Legal Opinion Letter

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COURT ENDORSES TORT DEFENSES IN DIET DRUG LITIGATION

by
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In a series of decisions important to pharmaceutical, biotech, and other medical product industries, a Pennsylvania court recently dismissed several product liability actions seeking compensation for alleged failure to warn of the side effects of diet drugs based upon a lack of proximate causation and the learned intermediary doctrine. *See Anderson v. Wyeth, et al*., 2005 WL 138174 (Phila. CCP. June 7, 2005); *Adams v. Wyeth, et al.*, 2005 WL 1528656 (Phila. CCP June 13, 2005); *Berry v. Wyeth, et al*., 2005 WL 1431742 (Phila. CCP June 13, 2005). The Honorable Norman Ackerman, coordinating judge of Philadelphia's Complex Litigation Center, granted motions for summary judgment to Wyeth Pharmaceuticals in three cases in which the plaintiffs failed to show that the prescribing physician would not have prescribed the diet drugs had he or she received a warning from Wyeth as to their possible side effects. These decisions, which are on appeal, set a firm burden of proof that plaintiffs must satisfy in order to get to a jury in actions against pharmaceutical manufacturers.

In each of the three cases, physicians prescribed Wyeth's diet drugs, Pondimin or Redux to the plaintiffs. The plaintiffs alleged that they developed heart valve regurgitation as a result of their ingesting Wyeth's diet drugs. The plaintiffs further alleged that Wyeth's negligence caused their injuries because it failed to warn of heart valve regurgitation as a possible side effect of the diet drugs. The plaintiffs pursued negligence claims because Pennsylvania does not allow strict liability claims against pharmaceutical manufacturers.

Pennsylvania's negligence requirements and learned intermediary doctrine are typical of most jurisdictions. A "manufacturer [of prescription drugs] is liable only if he fails to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous." *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984). Under the learned

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intermediary doctrine, a pharmaceutical manufacturer owes a duty to warn only to the prescribing physician and not to the patient or general public. *See Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971). Accordingly, under the law of Pennsylvania and many other states, the plaintiff must establish proximate causation by showing that had the pharmaceutical defendant issued a warning to the prescribing physician as the learned intermediary, he or she would have altered their prescribing behavior and the injury would have been avoided.

In each of the three cases at hand, the court granted summary judgment because the plaintiff failed to secure any testimony from the prescribing physicians that they would not have prescribed the diet drugs to the plaintiffs if they had known that heart regurgitation was a possible side effect. In *Anderson*, the prescribing physician was deceased. In *Adams*, the prescribing physician could not be located and was assumed deceased by the plaintiff. In *Berry*, there were two prescribing physicians: (1) one physician was never deposed and lived in Russia making him "virtually unreachable" according to the plaintiff and (2) the other physician was deposed but could not testify that he would have altered his prescribing habits because he never read the diet drug warnings.

The court rejected two arguments advanced by the plaintiffs in opposition to the summary judgment motions. First, the court found that the plaintiffs could not establish proximate causation by submitting evidence that a "reasonable physician" would not have prescribed the diet drugs if they had known of the risk of heart valve regurgitation. The court found that such evidence, offered in the form of affidavits from plaintiffs' experts, was "irrelevant" and "contrary to the legal standard long established under Pennsylvania law." The court found that there was no material issue of fact on proximate causation because there was no evidence that the prescribing physicians (as opposed to any other physician or any "reasonable physician") would not have prescribed the diet drugs. Second, the court concluded that the heeding presumption — in which it is presumed that a person would follow a warning if one had been provided — could not be used to "presume" that the prescribing physician would not have prescribed the diet drugs.

Adams, *Berry*, and *Anderson* are noteworthy because they form a possible basis for dismissal of pharmaceutical product liability cases in which the plaintiff fails to secure the prescribing physician's testimony due to death, unavailability, or any other reason. Furthermore, the court's rejection of the plaintiffs' "reasonable physician" and "heeding presumption" arguments suggests that this burden will not be one easily avoided by the plaintiffs. It is a burden that plaintiffs should have to meet in most, if not, all states.

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