United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
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Lyle W. Cayce
Clerk

No. 21-60689

DENNIS NELSON; KATHY NELSON,

Plaintiffs—Appellants,

versus

C. R. BARD, INCORPORATED; BARD PERIPHERAL VASCULAR, INCORPORATED,

Defendants—Appellees.

Appeal from the United States District Court
for the Southern District of Mississippi
USDC No. 2:19-CV-135

Before HIGGINSON, WILLETT, and HO, *Circuit Judges*.

STEPHEN A. HIGGINSON, *Circuit Judge*:

In this products liability case, plaintiffs, Dennis Nelson and his wife, Kathy Nelson ("the Nelsons") sued defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. ("Bard"), due to complications Dennis Nelson experienced after implantation of a filter used as a medical device. The Nelsons now appeal the district court's grant of summary judgment to Bard on their failure to warn and design defect claims. We AFFIRM.

I.

A.

The Nelsons brought this product liability action after Dennis Nelson experienced complications following the implantation of an inferior vena cava filter, called the Recovery IVC Filter (the "Filter"). Generally, such filters are placed inside the body in an effort to prevent blood clots from reaching critical organs such as the heart, lungs, or brain. The Filter, a "venous interruption device[] designed to prevent pulmonary embolism," is designed, manufactured, marketed, and sold by Bard. It was approved by the FDA as an optional retrievable filter in 2003 and could thus be used permanently or temporarily.[1]

Each Filter comes with an Information for Use pamphlet ("IFU") that sets forth various pieces of information, including warnings, precautions, and instructions. Under the bolded "**Warnings**" heading, the IFU read, in relevant part:

> 8. Filter fracture *is a known complication* of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
>
> 9. Movement or migration of the filter *is a known complication* of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment,

[1] Though the parties appear to dispute whether the Filter was intended to be used on a permanent or temporary basis when implanted in Dennis Nelson, neither party provides a record cite directly supporting their position.

> deployment into clots and/or dislodgment due to large clot burdens.

(emphasis added). The IFU also contained a section titled "Potential Complications," and this section included the following information (bold at end in original):

> Procedures requiring perculaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.
>
> Possible complications include, but are not limited to, the following:
>
> - Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
> - Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
> - Perforation or other acute or chronic damage of the IVC wall.
> - Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
> - Caval thrombosis/occlusion.

- Extravasation of contrast material at time of venacavogram.
- Air embolism.
- Hemaloma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage.
- Restriction of blood blow.
- Occlusion of small vessels.
- Distal embolization.
- Infection.
- Intimal tear.
- Stenosis at implant site.

All these above complications have been associated with serious adverse events such as medical intervention and/or death. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

The Filter was restricted to sale "by or on the order of a physician."

As early as May 2004, Bard internal emails referencing the Filter began to note that there were complications associated with it. Then, on December 17, 2004, Bard's medical director issued an internal document titled "Health Hazard Evaluation" concerning a consultant's report on the Filter. The internal Bard document stated, in part:

> An analysis of reporting rates of serious adverse events for all inferior vena cava filters, as determined by analysis of the MAUDE and IMS databases by a consultant, revealed that reporting rates for Recovery are significantly higher than other filters. However, these databases are subject to known,

> significant biases that make calculation or comparison of incidence rates among products unreliable and inadvisable . . . . Nevertheless, the number of reported complaints, and the size of the differences between Recovery and other filters, warrant further investigation.

The document continued:

> Reports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rates for all other filters. These differences were all statistically significant. Recovery's reporting rates for all adverse events, filter fracture, filter migration, and filter migration deaths were found to be significantly higher than those for other removable filters.

On May 16, 2005, Dr. Daniel DeVun implanted Dennis Nelson with a Filter. Dr. DeVun performed this procedure as a prophylactic measure to prevent deep venous thrombosis and pulmonary embolism prior to Dennis Nelson's temporary cessation of anticoagulation medication in anticipation of a liver transplant. Medical imaging taken fourteen years later in 2019 revealed that the Filter had fractured. Some of the struts of the Filter had penetrated through the inferior vena cava wall, and some migrated to other parts of Nelson's body. Nelson underwent three surgical procedures to remove the Filter and its fragments. Though the procedures were partially successful, one fragment remains in Nelson's pulmonary artery.

B.

In September of 2017, the Nelsons brought a product liability action against Bard, as a part of a multidistrict litigation suit. The case was transferred to the Southern District of Mississippi in September of 2019. In March of 2021, both the Nelsons and Bard filed motions for summary

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