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*An Update from the Pharmaceutical  
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# PRODUCTIVELY Thinking

June/2008, No. 5

## MIXED RESULTS FOR DRUG MAKERS IN LANDMARK APPEAL OF TWO NEW JERSEY VIOXX VERDICTS

On May 29, 2008, in *McDarby v. Merck & Co.*, \_\_\_ N.J. Super. \_\_\_ (App. Div. 2008), the New Jersey Appellate Division issued a published opinion with significant implications for pharmaceutical product liability litigation. At trial, the claims of plaintiffs McDarby and Cona were tried together. The jury found for McDarby on product liability (failure to warn) and consumer fraud claims, awarding \$15.7 million in compensatory and punitive damages and attorneys' fees and costs. The jury rejected Cona's product liability (failure to warn) claim – finding that Vioxx did not cause him any physical injuries – but did award \$2.27 million in compensatory and punitive damages and attorneys' fees and costs on a consumer fraud claim. Merck appealed both judgments and the court issued one opinion addressing both appeals. After an extended statement of facts as to the development, approval, marketing, and withdrawal of Vioxx, which the court viewed “as necessary to place in perspective the issues regarding the applicability of the New Jersey Product Liability Act (PLA) . . . and the New Jersey Consumer Fraud Act (CFA),” the court addressed several important issues for pharmaceutical manufacturers facing product-related claims in New Jersey:

In a boon for plaintiffs, the court first held that the PLA was not preempted by federal law or recent FDA regulatory statements. The court found that a failure-to-warn claim was neither expressly nor impliedly preempted because drug makers may revise drug labeling to include additional warning information without FDA pre-approval. The court also rejected the notion that the FDA's pro-preemption statement in the Preamble to “Requirements on

Content and Format of Labeling for Human Prescription Drug and Biological Products,” 71 Fed. Reg. 3922, 3933-36 (Jan. 24, 2006), was entitled to preemptive effect. The court based its rejection on a number of factors, including that manufacturers can, under existing FDA regulations, supplement label warning information without violating federal law, that the Preamble language was not subject to notice and comment rulemaking, and that the FDA's newly espoused broad preemption view would contradict past agency history and thwart traditional state police powers.

The court again favored plaintiffs in addressing the presumption, in pharmaceutical failure-to-warn cases in New Jersey, that an FDA-approved warning is adequate absent evidence of “deliberate concealment or non-disclosure” on the part of the drug maker. Making new law, the court added a third basis on which to rebut the presumption of adequacy: “Merck's economically-driven manipulation of the post-market regulatory process.” Unfortunately, while the court explained at length its decision to adopt this new exception, it failed to articulate a succinct statement of what, exactly, the basis of the exception should be.

After some case-specific evidential determinations, the court next reaffirmed the applicability of the “heeding presumption” to pharmaceutical failure-to-warn cases, finding no persuasive reasons to depart from prior caselaw that applied the heeding presumption to assist plaintiffs in proving that a lack of an adequate warning caused injury. The court also determined that “but for” medical causation was not required in pharmaceutical product liability

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ity cases in which multiple concurrent factors could have had causal responsibility for the alleged injury. Instead, the court held that “substantial factor” causation, as instructed by the trial court, was the appropriate standard.

In a significant victory for defendants, however, the court ruled that plaintiffs’ punitive damages claims were preempted by federal law. The PLA precludes punitive damages for FDA-approved prescription drugs unless the “manufacturer knowingly withheld or misrepresented information required to be submitted under the agency’s regulations, which information was material and relevant to the harm in question[.]” The court recognized that this exception was akin to the “fraud on the FDA” claims that were preempted in Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341 (2001) and, accordingly, reversed the punitive damage awards against Merck. This argument – that punitive damage claims for FDA-approved prescription drugs should not be allowed to proceed in light of Buckman – has often been presented to New Jersey courts in the past several years, and this decision will give it significantly more preclusive weight.

In a second significant victory for defendants, the court also held that plaintiffs’ CFA claims, the basis for which was the same as plaintiffs’ failure-to-warn claims, could not be pursued separately and were instead subsumed within plaintiffs’ PLA claims. This is a particularly significant ruling because, while the economic loss damages often alleged by CFA plaintiffs are not substantial, a successful CFA claim entitles the plaintiff to recover attorneys’ fees and costs. (Here, for example, the compensatory award to McDarby was \$3968 before trebling, but attorneys’ fees and costs were nearly \$1.8 million; likewise, Cona’s pre-trebling compensatory award was \$45, but attorneys’ fees and costs exceeded \$2.4 million.) The possibility of recovering attorneys’ fees and costs is what has made CFA claims particularly appealing to plaintiffs – and particularly troubling to defendants – in recent years, and this ruling should

substantially quell much of that unease.

## IMPACT ON NEW JERSEY DEFENDANTS

Several of the court’s rulings will have an impact on pharmaceutical defendants facing failure-to-warn claims in New Jersey. In particular, New Jersey drug and device defendants will benefit from significant victories as to punitive damages and CFA claims.

*Authored by H. Lockwood Miller, III, Esq.*

### *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>Zometia/Aredia</i>	<i>J. Higbee, Atlantic County</i>

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