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Never-Ending Liability Under Novartis

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The Evolution of Innovator Liability for Pharmaceutical Manufacturers

Brand-name drug manufacturers are not unfamiliar with the concept of Innovator Liability, under which they can be held liable for injuries caused by a product they did not make. In other words, Innovator Liability holds a manufacturer liable by virtue of being an innovator.

Innovator Liability, usually brought under a failure to warn theory, can be traced back to a 2008 California case, *Conte v. Wyeth, Inc.*, where the Court of Appeal held that a branded drug manufacturer's duty to warn extends to patients taking the generic counterpart. The court reasoned that it is foreseeable that physicians and pharmacists may rely on the brand drug's label to prescribe the drug's generic counterpart for patients.[i] *Conte* has been rebuffed nationwide. By July 2014, more than 100 courts in 49 states, including the U.S. Courts of Appeals for six different circuits, rejected Innovator Liability.[ii] The Supreme Court of Iowa described Innovator Liability as "deep-pocket jurisprudence [which] is law without principle."[iii]

Despite the overwhelming rejection of this theory of law, California continues to breed even more extreme decisions under Innovator Liability. On December 21, 2017, the California Supreme Court decided *T.H. v. Novartis Pharmaceuticals Corp*. (*Novartis*). The court unanimously upheld Innovator Liability against a brand-name drug company *six years after* the company sold all the rights to that drug.[iv] Furthermore, by a 4-3 decision, the court went beyond *Conte* to hold that predecessor drug manufacturers can be held liable, as a matter of law, for their successors' failure to warn, because it is foreseeable that the successor company may be just as negligent as its predecessor in fulfilling the duty to warn.[v]

The *Novartis* decision creates an open-ended, never-ending liability for brand-name drug manufacturers, and calls for new business strategies to avoid, or reduce, the risk of litigation.

The *Novartis* Opinion

The product at issue in *Novartis* was Brethine, a beta-adrenergic agonist used for asthma treatment. Novartis owned the New Drug Application (NDA) of Brethine and manufactured the drug until 2001, when it sold both the drug and its NDA to a successor company.[vi]

In 2007, the plaintiffs' mother was prescribed the generic version of Brethine, terbutaline, for its off-

label use of suppressing premature labor. The mother continued taking terbutaline until the end of a full-term pregnancy and gave birth to twin boys, who were later diagnosed with autism. With their father as Guardian *ad litem*, the twins sued Novartis for failure to warn. Plaintiffs alleged that Novartis knew, or should have known, that Brethine had the effect of penetrating the placental barrier and damaging the fetal brain. Plaintiffs alleged that for many years Brethine had been prescribed for the off-label use of preventing pre-term labor, yet Novartis never updated the drug's label to include the fetal damage side-effect.[vii]

Novartis moved to dismiss the complaint, arguing that, as a matter of law, it did not owe a duty to the plaintiffs because it did not manufacture the drug that the mother took ? terbutaline. Novartis further argued that since 2001 when it sold the NDA of Brethine, it has had no control over the content of Brethine's label. The trial court dismissed the complaint without leave to amend. The appellate court reversed, directing the trial court to grant plaintiffs leave to amend their complaint as to the negligence and negligent misrepresentation claims.[viii] The California Supreme Court granted review to determine a single issue ? whether, and if so, under what circumstances, a brand-name drug manufacturer may be sued under Innovator Liability, when its drug's label was alleged to be deficient, but the plaintiffs were injured by the drug's generic version bearing the same label?[ix]

The Court answered this question affirmatively, and in two parts:

- In the first part, the court held that a branded drug manufacturer's duty to warn extends to consumers of the generic bioequivalent. As in *Conte*, the court based its decision on foreseeability. The court reasoned that if Novartis knew that its label was deficient when it held rights to the drug, it should have foreseen that (1) generic manufacturers would not change the label, because they are required by the FDA to copy the brand drug's label verbatim and (2) physicians or pharmacies would rely on Brethine's label to prescribe terbutaline to patients.[x]

- In the second part, the majority addressed the unique issue with Novartis ? the alleged injury occurred *six years after* Novartis sold the drug and the NDA. The majority held that a predecessor should foresee that its successor may be just as negligent as the predecessor in fulfilling its duty to warn. Noting that 50 percent of Brethine's sales were for the off-label use of preventing premature labor, the majority assumed that Novartis must have been reluctant to include the fetal side-effect in Brethine's warning label for financial reasons. Thus, according to the court, it is foreseeable that the successor will have the same financial disincentive to update the drug's label.[xi]

In the majority's view, a predecessor drug manufacturer and its successor are not categorically distinguishable in their likelihood of being conscientious about their obligations to disclose relevant risks. Under that view, the lapse of time (in this case, six years) from the predecessor's divestiture of the NDA to the time the injury occurred has no bearing on the issue of duty, "which must be addressed at a higher level of generality."[xii]

Risk Considerations for Brand-Name Drug Manufacturers

The *Novartis* decision creates a warning liability "in perpetuity." The majority provides no guidance as to how long a predecessor will be held liable for its successor's business conduct, or whether a predecessor should foresee the potential negligence of only its immediate successor, or of generations of successors. In addition, the court views the prescription drug market as a unique

market “where one entity’s misrepresentations about its own product *foreseeably and legally contributed substantially to* the harm caused by another entity’s product.”[xiii] Under these holdings, branded drug manufacturers are facing potential litigation arising from products they are making, did make in the past, or have never made, and the potential liability will exist, essentially, forever.

Branded drug manufacturers must take actions to protect themselves from future *Novartis*-type litigation. Different strategies can be adopted by companies at different stages with respect to the drug. Companies that are manufacturing the drug and own the NDA need to monitor new scientific developments very closely, and the update of the label should be considered whenever new side-effects are discovered. Companies that already sold the drug and the NDA should continue monitoring scientific developments concerning its former product; this can be done in collaboration with the successor company that bought the drug and the NDA, since the company that acquired the NDA now has the ability to update the drug’s warnings. It provides additional benefits for the companies to establish a dialogue with the FDA regarding their post-marking surveillance on the drug’s side-effects or complications, but of course this needs to be done with extreme caution to avoid being taken as an admission of fault.

Companies that are considering selling their brand-name drugs and divesting the NDAs are at the key stage to take actions to reduce the risk of future *Novartis* liabilities. Several actions can be taken toward that goal:

- First, as the *Novartis* majority advised, indemnification provisions must be in place when the ownership of the NDA is transferred. Although it will not entirely avoid the prospect of extended exposure as the majority assured, an indemnification clause could still help put most of the litigation burden on the actual manufacturer of the drugs ? the generic drug companies.

- Second, predecessor companies need to conduct more careful due diligence on potential buyers, especially on the buyers’ financial resources and approach to safety. It is at least implied in the majority’s opinion that the successor company’s lack of financial means factored into the determination of foreseeability.

- Third, before selling its product and NDA, a predecessor company may consider whether it is feasible to revise the label and include in the warnings as many side-effects as the available scientific evidence suggests. Although there is always a risk that overwarning may cause the consumer to disregard the warning label’s content, it is still an effective way to avoid future failure-to-warn liability.

- Lastly, if financially feasible, drug innovators may consider forming a “special-purpose entity” (SPE) for the development, manufacture and distribution of each drug that carries a high risk of severe side-effects.[xiv] A SPE can take the form of a limited liability company, and can be wound up (*e.*, discontinued) when the parent company decides to sell the drug. The establishment of a SPE may help to legally isolate the parent company of a high-risk project and to allow other investors to take a share of the risk.

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[i] 168 Cal.App.4th 89 (Ct. App. 2008).

[ii] Bexis, Innovator Liability at 100, Drug and Device Law (July 18, 2014). https://www.druganddevicelawblog.com/?s=innovator+liability+at+100

[iii] *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 380 (Iowa 2014).

[iv] 4 Cal.5th 145; 226 Cal.Rptr.3d 336 (2017).

[v] Id.

[vi] *Novartis, supra*, 4 Cal.5th at 158.

[vii] *Id.* at 160-162.

[viii] *Id.* at 161-162.

[ix] *Id.* at 155.

[x] *Id.* at 166-191.

[xi] *Id.* at 183.

[xii] *Id.* at 183-184.

[xiii] *Id.* at 180.

[xiv] Sainati, Tristano; Brookes, Naomi; Loatelli, Giorgio (2016-09-19). "Special Purpose Entities in Megaprojects: empty boxes or real companies? Literature Review." *Project Management Journal*. 48:55-73.

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