DechertOnPoint

July 2008 / Issue 45

A legal update from Dechert's Mass Torts and Product Liability Group

New Jersey Court Rules HRT Labeling Adequate as a Matter of Law

On July 11, 2008, the mass tort judge handling hormone replacement cases in New Jersey granted summary judgment dismissing *Bailey v. Wyeth*, No. L-999-06 MT (N.J. Super.), ruling that the labels used by defendants Wyeth and Upjohn were adequate as a matter of law. The failure to warn claims were dismissed because the plaintiffs could not overcome the presumption of adequacy of FDA-approved labels created by the New Jersey Products Liability Act (NJ PLA). The claims for fraud, negligent misrepresentation, and consumer fraud likewise failed because they are subsumed by the NJ PLA and could not be asserted as independent causes of action. The decision may have far-reaching significance for many drug failure to warn claims governed by New Jersey law.

The court reviewed in detail the prior New Jersey case law concerning the statutory presumption of adequacy:

> Presently, the presumption of an adequate warning based on compliance with FDA regulations will be deemed rebutted only if the following proof is presented: (i) deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects ("*Perez/Rowe* exception") or (ii) manipulation of the post-market regulatory process ("*McDarby* exception").[1]

Absent such evidence, "compliance with FDA standards should be virtually dispositive of a failure to warn claim."[2] The New Jersey intermediate appellate court that announced the "*McDarby* exception" to the presumption of adequacy earlier this year acknowledged that it was a "hitherto unrecognized legal basis" for liability under the NJ PLA. This exception is currently on appeal to the New Jersey Supreme Court.

The plaintiffs could not offer evidence satisfying either exception. The plaintiffs' expert conceded that there is no evidence that the defendants withheld from the FDA any information on safety prior to the approval of the drug labels,[3] nor did the plaintiffs present evidence that post-approval knowledge was concealed or manipulated. Far from it, the court noted that the FDA had considered the potential risks of breast cancer associated with the drug and that "[t]he FDA decision not to include a more specific breast cancer warning in its labeling guidelines or guidance was both deliberate and informed."[4] The court also firmly rejected the plaintiffs' argument that the presumption of adequacy can be overcome by showing that

1 Slip Op. at 30-31.

2 *Id.*

3 *Id.* at 34.

4 *Id.* at 47.

the drug company should have done additional tests, the results of which would have altered the FDA's decisions:

> If the court were to accept plaintiffs' theory that Wyeth failed to test before filing its NDA, then in any failure to warn case, the presumption of adequacy accorded an FDA-approved drug labeling could be nullified by a plaintiff contending that the FDA would have approved a different warning had the defendant manufacturer done additional tests before filing its NDA.[5]

Mere failure to test does not constitute "concealment" or "manipulation,"[6] nor does initiating or "ghostwriting" truthful, peer-reviewed medical articles.[7] The court also concluded that off-label use of the drug with the knowledge of the FDA could not overcome the presumption of adequacy.[8]

The court also disagreed with the plaintiffs' argument that the statutory presumption applies only to drug cases involving direct-to-consumer advertising, ruling that presumption applies to all FDA-approved labels.[9] The court further rejected the plaintiffs' argument that the presumption disappears in the face of any controverting evidence. Instead, a plaintiff must offer "substantial evidence" to overcome the presumption.[10] Expert testimony is not enough.[11]

More broadly, the court concluded that a drug company's right to alter its label under the "changes being effected" regulation is limited to "newly discovered risks" not previously known by the FDA.[12]

The court's grant of summary judgment has important implications for other drug failure to warn cases governed by New Jersey law. First, the ruling reinforces the significant hurdle plaintiffs will have to clear to overcome the statutory presumption of adequacy of FDA-approved labels. New Jersey courts may be reasonably strict in both the type and quantum of evidence needed to rebut the presumption. Second, the ruling reflects an increased understanding of and deference to the extensive role of the FDA in reviewing and approving drug labels both before and after initial approval. This deference may be important not only in applying the NJ PLA's presumption of adequacy, but in applying principles of conflict preemption as well.

To view a copy of the court's full decision, visit www.judiciary.state.nj.us/mass-tort/hrt/hrt_bailey_opinion_july_2008.pdf.

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5 *Id.* at 36-37.

6 *Id.* at 36-37.

7 *Id.* at 38-39.

8 *Id.* at 42-43.

9 *Id.* at 31-32.

10 *Id.* at 31.

11 *Id.*

12 *Id.* at 9.

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