

# The Presumption of Adequacy Arising From FDA-Approved Labels

## Does *McDarby* Establish the Proofs Needed to Overcome the Presumption?

by Alan H. Sklarsky

While the United States Supreme Court grapples with sweeping preemption arguments by the pharmaceutical industry in *Wyeth v Levine*,<sup>1</sup> on another level New Jersey courts have been deciding just how much deference they should afford FDA-approved labeling when weighing the rebuttable presumption of adequacy afforded by New Jersey's Product Liability Act (PLA).<sup>2</sup> Since the inception of the PLA, few New Jersey courts have had occasion to specifically address the operation and effect of the rebuttable presumption. This changed recently with the Appellate Division's decision in *McDarby v Merck & Co., Inc.*<sup>3</sup>

In March 2000, John McDarby visited his family physician seeking treatment for osteoarthritis. His doctor prescribed Vioxx, which McDarby continued to take daily until suffering a heart attack in April 2004. The initially approved labeling in 1999 contained no warning of cardiovascular risk. Vioxx had been developed to provide the same relief afforded by traditional NSAIDs, but without the risk of gastrointestinal complications. Because Merck had not substantiated its gastrointestinal claims, the FDA did not permit Merck to make such claims in its initial labeling, but left the door open for label revision in the event additional information became available.

Thus, in a subsequent study known as the VIGOR study, Merck demonstrated that Vioxx did, in fact, provide gastrointestinal protection. But the study also revealed that users of Vioxx had five times more heart attacks than those on naproxen. Merck contended that the higher rate of heart attacks in the group was not due to Vioxx, but was instead the result of the cardio-protective qualities of naproxen, similar to the effectiveness of aspirin in preventing heart attacks. However, at trial, evidence was adduced to show that Merck's scientists had been unable to locate appropriately focused studies that supported its theory that naproxen was cardio-protective.<sup>4</sup> Nonetheless, Merck succeeded in convincing the FDA that revised labeling need not mention cardiovascular risk in the warnings section. Instead, the FDA only required a statement in the precaution section that limited use of Vioxx only among patients "with a medical history of ischemic heart disease—patients whose already-diagnosed coronary artery disease was symptomatic."<sup>5</sup> Merck continued to market Vioxx with the revised label until September 2004, when it voluntarily withdrew it from the market as a result of evidence of cardiovascular events reported in Merck's APPROVe study.<sup>6</sup>

The jury returned a verdict in favor of the plaintiffs, awarding \$4.5-

million compensatory damages and \$9 million in punitive damages.<sup>7</sup> In its opinion, which affirmed in part and reversed in part that verdict, the Appellate Division analyzed in great detail the plaintiffs' proofs establishing Merck's understanding of the potential cardiovascular risk at the time the drug was first approved; its marketing of the drug without warning of the risk; its failure to include a cardiovascular warning after learning the results of the VIGOR study; and its campaign to convince the FDA that a warning of cardiovascular risk was unwarranted.

### WHAT IS THE REBUTTABLE PRESUMPTION OF ADEQUACY?

Of the many issues raised in this case, Merck, on appeal, contended that the trial judge failed to give proper effect to the PLA's presumption of adequacy for prescription drug warnings approved by the FDA. FDA approval under the PLA creates a rebuttal presumption that the warning is adequate. More specifically, the act provides 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 [FDA], a rebuttable presumption shall arise that the warning or instruction is adequate."<sup>8</sup> This section of the statute creating a "rebuttable presumption" was enacted in 1987 as part of the NJPLA. The purpose of the act has been described

as an attempt to limit the liability of manufacturers to balance the interests of the public and the individual with a view toward economic reality.<sup>9</sup> But nothing in the legislative history provides any insight into why a rebuttable presumption was chosen as opposed to a more conclusive standard, or how the presumption should be applied at the trial level.<sup>10</sup>

Without any legislative history for guidance or statutory language setting forth the effect and operation of the rebuttable presumption, disagreement exists regarding the degree of deference trial courts owe to the statutory presumption of adequacy. The New Jersey Supreme Court first addressed the rebuttable presumption in *Feldman v. Lederle Labs (Feldman II)*,<sup>11</sup> where the defendant argued that on retrial, the plaintiff would not be able to prevail as a result of the presumption of adequacy created by the statute. The plaintiff sought damages based on the pharmaceutical company's failure to incorporate a tooth discoloration warning on its antibiotic, Declomycin. The Court rejected the defendant's view as "overstat[ing] the import of the statute."<sup>12</sup>

In turn, the Court held:

The actual effect of the statute, however, is less clear. Its plain language defies the conclusion that the presumption cannot be overcome. Once the determination goes to the jurors, irrespective of an instruction for the court, they are free to disregard evidence of "approval" by the FDA.<sup>13</sup>

The *Feldman* Court further pointed out that, at the time the PLA was enacted, federal regulations required drug companies to revise warnings as soon as they learned of adverse side effects based on "reasonable evidence." Such language suggests that so long as a plaintiff comes forward with reasonable evidence to establish that the approved warning was not adequate, the jury is free to disre-

gard the evidence of FDA approval. This approach comports with New Jersey's evidence rules concerning presumptions, which provides that "if evidence is introduced tending to disprove the presumed fact, the issue shall be submitted to the trier of fact for determination..."<sup>14</sup>

If *Feldman II* lacked clarity regarding what standard should be applied, further uncertainty later resulted from the Court's *dictum* in *Perez v. Wyeth Labs, Inc.*<sup>15</sup> In addressing direct-to-consumer advertising, the Court in *Perez* observed that "for all practical purposes, absent deliberate concealment or non-disclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive" in a failure to warn case. More recently, that language again appeared in *Rowe v. Hoffman-LaRoche, Inc.*<sup>16</sup> However, neither *Perez* nor *Rowe* comment on the standards discussed in *Feldman II* or indicate that *Feldman II* should be disregarded or modified.

#### THE TRIAL COURT IN *MCDARBY* CHOOSES A MIDDLE GROUND

With this background in mind, the trial court in *McDarby* faced the question of how, if at all, to charge the jury on the proof necessary to overcome the presumption of adequacy contained in the PLA. Merck urged the court to charge the *Perez* standard, while the plaintiff contended that the evidence rules, specifically N.J.R.E. 301 governing presumptions and their rebuttal, outlined the procedures to be followed where one party, as here, simply receives the benefit of one. The trial judge, however, chose another route, charging the jury that in order for the plaintiffs to overcome the presumption of adequacy, the plaintiffs had to produce "substantial evidence" that the approved label was not an adequate warning.<sup>17</sup>

Merck, on appeal, reiterated its objections to the instructions given to the jury, and claimed that the

rebuttable presumption of adequacy set forth in the PLA precludes liability as a result of the language in *Perez*, limiting exceptions to instances of deliberate concealment or non-disclosure. Merck contended that the proofs were insufficient to establish deliberate concealment or nondisclosure since Merck submitted the results of the VIGOR study in a timely fashion and the FDA was aware of those results when it approved the revised Vioxx label. The Appellate Division disagreed, concluding that the Court in *Perez* did not intend to restrict liability to only cases involving deliberate concealment or nondisclosure.

The panel wrote:

...we are unwilling to construe the presumption as Merck urges, finding the record in this case to be sufficient to support the recognition of an additional basis for overcoming the presumption of adequacy set forth in the PLA, applicable to Merck in the post-market warning context presented here. Specifically, we do not rest our decision to recognize this compensatory damage claim as one of "those rare cases when the presumption [of warning adequacy] is overcome," *Perez, supra*, 161 N.J. at 25, upon any claim of fraud on the FDA, thereby implicating the punitive damage aspects of the PLA. Our focus rests solely upon plaintiffs' claims of Merck's economically driven manipulation of the post-market regulatory process.<sup>18</sup>

The panel further noted that *Perez* was decided well before disclosure of flaws in the FDA's regulatory system, rendering "the dictum of *Perez* less all-encompassing than it might then have appeared."<sup>19</sup> Accordingly, the panel concluded that "[f]acts unavailable to the Supreme Court at the time of the *Perez* decision demonstrate that such a restriction is too narrow."<sup>20</sup>

While finding that evidence of "economically driven manipulation of the post-market regulatory process" was sufficient to overcome

the presumption of adequacy, the panel did not require the trial court to give a specific instruction on this standard. On the contrary, the panel held that “[t]he instruction at issue adequately informed the jury that the presumption of adequacy could only be overcome by ‘substantial evidence,’ thereby according the presumption a significance greater than would otherwise be the case, while not according it conclusive effect.”<sup>21</sup>

Merck filed a petition for certification with the New Jersey Supreme Court, seeking review of numerous issues, including the Appellate Division’s failure to adhere to the *Perez/Rowe* standard. On Oct. 8, 2008, the Supreme Court granted Merck’s petition, but limited solely to the issue of whether federal preemption precludes liability, thus leaving intact the Appellate Division’s decision as it relates to the PLA’s presumption of adequacy.

#### **DOES MCDARBY END THE DEBATE?**

The debate continues over what showing is required to rebut the presumption and what charge must be given to the jury. Pharmaceutical companies are likely to contend that *McDarby*, at most, establishes an additional exception to the *Perez* standard—economically driven manipulation of the post-market regulatory process. Plaintiffs will contend that the affirmance of the trial court’s jury instruction and the Supreme Court’s decision to deny certification on this issue establishes “substantial evidence” as the appropriate standard.

A question remains, however, regarding whether the Appellate Division in *McDarby* was simply creating a new exception to the presumption of adequacy or merely analyzing the specific facts of the case and finding evidence of economically driven manipulation of the post-market regulatory process to be adequate to overcome the presumption. But the larger question is whether, in the absence of

express language, the Legislature intended to restrict liability to limited exceptions, and thereby prevent injured parties from recovery where a drug company fails to do everything it needs to do or could have done to warn doctors and patients about the dangers of its products. ■

#### **ENDNOTES**

1. On Nov. 3, 2008, the Court heard arguments regarding whether pharmaceutical companies should be given a blanket shield from accountability for injuries caused by their drugs on federal preemption grounds. *Wyeth v. Levine*, 944 A.2d 179 (VT 2006) *cert. granted*, 128 S. Ct. 1118 (2008).
2. N.J.S.A. 2A:58C-4.
3. 401 N.J. Super. 10 (App. Div. 2008), *cert. granted*, \_\_ N.J. \_\_ 2008 (petition for certification granted limited solely to the issue of whether federal preemption applies.
4. *Id.* at 30.
5. *Id.* at 47.
6. *Id.* at 48.
7. While beyond the scope of this article, the Appellate Division also rejected Merck’s federal preemption arguments, and ruled that the use of a heeding presumption is applicable in pharmaceutical cases. Merck was successful in reversing the punitive damages award as preempted by the FDCA. The court also found that plaintiffs were improperly awarded damages and attorneys’ fees under the New Jersey Consumer Fraud Act (CFA), as those claims were subsumed within the PLA. The New Jersey Supreme Court has granted Merck’s petition for certification limited solely to the issue of whether the FDCA preempts state law tort claims. *McDarby v. Merck*, C-204 September term 2008.
8. N.J.S.A. 2A:58C-4.
9. *Zazz v. Marquess & Neil, Inc.*, 144 N.J. 34, 47-48 (1996).
10. *See, Rowe v. Hoffman-LaRoche, Inc.* 189 N.J. 615 (2007) (legislative history of NJPLA does not specifically address why the legislature created only a rebuttable presumption).
11. *Feldman v. Lederle Labs (Feldman II)*, 125 N.J. 117 (1991).
12. *Id.* at 156.
13. *Id.* at 157.
14. N.J.R.E. 301.
15. 161 N.J. 1, 25 (1999).
16. 189 N.J. 615, 626 (2007).
17. *McDarby*, 401 N.J. Super. at 69-71.
18. *Id.* at 63.
19. *Id.* at 64.
20. *Id.* at 66.
21. *Id.* at 71.

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