Weekly Law Resume

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WEEKLY LAW RESUME™
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Federal Preemption Expanded as to State Law Product Liability Claims Involving Medical Devices

Thomas S. Robinson v. Endovascular Technologies, Inc.
Court of Appeal, Sixth District (November 19, 2010)

This case considered the scope of federal preemption of state law product liability claims involving a medical device. The court held that for a medical device that has been approved for clinical testing pursuant to an Investigational Device Exemption ("IDE"), the plaintiff's state law product liability claims were preempted by 21 U.S.C. § 360(k) of the Medical Device Amendments of 1976 ("MDA").

In November, 2003, plaintiff filed a complaint in which he alleged that he had suffered severe injuries after he had been implanted with the Ancure Endograft System ("Ancure Device") in December, 1998. The plaintiff's complaint alleged seven causes of action: (1) strict product liability (failure to warn); (2) strict product liability (Restatement 2nd of Torts, § 402A); (3) negligence; (4) breach of express warranty; (5) breach of implied warranty; (6) fraudulent concealment; and (7) punitive damages.

In June, 1994, the defendant submitted an application for an IDE to conduct clinical trials for the Ancure Device. By way of background, the MDA divides medical devices into three classifications: Class I, Class II and Class III. A Class III device, such as the Ancure Device, requires pre-market approval by the Food and Drug Administration ("FDA"). However, prior to obtaining pre-market approval, a manufacturer of a Class III device may apply to the FDA for

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authorization to use the device for clinical testing pursuant to an IDE. In order to obtain an IDE, an applicant must submit extensive information about the product. After reviewing the information, the FDA notifies the applicant that the proposed investigation has been approved, approved with modifications, or disapproved.

On December 16, 1998, the plaintiff agreed to participate in the IDE clinical study for the Ancure Device. While courts had recognized that the preemption provision in the MDA barred common law claims that challenged the safety and effectiveness of Class III devices which had received pre-market approval by the FDA, the Ancure Device had only received an IDE.

Plaintiff argued that his state law claims could only be preempted after an FDA finding of safety and effectiveness. However, the court found that an IDE approval of a medical device is similar to pre-market approval. The court noted that in granting IDE approval, the FDA imposes detailed requirements on the design, manufacture and warnings for Class III devices, as well as the conduct of the clinical investigation. Prior to IDE approval, the FDA must determine whether "the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or the investigation is scientifically unsound, or there is reason to believe that the device as used is ineffective." Thus, according to the court, these requirements allow the FDA to "evaluate the safety and effectiveness of the device."

The court also noted that the FDA will not grant an Investigational Device Exemption unless it believes that the device has sufficient promise of being proved safe and effective to justify the risk of it being used on human beings. Although that belief is different from the certification that the design of the device is safe and effective, it is a certification that the design is "sufficiently safe and effective" to allow experimental use on human beings. Since the FDA authorized the use of the Ancure Device for clinical testing pursuant to an IDE prior to the plaintiff's surgery, the FDA approved the device's design, testing, intended use, manufacturing methods, and labeling. Thus, to the extent that the plaintiff's complaint alleged that the Ancure Device was unsafe and its warnings were inadequate, plaintiff was seeking to impose state law

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requirements that were "different from, or in addition to" the MDA. As such, the plaintiff's state law claims were preempted under the MDA.

COMMENT

A manufacturer of a medical device that has obtained pre-market approval by the FDA cannot be sued under state law for claims of product liability or negligence. Those claims are preempted by federal law. The rationale for such an exemption is equally applicable to a medical device that has obtained an Investigational Device Exemption. As long as the complaint does not allege that the manufacturer violated FDA regulations, deceived the FDA, or provided incomplete or inaccurate information in connection with the IDE application, state law tort claims are preempted by the MDA.

For a copy of the complete decision see:

HTTP://WWW.COURTINFO.CA.GOV/OPINIONS/DOCUMENTS/D055632.PDF

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