophy rather than a guarantee of a specific remedy. Nonetheless, we believe that a statement of 'constitutional philosophy' is reflective of [a] strong public policy" of, in that case, protecting medical records from discovery in personal injury litigation. *Best v. Taylor Mach. Works*, 689 N.E.2d 1057, 1100 (Ill. 1997). In a close case, Illinois public policy is to provide certain remedies for injuries and wrongs of the sort Mr. Cartee has suffered.

Second, nothing replaces a grounding in how the Illinois supreme court has actually evaluated the consequences of tort liability in significant cases. At almost every opportunity, it has expanded, not contracted, liability. For example, in a break

with Iowa and several other states more solicitous of public coffers, the Illinois supreme court "abolish[ed] the public duty rule and its special duty exception" which protected police and firefighters from tort liability. *Coleman v. E. Joliet Fire Prot. Dist.*, 46 N.E.3d 741, 758 (Ill. 2016) (expressly disagreeing with *Raas v. State*, 729 N.W.2d 444, 448 (Iowa 2007)). In a nationwide first, the Illinois supreme court interpreted the Biometric Information Privacy Act—which comes with a minimum of $1,000 in statutory damages per offense—not to require any actual harm beyond a technical violation of the statute, allowing what the defense bar calls no-injury class actions. *Rosenbach v. Six Flags Ent. Corp.*, 129 N.E.3d 1197, 1205 (Ill. 2019).

Even when the legislature has tried to reign in pharmaceutical tort suits through tort reform, the Illinois supreme court has pushed back. It invalidated a $500,000 damages cap on noneconomic damages as an unconstitutional "legislative remittitur" that "disregards the jury's careful deliberative process in determining damages that will fairly compensate injured plaintiffs who have proven their causes of action." *Best*, 689 N.E.2d at 1080. The attempted worker's compensation reform violated "principles of due process and equal protection." *Id.* at 1087. The elimination of joint and several liability out of defendants' concerns over excessive liability relied an argument the "court rejected," *id.*, but in any case was unconstitutional because "the legislature may not adopt an arbitrary means of achieving [its] goal" and the "stated legislative goal of achieving fairness does not

justify singling out a select group of tort plaintiffs for special treatment." *Id.* at 1088. The law "include[d] a general severability provision," but the court nonetheless found every part of it inseverable, relying in part on purposes and legislative history. *Id.* at 1101. Consequently, other reforms (including stricter jury instructions, shorter repose and limitations periods, a regulatory compliance defense, and others) were all eliminated. *Id.* at 1105. From the Wall Street Journal, former Attorney General Dick Thornburgh said, "The imperial sweep of the Illinois ruling was astonishing."[12] Victor Schwartz—who the district court repeatedly relied upon—said this foundational opinion "overreach[ed]" and "ignored the fundamental separation of powers principle upon which our entire system of government is based."[13]

Much the same thing happened twenty years later, after a new push for tort reform in light of a "health-care crisis" in Illinois. *Lebron v. Gottlieb Mem'l Hosp.*, 930 N.E.2d 895, 902 (Ill. 2010). Again, the legislature placed a cap on non-economic damages. The Wall Street Journal warned that "The Illinois Supreme Court can once again do the bidding [of the] plaintiffs' bar, or this time side with patients and the rule of law."[14] Again, the Illinois Supreme Court struck it down,

---

[12] Dick Thornburgh, *A New Judicial Imperialism*, Wall Street Journal (May 18, 1998) https://www.wsj.com/articles/SB895269242414489500.

[13] Victor E. Schwartz, et al., *Fostering Mutual Respect and Cooperation between State Courts and State Legislatures*, 103 W. Va. L. Rev. 1, 9–10 (2000).

[14] Wall Street Journal, *Messing with Malpractice Reform*, (Dec. 1, 2008) https://www.wsj.com/articles/SB122809479886668021.

reiterating its rulings from *Best*: "the damages limitation actually undermined the statute's stated goal of providing consistency and rationality to the civil justice system" *id.* at 905, and "reducing the systemic costs of tort liability was [in]sufficient . . . [because] the entire burden of any cost savings would impermissibly rest on one class of injured plaintiffs." *Id.* at 906. The commonality of damages caps in other states was irrelevant: "That 'everybody is doing it' is hardly a litmus test for the constitutionality of the statute." *Id.* at 914. Again, the court "h[e]ld the Act invalid and void in its entirety." *Id.* To the extent Defendants' arguments in this case rely on the dire consequence from rejecting pro-business rules from other states, the Illinois supreme court's justices would not be a receptive audience.

Each prong of Illinois' duty test is amply met.

C. Illinois Is Similar to California, not West Virginia.

To adequately predict state law under *Erie*, a federal court must realistically assess what a state supreme court would do. When California and Massachusetts are on one side of a novel question, and Iowa and West Virginia are on the other, can anyone profess bafflement on where Illinois will end up? Supreme court decisions are, of course, not on the ballot, but the legal culture and public policy of different states are not mysterious. Take it from the defense bar.

The American Tort Reform Association—whose general counsel is one Victor Schwartz—deems Illinois a "judicial hellhole," and claims it is "a preferred

jurisdiction for plaintiffs' lawyers thanks to no-injury lawsuits, plaintiff-friendly rulings in asbestos litigation, and the promise of a liability-expanding legislative agenda each and every year."[15] In a ranking of "how plaintiff-friendly each state's civil liability system is," The Cato Institute ranks Illinois 49th out of 50 states (*i.e.*, nearly the most friendly, a bad thing in the Institute's view).[16] The U.S. Chamber of Commerce's Institute for Legal Reform ranked Illinois dead last in its ranking of "the fairness and reasonableness of state liability systems."[17] That list has helpful sub-categories, including "overall treatment of tort and contract litigation" (50th out of 50), and—particularly relevant here, given the goal of predicting what the state high court would do—"quality of appellate review" (50th out of 50). *Id.* at 12. Plaintiffs might riposte that, in truth, Illinois is the *most* fair, *most* reasonable, has the *best* tort litigation treatment, and has *excellent* appellate review, but however one spins it, the point is that *all* agree Illinois is a friendly forum for tort law innovation.

On each of these pro-business publications, California is close-by. West Virginia and Iowa, generally, are not. The mores of the people in the several states

---

[15] American Tort Reform Foundation, *Judicial Hellholes 2020/2021* (Dec. 2020) https://www.judicialhellholes.org/wp-content/uploads/2020/12/ATRA_JH20_layout_09d-1.pdf.

[16] The Cato Institute, *Freedom in the 50 States* (2016) https://www.freedominthe50states.org/lawsuit/illinois.

[17] U.S. Chamber Institute for Legal Reform, *2019 Lawsuit Climate Survey: Ranking the States*, (Sept. 2019) https://instituteforlegalreform.com/wp-content/uploads/2020/10/2019_Lawsuit_Climate_Survey_-_Ranking_the_States.pdf.

are not uniform. Predictions of their laws should not be either. Since "[f]ederal courts, when sitting in diversity, are no ostriches," *Lupu*, 903 F.3d at 395, this basic difference in legal culture—well-recognized by the defense bar except when briefing this issue—should build confidence in a guess that Illinois would join California and Massachusetts in recognizing a duty by brand-name manufacturers to those harmed by their label.

* * *

As the above analysis shows, *Erie* predictions in the absence of on-point precedent are hard work. A good prediction requires diving deeply into the law of the state in adjacent areas and building a mosaic from diverse strands of evidence. This careful analysis is not possible on a mere two pages of briefing per state, which is perhaps why the district court was tempted to short-circuit its analysis with the easy answer of *Erie* conservatism. The district court considered only an extremely truncated version of the argument above, because plaintiffs had no space to explain Illinois law. This Court has discretion to rule only on the first question presented in this appeal, vacating the decision below on the ground that *Erie* conservatism distorted its legal analysis, and remanding with instructions for the district court to consider the full picture under Illinois law in the first instance.

CONCLUSION

For the foregoing reasons, Plaintiff-Appellant Cartee respectfully requests that the decision below be reversed.

Dated: March 29, 2021

Respectfully submitted,

/s/ Ashley Keller

Ashley Keller
KELLER LENKNER LLC
150 N. Riverside Plaza, Suite 4270
Chicago, IL 60606
Tel: (312) 741-5222

Noah Heinz
KELLER LENKNER LLC
1300 I Street, N.W., Suite 400E
Washington, DC 20005
Tel: (202) 918-1841

Leslie A. Brueckner
PUBLIC JUSTICE, P.C.
475 14th Street, Suite 610
Oakland, CA 94612
Tel: (510) 622-8205

Edward A. Wallace
Timothy E. Jackson
WEXLER WALLACE LLP
55 W. Monroe St., Suite 3300
Chicago, IL 60603
Tel: (312) 346-2222

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 12,978 words, excluding the parts exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a) because it has been prepared in a proportionately spaced typeface using Microsoft Word Times New Roman 14-point font.

Dated: March 29, 2021

/s/ Ashley Keller
Ashley Keller
Counsel for Plaintiff-Appellant Arthur Cartee

CERTIFICATE OF SERVICE

On March 29, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. All participants in this case are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

/s/ Ashley Keller
Ashley Keller
Counsel for Plaintiff-Appellant Arthur Cartee