Client Update

T.H. v. Novartis: Implications for Companies That Have Sold or Are Considering Selling the Rights to Innovator Drugs

The California Supreme Court's recent decision in *T.H. v. Novartis*[1] further expands the potential liability of innovator pharmaceutical companies in California courts. This decision permits a plaintiff to bring a failure to warn product liability claim against an innovator pharmaceutical company regarding a drug it no longer sells even though the company (i) did not manufacture the drug ingested by the plaintiff and (ii) previously sold rights to the drug to a third party. The decision therefore raises serious questions for innovator pharmaceutical companies that have stopped manufacturing a drug, sold the rights to a third party, or are considering a future sale.

The facts of *T.H.* are straightforward. Until 2001, Novartis manufactured the prescription drug Brethine. Novartis then sold all rights to the drug to aaiPharma. aaiPharma subsequently manufactured and marketed the drug using the label that Novartis had drafted. In 2007, plaintiffs' mother ingested a generic version of the drug (terbutaline) during pregnancy to prevent premature labor. Her twin children—the plaintiffs—allegedly suffered significant harm as a result. Based upon established Supreme Court precedent, the plaintiffs were unable to bring an action against the generic drug company. Instead, the plaintiffs sued Novartis, alleging that Novartis should have changed the drug's label in 2001 based on information then known to the company. Novartis filed a motion seeking to dismiss the case on the basis that it had no duty to plaintiffs because, at the time the mother ingested the drug, Novartis no longer had any rights to the drug and was not manufacturing it. The California Supreme Court disagreed, holding that Novartis could be held liable under a failure to warn theory based on what it knew in 2001.

The court based its decision on the foreseeability of harm. It reasoned that if Novartis knew that its label was deficient when it held rights to the drug, then it was foreseeable that aaiPharma would not change the label after its purchase because warning that the drug posed risks to fetal development could jeopardize a significant portion of the drug's sales. In addition, the court

[1] No. S233898.

stated that it was likely that the plaintiffs' doctor would rely on the innovator's label since, with limited exceptions, generic manufacturers must copy the branded label verbatim.

T.H. expands upon the 2008 California appellate court decision in *Conte v. Wyeth*, which held that an innovator pharmaceutical company could be liable under a failure to warn theory even though the plaintiff took a generic version of the drug. That decision was also predicated on foreseeability: it was foreseeable, according to the court, both that prescriptions for an innovative drug would be filled with a generic version and that the plaintiff's doctor would prescribe the generic drug in reliance on the innovator's label.

Two years later, in *PLIVA v. Mensing*, the U.S. Supreme Court held that federal law preempted a failure to warn product liability claim against a generic manufacturer because a generic manufacturer is not allowed unilaterally to change a drug's label. As a result of this decision, plaintiffs who claim to be injured by a generic drug can bring failure to warn claims only against the innovator (and only in states such as California, where such suits are allowed at all). The *T.H.* decision goes a major step further. It allows a California plaintiff who ingested a generic drug to sue the innovator that designed the label, notwithstanding that the innovator sold its rights to the drug years earlier to another innovator drug company.

The vast majority of states have rejected the type of innovator liability adopted by the California courts. In Alabama, for example, after the state supreme court issued a decision similar to *Conte*, the state legislature overturned that decision. A number of other states have product liability statutes that have been interpreted to preclude innovator liability because they allow plaintiffs to sue only the entity that actually manufactured, distributed or sold the product that is alleged to have caused harm. Federal appellate decisions have similarly recognized an "overwhelming national consensus" that innovators cannot be sued for harm for injuries caused by ingesting generic products. However, because California is the nation's largest state, innovators unfortunately must address the risks posed by *Conte* and now *T.H.*

WHO IS RESPONSIBLE FOR UPDATING THE LABEL OF APPROVED PRESCRIPTION DRUGS TO ADD NEW WARNINGS TO THE LABEL?

Food and Drug Administration ("FDA") regulations provide that if an innovator pharmaceutical company learns—or is informed by the FDA—about a serious risk that is not reflected on the drug's label, then the innovator is obligated to update the label accordingly. An innovator is obligated to update the label to reflect such risks so long as it maintains a New Drug Application ("NDA") with the FDA—regardless of whether it is continuing to manufacture the drug. Changes to innovator drug labels to add or update warnings are typically done through the filing of an NDA Supplement (typically via the "Changes Being Effected" process). Under this process, the innovator generally must notify the FDA at least 30 days before any changes to the label are made. Affirmative FDA approval is not required, but the FDA can object or request other changes. The FDA also conducts its own surveillance of safety data regarding approved drugs

and can require innovators to change their labels to reflect new safety risks if the innovator is unwilling to do so.

For generic drug manufacturers, the situation is complex. If they are manufacturing a drug for which there is a New Drug Application on file with the FDA, the generic typically must follow verbatim the label of the NDA-approved drug. Although the FDA under the Obama Administration issued a proposed rule (known as the "generic drug labeling rule") that would have allowed generics to alter drug labeling, that rulemaking was never finalized due to strong opposition from the generic industry and other stakeholders.

However, a generic does have labeling obligations when an NDA has been withdrawn for reasons unrelated to safety or efficacy. Innovators sometimes withdraw NDAs when they no longer wish to manufacture the drug at issue and do not sell rights to the drug to another entity. If so, there is no longer any innovator "reference listed drug." In such circumstances, the generic company may be obligated to update the label for reasons such as achieving consistency with similar drugs, correcting outdated information, or following recent FDA labeling guidance. Generics may also be required to provide new warnings on drug labels regarding safety risks. Changes made under these circumstances must be implemented via the filing of an NDA Supplement.

WHAT DOES *T.H.* MEAN FOR INNOVATOR DRUG COMPANIES WHO HAVE SOLD THEIR RIGHTS TO A DRUG OR STOPPED MANUFACTURING IT FOR OTHER REASONS?

Innovators who have stopped manufacturing certain drugs (including due to a sale of rights) should consider whether they now face potential liability in light of *T.H.* The risk of a lawsuit is likely to be greatest if the innovator has withdrawn the NDA or sold it to another company that has limited resources. In those circumstances, plaintiffs are likely to look at the innovator as an attractive "deep pocket."

Innovators should consider conducting retrospective reviews of drugs that are most likely to face litigation exposure in light of *T.H.* Such reviews should be done under the leadership of counsel so that any findings are more likely to be protected from discovery by attorney-client privilege. Such a review should include determining what information was known to the company before it sold the drug or withdrew the NDA. In addition, while review of later data should be unnecessary under the rationale relied on by the *T.H.* court, it may be difficult to put the genie back into the bottle. For example, an innovator may have been aware of limited information about a potential risk at the time that it stopped manufacturing the drug, but the full extent of the risk became clear only later. Indeed, that may be the case in *T.H.*, as the court recognized that half of the studies cited in the complaint post-dated Novartis' sale of the rights to the drug. From a risk-mitigation perspective, therefore, it may be prudent to consider data both before and after rights to the drug were sold or the NDA was withdrawn.

What should an innovator do if a retrospective review identifies information that could be fodder for a failure to warn claim? If the company has sold the drug or withdrawn the NDA, then changing the label is not an option. Determining what to do next requires a complex inquiry that should involve input from litigation and regulatory counsel. If the company concludes that the risk is sufficiently high, then it may want to consider the possibility of notifying the successor company (if there is one) or the FDA of its concerns. This might allow the company to argue in subsequent litigation that it had taken reasonable steps to raise awareness about the issue. However, any such notification should be carefully drafted to maximize the likelihood that the court will view it as a subsequent remedial measure and not an admission of liability.

Ultimately, the FDA and a successor manufacturer (if there is one) would have to decide whether to change the label because only they would have access to nonpublic information about the drug that is typically essential to deciding whether a labeling change is necessary. Such information is often confidential and would not be available to an entity that no longer manufactured the drug.

HOW SHOULD FUTURE TRANSACTIONS INVOLVING INNOVATOR DRUGS BE STRUCTURED IN LIGHT OF *T.H.*?

T.H. creates a complicated dynamic for sales of innovator drug rights because such sale no longer automatically extinguishes the risk of a failure to warn claim based on future sales of the drug. One issue that the seller may decide to investigate as part of a potential transaction is the buyer's financial worth and approach to safety. An unspoken factor underlying the *T.H.* decision is that aaiPharma was a small company that went bankrupt less than two years before the events that led to this case. The court may have assumed that if a large, sophisticated company like Novartis was unwilling to change the drug's label, then a small company like aaiPharma certainly would not change the label. Moreover, if the buyer has a drug safety unit that is well regarded in the industry, then the predecessor would have a better argument that it was foreseeable that the buyer would carefully monitor safety data and would update the label as necessary.

Once a buyer is identified, the most practical way for a seller to protect itself against *T.H.*-type litigation is to seek an indemnity. The scope of the indemnity (if any) will have to be negotiated because many buyers will not want to provide open-ended indemnities. One option may be to establish an indemnity for a limited period of time. That should provide the seller with some comfort because with the passage of time, it may become more difficult (although not necessarily impossible) for plaintiffs to allege that their injuries resulted from decisions made many years earlier.

DOES *T.H.* CHANGE AN INNOVATOR DRUG COMPANY'S CALCULATION REGARDING WHAT IT SHOULD DO AFTER GENERIC DRUGS ENTER THE MARKET?

The interplay between *T.H.* and FDA labeling regulations creates a potential incentive for innovators to withdraw NDAs if and when generics take over the market and selling the innovator drug is no longer profitable. While withdrawing the NDA cannot extinguish liability for drug sales prior to the withdrawal, it may reduce the risk of liability going forward. Once an NDA is withdrawn, companies selling generic drugs that relied upon the withdrawn NDA have the ability to change the label. Under such circumstances, the innovator could argue that *T.H.* is distinguishable, and the innovator should not be liable, because the generic now has the ability to alter the label and therefore may be held liable in a failure to warn product liability case.

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Please do not hesitate to contact us with any questions.

NEW YORK

Andrew L. Bab
albab@debevoise.com

Jennifer L. Chu
jlchu@debevoise.com

Mark P. Goodman
mpgoodman@debevoise.com

Maura Kathleen Monaghan
mkmonaghan@debevoise.com

Kevin A. Rinker
karinker@debevoise.com

Jacob W. Stahl
jwstahl@debevoise.com

WASHINGTON, D.C.

Paul D. Rubin
pdrubin@debevoise.com

Melissa B. Runsten
mrunsten@debevoise.com