Top Food and Drug Cases, 2017, & Cases to Watch, 2018

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T.H. v. Novartis Pharmaceuticals Corp.

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WHY IT MADE THE LIST

T.H. v. Novartis Pharmaceuticals Corp.[1] represents a significant departure from established product liability and innovator liability law. The case tackles two high-stakes theories of liability for brand-name manufacturers of pharmaceutical products: (1) whether they can be liable for injuries caused by a generic manufacturer's drug; and (2) whether that liability extends after the brand-name manufacturer transfers rights to the product and no longer makes or sells it. Nearly every court that has addressed these theories has rejected them. In *T.H.*, the California Supreme Court charted a different course. It held that a brand-name manufacturer can be liable for failure to update a label even when the plaintiffs used a generic version of the product, years after the brand-name manufacturer last held rights to it.

The Facts

Plaintiffs, fraternal twins, sued Novartis in California state court for negligence and negligent misrepresentation for alleged failure to warn of the risks of Brethine (generic name terbutaline), an asthma medicine that works by relaxing smooth muscle tissue. Novartis initially owned the rights to market Brethine in its oral form. In December 2001, however, Novartis transferred the New Drug Application (NDA) for Brethine to NeoSan Pharmaceuticals Inc., a wholly owned subsidiary of AAIPharma.[2]

Plaintiffs' mother, J.H., was hospitalized for premature labor in September 2007—nearly six years after Novartis divested Brethine—and was prescribed the generic version, terbutaline.[3] Terbutaline was not FDA-approved for such a use, and her prescription was thus off-label.[4]

Plaintiffs alleged that the terbutaline passed to them *in utero*, causing them to suffer neurological damage, including autism.[5] They claimed that pre-2001 studies questioned the efficacy of terbutaline to prevent preterm labor and demonstrated the risks of the drug to fetal brain development. They further alleged that Novartis knew or should have known this information and updated the label warning accordingly.

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1 407 P.3d 18, S233898 (Cal. Dec. 22, 2017).

2 *See id.*, slip op. at 9.

3 *Id.*, slip op. at 9-10.

4 *See id.*, slip op. at 7.

5 *Id.*, slip op. at 10.

Instead, they contended, Novartis falsely represented that terbutaline was safe and effective for pregnant women.

Novartis moved to dismiss on two grounds: First, that it did not owe Plaintiffs a duty of care because it did not manufacture the generic terbutaline ingested by Plaintiffs' mother; and second, that it was not the NDA holder when Plaintiffs' mother took terbutaline and thus had no ability or legal duty to update the product labeling.

The Holding and Analysis

Question 1: Did Novartis owe a duty to the users of generic terbutaline?

The California Supreme Court started its analysis with what it perceived as the central issue: Does a brand-name drug manufacturer have a duty to warn to users of generic drugs manufactured and marketed by other companies? The answer from the court was a resounding "yes."

Before diving into the court's analysis, some background on applicable federal regulations is necessary. A brand-name manufacturer is responsible for drafting, updating, and maintaining the warnings in a prescription drug label. In most circumstances, it must obtain FDA approval before changing the product labeling. However, an exception allows a brand-name manufacturer to change a label—prior to FDA approval—to add or strengthen warning information under certain circumstances[6] (i.e., a Changes Being Effected or CBE label change). A generic manufacturer, by contrast, must ensure only that its labeling is identical to that of the brand-name drug.[7] In *PLIVA, Inc. v. Mensing*, the U.S. Supreme Court ruled on this dichotomy between brand-name and generic manufacturers in a case brought against a generic.[8] Because generic manufacturers have a duty of "sameness" and cannot independently update product labeling, the Court held federal law preempts state tort claims based on generics' failure to warn.

In the wake of *Mensing*, plaintiffs' attorneys have brought cases against brand-name manufacturers for injuries allegedly caused by generic products. They argue that a brand-name manufacturer has a duty to warn users of both brand-name and generic products because it is reasonably foreseeable that the generic product labeling will be identical to that of the branded. Courts have almost universally rejected this argument, however, holding that only the seller or manufacturer of a product is liable for product liability claims.[9]

The result, in theory, should be no different under California product liability law.[10] But California courts have charted a different course. In *Conte v. Wyeth, Inc.*,[11] the California Court of Appeal rejected the widely accepted rule in

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6 *See* 21 C.F.R. 314.70(c).

7 *See* 21 U.S.C. § 355(j)(v).

8 564 U.S. 604 (2011).

9 *See, e.g.*, Strayhorn v. Wyeth Pharmaceuticals, Inc., 737 F.3d 378, 404-06 (6th Cir. 2013).

10 *See* O'Neil v. Crane Co., 53 Cal. 4th 335, 365-66 (2012) (manufacturer of valve cannot be liable for injuries caused by asbestos used to insulate valve because imposing liability on company for a product it did not manufacture or sell would "exceed the boundaries established over decades of product liability law").

11 168 Cal. App. 4th 89 (2008).

pharmaceutical product liability cases. In *Conte*, the plaintiff alleged that she developed tardive dyskinesia after taking the generic version of Reglan and alleged negligent misrepresentation by the brand-name manufacturer.

The court found that negligent misrepresentation claims turn, not on whether the defendant manufactured the product, but on whether the harm is foreseeable. According to the court, it is "eminently foreseeable" that a physician might prescribe a generic product in reliance on the branded labeling.[12] While *Conte* has not gained traction elsewhere, it formed the basis of the California Supreme Court's reasoning in *T.H.*

As in *Conte*, the court in *T.H.* held that a brand-name manufacturer's duty and potential liability hinges on the foreseeability of harm. Because generic manufacturers are bound by the requirement of "sameness," a brand-name manufacturer exercises "complete control" over the product label. It "knows to a legal certainty [] that any deficiencies in the label for its drug will be perpetuated in the label for its generic bioequivalent."[13] Thus, it is foreseeable that a doctor may rely on branded product labeling even when prescribing a generic product, and a brand-name manufacturer accordingly owes a duty of care to users of both the branded and generic product.

Policy concerns drove much of the court's analysis. The brand-name manufacturer is the only one in a position to change the product labeling, yet, the court reasoned, a brand-name manufacturer's incentive to do so "declines once the patent expires and generic manufacturers enter the market." With liability for generic products at stake, a brand-name manufacture will continue to update labeling with risk information, thus safeguarding patients.[14] At the same time, the court rejected concerns that it was effectively making brand-name manufacturers insurers for the entire market. It deemed its holding to apply in only "narrow circumstance" because generics can still be liable for manufacturing defects, for failing to meet the "sameness" requirement, or for promoting off-label.[15]

Question 2: Did Novartis continue to owe a duty of care after it transferred the NDA?

The court next turned to the thornier issue: the fact that Novartis had not held marketing rights to the product for six years before the alleged injury occurred. The court recognized that only the current NDA holder has the authority to update a product label.[16] Nor was there any doubt that Novartis had not held the NDA for years before plaintiffs' mother was prescribed terbutaline. Facing similar facts, other courts have held that the predecessor manufacturer is not liable, either because it does not owe a duty of care to the plaintiff or because its negligence is too remote from the plaintiff's injury to constitute proximate cause.[17]

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[12] *Id.* at 105.

[13] *See* T.H. v. Novartis, S233898 (Cal. Dec, 22, 2017), slip op. at 18.

[14] *See id.*, slip op. at 22.

[15] *Id.*, slip op. at 24.

[16] *See id.*, slip op. at 40.

[17] *See, e.g.*, In re Minnesota Breast Implant Litig., 36 F Supp. 2d 863 (D. Minn. 1998); Christian v. Minnesota Min. & Mfg. Co., 126 F. Supp. 2d 951 (D. Md. 2001); Lyman v. Pfizer, Inc., 2012 WL 2970627 (D. Vt. 2012).

But the California court once again framed this issue as one of foreseeability. Plaintiffs alleged that the terbutaline label was deficient in 2001 when Novartis transferred the label. The court reasoned that it was "reasonably foreseeable" that the new NDA holder, AAIPharma, would not update the label. According to the court, it was "at least plausible" that AAIPharma would not independently review the medical literature to determine if a label change was needed, but would instead rely on its predecessor for adequate labeling.[18] Further, Novartis could have predicted that AAIPharma would be "reluctant to add warnings about the risk to fetal brain development" in order to protect its market share of off-label prescriptions for premature labor.[19] And, the court found, any negligence by AAIPharma with respect to labeling updates was "reasonably foreseeable" and did not excuse Novartis from liability.

IMPACT

The California court's decision may embolden other courts looking to protect consumers of generic products. Indeed, the Supreme Court of Massachusetts issued one such opinion in March, holding that a brand-name manufacturer may be liable for reckless failure to warn because it would be unfair to leave generic drug users without legal recourse.[20]

There are holes in the court's rationale that other courts may not be so keen to ignore, however. For example, the court overstated Novartis' ability to change the label before it transferred the NDA. While the CBE process allowed Novartis to make unilateral labeling changes, it is far from clear that it could have used a CBE label change to add information about an *off-label* indication without prior approval from FDA.[21] In fact, FDA regulations specifically caution against any labeling that suggests a product can be used off label.[22]

Other courts may take particular issue with the application of predecessor liability in *T.H*, which thus far has met universal rejection. As noted in the concurring and dissenting opinion, after a divestiture, a brand-name manufacturer has no ability to change the label.[23] "Predecessor manufacturers have a right to presume successors will perform their duty and follow the law."[24] The majority's embrace of predecessor liability indefinitely extends a branded manufacturer's duty to warn.

While proximate cause perhaps could serve as a backstop to this indefinite liability, the court paid it no heed. It played up the weight of the evidence linking terbutaline to fetal health, leaving it to the dissenting judge to note that it was not until 2001—the same year in which Novartis transferred the NDA—that a long-term study first demonstrated a potential link between terbutaline and human

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[18] T.H. v. Novartis, S233898 (Cal. Dec, 22, 2017), slip op. at 43.

[19] *Id.* at *42.

[20] *See* Rafferty v. Merck & Co., Inc., 2018 WL 1354064 (Mass. Mar. 16, 2018).

[21] *See* 21 C.F.R. § 201.57(c)(6)(i) ("[a] specific warning relating to a use not provided for under the 'Indications and Usage' section *may be required by FDA*") (emphasis added).

[22] *See* 21 C.F.R. § 201.57(c)(2)(v) ("Indications or uses must not be implied or suggested in other sections of the labeling if not included in [the Indications] section.").

[23] *See* T.H. v. Novartis, S233898 (Cal. Dec, 22, 2017), slip op. dissenting opinion at 8.

[24] *Id.*, slip op. dissenting opinion at 5.

development.[25] Studies suggesting a link with autism did not appear until after Novartis transferred the NDA. The opinion provides no guidance as to when a failure to warn would be too attenuated or remote to be the proximate cause of an injury.

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While *T.H. v. Novartis* may not change the shape of product liability law across the country, it certainly represents an expansion of liability in California. Proximate cause is traditionally considered a question of fact that is hard to address at the motion to dismiss stage. Thus, under the court's holding, a brand-name manufacturer is potentially exposed to perpetual liability for its products and the generic equivalents, whether it continues to manufacture the product or not.

Other courts considering these issues should not follow *T.H.*'s lead. Not only does this decision overturn a fundamental tenet of tort law, but it also expands innovator liability well beyond what a brand-name manufacturer can reasonably be expected to control. That expansion—particularly if followed elsewhere—could have consequences as companies consider whether to market innovative and much needed drugs.

[25] *See id.*, slip op. dissenting opinion at 6.