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NOT ALL PRODUCT-CAUSED HARM IS “PRODUCTS LIABILITY”

Michael D. Green

There’s something happening here

What it is ain’t exactly clear.¹

ABSTRACT

Since two important federal preemption decisions by the United States Supreme Court, those injured by warnings defects in the drugs they take may sue the manufacturer only if the patient took a brand-name drug. Those who took the generic version of the drug, which comprise approximately 90 percent of all prescriptions,² cannot sue the drug manufacturer regardless of how inadequate its labeling is in explaining the risks of consuming the drug.

Clever plaintiffs’ lawyers began bringing suits on behalf of their generic-drug-consuming clients against brand-name manufacturers that, under the Food, Drug, and Cosmetic Act, control the labeling both on their drugs and on generic versions of their drugs. Instead of (or in addition to) asserting products liability claims, they assert negligent misrepresentation claims against the brand-name manufacturer.

In well over 100 court opinions in the last three decades, the overwhelming response has been to deny these claims for a variety of reasons. Arguably, the most prominent ground is that products liability claims must be made against the manufacturer of the product that injured the plaintiff. Such reasoning is specious because the plaintiff’s claim is not a products liability claim—it is a negligent misrepresentation claim. Courts have adopted other, equally unpersuasive reasons for denying these claims.

This Article catalogs and assesses the grounds that courts provide in denying these claims, concluding that they hold virtually no water. That courts continue down this path despite the illumination of at least one contrary decision and an excellent law review article explains the epigraph to this Article: How can this be?

¹ Visiting Professor of Law, Washington University in St. Louis School of Law. I would like to thank participants in the symposium honoring Aaron Tverski on April 20–21, 2023, for their comments and especially John Goldberg for his helpful insights into what might explain the court decisions discussed in this paper.

² Buffalo Springfield, For What It’s Worth, on Buffalo Springfield (Atco Records 1966). I borrow from Bill Powers, my friend and colleague, the first commentator I know of to use these lyrics to express bewilderment at some legal development. See William Powers, Jr., Judge and Jury in the Texas Supreme Court, 75 TEX. L. REV. 1699 (1997).

INTRODUCTION

Unlike the typical Festschrift in which the author takes a position on an issue related to the honoree’s body of work, this article spins out a puzzle, exemplified in the epigraph above. A puzzle that I hope Aaron, who has plumbed so much of the depths of products liability law in his career, might be able to help explain what I cannot: How so many courts have gotten it so wrong when it comes to “brand-name” drug manufacturers’ liability to generic-drug consumers.4

For reasons I will explain, I do not understand the courts’ response to this issue. I do not believe there is another issue in tort law that I have come across where so many courts seem to have gone so far wayward. Needless to say, Aaron, I need your help.

I. SETTING THE STAGE: THE MISCELLANEOUS PROVISIONS PROJECT OF THE RESTATEMENT (THIRD) OF TORTS AND NEGLIGENT MISREPRESENTATION

My initial encounter with this issue occurred in 2018 when the American Law Institute (ALI) sought to complete the Restatement (Third) of Torts. Beginning in 1992, the Third Restatement of Torts had already produced three completed subjects, with two more in progress. Parenthetically, it seems appropriate to note that Aaron was one of the two co-reporters who inaugurated the Third Restatement, joining his friend, collaborator, and sidekick Jim Henderson to prepare the Products Liability Restatement, which was completed and published in 1998. As a young professor teaching products liability, I had the privilege to travel on that Restatement ride, which proved to be an invaluable experience that provided me with insights and knowledge during my subsequent years of teaching and research.

Cut twenty years forward from the completion and publication of the Products Liability Restatement, and it was clear in 2018 that more was needed to fulfill a commitment made by the ALI in 2007 about the Third Restatement of Torts. The ALI decided that the Third Restatement should provide comprehensive coverage over all aspects of tort law. That meant “bringing forward” and restating all the material in the Second Restatement,

3. Or, if you are an apologist for the pharmaceutical industry, “innovator liability.” See Tarifa B. Laddon et al., Outlier or Wave of the Future: Innovator Liability for Drug Manufacturers, FOR THE DEF., Sept. 2018, at 1, 78, https://digitaleditions.walsworth.com/publication?m=55594&i=522552&p=80&ver=html5. Some new drug approvals by the FDA are for new chemical entities—justifying the “innovator” description. Others are chemically similar to previously approved drugs, justifying their classification as “me-too” drugs. See Jeffrey K. Aronson, & A. Richard Green, Me-Too Pharmaceutical Products: History, Definitions, Examples, and Relevance to Drug Shortages and Essential Medicines Lists, 86 BRIT J. CLINICAL PHARMACOLOGY 2114 (2020), https://doi.org/10.1111/bcp.14327 (“the me-toos greatly outnumber the medicines that are first in class”).

replacing its provisions entirely. Thus, the “Concluding Provisions” project was commissioned to address several key objectives. It aimed to clarify any remaining issues not covered by the subject-specific efforts up to 2018. This project was also tasked with covering essential topics omitted in prior Torts Restatements, such as medical malpractice and vicarious liability, as well as newly emergent subjects, like medical monitoring and cases involving wrongful pregnancy, birth, and life.

After carefully studying the matter, the Reporters selected for the Concluding Provisions were a bit overwhelmed with the number of tort subjects that required attention in the project. Negligent misrepresentation that causes physical harm, the subject this paper discusses, is one of the subjects that had fallen into the subject-specific cracks of the prior Third Restatement projects. Misrepresentation is most closely associated with deceit (or fraud) in the commercial realm and can be traced to the early writ system, which initially had a separate and limited writ for deceit that was later incorporated into the trespass-on-the-case writ. Commercial fraud is a subject that is often taxonomized by the harm it causes—financial or economic harm and misrepresentations causing that harm are addressed in Restatement (Third) of Torts: Liability for Economic Harm. For that reason, lawyers and judges often overlook that misrepresentations can cause harms other than financial ones. Thus, consider a school district that provides a glowing reference for a teacher who was the subject of credible complaints of sexual improprieties with students. If the teacher is hired in reliance on that reference and proceeds to sexually assault a student, a claim for fraud would lie. And if the school district was merely careless in ascertaining the

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5. For a comprehensive account of the initiation of the Third Restatement to its current status, which has four current projects, including Concluding Provisions (now denominated “Miscellaneous Provisions”), that will, when completed, comprise the Restatement (Third) of Torts, see ‘RESTATEMENT (THIRD) OF TORTS: MISCELLANEOUS PROVISIONS xvii Reporters’ Memorandum (AM. L. INST., Tentative Draft No. 1, Mar. 2022). For a comprehensive list of the subjects that will be covered in the now-titled Miscellaneous Provisions Restatement, see RESTATEMENT (THIRD) OF TORTS: CONCLUDING PROVISIONS xvii–xix (AM. L. INST., Tentative Draft No. 2, Mar. 2023).

6. THOMAS A. STREET, THE FOUNDATIONS OF LEGAL LIABILITY: A PRESENTATION OF THE THEORY AND DEVELOPMENT OF THE COMMON LAW 375–76 (1906). Fraud claims were limited to parties in privity of contract until Pasley v. Freeman, 100 Eng. Rep. 450 (K.B. 1789), which then facilitated fraud claims finding a home in tort law once it became a recognized category of law.

7. See RESTATEMENT (THIRD) OF TORTS: LIAB. FOR ECON. HARM §§ 5, 9 (AM. L. INST. 2020) (addressing respectively negligent and intentional misrepresentations).

8. See Doe v. Dilling, 861 N.E.2d 1052, 1066 (Ill. App. Ct. 2006) (discussing cases), aff’d, 888 N.E.2d 24 (Ill. 2008). For an example of failing to appreciate that there is more to negligent misrepresentation than causing pecuniary harm, see Forest v. E.I. DuPont de Nemours & Co., 791 F. Supp. 1460, 1470 (D. Nev. 1992) (in a case alleging personal injury, dismissing negligent misrepresentation claim, after quoting Section 552 of the Second Restatement, which addresses negligent misrepresentation causing pecuniary loss and concluding: “[i]t is clear from this passage that the tort is only available to those suffering pecuniary injury in the context of a business transaction”).

employment records of the same teacher and the same assault occurred, the
school district should also be liable for its negligent misrepresentation.10
Negligent misrepresentation, while not universally accepted in the physical
harm realm, has either clear support or inferential support in nearly half the
states.11 The Products Liability Restatement, also in the physical harm realm,
adressed misrepresentations by product manufacturers that cause such
harm.12

The Restatement (Third) of Torts: Intentional Torts to Persons has a
dedicated section addressing fraud that results in physical harm.13 However,
negligent misrepresentation, which had not been fully addressed in earlier
Third Restatement projects, was relegated to the Miscellaneous Provisions
project. Not a problem: There is a long history of the first two Restatements
recognizing claims for negligent misrepresentation that result in physical
harm.14 Negligent misrepresentation is, at bottom, merely a species of
negligence claims. However, it possesses two distinct wrinkles: the tortious
conduct involves communication, and reliance on these communications is
crucial for establishing factual causation.

Thus, we prepared material addressing liability for negligent
misrepresentation.15 However, we encountered significant opposition,
particularly from individuals associated with the pharmaceutical industry.
This resistance was rooted in a substantial body of case law that consistently
denied claims made by consumers of generic drugs against the manufacturers
of their counterpart brand-name drugs that the consumer did not use. Plainly,
a deeper dive into this subject was required to understand why there was such
a strong rejection of the application of the negligent misrepresentation
doctrine to drug manufacturers whose product labeling did not adequately
communicate the dangers of their (and generic versions of the) drug, resulting
in harm to consumers of the generic version of the drug.

II. THE FIRST JUDICIAL ENCOUNTER: FOSTER v. AMERICAN HOME
PRODUCTS CORPORATION

The place to start is the first case addressing the matter, which was
decided before the Supreme Court joined the game with its decisions on
federal preemption of inadequate warnings claims against both brand-name
and generic-drug manufacturers.16 In Foster v. American Home Products

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10. See id. at § 311.
11. See RESTATEMENT (THIRD) OF TORTS: MISCELLANEOUS PROVISIONS § 18A, rptrs note to
13. See RESTATEMENT (THIRD) OF TORTS: INTENTIONAL TORTS TO PERS. § 51 (AM. L. INST.,
Tentative Draft No. 6, Apr. 26, 2021).
15. See RESTATEMENT (THIRD) OF TORTS: CONCLUDING PROVISIONS § 18A (AM. L. INST.,
16. See infra text accompanying notes 104–16.
Corporation,\textsuperscript{17} for unexplained reasons, the plaintiffs, whose daughter’s unfortunate passing was linked to the generic version of Phenergan, chose not to sue the generic manufacturer of the drug.\textsuperscript{18} Instead, they pursued legal action against the brand-name manufacturer. On the defendant’s motion for summary judgment, the trial court dismissed all products liability claims but recognized that negligent misrepresentation constituted an alternative theory of liability, one that did not hinge on whether the deceased had consumed the defendant’s drug:

[I]f Defendant Wyeth made a false representation concerning the safety of promethazine hydrochloride for use in infants and Dr. Berger relied on the representation in prescribing a promethazine hydrochloride-based product for Brandy Foster, then Wyeth may be liable for any harm caused to Brandy as a result of the ingestion of promethazine hydrochloride, even if the drug ingested was not Wyeth’s product.\textsuperscript{19}

One might think that plaintiffs have the right to present alternative claims for relief, and they only need to succeed on one to secure recovery.\textsuperscript{20} However, that was not the view of the Foster court. Instead, while recognizing the validity of the negligent misrepresentation claim, the court denied that the plaintiff could assert such a claim, stating: “[T]he allegations of negligent misrepresentation are an effort to recover for injuries caused by a product without meeting the requirements the law imposes in products liability actions,”\textsuperscript{21} providing the grist for the title of this paper.

The court elaborated, citing cases that had previously denied recovery when plaintiffs were unable to identify the manufacturer of the specific

\textsuperscript{17} Foster v. Am. Home Prods. Corp., 29 F.3d 165 (4th Cir. 1994) (applying Maryland law).
\textsuperscript{18} I was unable to reach the plaintiff’s lawyer of record in the case or anyone else at his firm who might explain why the generic manufacturer was not sued. However, I was able to reach the second lawyer for the plaintiff in the second brand-name case, Flynn v. American Home Products Corporation, 627 N.W.2d 342 (Minn. Ct. App. 2001), who did sue the provider of the compounded drug that his client took. When he ran into difficulty in pursuing that claim, he amended the complaint and asserted a claim against the brand-name manufacturer. Telephone interview with Ron Goldser (Apr. 11, 2023). After these cases, it appears that, generally, plaintiffs sued both generic and brand-name manufacturers until the Supreme Court closed off warnings claims against generic manufacturers in 2011. See, e.g., Beutella, v. A.H. Robins Co., No. 980502372, 2001 WL 35669202, at *2 (Utah Dist. Ct. Dec. 10, 2001) (“Plaintiff brought claims against the generic manufacturers which allegedly manufactured the metoclopramide taken by Plaintiff.”).
\textsuperscript{19} Foster, 29 F.3d at 167.
\textsuperscript{20} See, e.g., Martens Chevrolet, Inc. v. Seney, 439 A.2d 534, 539 (Md. 1982) (“Nothing prohibits a plaintiff from pleading both deceit and negligent misrepresentation in one declaration and then relying on the same nucleus of facts in an attempt to satisfy the differing burdens of proof on these alternative claims.”); Spectro Alloys Corp. v. Fire Brick Eng’rs Co., 52 F. Supp. 3d 918, 932 (D. Minn. 2014); cf. Jane L. v. Bangerter, 61 F.3d 1505, 1512 (10th Cir. 1995) (addressing the appropriate award of attorneys’ fees in a case in which plaintiffs succeeded on one claim but were unsuccessful in others).
\textsuperscript{21} Foster, 29 F.3d at 168.
product they had consumed or to which they were exposed, such as the litigations related to DES\textsuperscript{22} and asbestos\textsuperscript{23}:

The Fosters are attempting to hold Wyeth liable for injuries caused by another manufacturer’s product, and we are persuaded that the Maryland courts would reject this effort to circumvent the necessity that a defendant be shown to have manufactured the product that caused an injury prior to being held liable for such injury.\textsuperscript{24}

What the court failed to appreciate with its invocation of cases in which the plaintiff was unsuccessful for failure to identify the product manufacturer was that those cases were products liability cases—\textit{not} negligent misrepresentation claims.\textsuperscript{25} In \textit{Foster}, the plaintiffs did identify the entity they alleged committed the negligent misrepresentation—the brand-name manufacturer that provided the labeling for the drug—and claimed that notwithstanding that the generic drug consumed was a cause of harm, the brand-name manufacturer’s misrepresentation was also a cause of the harm.\textsuperscript{26}

Indeed, the \textit{Foster} court’s insistence that the plaintiffs pursue only the manufacturer of the drug that caused the plaintiffs’ decedent’s death failed to appreciate other instances in which an entity may be held liable for harm caused by a product it did not manufacture or sell. In fact, various entities, such as trade associations, cause associations, testing laboratories, and endorsers of a product, have been held liable based on non-products-liability theories in similar cases.\textsuperscript{27} The \textit{Foster} court’s assessment of the state of the law ignored this head of liability for those who did not manufacture the product that injured the plaintiffs.

Perhaps the \textit{Foster} court might have appreciated the error of its ways if it had had the benefit of the Bible—the bible, that is, of Products Liability: the Products Liability Restatement\textsuperscript{28}—but, regrettably, it was not published until several years after \textit{Foster}. Section 9 of that Restatement explained liability based on misrepresentation, specifically advertising to the more general provisions contained in Sections 310 and 311 of the Second

\textsuperscript{22} DES (diethylstilbestrol) was a widely prescribed drug for pregnant women between 1940 and 1971 to prevent, among other things, miscarriage. In 1971, researchers discovered that DES caused daughters exposed in utero to develop vaginal adenocarcinoma when they reached their late teens or early twenties. See Hymowitz v. Eli Lilly & Co., 539 N.E.2d 1069, 1072–73 (N.Y. 1989).

\textsuperscript{23} Because there were hundreds of manufacturers that sold DES, victims found it difficult, if not impossible, to connect the DES to which they were exposed with its manufacturer.

\textsuperscript{24} \textit{Foster}, 29 F.3d at 168.

\textsuperscript{25} \textit{Id.}

\textsuperscript{26} \textit{Id. at} 167–68.

\textsuperscript{27} \textit{See RESTATEMENT (THIRD) OF TORTS: MISCELLANEOUS PROVISIONS} § 18A, rptrs note to cmt. p (AM. L. INST., Tentative Draft No. 2, Apr. 2023) (citing cases affirming the existence of viable non-products claims against these entities).

\textsuperscript{28} \textit{RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB.} (AM. L. INST. 1998).
Restatement of Torts. While it is true that the Products Liability Restatement addresses misrepresentations only by product sellers and distributors, this limitation is due to the scope of the Restatement itself, which focuses explicitly on the liability of commercial product sellers and distributors, not because Sections 310 and 311 are applicable only to product sellers and distributors.

Before moving forward, let us take a moment to delve into the Products Liability Restatement—a minor sin I trust Aaron will forgive. I would like to consider the language of Section 9, situated within a chapter entitled “Liability of Commercial Product Sellers Not Based on Product Defects at Time of Sale”:

§ 9 Liability of Commercial Product Seller or Distributor for Harm Caused by Misrepresentation

One engaged in the business of selling or otherwise distributing products who, in connection with the sale of a product, makes a fraudulent, negligent, or innocent misrepresentation of material fact concerning the product is subject to liability for harm to persons or property caused by the misrepresentation.

If read literally, could this language apply to a brand-name drug manufacturer that is, of course, a commercial seller, as required, and who makes a negligent misrepresentation concerning the sale of a (generic) product? Of course, the “product” the brand-name manufacturer sells is not the product referred to in the “sale of a product” clause, but the language of Section 9 does not require that. Yet, it seems unlikely this was the Reporters’ intent, as they state in the introduction: “This Restatement deals with the liability of commercial product sellers and distributors for harm caused by their products.”

Another aspect of Foster deserves mention: the court stated that generic manufacturers have the freedom to change the labeling on their drugs “to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval.” Thus, the court concluded that “[m]anufacturers of generic drugs, like all other manufacturers, are responsible for the representations they make regarding their products.” This interpretation of the federal laws governing the labeling of generic drugs is plainly incorrect. Federal law requires generic-drug manufacturers to conform to the labeling employed (and controlled) by the brand-name

29. Id. § 9, cmt. a (“[T]here can be no doubt that product sellers are subject to liability for fraudulent or negligent misrepresentation.”).
30. Id. at Introduction (“This Restatement deals with the liability of commercial product sellers and distributors for harm caused by their products.”).
31. Id. § 9.
32. Id. at Introduction.
34. Id.
manufacturer. Subsequent courts built on this erroneous interpretation, using the generic manufacturers’ obligation to warn their purchasers of the risks of their drugs as a reason why brand-name manufacturers have no duty for their misrepresentations about the drug.

One might anticipate that future courts would recognize the flaws in Foster and either acknowledge the viability of a claim for negligent misrepresentation against a brand-name manufacturer or present more compelling reasons—or, at least, reasons more persuasive than those proffered by Foster—as to why such a case should not stand. Well, one would be wrong.

III. THE FOSTER SEQUELAE

For many subsequent courts, Foster seems to have cast a mesmerizing spell, leading them to dismiss negligent misrepresentation claims without providing any substantive explanations beyond citing Foster. Furthermore, some of these courts persisted in reiterating Foster’s inapt analogy to products liability lawsuits in which plaintiffs could not identify the manufacturer responsible for the product that caused their harm.

Some courts staunchly insisted that negligent misrepresentation claims are products liability claims, requiring the plaintiff to sue the manufacturer


38. Indeed, a prominent commentator and lobbyist reiterated this argument, claiming that brand-name manufacturer liability: “[p]roduct identification and causation are fundamental requirements under all product liability law, meaning that when harm arises out of a product, a cause of action exists only against the manufacturer of the product in question.” 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, 1862–63 (2013).
of the drug he or she consumed.\textsuperscript{39} Those courts did not even get to where \textit{Foster} got, which was to recognize that negligent misrepresentation is a tort independent of a products liability claim. A prominent commentator, albeit one whose practice involves lobbying for defense interests, joined those courts. He claimed that anyone injured by a drug “can sue only the manufacturer of the product that caused the injury,”\textsuperscript{40} and, therefore, claims could not be made against brand-name manufacturers by generic-drug consumers.

An interesting variation on the failure to appreciate that there are theories beyond products liability emerged in courts that hinged their decisions on causation. In \textit{DaCosta v. Novartis AG},\textsuperscript{41} the court reasoned that because the defendant had not manufactured the drug that the plaintiff consumed, the defendant could not have caused the plaintiff’s injuries.\textsuperscript{42} This analysis, of course, fails to appreciate the fundamental distinction between a products liability claim, which does require that the defendant’s product caused the plaintiff’s harm, and a misrepresentation claim, where the tortious conduct is \textit{not} the sale of a defective product but negligent communication. It is that tortious conduct—the misrepresentation itself—that must be a factual cause of harm rather than some unrelated tortious act irrelevant to the plaintiff’s misrepresentation claim.

Other courts uncritically accepted \textit{Foster}’s claim that the plaintiff could not prevail because plaintiffs are required to pinpoint and sue the manufacturer of the product responsible for their injuries.\textsuperscript{43} These courts, like \textit{Foster}, often cited cases that rejected market-share liability or asbestos cases in which plaintiffs’ products liability claims faltered due to their inability to identify the manufacturers of the asbestos products to which they were exposed.\textsuperscript{44} None of those courts recognized the critical distinction between

\textsuperscript{39} See, e.g., Sheeks v. Am. Home Prods. Corp., No. 02CV337, 2004 WL 4056060, at *1 (Colo. Dist. Ct. Oct. 15, 2004) (addressing plaintiff’s negligent misrepresentation claim: “[r]egardless of how termed, the action brought by the [plaintiffs] is a product liability action”); Smith v. Wyeth, Inc., 657 F.3d 420, 422 (6th Cir. 2011) (applying Kentucky law) (commenting that “adopting [Plaintiff’s] theory of liability would require the court to attribute any deficiency in a name-brand manufacturer’s labeling and marketing of its products to products manufactured by its generic competitors. Such a theory, however, fails to satisfy the threshold requirement of a products-liability action—that the defendant’s product have injured the plaintiff”) (emphasis omitted).

\textsuperscript{40} Schwartz et al., \textit{supra} note 38, at 1860.


\textsuperscript{42} See also Schwartz et al., \textit{supra} note 38, at 1862–63 (claiming that causation is a “fundamental requirement” under all product liability law” and thus, “when harm arises out of a product, a cause of action exists only against the manufacturer of the product in question”).


\textsuperscript{44} See, e.g., \textit{In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.}, 756 F.3d 917, 938 (6th Cir. 2014) (stating the plaintiff “has effectively brought a product liability action and cannot circumvent the product identification requirement of applicable state product liability law”); Foster v. Am. Home Prods. Corp., 29 F.3d 165, 168 (4th Cir. 1994).
those cases, which asserted products liability claims and claims against brand-name manufacturers alleging misrepresentation. As for the latter class of cases, plaintiffs do identify the entity alleged to have engaged in the tortious conduct that caused their harm—the brand-name drug manufacturer that provided the misleading labeling.45

State products liability statutes, often with the assistance of the courts, also played a part in the flawed analysis. In several states, legislatures have codified products liability laws, often specifying the bases for determining when a product is considered defective.46 Thus, one court reasoned that the state’s products liability act is their “exclusive remedy”; “the PLA, by its terms,” made clear ‘these ‘causes of action ‘ie; manufacturing defects, failure to warn, [and] design defect’ are intended to be inclusive, as the sole basis for recovery on a product claim against the manufacturer or seller to the other terms of the statute.’”47 This statement reveals, once again, a failure to appreciate that not all claims against product manufacturers are products liability claims.48 In another case, in which the products liability act covered actions “brought by a user or consumer . . . for physical harm caused by a product . . . regardless of the substantive legal theory or theories upon which the action is brought,”49 the court concluded that the act governed and barred the plaintiff’s negligent misrepresentation claim, without the slightest pause at the ambiguity of whether “caused by a product” referred to the product consumed by the “user or consumer,” in which case the act would not apply, or, alternatively, if it referred to any product, in which case the act would apply.50 A reasonable case could be made for either interpretation, in my view, but what I find interesting is the court’s shortcut to concluding that the act applied and barred the plaintiff’s misrepresentation claim.

45. See, e.g., Evans v. Johnson & Johnson Co., No. CV 14-1316-RGA, 2020 WL 616575, at *6 (D. Del. Feb. 10, 2020) (relying on asbestos and benzene products liability claims in which the plaintiff was unable to identify the manufacturer of the asbestos or benzene to which the plaintiff was exposed); Huck v. Wyeth, Inc., 850 N.W.2d 353, 369 (Iowa 2014) (similar to Evans); Schrock v. Wyeth, Inc., 601 F. Supp. 2d 1262, 1266 (W.D. Okla. 2009) (granting defendant’s motion for summary judgment, in part because “Oklahoma has rejected market share liability, alternative liability theory, the concert of action theory and enterprise liability”), aff’d, 727 F.3d 1273 (10th Cir. 2013). But see In re Fluoroquinolone Prods. Liab. Litig., 517 F. Supp. 3d 806, 818 (D. Minn. 2021) (explaining the difference between negligent misrepresentation suits against brand-name manufacturers, on the one hand, and products liability cases in which plaintiff cannot identify the manufacturer of the product that injured plaintiff, on the other).
46. See e.g., N.J.S.A. 2A:58C-1 et seq.
48. The Sloan court did, after claiming that the New Jersey Products Liability Act was exclusive, advert to the plaintiff’s “bypass” of the Act by asserting a negligent misrepresentation claim, which the court concluded failed for lack of a duty by the brand-name manufacturer. Id.
I recognize that there are state products liability statutes, unlike the ones in New Jersey and Indiana, to which I refer above, that are worded so broadly that they exclude non-products-liability theories in any case in which an individual was injured by a product. The Louisiana Products Liability Act (LPLA) might be such a statute. It provides its scope:

This Chapter establishes the exclusive theories of liability for manufacturers for damage caused by their products. A claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in this Chapter.51

The first sentence would not affect the availability of a negligent misrepresentation claim against a brand-name manufacturer, as such a claim is not one against a manufacturer based on damage caused by the manufacturer’s products. But the second sentence is not limited to the manufacturer’s products and so would require any claim to be one provided by the LPLA. One might think that the best understanding of those two conflicting scope sentences is that the legislature did not address the brand-name manufacturer issue nor speak to it in the LPLA. That is not what the court in Possa v. Eli Lilly & Co. reasoned; instead, it summarily stated, “the plaintiffs’ claims against [defendant] are limited to those authorized by the Louisiana Products Liability Act (LPLA).”52 Nevertheless, in jurisdictions with broad and exclusive products liability statutes, denial of brand-name liability seems more solidly grounded than the common law decisions addressed in this paper.53

Other courts played the duty card—asserting that brand-name manufacturers owed no duty to third parties who did not take the manufacturer’s drug.54 That rationale—seemingly influenced by the fact that the plaintiff and the brand-name manufacturer were not connected by a product—has to be wrong, both as a matter of products liability law and as a matter of negligent misrepresentation law, at least since the strict liability era ushered in by Section 402A, rarely invokes “duty” as playing a role in

53. For instances where other courts concluded that the state’s products liability acts encompassed negligent misrepresentation claims and required the plaintiff to have been injured by the defendant’s product, thereby requiring the dismissal of misrepresentation claims against brand-name manufacturers, see Lashley v. Pfizer, Inc., 750 F.3d 470, 476–78 (5th Cir. 2014) (Mississippi and Texas products liability acts); Strayhorn v. Wyeth Pharm., Inc., 882 F. Supp. 2d 1020, 1030 (W.D. Tenn. 2012), aff’d, 737 F.3d 378 (6th Cir. 2013).
54. See, e.g., Lashley, 750 F.3d at 476 (applying Mississippi law) (“because Appellants did not ingest the brand manufacturers’ products, these defendants have no common-law duty to them.”); Johnson v. Novartis Pharm. Corp., 845 F. App’x 305, 310 (5th Cir. 2021) (applying Texas law) (“this Court has held that brand-name drug manufacturers owe no common-law duty under Texas law to those who do not ingest their drugs.”); see also Schwartz et al., supra note 38, at 1865–66.
determining liability. More importantly, since the early days of strict products liability, the liability of manufacturers has extended to non-
purchasing bystanders. If a defective oral drug, after being swallowed and 
reaching gastric acid, explodes, injuring the child of the consumer, duty will 
not prevent recovery by the child.

With regard to negligent misrepresentation—especially in cases in which 
the misrepresentation results in physical harm—there should be no 
substantial duty limitation that would affect brand-name claims. A party who 
makes a negligent misrepresentation creates a risk that another will be injured 
by that misrepresentation. This is the classic circumstance of misfeasance, in 
which tort law imposes a duty of reasonable care. The Third Restatement 
of Torts reflects the lack of a duty requirement for misrepresentations, 
imposing liability when a negligent misrepresentation causes harm to another 
party within the defendant’s scope of liability. The Second Restatement 
of Torts also established a duty to all whom the misrepresenter should 
reasonably expect to be put at risk by the misrepresentation. Thus, courts

55. Or, as I explain to my students, there is implicitly a duty not to sell or distribute a defective 
product, thereby collapsing the duty and breach elements.
56. See Elmore v. Am. Motors Corp., 451 P.2d 84 (Cal. 1969); RESTATEMENT (THIRD) OF 
TORTS: PRODS. LIAB. § 1 (AM. L. INST. 1998) (providing for liability to “persons” harmed by a 
product defect).
57. But see Gourdin v. Crews, 955 A.2d 769, 788 (Md. 2008) (holding manufacturer of insulin 
drug owed no duty to third party injured when diabetic who used the drug suffered disabling episode 
and lost control of her car).
58. See RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL AND EMOTIONAL HARM § 7 
(AM. L. INST. 2010) (“An actor ordinarily has a duty to exercise reasonable care when the actor’s 
conduct creates a risk of physical harm.”).
59. See RESTATEMENT (THIRD) OF TORTS: MISCELLANEOUS PROVISIONS § 18A (AM. L. INST., 
Tentative Draft No. 2, Mar. 2023). The Foster court, which also relied on no duty in holding against 
brand-name manufacturer liability, was supported by a quirk in Maryland law. When the Maryland 
Supreme Court recognized negligent misrepresentations causing physical harm in 1938, it adverted 
to a factual dispute about where the plaintiff was located but observed that, regardless of his 
location, the defendant owed him a duty. Virginia Dare Stores v. Schuman, 1 A.2d 897, 899 (Md. 
1938). That reference to duty was carried forward in subsequent negligent misrepresentation cases 
in formulating the elements of such a claim. See Martens Chevrolet, Inc. v. Seney, 439 A.2d 534, 
539 (Md. 1982) (including in the elements of a negligent misrepresentation claim that the defendant 
owed a duty to the plaintiff).
60. See RESTATEMENT (SECOND) OF TORTS § 311 (AM. L. INST. 1965). To risk being labeled a 
quibbler, to Palsgraf-ian atheists, the language of Section 311, which limits the defendant’s liability 
for negligent misrepresentation to third parties foreseeably at risk of harm, is better understood as a 
scope of liability requirement because it depends on the specific facts of the case rather than a 
categorical rule addressing circumstances in which a duty of reasonable care is omitted or modified. 
See RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL AND EMOTIONAL HARM § 29, cmt. f 
(AM. L. INST. 2010) (explaining the reasons for treating the issue of unforeseeable plaintiffs as a 
matter of scope of liability rather than as duty, contrary to Judge Cardozo in Palsgraf). Palsgraf-ian 
adherents will, by contrast, see this as a duty matter. For purposes of brand-name manufacturers, 
this is of no matter for the unusual case—not yet reported—where there is a serious question about 
the foreseeability of the plaintiff, which would raise the question of whether foreseeability is for 
the court under a duty analysis or for the factfinder as a matter of the scope of liability. See W. Jonathan 
(2011).
have no real doctrinal hook for relying on no duty to deny recovery in suits against brand-name drug manufacturers.\textsuperscript{61}

A subtle reframing may make the argument sound more plausible. One federal district court characterized the issue as: “The law is clear that Louisiana imposes on a manufacturer no duty to warn of the dangers of another company’s product.”\textsuperscript{62} When phrased in this manner, it invokes the familiar doctrine that there is no duty to rescue someone for whom the defendant played no role in creating the risk with which the plaintiff is confronted.\textsuperscript{63} Swicegood v. Pliva, Inc.,\textsuperscript{64} took precisely this tack, relying on the no-duty-to-rescue rule to conclude that any brand-name manufacturer’s duty to warn consumers of the equivalent generic drug would have to be found in the exceptions to the no-duty-to-rescue rule, often referred to as “affirmative duties.” The court reasoned that while the brand-name manufacturers undertook an affirmative duty by their act of providing warnings for their products, they did not undertake to provide warnings for generic versions.\textsuperscript{65} What these courts miss is that a negligent misrepresentation claim relies on the risk created by the misrepresentation and the harm it caused the plaintiff—far from resembling a bystander scenario in which the plaintiff is harmed.

A refined version of this no-duty argument could proceed—although some courts might not explicitly state it but may have it subconsciously in mind—in the following manner: Reglan, for example, prescribed for gastrointestinal disorders, including reflux,\textsuperscript{66} creates a risk of tardive dyskinesia—a potentially serious condition characterized by repetitive and involuntary body movements, such as sticking out the tongue. Plaintiffs in these cases allege that the warning for Reglan failed adequately to inform about the risks of tardive dyskinesia, especially when the drug is used for longer than twelve weeks. Here, the manufacturer might argue that this was an omission rather than a misrepresentation; thus, no duty is appropriately invoked.

\begin{footnotesize}
\begin{itemize}
\item\textsuperscript{61} To be fair, the Iowa Supreme Court justified its no-duty ruling by advertizing to policy for denying a duty. See infra notes 118–138 and accompanying text.
\item\textsuperscript{63} See Restatement (Third) of Torts: Liab. for Physical and Emotional Harm § 29 (Am. L. Inst. 2010).
\item\textsuperscript{65} Id. at 1356.
\item\textsuperscript{66} Brand-name cases involving Reglan were, by far, the predominant ones. Among the first seventy cases—through mid-2012—addressing the matter, I count forty-six that involved Reglan; no other drug was involved in more than a handful of cases. Reglan cases declined in later years, likely because a black box warning was added in 2009 to the labeling that both warned of tardive dyskinesia and strongly discouraged use of the drug for longer than twelve weeks: “[t]reatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia.” Drugs@FDA: FDA-Approved Drugs, NDA 017854, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=017854 (last visited Nov. 22, 2023).
\end{itemize}
\end{footnotesize}
Well, nice try, but no. An omission can constitute a misrepresentation in two contexts: first, when the omission makes what was stated a misleading half-truth; and second, when there is an obligation to disclose information that is omitted. Both of these provisions apply to statements made by the manufacturer of a prescription drug in its labeling. When a drug’s side effects are stated, as is required by law, and one is omitted, it can leave physicians or consumers with the impression that all material risks have been disclosed, thus leading to the incorrect belief that tardive dyskinesia is not a risk associated with consuming Reglan. Moreover, given federal prescription drug labeling requirements, there is an obligation to disclose all material risks revealed in pre-marketing testing that emerge after approval. So, a realistic assessment of the obligations of drug manufacturers is that they do have a duty to reveal risks connected with the use of their drugs.

Duty, however, holds great appeal for courts already inclined to limit liability. In such cases, courts often issue terse no-duty rulings without fully explaining their rationale. For instance, in Stanley v. Wyeth, Inc., the court went so far as to repeat its conclusion twice in case the reader missed it the first time:

[W]e conclude that the trial court did not err in holding that there is no viable cause of action alleged, since the Plaintiffs failed to show that Wyeth owed them a legal duty, regardless of the theory of recovery asserted. After reviewing the controlling and persuasive jurisprudence, we conclude that, as a matter of law, Wyeth owed no duty to Mrs. Stanley to protect her from this particular harm.

The absence of a duty limitation for victims of misrepresentations involving physical harm leads to another error courts make in denying brand-name manufacturer liability. Some courts have relied on limitations that exist for misrepresentations that cause economic harm rather than physical harm.

67. See RESTATEMENT (THIRD) OF TORTS: MISCELLANEOUS PROVISIONS § 18 a, cmt. l (AM. L. INST., Tentative Draft No. 2 Mar. 2023) (“True statements may also be misrepresentations when they imply a false state of affairs (a ‘half-truth’).”).

68. See id. at cmt. m (explaining that a duty to disclose exists when “when the context of the relationship is such that the actor has superior knowledge and knows or should know the other is reasonably relying on the actor to furnish accurate information.”).

69. Stanley v. Wyeth, Inc., 991 So. 2d 31, 34 (La. Ct. App. 2008). The court added: “In Louisiana, a drug manufacturer has no duty to warn the consumer directly.” Id. The relevance of that observation to a case in which the plaintiff alleged that the defendant misled physicians about the risks of the drugs is a bit difficult to discern.

70. See e.g., Strayhorn v. Wyeth Pharm., Inc., 882 F. Supp. 2d 1020, 1030 (W.D. Tenn. 2012) (relying on Section 552 of the Restatement (Second) of Torts, which addresses liability for pure economic harm, to conclude the plaintiff could not pursue a negligent misrepresentation claim for her physical injury), aff’d, 737 F.3d 378 (6th Cir. 2013); Goldych v. Eli Lilly & Co., No. 5:04-CV-1477 (GLS/GJD), 2006 WL 2038436, at *4 (N.D. N.Y. July 19, 2006) (“Moreover, ‘claims of fraudulent concealment and negligent misrepresentation also require the plaintiff to demonstrate the existence of a special relationship of trust or confidence between the parties giving rise to a duty to impart correct information[,]’“ (quoting Rose v. Am. Tobacco Co., No. 101996/2002, 2004 WL 986239, at *5 (N.Y. Sup. Ct. Feb 20, 2004)); Swicegood v. Pliva, Inc., 543 F. Supp. 2d 1351, 1356...
Recovery for economic harm is more circumscribed than for physical harm because economic harm can ripple through the economy, resulting in large numbers of persons harmed.\footnote{As explained in the \textit{RESTASTATEMENT (THIRD) OF TORTS: LIAB. FOR ECONOMIC HARM} § 1, cmt. c(1) (AM. L. INST. 2020):}

\begin{quote}
Economic losses proliferate more easily than losses of other kinds. Physical forces that cause injury ordinarily spend themselves in predictable ways; their exact courses may be hard to predict, but their lifespan and power to harm are limited. A badly driven car threatens physical harm only to others nearby. Economic harm is not self-limiting in this way. A single negligent utterance can cause economic loss to thousands of people who rely on it, those losses may produce additional losses to those who were relying on the first round of victims, and so on.
\end{quote}

\footnote{See also \textit{W. PAGE KEETON, ET AL., PROSSER AND KEETON ON TORTS} § 107, at 745 (5th ed. 1984) (contrasting courts’ concern with the potential for liability of unknown or virtually unlimited extent for economic loss with liability for misrepresentations causing physical harm where courts have treated such cases the same as other negligence cases).}

\footnote{Thus, in \textit{Moretti v. Wyeth, Inc.}, No. 2:08-CV-00396-JCM-(GWF), 2009 WL 749532, at *3 (D. Nev. Mar. 20, 2009), while the court cited Section 311, it denied that Nevada recognized such claims and cited to two cases that reflected ignorance of Section 311 in the course of addressing the limits of Section 552.}

\footnote{Huck v. Wyeth, Inc., 850 N.W.2d 353, 377 (Iowa 2014).}

\footnote{49 U.S.C. § 40101 note.}
not be adventurous in adopting new tort claims ungrounded in existing state law. The Eleventh Circuit expressed that view in the course of affirming the lower court’s summary judgment for the brand-name manufacturer: “[N]o Florida court has recognized a potential cause of action against a brand manufacturer by the consumers of a generic product, and considerations of comity and federalism counsel that we proceed gingerly when venturing into uncharted waters of state substantive law.”75 In many of those cases, however, the defendant removed the claim to federal court.76 If the fundamental principle of Errie is that cases should reach the same result whether in state or federal court, this reluctance to make the best prediction of state law when state decisions do not exist appears misguided.77 As the court in In re Methyl Tertiary Butyl Ether (“MTBE”) Products Liability Litigation explained:

When a defendant removes a case from state to federal court, the principle of dual sovereignty requires the application of a liberal construction of state law in order to protect a party who sought to obtain a resolution of state law claims from state courts. If this Court were to adopt a more restrictive reading of state law than the highest courts of the relevant states would be likely to adopt, the parties would be treated differently than they would be in a state court—a result directly contrary to the fundamental goals of Errie, namely the “discouragement of forum-shopping and avoidance of inequitable administration of laws.”78

The premise of those federal courts that adopting brand-name manufacturer liability would entail uncharted legal waters is based on a narrowing of the issue to address the specific context of brand-name prescription drug manufacturers and their liability to generic-drug consumers. As noted above, there is reasonably well-established liability for negligent misrepresentations that cause physical injury. Thus, in Westerlund

75. Guarino v. Wyeth, LLC, 719 F.3d 1245, 1251 (11th Cir. 2013) (applying Florida law); see also Schrock v. Wyeth, Inc., 601 F. Supp. 2d 1262, 1266 (W.D. Okla. 2009) (“Recognition of such a duty [by brand-name manufacturers] would constitute new Oklahoma law, and as the Tenth Circuit instructed: “As a federal court, we are generally reticent to expand state law without clear guidance from its highest court.””) (citation omitted), aff’d, 727 F.3d 1273 (10th Cir. 2013).


v. Wyeth, Inc., the court summarily rejected the plaintiff’s brand-name manufacturer claim: “That is not the current law in New Jersey. The Court declines to extend the law in this field and is not accepting that argument in this case today.” 79 In that conclusion, the court ignored a New Jersey appellate decision that employed Section 311 of the Second Restatement’s provision for negligent misrepresentation in a case involving a plaintiff bitten by a vicious dog and that court’s citation to several earlier New Jersey decisions employing negligent misrepresentation, albeit in cases involving pecuniary loss. 80

IV. A BREATH (ALBEIT BRIEF) OF REALLY FRESH AIR: CONTE V. WYETH

By 2008, more than two dozen courts, including both state and federal jurisdictions, had rejected claims brought by generic-drug consumers against the brand-name manufacturer of those drugs. 81 This widespread pattern might have led one to believe that the issue effectively had been resolved. Then, the California Court of Appeals addressed the issue in Conte v. Wyeth, Inc. 82

I cannot recall the last time—perhaps because it has never occurred before—when my head nodded so vigorously in agreement as if it were on a pogo stick while reading a legal case. But that was precisely my experience when I read the Conte case, which was undoubtedly influenced by the less-than-satisfactory state of the case law that preceded it.

The plaintiff was allegedly injured by prolonged use of the generic version of Reglan, known as metoclopramide. 83 She claimed that the drug’s labeling inadequately explained the risks associated with its extended use despite being FDA-approved for use only up to twelve weeks. 84 Although the

84. The following warning was listed on the drug’s label:

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use REGLAN ODT™ safely and effectively. See full prescribing information for REGLAN ODT™.

REGLAN ODT™ (metoclopramide) orally disintegrating tablets

Initial U.S. Approval: 1979
merits of her claim are irrelevant to whether she could maintain a negligent misrepresentation claim against Wyeth—the brand-name manufacturer of Reglan—a well-established requirement for an adequate warning is identification of the risks, their seriousness, and where there are such, means to eliminate or ameliorate the risks identified. Wyeth sought summary judgment on the same no-duty ground employed in prior brand-name litigation: Wyeth, the brand-name manufacturer, owed no duty to the plaintiff who had not used Wyeth’s drug. Elaborating on this argument, Wyeth contended that the plaintiff was making a products liability claim that failed because she neither ingested nor was harmed by Wyeth’s product.

The first insightful step by the Conte court was rejecting Wyeth’s claim that Ms. Conte’s negligent misrepresentation was “merely a products liability lawsuit disguised as an action for fraud and misrepresentation.” This case asserted a legal claim for negligent misrepresentation by Wyeth, not a products liability claim. Therefore, the cases Wyeth presented in support of the idea that a plaintiff could not succeed in a products liability claim against a party other than the product seller were irrelevant to the negligent misrepresentation claim. Nod.

The second step was the court recognizing that the claim against Wyeth was not a new tort that required careful assessment and consideration of

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**WARNING: TARDIVE DYSKINESIA**

*See full prescribing information for complete boxed warning.*

Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible.

Metoclopramide therapy should be discontinued in patients who develop signs or symptoms of tardive dyskinesia.

Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia. (5.1)

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86. See Conte, 85 Cal. Rptr. 3d at 304. It also claimed that any inadequacy in the labeling was not a factual cause of the plaintiff’s harm because her physician did not rely on labeling information in the Physician’s Desk Reference in deciding to prescribe metoclopramide for Ms. Conte. Id. That argument also has no bearing on the legitimacy of Ms. Conte’s claim of negligent misrepresentation against Wyeth.

87. Id. at 309; see supra text accompanying notes 54–69.

88. Conte, 85 Cal Rptr. at 314.

89. “[N]egligent misrepresentation] and strict products liability are separate and distinct bases for liability that do not automatically collapse into each other because the plaintiff might allege both when a product warning contributes to her injury.” Id. at 310. Another nod.

90. Id. at 310–11.
whether to defer to the legislature, as some prior courts had reasoned.\footnote{See Block v. Wyeth, Inc., No. CIV.A. 3:02-CV-10777., 2003 WL 203067, at *3 (N.D. Tex. Jan. 28, 2003) (“Block invites this Court to extend Texas tort law into new and uncharted territory.”).} “We are not marking out new territory,” the court explained.\footnote{The court elaborated:}

We are not marking out new territory by recognizing that a defendant that authors and disseminates information about a product manufactured and sold by another may be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on that information and the product causes injury, even though the defendant would not be liable in strict products liability because it did not manufacture or sell the product. . . . We perceive no logical or legal inconsistency between allowing the suit for negligence and disallowing the suit for strict products liability.\footnote{Conte, 85 Cal. Rptr. 3d at 311. Conte’s recognition that negligent misrepresentation is a well-established doctrine stands in contrast to Swiecegood v. Pliva, Inc., which explained its dismissal of the complaint against brand-name manufacturers by adopting their argument that accepting a claim for negligent misrepresentation would “result in an unprecedented departure from traditional Georgia tort law.” Swiecegood v. Pliva, 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008) (citation omitted).}

On the duty score, the court turned directly to Sections 310 and 311 of the Second Restatement, which address intentional and negligent misrepresentations, respectively. The court highlighted language in Section 311 that imposes liability for harm to third parties whom the misrepresenter should expect would be exposed to the risk of physical harm by the misrepresentation.\footnote{Hanberry v. Hearst Corp., 81 Cal. Rptr. 519 (Cal. Ct. App. 1969).} Nod. Given that pharmacists have the authority to substitute generic drugs even when a brand-name drug is prescribed, with the lower price of the former providing incentives to do so, brand-name manufacturers could readily anticipate that generic consumers could be affected by the labeling that Wyeth provided. Nod.

The court then considered other duty-determination factors as prescribed by California law. It rejected Wyeth’s public policy claim that brand-name liability would chill innovation in the pharmaceutical field with negative consequences for public health.\footnote{For other cases in which a non-manufacturer was found subject to liability for harm caused by a product based on theories other than products liability, see RESTATEMENT (THIRD) OF TORTS: MISCELLANEOUS PROVISIONS § 18A, rptrs note to cmt. p (AM. L. INST., Tentative Draft No. 2, Mar. 2023).} In addition to an absence of evidence in the

\footnote{See Conte, 85 Cal. Rptr. 3d at 313 (“In California, as in most states, pharmacists have long been authorized by statute to fill prescriptions for name-brand drugs with their generic equivalents unless the prescribing physician expressly forbids such a substitution.”).}

\footnote{Not addressed by the Conte court is evidence to the contrary: Generic competition provides incentives for brand-name manufacturers to increase their research efforts to find new drugs to replace the market share lost by losing patent protection on older drugs. See Jack DeRuiter & Pamela L. Holston, Drug Patent Expirations and the “Patent Cliff,” 37 U.S. PHARM. 12 (June 20, 2012) (“Pharmaceutical companies have explored and continue to investigate a variety of strategies to minimize the impact [patent competition with its attendant loss of revenue] and maintain their}
record supporting that claim, any such consequence had to be balanced
against the incentives provided for more accurate warning labels that could
prevent harms like those suffered by the plaintiff.97 Nod.

Finally, the court confronted the argument from precedent: Multiple
courts across the country had rejected brand-name manufacturer liability. The
court then proceeded to critique Foster and its cramped consideration and
resolution of brand-name liability, Nod.

As I concluded my reading of Conte, I could not help but think that this
case would be a turning point in the landscape of brand-name manufacturer
liability. The clear-headed analysis, recognition of manufacturer liability
beyond the confines of products liability, and the rejection of spurious
reasons for denying these claims in prior decisions seemed like a
breakthrough moment that could enable courts to see the way forward and
stem the tide of wretched analysis and misunderstanding of tort law. Wrong.

Unsurprisingly, defense interests treated Conte like a dreaded
communicable disease. One blogger who represents defense interests in
pharmaceutical and medical device products litigation branded it “the worst
judicial decision of 2008 in our field.”98 Retreading the failure to appreciate
that a product manufacturer may be liable based on non-products-liability
theory, the blogger complained:

Well, since the dawn of product liability, we thought we knew the answer
to that question. You can only sue the manufacturer of the product that
injured you. Only the manufacturer made a profit from selling the product,
and only the manufacturer controls the safety of the product it makes, so
only the manufacturer can be liable.

Black letter law (and sound public policy), right?99

Well, no. Individuals responsible for causing harm to others can be held
liable for their actions, regardless of whether they directly profited from their
tortious conduct. (The drunk driver who kills a pedestrian does not profit
from the drunk driving.) And, no, in the context of generic drugs, it is the
brand-name manufacturer that wields control over critical safety aspects
concerning generic drugs.

While it is understandable that a partisan might react this way,
subsequent courts treated Conte like it was best quarantined. The first court
to be confronted with Conte was not moved an inch, rejecting it out of hand
and concluding it was contrary to “well-established Nevada law” and “every

97. Conte, 85 Cal. Rptr. 3d at 314.
98. See Beck/Hermann, supra note 4.

profitability. Most obviously, there has been continued investment in new drug discovery and
development of a ‘pipeline’ of promising agents that address unmet medical needs and are
profitable.”).
other court that has considered this issue,” stating: “Simply put, Conte stands alone and is contrary to Nevada law and public policy.” A trial court in Florida treated Conte in a similar fashion, noting the “overwhelming [contrary] weight of authority” and declaring that it “bears no resemblance to Florida law.” The court also asserted that “[n]o Florida court has ever adopted section 311 [on which Conte relied].” A number of courts dismissed Conte by simply observing that it was contrary to the great weight of decisions on the subject, with one court stating, “The California court’s holding in Conte is anomalous.” As of September 2023, Westlaw’s “Negative Treatment” tab for Conte lists thirty-two cases.

Professor Alan Rostron aptly summarized Conte’s reception but also offered a glimmer of sunlight that reinforced my view on the state of the case law:

Although courts and commentators have overwhelmingly sided with the drug manufacturers, treating the Conte decision as a lonely and misguided deviation from past precedents and sound principles of products liability law, I contend that Conte should instead be seen as the first case in which a court finally got this issue right. The Conte court saw through distracting mischaracterizations of the issue that plagued judicial analysis in Foster and other past cases. Applying basic rules of liability for negligence, the court correctly recognized that a manufacturer may be liable in some instances for tortious conduct other than having made or sold the product that inflicted plaintiff’s injuries. Although all questions about liability for prescription drugs should be handled with special care because of the unique difficulty of developing new drugs and their immense potential benefits for consumers, the Conte court soundly concluded that fairness and policy considerations ultimately weigh against giving brand-name manufacturers complete immunity from liability for generic drug injuries.

101. Dietrich v. Wyeth, Inc., No. 50-2009-CA-021586XXX, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009). While no case in Florida appears to have adopted Section 311 of the Second Restatement, numerous Florida courts have accepted and applied the tort of negligent misrepresentation without apparent limitation to the type of harm involved. See Wallerstein v. Hosp. Corp. of Am., 573 So. 2d 9, 10 (Fla. Dist. Ct. App. 1990) (concluding negligent misrepresentation claim could be made against doctors who assured the plaintiff-adoptive parents that the child they were adopting was healthy and suitable for adoption without identifying the harm for which the plaintiffs sought to recover, which plausibly included emotional harm); Fla. Women’s Med. Clinic, Inc. v. Sultan, 656 So. 2d 931, 933 (Fla. Dist. Ct. App. 1995) (stating the elements of a negligent misrepresentation claim without any type of harm constraint).
V. RATCHETING UP THE STAKES: THE SUPREME COURT PREEMPTS STATE TORT CLAIMS AGAINST GENERIC-DRUG MANUFACTURERS

Shortly after Conte, the stakes in brand-name manufacturer suits were ratcheted upward because of two Supreme Court preemption decisions. The Food, Drug, and Cosmetic Act (FDCA) contains no express preemption provision regarding state tort suits against pharmaceutical companies. But, following the Court’s decision in Cipollone v. Ligget Group, Inc., which held for the first time that federal law impliedly preempted certain tort claims against cigarette manufacturers, defendants sought the immunity cloak provided by federal preemption in a wide variety of areas governed by federal regulatory law, including prescription drugs.

In Wyeth v. Levine, the Court addressed those efforts. The drug manufacturer claimed two bases for implied preemption of the plaintiff’s state-law inadequate-warning claim, with the one of interest being that the state tort claim was preempted because the labeling (which contains warnings of adverse effects and risks of improper use) is required by federal law. Thus, FDA approval of a new drug is conditioned on the inclusion of language agreed upon by the manufacturer and the FDA. The defendant argued that if its warning were found inadequate in a state tort claim, it would be impossible to comply with federal law, which mandates the use of the existing labeling, and the judgment in the state case, which would be based on the labeling being deemed inadequate.

The FDA’s “Change Being Effected” regulation (CBE) came to the plaintiff’s rescue. Under the CBE, the drug manufacturer can unilaterally change the drug’s labeling to add warnings, although it is required to file a supplemental application with the FDA to notify it of the change. Thus, the manufacturer would not be stuck between the rock of federally required labeling and the hard place of a state law judgment based on an inadequate warning. As the Levine Court concluded:

[I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It

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106. For an explanation of the scope of preemption provided by Cipollone and a little appreciated gap in that preemption, see Michael D. Green, Cipollone Revisited: A Not So Little Secret About the Scope of Cigarette Preemption, 82 IOWA L. REV. 1257 (1997).
108. The Court also rejected the defendant’s claim that state tort liability of drug manufacturers would conflict with Congress’s objectives in enacting the FDCA. See id. at 574–75.
109. Id. at 563.
110. 21 C.F.R. § 314.70. It permits a manufacturer to adopt “[c]hanges in the labeling to reflect newly acquired information . . . to add or strengthen a contraindication, warning, precaution, or adverse reaction.”
111. 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C).
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.\textsuperscript{112}

Not so for those taking generic drugs—unlike their brand-name cousins—generic manufacturers would be protected from tort liability as the Court ruled two years after Levine. In PLIVA, Inc. v. Mensing, the Court encountered a similar situation involving the preemption of state tort claims by the FDCA.\textsuperscript{113} This time, however, the focus was on generic-drug manufacturers.\textsuperscript{114} The FDCA mandates that generic-drug manufacturers maintain identical drug labeling to that of the brand-name manufacturer, offering no room for changes by the generic-drug manufacturers.\textsuperscript{115} Without the flexibility afforded by the CBE, the Court held that a generic manufacturer subject to state tort claims based on inadequate warnings would indeed face the fate of being caught between the rock and the hard place that brand-name manufacturers dodged—and thus, state law tort claims based on the inadequacy of the generic-drug warnings were preempted.\textsuperscript{116}

Levine and Mensing significantly raised the stakes in lawsuits against brand-name manufacturers. Before the implied preemption of generic manufacturers, brand-name manufacturers provided only an additional source of recovery alongside generic manufacturers. However, once tort claims against those generic manufacturers were preempted, brand-name manufacturers were left as the sole source of recovery for individuals injured by inadequate drug warnings. Despite these shifts, the course of decisions in this line of cases has not changed: Victims cannot recover, as courts have routinely rejected the argument that Mensing, by insulating generic manufacturers from liability, requires a different outcome for negligent misrepresentation claims.\textsuperscript{117}

VI. THE COURTS’ ASSESSMENT OF PUBLIC POLICY

The story would not be complete, though no less bewildering, without coverage of the policy assessments of courts over nearly two decades of deciding these cases. The story begins with the first case, Foster, which began the public policy discussion by invoking fairness:

\begin{itemize}
\item \textsuperscript{112} Levine, 555 U.S. at 570–71.
\item \textsuperscript{113} See PLIVA, Inc. v. Mensing, 564 U.S. 604, 613 (2011).
\item \textsuperscript{114} See id.
\item \textsuperscript{115} See 21 U.S.C. § 355 (j)(2)(A)(v) (requiring an abbreviated new drug application contain “information to show that the labeling proposed for the new drug is the same as the labeling approved for the [brand-name] drug”).
\item \textsuperscript{116} PLIVA, Inc., 564 U.S. at 604.
\end{itemize}
There is no legal precedent for using a name brand manufacturer’s statements about its own product as a basis for liability for injuries caused by other manufacturers’ products. . . . This would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer’s statements by copying its labels and riding on the coattails of its advertising.\textsuperscript{118}

The \textit{Foster} court further asserted that the brand-name drug manufacturer has no control whatsoever over the manufacturing or labeling of the generic substitute.\textsuperscript{119} Notably, several other courts embraced \textit{Foster’s} unfairness rationale.\textsuperscript{120}

The Iowa Supreme Court subsequently added an instrumental argument when it denied brand-name manufacturer liability. In \textit{Huck v. Wyeth, Inc.}, the court asserted that because brand-name manufacturers shoulder the considerable research and development costs required to bring new drugs to market, imposing on them liability for generic drugs that cause harm would alter the existing relationship between brand-name and generic manufacturers, which, as a result, could impede investment in and development of new drugs.\textsuperscript{121} Ultimately, the court concluded that the “[P]laintiff fail[ed] to articulate any persuasive case that public health and safety would be advanced through imposing tort liability on brand defendants for injuries caused by generic products sold by competitors.”\textsuperscript{122}

The \textit{Huck} court continued its policy assessment, invoking “[f]undamental tort principles of risk apportionment.”\textsuperscript{123} The court found that the party best equipped to identify and mitigate the risks associated with generic drugs is the generic-drug manufacturer, not the brand-name manufacturer, the latter of which, it noted:

\begin{quote}
\textit{d[id] not place [the generic product] in commerce, ha[d] no ability to control the quality of the product or the conformance of the product with its design, and \textit{d[id]} not have the opportunity to treat the risk of producing the product as a cost of production against which liability insurance can be obtained.}\textsuperscript{124}
\end{quote}

\textsuperscript{119} \textit{Id}. It is not clear why the \textit{Foster} court thought the generic manufacturer benefitted from using the labeling developed by the brand-name drug manufacturer to enable FDA approval. FDA regulations require the generic manufacturer to use the same labeling as is used by its brand-name counterpart.


\textsuperscript{121} Huck v. Wyeth, Inc., 850 N.W.2d 353, 377 (Iowa 2014).

\textsuperscript{122} \textit{Id}. It appears that this argument was initially expressed in \textit{Dietrich}. See Dietrich v. Wyeth, Inc., No. 50-2009-CA-021586XXX, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009). It was repeated in Schwartz et al., \textit{supra} note 38, at 1865.

\textsuperscript{123} \textit{Huck}, 850 N.W.2d at 378.\

\textsuperscript{124} \textit{Id} (quoting AM. L. PROD. LIAB. 3d § 5:10).
Thus, brand-name manufacturers will be squeezed not only by declining market share due to the competition with generics but also by the liability related to their generic competitors’ drugs.\footnote{Between 2017 and 2021, generics accounted for the vast majority of prescription sales, somewhere between 85 and 93 percent of sales. See \textit{The Use of Medicines in the U.S. 2022}, IQVIA INST. 28 (Apr. 21, 2022), https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022.}

Finally, at least one court invoked the societal benefit of prescription drugs: “As Defendant GSK correctly argues, Pennsylvania courts have recognized the societal importance of new and effective prescription drugs . . . . To encourage this process, the courts have also recognized the need not to unduly burden the pharmaceutical industry with unfettered liability.”\footnote{Colaciccio v. Apotex, Inc., 432 F. Supp. 2d 514, 542 (E.D. Pa. 2006), \textit{aff’d}, 521 F.3d 253 (3d Cir. 2008), \textit{cert. granted, judgment vacated}, 556 U.S. 1101, 129 S. Ct. 1578, 173 L. Ed. 2d 672 (2009).}

These are all plausible (although not, in my view, persuasive) reasons for protecting brand-name manufacturers from liability. What is missing, however, and pretty obviously so, is any contrary policy concerns, critical assessment of those proffered, and correction of a legal error predating \textit{Foster’s} fairness claim.\footnote{To be sure, the \textit{Conte} court addressed and responded to two policy arguments made by the defendant in connection with assessing the California duty factors. Whether imposing liability would chill innovation in the pharmaceutical industry, as the defendant argued, was an issue on which the summary judgment record contained no evidence. \textit{Conte v. Wyeth}, Inc., 85 Cal. Rptr. 3d 299, 314 (Ct. App. 2008). The court also demurred to Wyeth’s claim that imposing liability would subject it to “permanent and uncontrolled liability” because Wyeth had sold the rights for Reglan to another company in 2001. \textit{Id.} Despite \textit{Conte}, the policy arguments set out above remained entirely one-sided.}

The most balanced treatment of the policy concerns did not occur until the 2018 decision by the Massachusetts Supreme Judicial Court in \textit{Rafferty v. Merck & Co.}, 92 N.E.3d 1205 (Mass. 2018). There, the court recognized that brand-name manufacturers are subject to a duty with regard to their communications, independently of those who take their drugs, because they put others at risk. \textit{Id.} at 1215. Nevertheless, the court considered policy reasons that might justify negating or modifying the ordinary duty of reasonable care. The court acknowledged policy concerns about the special benefits of the drug industry and the difficulties of brand-name manufacturers coping with liability costs to generic-drug consumers in the face of precipitously declining market share, due to generic competitors. \textit{Id.} at 1216–17. Unlike the policy analyses of the courts explained in the text, the \textit{Rafferty} court recognized the benefits of imposing liability on brand-name manufacturers: such liability would provide further incentives to provide full information about the risks of their drugs and provide a source for compensating those patients who were injured by the generic drugs they took. \textit{Id.} at 1217–18. Concluding, the court expressed concern that permitting negligent misrepresentation claims posed too great a risk of interfering with the development of new drugs but that public policy required the compromise of permitting suits against brand-name manufacturers that acted in reckless disregard of serious risks of death or bodily injury:

\begin{quote}
Under this standard, a brand-name manufacturer that intentionally fails to update the label on its drug to warn of an unreasonable risk of death or grave bodily injury, where the manufacturer knows of this risk or knows of facts that would disclose this risk to any reasonable person, will be held responsible for the resulting harm.
\end{quote}
To take the legal mistake first, *Foster’s, Huck’s*, and other courts’ claim that generic-drug manufacturers control the labeling of their drugs is stunningly blind to the fact that, as explained above, under the law governing the labeling of prescription drugs, it is the brand-name manufacturer—*not* the generic manufacturer—that provides the labeling for both its drug and generic equivalents.128 Even worse, it is the brand-name manufacturer that holds the authority to make changes to the labeling provided for both brand-name drugs and their generic equivalents, given that the latter are required to follow the labeling of the former.129

Thus, contrary to the claim by *Huck* that generic manufacturers are the best cost avoiders, it is the brand-name manufacturers that are in a position to change the labeling of a drug to provide an adequate account of the risks of consuming a drug and the methods to eliminate or ameliorate the risk. To illustrate, consider once more the case of Reglan,130 a drug that poses significant risks to consumers who use either the brand-name or the generic version for longer than twelve weeks. It follows that the argument for public health and safety, which the *Huck* court failed to recognize when it came to imposing liability on brand-name manufacturers, is quite simple and straightforward: Holding accountable those responsible for creating unreasonable risks serves as a deterrent against socially costly behavior.131

The *Foster* court—along with subsequent courts that adopted its argument regarding generic-drug manufacturers benefiting from brand-name manufacturer advertising—failed to appreciate the strategy of brand-name manufacturers when their drugs go off patent. First, advertising expenditures

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128. See supra text accompanying notes 107–09.
129. See supra text accompanying notes 111–15.
130. See supra text accompanying note 66.
131. To be sure, the extent of interference with drug research and development compared to the extent of socially beneficial deterrence is an empirical question that is not easy to answer. See Steven Garber, PRODUCT LIABILITY AND THE ECONOMICS OF PHARMACEUTICALS AND MEDICAL DEVICES 123–41 (1993). But contrary to the *Huck* court, there are two sides to the liability coin.
decline significantly during the last two years before patent expiration, with one study finding a reduction of 10 percent even before generic entry.\textsuperscript{132} This reduction continues as generics enter the market, further decreasing by approximately 20 percent with the introduction of the first generic competitor.\textsuperscript{133} Eventually, it reaches around 78 percent when there are ten or more generic manufacturers competing with the brand-name drug.\textsuperscript{134} Moreover, and not surprisingly, the thrust of brand-name manufacturers’ advertising shifts from promoting the benefit of the drug and expanding the market to enhancing brand loyalty to limit competition from generic manufacturers.\textsuperscript{135}

As to the prospect of indefinite and uncontrolled liability, as was argued in Conte, one might hope that liability for an inadequate warning would provide incentives for the brand-name manufacturer to change the labeling to reflect newly emerged evidence of the drug’s risks.\textsuperscript{136} Manufacturers that do so will no longer be subject to liability for the warnings on their drugs or on their generic equivalents, as generic manufacturers will necessarily change their labeling to conform to the new brand-name warnings. For manufacturers whose drugs are no longer profitable, they can voluntarily remove their branded drugs from the market.\textsuperscript{137} Doing so enables the generic manufacturer to pursue a fast track with the FDA to change the drug’s labeling.\textsuperscript{138}

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\textsuperscript{132} Henry Grabowski et al., \textit{Updated Trends in US Brand–Name and Generic Drug Competition}, 19 J. Med. Econ. 836, 840 (2016) (brand-name drugs facing generic competition between 2013 and 2014 saw market share by volume fall an average of 12 percent within first year).
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\textsuperscript{133} Id.
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\textsuperscript{134} Id.
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\textsuperscript{135} See Mark A. Hurwitz & Richard E. Caves, \textit{Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals}, 31 J.L. & Econ. 299, 317–18 (1988) (“The evidence is consistent with a “‘persuasive’” role for innovators’ promotion outlays both in building up the goodwill stock under patent and preserving loyalty afterward.”).
\end{flushleft}

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\textsuperscript{136} Clinical trials that assess the safety and efficacy of new drugs that support new drug applications to the FDA do not reveal a substantial amount of risk posed by the drug; rare side effects can be missed because of the limited population studied, subpopulations may not be among those enrolled in the studies, and delayed adverse effects can be missed because of the limited time during which clinical trials are conducted. See David A. Kessler & David C. Vladeck, \textit{A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims}, 96 Geo. L.J. 461, 466 (2008). Drug risks that emerge after approval and use by a larger, more diverse population exist for somewhere between half and a third of all new drugs approved. See Nicholas S. Downing et al., \textit{Postmarket Safety Events Among Novel Therapeutics Approved by the US Food and Drug Administration Between 2001 and 2010}, 317 JAMA 1854 (2017) (32 percent of new drugs approved between 2001 and 2010 were either withdrawn, required an added “black box” warning, or the issuance of a safety announcement about newly emergent risks); U.S. GEN. ACCT. OFF., FDA DRUG REVIEW: POSTAPPROVAL RISKS 1976–85, at 3 (1990) (reporting that among new drugs approved between 1976 and 1985, 51.5 percent had serious risks that were not discovered until after FDA approval).
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\textsuperscript{137} See 21 C.F.R. \textsection 314.150.
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\textsuperscript{138} See 21 C.F.R. \textsection 314.93 (requiring the FDA to decide to approve within ninety days of a petition to change the labeling of a generic drug for which the brand-name drug has been voluntarily withdrawn).
\end{flushleft}
Finally, the argument that the drug industry, which provides so much social benefit, should be protected from liability collapses the macro with the micro. Yes, the drug industry provides an enormous boost to health and longevity. But, at the marginal level, it may have inefficiencies that, if eliminated, would provide additional social utility. Thus, consider the development of kidney dialysis, a medical innovation that undeniably improves the lives of those with kidney disease. Now, imagine a dialysis machine that has a flaw in its electrical system that randomly and infrequently electrocutes a dialysis patient. In such a situation, we should embrace liability to provide incentives for the manufacturer to design the machine so as to eliminate the risk of electrocution, which has no connection to the benefits of the dialysis machine. So, too, with pharmaceuticals, which, as active biological agents, can have adverse effects on those who benefit from the drug. Proper labeling can ameliorate those risks, and brand-name manufacturers are the entities with the legal authority to improve labeling as new risk information develops. We should not shrink from imposing liability on them when they fail promptly to do so.

One may disagree with my cut on the policy implications of brand-name manufacturer liability discussed above. But the fact that the policy discussion in the case law was as one-sided as the outcomes of the cases deciding the issue contributes to my wonderment about the trajectory of brand-name manufacturer liability.

CONCLUSION

I recently spoke about this issue with Mark Behrens, a partner in the (euphemistically named) Public Policy group at Crowell & Moring, headed by Victor Schwartz. Victor is the leading advocate and lobbyist for many entities and industries subject to tort suits. Interestingly, Mark acknowledged the weaknesses in the rationales of courts that deny negligent misrepresentation claims identified in this paper. However, Mark set me back on my heels when he asked, “What do you suppose is going on here, Mike?” This brings me to the epigram with which I started this Article—something is certainly going on here, but it remains far from clear, and I must admit to being largely clueless about what that might be.

One noteworthy aspect of the evolution of the law in this area is the timing of suits against brand-name manufacturers. These cases emerged well before the Supreme Court’s 2011 decision in *Mensing*, which established the preemption of claims against generic manufacturers. This decision effectively closed off what had appeared to be the most plausible avenue for pursuing liability—namely, the generic-drug manufacturer.139 Thus, in the

139. Another possibility is a medical malpractice suit against the prescribing physician, especially those prescribing the drug for use beyond twelve weeks. But the costs of pursuing a medical
seminal case addressing negligent misrepresentation asserted against the brand-name manufacturer, Foster, the dismissal of the brand-name manufacturer did not leave the plaintiff remediless but retained what seemed like the most plausible target for liability: the manufacturer of the drug the plaintiff consumed. In the years following Foster, but preceding Mensing, courts held that generic-drug manufacturers could be sued by consumers of their drugs, with some pointing out that the plaintiffs had a viable alternative claim against the generic manufacturer.

After Mensing, generic-manufacturer liability changed, and victims of drug-related issues could no longer pursue legal action against generic manufacturers, leaving brand-name manufacturers as the sole avenue for recovery. Of course, the availability of the generic manufacturer has no legal relevance to the viability of negligent misrepresentation claims against brand-name manufacturers, but one might have thought that it would be easier to deny brand-name claims when they were alternative claims. Yet, in the post-Mensing legal environment, courts remained resolute in rejecting brand-name claims, just as they had before Mensing. As one court aptly put it when confronted with the plaintiff’s argument that the law should adapt to the lack of a remedy against generic manufacturers, imposed by Mensing, by permitting brand-name suits: “[The] holding in Mensing neither created nor abrogated any duty under Maryland law with regard to brand-name manufacturers.” At the symposium at which I presented an earlier version of this paper, Aaron confessed to being as baffled as I am about the course of the brand-name manufacturer litigation. Indeed, after sharing his own sense

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malpractice suit and the fact that some cases of tardive dyskinesia are mild to moderate and reversible by ceasing use of the drug likely means such claims were relatively rarely pursued.


141. See, e.g., Mensing v. Wyeth, Inc., 588 F.3d 603, 612 (8th Cir. 2009) (“[W]e decline to assume that Congress intended to shield from tort liability the manufacturers of the majority of the prescription drugs consumed in this country and leave injured parties like Mensing no legal remedy.”), rev’d sub nom. PLIVA, Inc. v. Mensing, 564 U.S. 604, 604 (2011); Demahy v. Wyeth Inc., 586 F. Supp. 2d 642, 656 (E.D. La. 2008) (marshalling cases that concluded, based on Foster, that warnings claims against generic-drug manufacturers were not preempted), aff’d sub nom. Demahy v. Actavis, Inc., 593 F.3d 428 (5th Cir. 2010), rev’d sub nom. PLIVA, Inc., v. Mensing, 564 U.S. 604 (2011); Kelly v. Wyeth, No. CIV.A.MICV200303314B, 2005 WL 4056740, at *5 (Mass. Super. Ct. May 6, 2005) ((quoting Foster, 29 F.3d 165 at 168) (“The statutory scheme governing premarketing approval for drugs simply does not evidence Congressional intent to insulate generic-drug manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state product liability law. Manufacturers of generic drugs, like all other manufacturers, are responsible for the representations they make regarding their products.”)).


143. Gross v. Pfizer, Inc., No. 10-CV-00110-AW, 2011 WL 4005266, at *2 (D. Md. Sept. 7, 2011); see also Metz v. Wyeth LLC, 830 F. Supp. 2d 1291, 1294 (M.D. Fla. 2011) (same as Gross and remarking that if change to state law should be made, it falls to the legislature or state supreme court to do so), aff’d, 525 F. App’x 893 (11th Cir. 2013).
of bewilderment, he quickly pivoted the conversation to the liability of Amazon for products sold on its website. He expressed the same puzzlement about the large majority of cases that do not permit such suits, which, alas, does not contribute to a better understanding of the brand-name manufacturer case law.

But the Symposium did spur explanatory comments from John Goldberg that strike me as potentially helpful, if unrevealed, in the many court opinions addressing this subject. John suggests that courts possess certain intuitions about product manufacturer communications that link them to warnings provided by their products. This connection makes it difficult for courts to distinguish between miscommunications in the two realms. As John succinctly put it, “The line between liability for misrepresentation and for failure to warn is very thin, such that courts are inclined to see the complaint as focused on the product, and not consumers/users of other manufacturers, similar products.” This explanation seems more plausible for the early cases on this subject, which did not acknowledge the independence of the products liability and misrepresentation claims. But later cases reflect an appreciation that the two claims are distinct and warrant separate consideration.

Notwithstanding John’s helpful comments, I remain largely in the sway of the Buffalo Springfield observation with which this article begins.

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144. See supra notes 39–40 and accompanying text.
145. See supra notes 70–72 and accompanying text.