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IN THIS ISSUE

David L. Ferrera and Michael J. Leard review the resurgence of the novel tort theory of Innovator Liability - by which a brand-name drug manufacturer may be held liable for injuries allegedly caused by the use of a generic drug - and discuss what the future may hold.

Innovator Liability: A Recent Resurgence

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ABOUT THE COMMITTEE

The Drug, Device and Biotechnology Committee serves as an educational and networking resource for in-house counsel employed by pharmaceutical, medical device and biotech manufacturers and the outside counsel who serve those companies. The Committee is active in sponsoring major CLE programs at the Annual and Midyear Meetings as well as internal committee programs. The Committee also publishes a monthly newsletter that addresses recent developments and normally contributes two or more articles to the *Defense Counsel Journal* annually. Learn more about the Committee at www.iadclaw.org. To contribute a newsletter article, contact:

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Innovator Liability is a tort theory by which a *brand-name* drug manufacturer, the "innovator," may be held liable for injuries allegedly caused by the use of a *generic* drug. Courts across the country have dealt with this novel theory since the Supreme Court insulated generic manufacturers from liability for state law failure to warn claims in its 2011 landmark decision, PLIVA, Inc. v. Mensing; however, recently, the theory has seen a resurgence, based on rulings from the highest courts of states on both coasts. Whether or not the theory gains further acceptance remains to be seen.

What is Innovator Liability?

Innovator Liability is a novel theory designed to circumvent federal preemption.

Pursuant to the Federal Food, Drug, and Cosmetic Act, pharmaceutical manufacturers cannot market drugs in interstate commerce without the approval of the U.S. Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). As part of the approval process, a brand-name manufacturer must establish that the proposed warning label for a new drug is accurate and adequate. In contrast, the FDA imposes only a duty of "*sameness*" on a generic manufacturer, that is to say a manufacturer of a generic drug need merely establish that the proposed warning label for the generic drug is the *same* as the label approved for its brand-name equivalent. Generally, generic manufacturers are prohibited from making unilateral changes to their drug labels once approved by the FDA.

In light of a generic manufacturer's inability to independently revise its warning label, the U.S. Supreme Court held in PLIVA, Inc. v. Mensing that state law failure to warn claims against generic manufacturers are preempted by FDA regulations. 564 U.S. 604, 608-09 (2011). In Mensing, the plaintiffs alleged that they developed tardive dyskinesia as a result of their ingestion of a generic digestive aid, metoclopramide. The plaintiffs' claims that the generic manufacturers failed to warn of the risk of tardive dyskinesia were preempted; however, because it would have been "impossible" for the generic manufacturers to simultaneously comply with state tort law – which required a revised warning label – and federal FDA labeling regulations – which prohibited any such revision absent action by the brand-name manufacturer.

In the wake of the Supreme Court's 2011 decision in Mensing, the plaintiffs' bar has championed the novel theory of Innovator Liability in an attempt to circumvent the practical consequence of the Court's holding – that generic consumers are without remedy for failure to warn claims due to federal preemption. The significance of the imposition of such liability cannot be overstated for brand-name manufacturers. According to *The New York Times,* in 2016, 89 percent of all U.S. prescriptions were filled with generic drugs. Adoption of Innovator Liability would therefore subject

brand-name manufacturers to liability nearly ten times the size of their market share – potentially for years after loss of market share – effectively turning brand-name manufacturers into insurers of their market.

The Vast Majority of Courts Have Rejected Innovator Liability

The vast majority of state courts considering Innovatory Liability have rejected it, including Colorado, Florida, Georgia, Indiana, Iowa, Kansas, Louisiana, Minnesota, Missouri, New Jersey, New York, Oregon, Pennsylvania, Texas, Utah, and West Virginia. The following federal district courts, applying various states' laws, have also rejected the theory: Arkansas, Florida, Georgia, Illinois, Kentucky, Louisiana, Maryland, Massachusetts (applying foreign states' law), Minnesota, Mississippi, Missouri, Nevada, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, and West Virginia.

In addition, all U.S. Circuit Courts of Appeal that have addressed the issue post-Mensing have rejected Innovator Liability.

Only a small minority of state courts have adopted Innovator Liability, including Alabama (subsequently abolished by statute), California, and Massachusetts, as well as the federal district courts of Illinois (applying Illinois law- further discussed below) and Vermont (applying Vermont law). Although still the minority position, the adoption of Innovator Liability by the high courts of California, in 2017, and Massachusetts, in 2018, has reinvigorated the theory. The common theme among these courts is a heightened emphasis on the element of foreseeability, typically at the expense of traditional products liability concepts.

"Innovation" on the Coasts - Abandoning Traditional Products Liability Principles

There are two fundamental tenants of products liability law: (1) a plaintiff must prove product identification, i.e., that the product at issue was manufactured, sold, or supplied by the defendant; and (2) a defendant cannot be held liable for failure to warn of risks created solely by the use or misuse of a product manufactured by an unrelated entity.

The majority's rejection of Innovator Liability is based on the notion that a brand-name manufacturer should not be held liable for a generic product it did not manufacture, sell, or supply.

In contrast, the handful of jurisdictions which have adopted Innovator Liability have had to expand traditional products liability concepts or disregard them altogether. In T.H. v. Novartis Pharma. Corp., the Supreme Court of California stretched the very definition of a "product" itself, holding that a drug's warning label – not the generic drug which was ingested – constituted the "product" for purposes of imposing Innovator Liability. 407 P.3d 18, 39 (Cal.

2017). In T.H., the plaintiffs' mother was prescribed generic terbutaline to suppress premature labor during pregnancy. After birth, the plaintiffs were diagnosed with developmental delays and autism. The plaintiffs alleged that Novartis' failure to include a warning regarding the risk to fetal brain development on its brand-name Brethine caused the plaintiffs harm. Although the plaintiffs' mother never ingested Brethine, the Supreme Court of California reasoned that liability was warranted because, due to the FDA's "sameness" requirement, Novartis effectively controlled the content of the warning label on the generic terbutaline at issue.

Further, in Rafferty v. Merck & Co., Inc., the Massachusetts Supreme Judicial Court ("SJC") skirted traditional products liability law altogether, finding that "Rafferty did not bring a products liability claim… [i]nstead, he has brought a *general negligence claim*, relying on 'a general principle of tort law' that… every actor has a duty to exercise reasonable care to avoid physical harm to others… ." 479 Mass. 141, 148-49 (2018). In Rafferty, the plaintiff ingested generic finasteride for treatment of enlarged prostate, and subsequently developed erectile dysfunction and decreased libido. Despite discontinuing use of finasteride, the plaintiff's symptoms continued. The plaintiff alleged that Merck, which manufactured brand-name Proscar, failed to warn that his sexual dysfunction would persist after discontinuing use of generic finasteride. While the Massachusetts SJC conceded that the plaintiff did not have a viable product liability claim against Merck – because the plaintiff did not ingest Proscar – it instead reasoned that because it was "certain that the warning label provided by [Merck] will be identical to the warning label provided by the generic manufacturer," Merck owed a duty to consumers of the generic not to act in reckless disregard of an unreasonable risk of death or grave bodily injury.

Each of these state supreme courts remanded their case to the trial court for further proceedings.

Affirmation of the Majority Position

Despite the T.H. and Rafferty decisions adopting Innovator Liability in late-2017 and early-2018, a nation-wide shift in favor of the theory appears unlikely. In May 2018, the Supreme Court of Appeals of West Virginia in McNair v. Johnson & Johnson rejected the theory of Innovator Liability. 2018 WL 2186550, *6 (W. Va. May 11, 2018). In McNair, the plaintiff developed acute respiratory distress after ingesting generic levofloxacin. The plaintiff alleged that Janssen, which manufactured brand-name Levaquin, was aware of the risk of acute respiratory distress, but negligently failed to include a warning, knowing that the omission would not only relate to the Levaquin label, but also the label accompanying generic levofloxacin. The McNair court; however, rejected plaintiff's attempt to expand the definition of "product" to mean "the warning label drafted by Janssen and not the generic drug

ingested by Mrs. McNair." The court concluded that "[j]ust as the Supreme Court refused to distort the Supremacy Clause in Mensing to prevent the undesirable result of providing immunity to generic manufacturers in failure to warn cases, we decline to distort our products liability law to hold a brand manufacturer liable for injuries allegedly caused by a generic drug that the brand manufacturer neither manufactured nor sold."

In August 2018, the Seventh Circuit had an opportunity to address Innovator Liability in Dolin v. GlaxoSmithKline LLC. 901 F.3d 803, 816 (3rd Cir. 2018). In Dolin, plaintiff's decedent ingested generic paroxetine for treatment of depression but committed suicide shortly thereafter. Plaintiff sued GlaxoSmithKline ("GSK"), the manufacturer of brand-name Paxil, on the theory that it negligently failed to include warnings that paroxetine was associated with suicide in patients older than 24. While an Illinois federal jury had awarded plaintiff $3,000,000 on her Innovator Liability claim, the Seventh Circuit declined to address Innovator Liability on appeal, noting that "Illinois courts have not yet considered the new theory of liability." Instead, the Seventh Circuit reversed the judgment on the closely-related grounds of federal preemption, rejecting plaintiff's state law claim that GSK should have warned of a risk of adult suicide in light of evidence that the FDA had denied "repeated" requests by GSK to change the Paxil warning label.

It is unknown as of the submission of this article whether Ms. Dolin will seek certiorari to the Supreme Court.

Looking to Mensing for Guidance

Should the issue of Innovator Liability ultimately be appealed to the Supreme Court, the Court's opinion in Mensing may provide insight into the Court's leanings. While the issue of Innovator Liability was not before the Court, the Court had the opportunity to address Innovator Liability and specifically did not. Instead, the majority lamented that its decision dealt an "unfortunate hand" to generic consumers, i.e., it left them without remedy. Even the dissent was unified on this point – "the majority's [decision] strips generic-drug consumers of compensation when they are injured by inadequate warnings." "If [a consumer] takes a generic drug, as occurs 75 percent of the time, she now has *no right to sue*." Just two years earlier in Wyeth v. Levine, the Court held that a brand-name manufacturer could be held liable for failure to warn, rejecting Wyeth's preemption defense. Accordingly, if the Court in Mensing intended to merely shift liability to brand-name manufacturers, it could have indicated that generic consumers still had *a* remedy for their injuries.

While the theory of Innovator Liability has seen a recent resurgence, the majority position continues to favor traditional products liability concepts.

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