Medical Device Update: Third Circuit Certifies Questions Concerning Device Manufacturers' Liability Under Pennsylvania Law

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Litigation Alert
7.16.21

The United States Court of Appeals for the Third Circuit has asked the Pennsylvania Supreme Court to clarify Pennsylvania's medical device liability law. On June 24, 2021 in *Ebert v. C.R. Bard, Inc.*, No. 20-2139, 2021 U.S. App. LEXIS 19517, the Third Circuit certified two questions to the Pennsylvania Supreme Court that have the potential to restrict or expand liability of medical device manufacturers under Pennsylvania law:

1. Under Pennsylvania law, must a plaintiff bringing a negligent design claim against a prescription medical device manufacturer prove that the device ***was too harmful to be used by anyone***, or may the plaintiff also prevail on other theories of liability where appropriate?
2. Under Pennsylvania law, are prescription implantable medical devices ***categorically subject to strict liability, categorically immune from strict liability, or immune from strict liability on a case-by-case basis***? If they are immune on a case-by-case basis, what test should a court apply to determine whether a particular device is immune?

These issues are ripe for determination because device manufacturers have faced unpredictable and inconsistent rulings in the cases of *Tincher v. Omega Flex, Inc.*, (2014); *Lance v. Wyeth*, (2014); and *Hahn v. Richter*, (1996). The ambiguity arising from these cases has resulted in diverging viewpoints among counsel and courts as to the state of Pennsylvania law with respect to medical devices.

As to the first question, some courts have found that Pennsylvania law requires plaintiffs to prove that a prescription medical device is "too harmful to be used by anyone" in order to establish liability. Other courts, however, have found that such a rule is "limited to the unique context of prescription drugs," and plaintiffs can support a negligent design claim through broader theories of liability, such as showing "an alternative safer design." Notably, the Third Circuit has suggested that it may favor broader theories of liability.

As to the second question, parties often dispute whether medical device manufacturers are even subject to strict liability claims due to the Pennsylvania Supreme Court's inconsistent application of strict liability in products liability cases. While the Pennsylvania Supreme Court held in 1996 that "prescription drugs are categorically immune from strict liability," the court then rejected "categorical exemptions from liability" in 2014. Some courts have found that the immunity for prescription medications extends to medical devices, but others have concluded that this immunity is not as far reaching. In *Ebert*, the Third Circuit has suggested that it would be inclined to support immunity for prescription medications only.

The Pennsylvania Supreme Court's ruling on these questions would provide needed clarity to medical device manufacturers given the proliferation of medical devices, the inconsistent application of precedent, and the impact the rulings have on the viability of products liability claims. Whether the Pennsylvania Supreme Court will accept certification and answer these questions remains to be seen, but large-scale changes may soon be coming for medical device liability in Pennsylvania.

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