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7 | 04

Life Sciences Law

The FDA Suggests Broad Preemption of State Law Tort Claims for Class III Medical Devices That Have Been Granted Premarket Approval

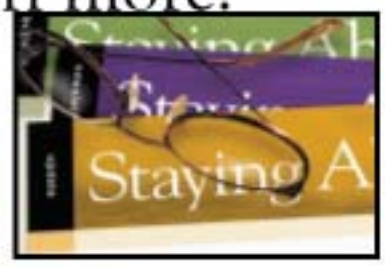
What happened?

In a recent filing with the federal appeals court in Philadelphia, the FDA explained that it *intends* to preempt State law tort claims against manufacturers of Class III medical devices alleging improper design, manufacture, labeling, or use, when it grants premarket approval of a Class III device.

What does it mean?

The FDA policy in favor of federal preemption for Class III medical devices that have undergone PMA scrutiny marks a significant change in agency policy. The federal appeals court is likely to give great weight to the FDA's expression of intent and, if so, manufacturers of Class III devices that have obtained PMA approval could gain significant protection from State law tort claims alleging products liability defects.

Learn more.



Turn the page to find out more background and the potential implications of the FDA brief.

The Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act (FDCA) provide that certain State law claims involving Class III medical devices are pre-empted when State law imposes requirements that differ from federal requirements. In 1996, the United States Supreme Court held in Medtronic v. Lohr, 518 U.S. 470 (1996), that a State product liability claim against a Class III device which had obtained FDA approval through the Section 510(k) process was not preempted because the Section 510(k) process did not create specific federal requirements for the design of the device. Under the Lohr analysis, a State cause of action is preempted by the MDA: 1) if federal law imposes device specific requirements on manufacturers, and 2) if State law causes of action impose requirements that are different from, or in addition to, the federal requirements. The Lohr opinion did not address whether the PMA process created specific federal requirements sufficient to trigger the MDA preemption analysis. Since Lohr, the federal Circuit Courts of Appeal have split on this issue. However, the majority of Circuits have held that the PMA process *does* create specific federal requirements and State law causes of action *would* impose different requirements, thereby triggering federal preemption.

After Lohr, the FDA had voiced its opinion in an amicus brief submitted to the United States Supreme Court in Smiths Industries Medical Systems, Inc. v. Kernats, 669 N.E. 2d 1300 (Ill. App. Ct. 1996), cert. denied, 522 U.S. 1044 (1998). In Kernats, the FDA argued that the PMA process *did not impose* specific requirements sufficient to trigger MDA preemption of State law tort claims of failure to warn, manufacturing defect, inadequate instructions, defective design claims, and inadequate testing against a manufacturer of a Class III device that had obtained approval through the PMA process.

However, in Horn v. Thoratec (No. 02-4597), *on appeal from* Horn v. Thermocardiosystems, Inc., 229 F. Supp 2d 381 (M.D. Pa. 2002), the FDA recently submitted a letter brief to the United States Court of Appeals for the Third Circuit in which it reversed its position in Kernats. In that brief, the FDA argues that under Lohr, the rigorous and thorough PMA process creates specific requirements for a Class III device's "design, performance, manufacture, labeling, and use," and that State tort actions impose requirements on manufacturers that are different from or in addition to the PMA process.

The FDA's current view is a significant change from the government's position in Kernats. In explaining its reasons for the change, the FDA argues that, as a matter of public policy, permitting State courts to interfere with the requirements set forth in the PMA process could cause inconsistencies among federal and State device approval requirements, and may cause manufacturers to stop designing and manufacturing Class III devices.

For manufacturers of Class III devices, the FDA's view suggests that manufacturers whose products undergo the PMA process may be insulated from certain State liability for claims arising out of the design, manufacture, performance, labeling, or use of the device. While the parameters of the FDA position may take some time to clarify, and for courts to evaluate and pass upon, the breadth of the comments contained in the FDA's letter brief suggest a broad intent to preempt for Class III devices that undergo the PMA process and are granted FDA approval.

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