

## Another Circuit Bars Tort Suits Under the MDA

The Third Circuit Court of Appeals has joined five other circuits in finding that personal injury suits are improper for medical devices approved by the Food and Drug Administration (FDA) through its Pre-Market Approval (PMA) procedures. This is good news to the medical device industry. Only one circuit has found to the contrary, but the issue remains to be definitively resolved by the U.S. Supreme Court.

### ***Horn v. Thoratec Corp.***

In *Horn v. Thoratec Corp.*, plaintiff Barbara Horn, the widow of a man who had a left ventricular device known as the HeartMate implanted while awaiting a heart transplant, sued the device manufacturer after her husband died of a brain embolism. The pump was designed to assist blood flow between the heart's ventricle and the aorta. Mrs. Horn filed suit in the federal district court in Harrisburg, Pennsylvania, against Thoratec Corporation (TCI) because a screw ring that linked the pump to the output side elbow disconnected, allowing an air embolus to travel to Mr. Horn's brain. Mrs. Horn claimed that the pump was defectively designed and manufactured, and that TCI failed to warn of these defects.

### ***MDA Pre-emption***

TCI moved for summary judgment on the ground that the plaintiff's state common law claims were pre-empted. The district court granted Thoratec's motion, adopting the Sixth and Eleventh Circuits' two-prong test, which provides that a state claim attacking the safety of a medical device is pre-empted by § 360k(a) of the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act if (1) the FDA has established specific federal requirements that are applicable to the particular device, and (2) the state claim is different from, or in addition to, the specific federal requirements. The district court concluded that the FDA's PMA process, to which the HeartMate was subject, established specific federal requirements applicable to the pump and that any jury verdict finding that the HeartMate was unsafe or defective, or that TMI failed to warn consumers of the risk, would differ from the FDA's conclusion that it was suitable for use.

### ***Third Circuit Affirms***

The Third Circuit agreed with the district court and affirmed the grant of summary judgment in TMI's favor. In reaching its decision, the circuit court first distinguished *Medtronic, Inc. v. Lohr*, which held that the FDA's approval of a cardiac pacemaker lead did not result in a pre-emption of the plaintiff's state law claims. The court found that *Lohr* was not controlling because the device in *Lohr* was not subject to the rigorous FDA approval process that the HeartMate underwent. The device in *Lohr* was approved by the FDA under § 510(k) of the Food, Drug and Cosmetic Act because it was "substantially equivalent" to an existing FDA-approved device and did not have to undergo the PMA process. *Lohr* did not conclusively resolve whether the more stringent PMA standards under § 360e(c) of the MDA creates specific federal requirements for the product.

Taking guidance from the FDA's *Amicus Curiae* Letter Brief, the Third Circuit in *Horn* found that the agency's PMA approval imposed mandatory conditions regarding the HeartMate's manufacturing, packaging, labeling, distribution and advertising that cannot be altered without the FDA's consent. Thus, the court found that the PMA process imposed requirements that were specifically applicable to the HeartMate and pre-empted Mrs. Horn's state law-based claims under § 360k(a).

In so ruling, the Third Circuit concluded that the plaintiff's claims would impose requirements on TCI that would differ or add to the requirements imposed by the FDA. The plaintiff's claims, if successful at trial, might require TCI, for example, to alter its product design and warnings, amounting to state substantive requirements different, or in addition to, the federal requirements imposed by the FDA. Therefore, the court held that the plaintiff's claims were pre-empted by the provisions of § 360k(a). Other U.S. courts of appeal have agreed. The Eleventh Circuit is alone in its ruling that § 360k(a) does not pre-empt state common law claims involving PMA-approved devices. Therefore, at this time six circuits are lined up in favor of pre-emption, and one circuit (and three others through district court decisions) are allied against pre-emption in this area.

In a 2001 ruling involving orthopedic bone screws, the U.S. Supreme Court unanimously found that fraud-on-the-FDA suits are impliedly pre-empted by the Food, Drug and Cosmetic Act. This decision was based on the Supreme Court's finding that Congress had vested enforcement authority solely in the FDA to police medical device submissions by the industry. This closed a potential back door left open by *Lohr* for tort claims arising from allegedly defective medical devices.

### ***The Debate Over MDA Pre-emption Will Likely Continue***

The Third Circuit, by joining with other federal courts of appeal, has weighed in on the side of the industry and the FDA in construing § 360k(a) to pre-empt state law-based claims of deficient product design and inadequate warnings. The debate, however, concerning the impact and precise holdings of *Lohr* is likely to continue outside of those circuits, such as the Third Circuit, which have upheld pre-emption. Although some may conclude that the FDA's PMA approval process creates a ceiling of maximum standards while others may contend it provides a floor of minimum standards, it is likely that neither proposition is entirely accurate. Even after receiving permission to market a PMA-approved medical device, manufacturers must continue reporting to FDA regulators information concerning adverse events. In addition, all changes to advertising, labeling, design and packaging require FDA approval. Also, some manufacturers, motivated by a concern for product quality, endurance and safety, as well as a desire to avoid the expense and publicity surrounding product recalls and "Dear Doctor" letters, may continue their research and development to improve the design and operation of medical devices even after they have reached the market.

Ultimately, we suspect, MDA pre-emption will be revisited by the U.S. Supreme Court, and the current split among the circuits on the issue heightens this prospect. Future changes in the Supreme Court's sitting justices may well influence the outcome. The Supreme Court's composition has not changed since *Lohr*, but changes are likely to occur in the near future as justices retire.

### **For Further Information**

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