Sills Cummis & Gross P.C.

Client Alert **Product Liability Law**

Bailey v. Wyeth, Inc. and *DeBoard v. Wyeth, Inc.*

New Jersey Product Liability Act's Presumption that FDA-Approved Warnings Are Adequate

After more than three years, the New Jersey Appellate Division affirmed a very important trial court decision dismissing two cases in the New Jersey Hormone Replacement Therapy ("HRT") litigation. In these cases, the trial court granted defendants' motion for summary judgment holding that plaintiffs failed to rebut the presumption contained in the New Jersey Product Liability Act, *N.J.S.A.* 2A:58C-1, *et seq.* ("PLA"), that warnings approved by the Food and Drug Administration ("FDA") are adequate as a matter of law. *See Bailey v. Wyeth, Inc.*, 2008 N.J. Super. LEXIS 313 (Law Div. July 11, 2008), *aff'd sub. nom. DeBoard v. Wyeth, Inc.*, 2011 N.J. Super. LEXIS 177 (App. Div. Sept. 29, 2011).

The plaintiffs in these two HRT cases, as in many of the other HRT cases pending in New Jersey and elsewhere, alleged that they developed breast cancer as a result of using various hormonal drug products to treat symptoms associated with menopause. Plaintiffs primarily asserted that the products were defective under the PLA because the defendant manufacturers failed to include an adequate warning of the risk of breast cancer. Wyeth moved for summary judgment relying on, among other things, *N.J.S.A.* 2A:58C-4, which sets forth the standard for determining the adequacy of a warning or instruction. This section of the PLA contains a rebuttable presumption to the effect that "[i]f the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration . . . a rebuttable presumption shall arise that the warning or instruction is adequate."

October
2011

In evaluating whether Wyeth was entitled to summary judgment, the trial court made two important preliminary rulings. First, the trial court determined that the adequacy of the warning could be determined as a matter of law. *See Bailey v. Wyeth, Inc.*, 2008 N.J. Super. LEXIS 313, at *48-49. Second, the trial court evaluated the nature and quantum of evidence needed to rebut the presumption. The trial court rejected plaintiffs' argument that the court was required to follow New Jersey Rule of Evidence 301, which provides that ordinary presumptions can be rebutted by showing some evidence tending to disprove the presumed fact. Instead, the trial court held that plaintiffs could rebut the presumption only through compelling or substantial evidence of: (1) deliberate concealment or non-disclosure of after-acquired knowledge of the drug's harmful effects, or (2) manipulation of the post-market regulatory process. *Id.* at *51 (citing *Rowe v. Hoffman-La Roche, Inc.*, 189 N.J. 615, 626); *Perez v. Wyeth Lab., Inc.*, 161 N.J. 1, 25 (1999); *McDarby v. Merck & Co., Inc.*, 401 N.J. Super. 10 (App. Div. 2008)).

Applying these standards, the trial court analyzed the regulatory history of the HRT products involved in the case and held that the FDA had been extensively involved in the labeling and safety monitoring of these medicines for several decades and had the express authority to mandate labeling changes if so warranted. The trial court found that plaintiffs had failed to present any evidence of deliberate concealment or non-disclosure of after-acquired knowledge by the defendants in the preapproval period. *Id.* at *55-56. Moreover, the trial court determined that plaintiffs had not presented a triable issue of potential manipulation by the defendants of the post-market approval regulatory process. The trial court rejected plaintiffs' arguments of manipulation through failure to adequately test the drugs, placing alleged misrepresentations in the drug label, and manipulating the regulatory process through "ghost writing" of peer reviewed articles concerning the safety and efficacy of the medications. *Id.* at *61-72. Having found that plaintiffs had failed as a matter of law to overcome the presumption of adequacy, the trial court granted defendants' motion for summary judgment ruling that the FDA approved warnings were adequate as a matter of law. *Id.* at *78.

In affirming the trial court, the Appellate Division adopted the trial court's "well-considered and exhaustive opinion". *DeBoard*, 2011 N.J. Super. LEXIS 177, at *4. In so doing, the Appellate Division further determined that the trial court properly rejected plaintiffs argument, seeking to extend the reasoning in *McDarby v. Merck & Co., Inc.*, 401 N.J. Super. 10 (App. Div. 2008), that the presumption of adequacy could be overcome by demonstrating that further testing, if voluntarily undertaken, would have disclosed an increased risk from taking the drugs at issue. This is a

major victory for pharmaceutical manufacturers seeking to apply the PLA's rebuttable presumption of adequacy in failure to warn cases as trial courts across the state will now by bound by the *Bailey/DeBoard* decision. Although the plaintiffs will likely seek further appellate review from the New Jersey Supreme Court, defendants should seek to apply its holding to other appropriate pharmaceutical and medical device cases.

If you would like additional information, please contact:

Beth S. Rose, Esq.
Chair, Product Liability Practice Group
brose@sillscummis.com | (973) 643-5877

Charles J. Falletta, Esq.
Member and Client Alert Editor, Product Liability Practice Group
cfalletta@sillscummis.com | (973) 643-5926