

Third Circuit Sends “Important and Unresolved” Medical-Device Liability Questions to Pennsylvania Supreme Court

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Recently, in *Ebert v. C.R. Bard, Inc.*, the Third Circuit considered two questions of medical-device liability left unresolved by Pennsylvania law. The first is whether a plaintiff claiming that a device was negligently designed must prove that the device was “too harmful to be used by anyone.” The second is whether a strict liability claim involving a medical device is cognizable under Pennsylvania law. Finding these questions too important to be resolved by an *Erie* “guess,” the Third Circuit asked the Pennsylvania Supreme Court to answer them instead. How that court does so will likely impact thousands of cases, including several active multi-district litigations.

The plaintiff in *Ebert* suffered from a deep vein thrombosis, a kind of blood clot “that could have potentially life-threatening complications.” *Ebert v. C.R. Bard, Inc.*, No. 20-2139, 2021 WL 2656690, at *1 (3d Cir. June 24, 2021). To catch any further clots before they became pulmonary embolisms, Ebert’s doctor installed in her inferior vena cava a device known as a G2 filter, which Bard manufactured. *Id.* Three years later, when the doctor tried to remove the device, he found that a piece of the filter had “fractured and grown into the wall of Ebert’s inferior vena cava.” *Id.*

Ebert sued Bard in the U.S. District Court for the Eastern District of Pennsylvania, alleging that the company was both negligent in designing a defective filter and strictly liable for its defective manufacture. *Id.* at *2. Each theory stemmed from a watershed decision by the Pennsylvania Supreme Court. In *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), that court held that prescription drug manufacturers, though immune from strict liability, are subject to state-law negligence liability for design defects. The *Lance* court grounded this decision in Section 6(c) of the Restatement (Third) of Torts, which states that manufacturers are negligent if they introduce or market a drug “with actual or constructive knowledge that [it] is too harmful to be used by anyone.” *Lance*, 85 A.3d at 459, 461 (citing Restatement (Third) of Torts: Prods. Liab. § 6(c) (1998)). Ebert argued that Section 6(c) did not foreclose alternative theories of design-defect liability—such as her theory which was that Bard could have chosen a “safer alternative design” for the G2 filter.

Ebert’s strict liability claim rested on a novel interpretation of *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014). There, the Pennsylvania Supreme Court rejected the notion that some products—aside from prescription drugs—should be exempted categorically from strict liability. Since *Tincher* did not speak with specificity to medical-device liability, Ebert argued that *Tincher* had stripped medical devices of their exemption from strict liability.

The district court granted summary judgment to Bard. *Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637, 641 (E.D. Pa. 2020). Judge Pappert first rejected Ebert’s contention that, under *Lance*, the existence of an “alternative safer design” could suffice as a theory of negligence. *Id.* at 644. Since accepting such an argument would require a court to speculate as to “whether FDA approval could be had for a new design,” he determined that “the alternative design approach [was] not an easy fit measured against conventional design theory.” *Id.* at 646 (citing *Lance*, 85 A.3d at 458–59). Thus, Ebert’s design defect theory was not cognizable under Pennsylvania law. *Id.*

Judge Pappert also found Ebert’s strict liability claim viable in theory and wanting in practice. He conceded that, under *Tincher*, Pennsylvania law might allow for strict liability for medical-device manufacturing defects. *Id.* at 652. And he predicted that the Pennsylvania Supreme Court would consider that question—and the applicability of the “unavoidably unsafe” exception—on a “case-by-case basis.” *Id.* at 652–53. Applying those forecasts to the “fully developed factual record,” however, Judge Pappert still found Bard’s filter “unavoidably unsafe” and shielded from strict liability. *Id.* at 653.

On appeal, the Third Circuit declined to answer these “important and unresolved issues of state products liability law” without the advice of the state’s highest court. *Ebert v. C.R. Bard, Inc.*, No. 20-2139, 2021 WL 2656690, at *1 (3d Cir. June 24, 2021). Writing for a unanimous panel, Judge Krause found that *Lance*’s “expansive language” fairly could be read to permit a design-defect theory sounding in the existence of a safer alternative design. *Id.* at *3–*4. And she concluded that *Tincher* had left available “three alternative ways to analyze strict liability” for prescription medical devices. *Id.* at *5. Left “unable to predict how the Pennsylvania Supreme Court would rule on those questions,” the Third Circuit certified to that court two questions of 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?” *Id.*

Ebert likely will determine the degree to which medical-device manufacturers can be held liable for design and manufacturing defects in the nation’s fifth-largest state, and may have reverberating effects in other jurisdictions.

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