PMA-Approved Medical Devices Shielded From Many State Law Tort Claims

What happened?

The Third Circuit recently followed the FDA’s lead in holding that certain State products liability claims against manufacturers of Class III medical devices are preempted by federal law.

What does it mean?

For manufacturers of Class III medical devices who have cases pending in the Third Circuit, this opinion may offer significant protection from State products liability claims.

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In *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), the Third Circuit found, 2-to-1, that certain State products liability claims involving Class III devices are preempted. As predicted in the July 2004 WHIM (http://www.saul.com/common/publications/pdf/377.pdf), the Third Circuit relied upon the FDA’s letter brief in which it contends that the PMA process provides sufficient consumer safeguards to protect consumers, and that the prosecution of State products liability claims based on Class III devices would only disrupt the FDA’s ability to efficiently and thoroughly regulate the medical device market.

Barbara Horn, the executrix of her husband’s estate, brought a products liability action against Thoratec Corporation, who manufactured a heart pump that had been implanted in her husband to provide circulatory support while he was awaiting a heart transplant. It is a Class III medical device, and thus was subject to the PMA process. Months after the implant, the screw-ring used to secure the connection between the pump and the outlet tube became disconnected. The disconnect allowed an air embolus to travel to Mr. Horn’s brain, and caused him to die from a brain hemorrhage. The estate alleged defective design and manufacture, as well as failure to warn of the alleged defects associated with the failed connection.

The central questions in *Thoratec* were (1) whether the PMA process constitutes a specific federal requirement, so as to trigger the preemption statute of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA), and (2) whether liability under State tort claims would conflict with federal requirements.

To hold that State tort claims were preempted, the *Thoratec* court had to distinguish the United States Supreme Court decision in *Medtronic v. Lohr*, 518 U.S. 470 (1996). In *Lohr*, the Supreme Court held that, if federal law imposes a specific requirement on manufacturers, and if State law causes of action impose requirements that are different from, or in addition to, the federal requirements, then a State tort action is preempted. However, *Lohr* characterized the 510(k) process as a general federal mandate, and concluded that it did not constitute a specific requirement, thus not preempting claims against 510(k)-approved devices. In *Thoratec*, the Third Circuit concluded that *Lohr* had not reached the question of whether the PMA process – which is required only for Class III devices – constitutes a specific federal requirement sufficient to trigger the preemption clause of the MDA.

The Third Circuit said that PMA requirements were precisely the kind of specific federal requirements contemplated by the exemption, as well as the Supreme Court in *Lohr*. Unlike the 510(k) process, the majority noted, the PMA process involves an “exhaustive inquiry.” In support of its conclusion, the court repeatedly cited to the FDA amicus brief which articulated its interpretation of the MDA and argued in favor of preemption.

The dissent criticized the extent to which the majority relied on the FDA's brief, particularly given the fact that this represented a significant change in the FDA’s position on preemption. The dissent concluded that there is no “conflict” between PMA requirements and the specific State law tort claims asserted and the PMA process is a “floor” of minimum standards for Class III devices, rather than a “ceiling.”

Next, the Third Circuit found that State law claims of product defect and negligence conflict with the FDA regulations. The court hypothesized that were a plaintiff’s negligence claims successful, a device manufacturer could be required to change the design of its product as a result of a civil suit. The court concluded that any change dictated by a tort claim would be inconsistent with the fact that the pre-liability design would be FDA-approved, and any change would require further FDA review and approval. The court also mentioned the FDA’s concern that disparate jury verdicts and large compensatory awards might lead device manufacturers to stray from FDA regulations. The fear expressed by the FDA in its brief is that manufacturers might opt for unapproved warnings or withdraw approved products from the market, resulting in scientifically unsubstantiated warnings and the underutilization of beneficial treatments. Thus, based on the FDA’s submission, the court found that State tort claims would conflict with the specific requirements of the PMA process.

The Third Circuit denied the plaintiff’s request for an *en banc* rehearing in *Thoratec* – where all the justices of the Third Circuit would have heard argument on the case. As of the publication of this article, a petition for certiorari to the United States Supreme Court has not been filed.

Manufacturers that have tort claims pending against products that are FDA-approved should consider appropriate motions citing to *Thoratec* and the FDA brief. Although there is a split amongst federal circuit courts, *Thoratec* is consistent with the majority of courts on the issue of preemption. Additionally, the FDA’s position might provide sufficient ammunition to preempt many State claims against Class III medical device manufacturers.

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