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NEW JERSEY HRT JUDGE HANDS FAILURE-TO-WARN VICTORY TO DEFENDANTS

In a significant decision for pharmaceutical and medical device manufacturers facing failure-to-warn product liability suits in New Jersey, Judge Jamie D. Happas of the Superior Court of New Jersey granted summary judgment to the defendants in the first two Hormone Replacement Therapy (“HRT”) cases scheduled for trial from among the cases designated as part of New Jersey’s HRT mass tort. Finding that plaintiffs’ non-Products Liability Act (“PLA”) claims were subsumed by the New Jersey PLA, and thus that all of plaintiffs’ claims should be adjudicated under the PLA, Judge Happas held in Dora Bailey v. Wyeth, Inc., et al., MID-L-999-06 (July 11, 2008), that plaintiffs had failed to provide the specific type of evidence necessary to overcome the PLA’s rebuttable presumption that FDA-approved labeling is adequate as a matter of law.

First, relying on recent decisions by the New Jersey Supreme Court in Sinclair v. Merck, 195 N.J. 51 (2008), and by the Appellate Division of the New Jersey Superior Court in McDarby v. Merck & Co., Inc., 401 N.J. Super. 10 (App. Div. 2008), Judge Happas ruled that all of plaintiffs’ claims – both those proffered under the PLA and those proffered under alternative theories, such as the New Jersey Consumer Fraud Act (“CFA”) and fraudulent and negligent concealment – were subsumed by the PLA, and thus should be adjudicated under the PLA’s statutory framework. In other words, plaintiffs’ cases turned on whether they could successfully maintain their failure-to-warn claims under the PLA.

Turning to the substantive provisions of the PLA, Judge Happas recognized that the PLA

affords a presumption of adequacy to a pharmaceutical label that has been approved by the FDA. Specifically, the PLA provides, “[i]f the warning or instruction given in connection with a drug ... has been approved or prescribed by the federal Food and Drug Administration under the ‘Federal Food, Drug, and Cosmetic Act,’ a rebuttable presumption shall arise that the warning or instruction is adequate.” Again drawing on several recent decisions from the Supreme Court and the Appellate Division, Judge Happas held that plaintiffs could overcome this presumption only by presenting substantial or compelling evidence of (i) deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, and/or (ii) manipulation of the post-market regulatory process. See Perez v. Wyeth Lab., Inc., 161 N.J. 1 (1999); Rowe v. Hoffman-La Roche, Inc., 189 N.J. 615 (2007), and McDarby, 401 N.J. Super. at 63. After carefully examining plaintiffs’ proffered evidence, Judge Happas concluded that it did not rise to a level sufficient to rebut the PLA’s presumption of adequacy. In so doing, Judge Happas also rejected plaintiffs’ assertion that the defendants should have conducted additional testing prior to submitting the drugs to the FDA for approval, recognizing that to accept plaintiffs’ argument would eviscerate the PLA’s presumption of adequacy because a plaintiff could always claim that the FDA would have required and approved a different label had it been provided with additional testing.

Judge Happas’ decision is a significant one, not only for the defendants facing HRT claims, but for all drug and device manufacturers facing failure-to-warn suits in New Jersey. As her ruling makes clear, if the FDA

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has approved a drug's label and the warnings contained therein, a plaintiff in New Jersey must come forth with compelling or substantial evidence showing either (i) deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, or (ii) manipulation of the post-market regulatory process. If a plaintiff fails to make this showing, that plaintiff's failure-to-warn claim will fail in New Jersey.

Given the import of this ruling – especially the direct effect it may have on all of the other pending HRT cases in New Jersey – we anticipate the likelihood of an appeal to the New Jersey Appellate Division. If such an appeal is taken, we expect this decision will continue to draw attention, not only from the parties involved, but also from various amici as well.

Authored by H. Lockwood Miller, III and Jonathan F. Donath

Current Mass Torts in New Jersey

<i>Accutane</i>	<i>J. Higbee, Atlantic County</i>
<i>Asbestos</i>	<i>J. McCormick, Middlesex County</i>
<i>Bextra/Celebrex</i>	<i>J. Higbee, Atlantic County</i>
<i>Ciba-Geigy</i>	<i>J. McCormick, Middlesex County</i>
<i>Depo-Provera</i>	<i>J. Harris, Bergen County</i>
<i>Gadolinium</i>	<i>J. Happs, Middlesex County</i>
<i>HRT</i>	<i>J. Happs, Middlesex County</i>
<i>Mahwah Toxic Dump Site</i>	<i>J. Harris, Bergen County</i>
<i>Ortho Evra</i>	<i>J. Happs, Middlesex County</i>
<i>Risperdal/Seroquel/Zyprexa</i>	<i>J. Happs, Middlesex County</i>
<i>Vioxx</i>	<i>J. Higbee, Atlantic County</i>
<i>Zometa/Aredia</i>	<i>J. Higbee, Atlantic County</i>

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