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Innovator Liability: A Pandora's Box For Pharma Cos.?

By **Monee Hanna and Nicholas Janizeh** (April 2, 2018, 1:30 PM EDT)

"[O]ur careful review of the federal regulatory scheme ... persuades us that a brand-name drug manufacturer has the duty ... to warn of the risks about which it knew or reasonably should have known, regardless of whether the consumer is prescribed the brand-name drug or its [competitors'] generic 'bioequivalent[s].'" — The California Supreme Court in T.H. v. Novartis

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Federal Regulations Governing Pharmaceuticals

Before a new brand-name drug enters the market in the United States, it must go through a rigorous safety review process culminating in U.S. Food and Drug Administration approval. This is called the new drug application process. If approved, the manufacturer of the brand-name drug will, for a time, have exclusive control of the market before other pharmaceutical manufacturers can start producing and selling generic versions the drug. The generic versions are bioequivalent to the brand-name version, meaning that they affect the body in the exact same ways.

Because of this, and for other reasons, generic versions must be accompanied by the same warnings and precautions as the brand-name labels. Generally speaking, however, it is the brand-name manufacturer who retains the sole ability to update the label.

The U.S. Supreme Court relied on this regulatory framework in PLIVA Inc. v. Mensing, when it held that failure-to-warn claims brought against manufacturers of generic medications under state law are preempted by federal law.[1] The result was a surge in the number of cases holding that generic drug manufacturers could not be held liable for state law failure-to-warn claims.[2] Notably, these cases further entrench a central tenet of product liability law — that a manufacturer should not be held liable for the alleged defects of products it did not manufacture.

What Is Innovator Liability?

An unconventional doctrine of liability that has steadily been gaining more acceptance from state high courts over the past several months now threatens to turn that central tenet of product liability law on its head. The innovator liability doctrine aims to hold brand-name prescription drug manufacturers —

i.e., innovators of new drugs — liable for inadequate labeling claims brought by patients who took a generic version of the drug. Put differently, under the doctrine, innovators can be liable for products they did not manufacture, sell or profit from.

The vast majority of states to address the issue have chosen not to recognize innovator liability.[3] And no federal circuit court has ever endorsed this doctrine. Yet, despite the overwhelming weight of authority declining to expand existing law, a growing number of states — most recently, California and Massachusetts — have adopted the doctrine.

California's Decade-Long History with Innovator Liability

California courts have been weighing in on the innovator liability doctrine for over a decade. The first case to bring the doctrine to the forefront was Conte v. Wyeth Inc. Conte arose from an early 2007 California trial court decision, which declined to hold a brand-name manufacturer liable for injuries purportedly caused by a generic version of its drug.[4]

The case centered on a woman who was prescribed a generic version of Wyeth's brand-name drug, Reglan.[5] Within months after taking the generic version, she allegedly developed tardive dyskinesia, an incurable neurological disorder that causes involuntary movement or twitches throughout the body.[6] Despite never ingesting Reglan, Elizabeth Conte sued Wyeth among the manufacturers of the generic version she was prescribed.[7] The trial court granted summary judgment to Wyeth,[8] reasoning that "Wyeth owe[d] no duty of care to the users of generic versions of its name-brand drug."[9]

On appeal, however, the appellate court breathed life into the innovator liability doctrine when, in 2008, it ruled in favor of Conte and reversed the lower court's grant of summary judgment in favor of Wyeth. The appellate court ultimately found that Wyeth owed a duty to the consumers of the generic versions of its drugs.[10] The court reasoned that it was "foreseeable" that doctors prescribing generic versions of a drug would rely on information that was sent to the FDA by the company that developed — or innovated — the drug.[11]

The Conte court's endorsement of innovator liability, however, was not binding on lower courts. It was not until nearly a decade later with T.H. v. Novartis Pharmaceuticals Corp., which was decided in the waning weeks of 2017, that the California Supreme Court recognized — and adopted — this form of liability on brand-name manufacturers.[12]

The T.H. v. Novartis case was brought on behalf of twin minors who allegedly sustained injuries in utero as a result of their mother's off-label use of a generic asthma medication, terbutaline (the brand-name version of which was developed by Novartis), to slow or stop premature labor. A California trial court sustained Novartis's demurrer, in which it argued that it could not be held liable because it did not manufacture the drugs that allegedly injured the plaintiffs, without leave to amend.[13]

The plaintiffs appealed and the case was taken up by the California Supreme Court. In December 2017, California's highest court reversed the lower court's decision even after considering the "'overwhelming' majority of courts that have declined to recognize warning label liability owed to those who were prescribed a generic version of the drug in reliance on the brand-name drug label" and ultimately decided to hold Novartis liable for negligent failure to warn and negligent misrepresentation under the doctrine of innovator liability.[14]

Just like the Conte court, the California Supreme Court reasoned that "it is entirely foreseeable that the

warnings included (or not included) on the brand-name drug label would influence the dispensing of the generic drug" and that any deficient warnings in the label for the brand-name drug — negligent or otherwise — "will be perpetuated in the label[s] for its generic bioequivalent[s]."[15]

The Novartis court even went a step further. Not only did the court expand the duty owed by brand-name manufacturers, but it also extended the temporal scope in which those manufacturers could be liable. It concluded that a brand-name manufacturer's duty continues even after it stops manufacturing or selling the drug — so long as the plaintiffs could show that "the injury was foreseeable at the time the brand-name manufacturer held the NDA."[16]

The California Supreme Court found that, although a brand-name manufacturer only owes a duty of care while it holds the NDA, "a breach of that duty can have enduring effects — effects that do not magically disappear merely because the brand-name manufacturer no longer holds the NDA."[17] Novartis was therefore still liable even though it sold its NDA to AAIPharma in 2001 and thus no longer had "control" over labeling revisions in 2007, when the plaintiffs' mother was prescribed the generic.[18]

Massachusetts' Adoption of an Innovator-Liability Recklessness Standard

In March 2018, just months after the California Supreme Court issued its decision in T.H. v. Novartis, Massachusetts too recognized a form of the innovator liability doctrine.[19] In Rafferty v. Merck, the plaintiff took a generic form of Merck's prostate drug, Proscar, and alleged that the product label failed to adequately warn of sexual dysfunction.[20]

The plaintiff commenced an action against Merck in 2013, asserting claims of negligence for failure to warn and a Massachusetts consumer protection violation.[21] Relying on "two well-established ... principles" of Massachusetts product liability law, the superior court ruled that, because Merck did not manufacture the product the plaintiff ingested, it could not be held liable for the plaintiff's injuries.[22]

The Massachusetts Supreme Judicial Court, in an attempt to balance Massachusetts' principles of tort law with growing public policy concerns, concluded that the plaintiff could not assert a general negligence claim against a brand-name manufacturer for failure to warn.[23] The Rafferty court recognized that "[p]ublic policy favor[ed] the development and marketing of new and efficacious drugs"; considered the "breadth and uncertain scope of [the legal] standard for negligen[ce]"; and conclusively reasoned that, "as a matter of public policy[,] allowing a generic consumer to bring a general negligence claim for failure to warn against a brand-name manufacturer poses too great a risk of chilling drug innovation, contrary to the public policy goals embodied in the Hatch-Waxman amendments" to the Federal, Food, Drug and Cosmetic Act.[24]

In an attempt to carve out a remedy, the Rafferty court would, however, allow the plaintiff to amend his complaint to bring a common-law recklessness claim against Merck for intentionally failing to update its label despite "knowing or having reason to know of an unreasonable risk of death or grave bodily injury."[25] Unlike T.H. v. Novartis, the Rafferty court emphasized that such a claim is "distinguishable from negligence" — i.e., the doctrine only applied where the brand-name manufacturer was "reckless" in its "fail[ure] to update the label."[26]

The Rafferty decision further contrasted the Novartis ruling in that it explicitly stated its rationale behind adopting innovator liability: "[P]ublic policy is not served if generic drug consumers have no remedy for the failure of a brand-name manufacturer. ..."[27]

At bottom, although Massachusetts now falls in the minority of states recognizing innovator liability, its application is far narrower than in California.

What Innovator Liability May Mean for Pharmaceutical Manufacturers

While innovator liability creates a remedy for generic drug users that may have been restricted by Mensing, it also forces brand manufacturers to shoulder the lion's share of the costs for prescription drugs. After all, they are now obligated to pay for injuries resulting not only from their drugs, but also from their generic competitors. This is in addition to the significant costs and risk associated with bringing a new drug to market.

Even after weighing the possible chilling effects these additional costs may have on the development of new drugs, a growing number of courts have chosen to nevertheless adopt the innovator liability doctrine. They appear motivated by fairness and providing consumers of generic versions of drugs a judicial remedy for their alleged harm. This is despite the fact that both Congress and the FDA knowingly created this regulatory scheme to allow for the proliferation of more accessible generic drugs.

Moreover, the FDA has for years been considering a rule to enable generic drug manufacturers to update a drug's warnings, which would fundamentally alter Mensing.[28] After several rounds of public comment, however, the proposed rule has been withdrawn — leaving the industry and courts without much-needed guidance.[29]

Holding brand-name manufacturers liable for drugs they did not manufacture is not the only complication innovator liability may impose on pharmaceutical companies. Indeed, with manufacturers of different drugs being sued in tandem, innovator liability threatens to open the door for more multi-manufacturer coordinated proceedings, especially in state court. And with this comes a whole host of issues: Manufacturers will have to protect trade secrets and other proprietary and confidential information from full disclosure, which may result in defendant-manufacturers needing to erect confidentiality barriers when engaging in fact discovery. These are factors that the Judicial Panel on Multidistrict Litigation itself has recognized to complicate case management and undermine the very purposes of coordination.[30]

Although only a handful of states have endorsed innovator liability, the cases discussed above demonstrate that the trend may be growing. Whether this trend is here to stay will be answered as more states weigh in on the issue. We expect the forthcoming decision from West Virginia's high court in McNair v. Johnson & Johnson will affect the tide.[31] But even if West Virginia or other states fall in line with California and Massachusetts, state legislatures (though not likely California) may step in, exercise their constitutional checks and balances and impose laws to circumvent the doctrine all together — i.e., so that manufacturers cannot be liable for products they did not make.

This is exactly what the legislature did in Alabama. After the Alabama Supreme Court unequivocally recognized the doctrine, the legislature quickly enacted laws to nullify the court's ruling and reinstate basic principles of product liability law.[32] As such, manufacturers could only be liable for products they "designed, manufactured, sold or leased" — "not ... similar or equivalent product[s]."[33]

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[1] 564 U.S. 604, 625 (2011).

[2] Id.

[3] See, e.g., Stanley v. Wyeth Inc., 991 So. 2d 31, 33-35 (La. Ct. App. 2008); Westerlund v. Wyeth Inc., No. MID-2174-05, 2008 WL 5592753, at *3 (N.J. Super. Law. Div. Oct. 20, 2008); Short v. Eli Lilly & Co., No. 49D12-0601-CT-2187, 2009 WL 9867531, at *4-9 (Ind. Super. Ct. Mar. 25, 2009).

[4] 85 Cal. Rptr. 3d 299, 305-06 (Ct. App. 2008).

[5] Id. at 305.

[6] Id.

[7] Id.

[8] Id. at 304-05.

[9] Id. at 306 (summarizing trial court's 2007 reasoning).

[10] Id. at 317-18.

[11] Id. at 304-05, 311-13.

[12] 407 P.3d 18 (Cal. 2017).

[13] See 199 Cal. Rptr. 3d 768, 773-74 (Ct. App. 2016) (explaining trial court's sustainment of Novartis's demurrer).

[14] 407 P.3d at 35.

[15] Id. at 30-31.

[16] Id. at 44-45.

[17] Id.

[18] Id.

[19] Rafferty v. Merck & Co., No. SJC-12347, 2018 WL 1354064, at *10-11 (Mass. Mar. 16, 2018).

[20] Id. at *3.

[21] Id.

[22] Id. at *3-4.

[23] Id. at *10-11.

[24] Id. at *7-8, 10.

[25] Id. at *1, 10-11.

[26] Id. at *10-11.

[27] Id.

[28] The Novartis court noted that this proposed FDA rule would "effectively abrogate PLIVA." 407 P.3d at 31 & n.2.

[29] "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products," Office of Info. & Reg. Affairs, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201710&RIN=0910-AG94 (last visited Mar. 26, 2018) (noting that the proposed rule has been "Withdrawn").

[30] See, e.g., In re: Invokana (Canagliflozin) Prods. Liab. Litig., 223 F. Supp. 3d 1345, 1348 (J.P.M.L. 2016); In re: Tropicana Orange Juice Mktg. & Sales Practices Litig., 867 F. Supp. 2d 1341, 1342 (J.P.M.L. 2012); In re: Watson Fentanyl Patch Prods. Liab. Litig., 883 F. Supp. 2d 1340, 1351 (J.P.M.L. 2012).

[31] 694 F. App'x 115 (4th Cir. 2017) (noting that question of adoption of innovator liability would be certified to Supreme Court of Appeals of West Virginia).

[32] Compare Wyeth Inc. v. Weeks, 159 So. 3d 649, 677 (Ala. 2014) (adopting innovator liability), with Ala. Code § 6-5-530(a) (superseding Weeks and explaining that, in product liability actions, the plaintiff must prove that "the defendant designed, manufactured, sold or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product").

[33] Ala. Code § 6-5-530(a) (emphasis added).