Products Liability Law Daily Wrap Up, WARNINGS ISSUES—DRUGS—Cal. Sup. Ct.: Novartis could be liable for generic labels of branded drug it no longer owns, (Dec. 27, 2017)

Products Liability Law Daily Wrap Up

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By Dietrich Knauth

In what the dissenting justice called "a more expansive, enduring liability on drug manufacturers than has been recognized elsewhere in tort law," the California Supreme Court held that the original manufacturer of a brand-name drug potentially could be liable for negligent warning labels on a generic version of the drug. The court determined this despite the manufacturer's having sold the rights to manufacture the brand-name drug to another company before the alleged injuries occurred (*T.H. v. Novartis Pharmaceutical Corp.*, December 21, 2017, Cuellar, M.).

Novartis Pharmaceutical Corporation was among the defendants sued by the parents of fraternal twins who allegedly suffered developmental disabilities and autism as a result of their mother's off-label use of terbutaline, a generic form of an asthma drug, Brethine®, to suppress premature labor during her pregnancy. Novartis, the original manufacturer of Brethine, sought a ruling that it could not be liable for negligent labeling because its duty to maintain and update the drug's label—which applied to both the brand-name and generic versions of the drug—had been transferred to another company, aaiPharma Inc., which had purchased the rights to produce the drug from Novartis.

Liability of brand-name manufacturer. The California Supreme Court found that Novartis could be liable for negligent failure to warn claims concerning the drug's risk to fetal brain development, because a label developed before the sale of the drug rights could be foreseeably relied upon by the purchaser of the rights. The court first found that Novartis could be liable for negligent labeling of a generic bioequivalent to its brand-name drug because generic drug manufacturers are legally obligated to use the exact same label used for the brand-name equivalent. The majority found that Novartis's potential liability was not extinguished when it sold ownership of Brethine to aaiPharma six years before the alleged injury to the plaintiffs. While aaiPharma also could be liable for warning label deficiencies, the original manufacturer could be liable at the same time, because it was reasonably foreseeable that a successor drug manufacturer could continue to use the same label it inherited, the court found.

Partial dissent. In a concurring and dissenting opinion, Justice Corrigan pointed out that no other jurisdiction had recognized such an expansive theory of liability for a brand-name drug manufacturer's duty to maintain a warning label for a drug it no longer owned. She also noted that the Food and Drug Administration (FDA) regulations creating the "duty of sameness" are under review and subject to imminent change, based on a proposed rule that would allow generic drug makers to revise their product warning labels and depart from the labeling of the brand-name drug (78 FR 67985, November 13, 2013). According to Corrigan, the majority's holding would unfairly put original manufacturers on the hook for updating labels based on scientific evidence that came to light only after selling the rights to a drug. The ruling could encourage undesirable outcomes such as over-warning of potential harms before the science is in and diminishing a successor manufacturer's incentive to update warning labels, since the original manufacturer could be on the hook for negligent labeling in perpetuity, she wrote.

The case is No. S233898.

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Companies: Novartis Pharmaceuticals Corp.; aaiPharma Inc.

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