Products Liability Law Daily Wrap Up, WARNINGS ISSUES—DRUGS—N.J. Super.: Accutane labels post-April 10, 2002 adequately warned of IBD risks, (Apr. 3, 2015)

Products Liability Law Daily Wrap Up

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By John W. Scanlan, J.D.

Hoffman-La Roche, Inc. and Roche Laboratories provided adequate warnings after April 10, 2002, of the risk of developing Inflammatory Bowel Disease (IBD) from ingesting the drug Accutane, a New Jersey Superior Court held in granting summary judgment to the manufacturers in multicounty litigation related to Accutane. The decision impacts a significant number of New Jersey plaintiffs, but the court held off applying it to plaintiffs in other jurisdictions until counsel could brief the court on the law and required levels of proof in those states (*In re: Accutane Litigation*, April 2, 2015, Johnson, N.).

Background. Working with the FDA, the manufacturers created a new prescribing procedure that was sent to prescribing physicians in January 2002. In order to prescribe Accutane after April 10, 2002, the physicians would have to read a booklet on best practices and to sign a letter affirming their understanding the safe and effective use of Accutane. After this, they would be sent Accutane Qualification Stickers that were required to be attached to Accutane prescriptions, and pharmacists were instructed not to fill prescriptions for Accutane without a sticker.

The Accutane package insert warned, since 1984, that the drug had been associated with IBD. There was a similar warning in a medication guide that pharmacies were required to provide to patients each time a prescription for Accutane was dispensed. Physicians were given patient brochures containing a warning with a consent form that patients were required to sign that affirmed that they had read and understood the safety information provided. Finally, 10-pill blister packs contained warnings accessible when the pills were removed.

Multicounty litigation (MCL 271) is ongoing in New Jersey with over 800 cases involving patients who took the drug Accutane on or after April 10, 2002. In the present proceeding, Hoffman-LaRoche, Inc. and Roche Laboratories, Inc. moved for summary judgment, arguing that their post-April 10, 2002 warnings for Accutane as distributed to prescribing physicians complied with the New Jersey Products Liability Act (NJPLA). The plaintiffs argued that the court was bound by prior rulings of the previous judge in the MCL regarding the adequacy of the warnings that established the law of the case.

Law of the case. Although the predecessor judge in the Accutane MCL previously had denied four of the manufacturers' motions on the adequacy of warnings, the present court declined to follow these rulings because there were new facts and law not available at the time they were issued. In *Bailey v. Wyeth, Inc.*, 424 *N.J. Super.* 278 (Law Div. 2008), the court found that New Jersey Rule of Evidence 301, *Effect of Presumption*, was not controlling on the plaintiffs' burden of overcoming a rebuttable presumption. This ruling was affirmed as being "legally unassailable" by *DeBoard v. Wyeth, Inc.*, 422 *N.J. Super.* 360 (App. Div. 2011). Both cases were approved for publication in September 2011, and the present court found them to be the new controlling authority in this case. Therefore, the court said it would not follow the decisions of the MCL court's predecessor judge.

Rebuttable presumption of adequacy. The court granted summary judgment to the manufacturers because the plaintiffs did not carry their burden of rebutting the presumption that the warning was adequate. The NJPLA provides that drug manufacturers that comply with FDA regulations are entitled to a rebuttable presumption of adequate labeling. To overcome this presumption, a plaintiff must prove either deliberate concealment/nondisclosure of after-acquired knowledge of harmful effects or manipulation of the post-market regulatory process. Although the plaintiffs asserted in their brief that there had been an economically-motivated manipulation of the post-marketing regulatory process and that it had been proven that the manufacturers

had a strategy to downplay the risk of IBD, the court observed that in three previous trials the MCL court had expressly found that the proof to support these assertions did not exist. Examining the warnings provided by the manufacturer, the court determined that they conveyed an unmistakable meaning about potential risks and consequences, and the court found it "inconceivable" that any dermatologist or physician of ordinary education, training, and experience could examine the warning literature and not conclude immediately that Accutane was associated with IBD.

Other jurisdictions. The court announced that it would limit initially the effects of the present decision to New Jersey plaintiffs only. It directed counsel to prepare briefs identifying the jurisdictions in which post-April 2002 warnings claims arise, which of those jurisdictions recognize the learned intermediary doctrine and which permit adequacy of drug label warnings to be decided as a matter of law, and which jurisdictions require a heavier burden of proof than New Jersey. Claims from jurisdictions requiring a heavier burden of proof must fail, the court said.

The case is No. 271 (MCL).

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