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Regulatory Preemption of Medical Devices

What is the boundary between federal and state laws that affect medical devices?

Federal regulatory preemption of medical devices has its genesis in the 1976 Medical Device Amendments (MDA)[1] to the Food, Drug and Cosmetic Act of 1938 (FDCA).[2] Under the FDCA, the Food and Drug Administration (FDA) was given jurisdiction over medical devices, but it did not provide for the rigorous pre-market approval (PMA) process of medical devices that it did for drugs. In 1976, however, the MDA extended the PMA process to medical devices.

Under Section 360(c) of the MDA, medical devices are categorized into three classes, based upon the degree of risk they pose to the consumer. Class I devices, such as tongue depressors, are subject only to minimal controls by the FDA because of their generally accepted safety standards. Class II devices, such as tampons, are subject to more specialized controls that may include performance standards or specific guidelines. Class III devices, such as pacemakers, must undergo the stringent PMA process because of the central role they play in saving lives. The PMA process requires extensive clinical testing and the disclosure of specifications, intended use, manufacturing methods, and proposed labeling.

Section 360e of the MDA provides two exceptions to the PMA process. The first is a grandfather clause, which applies to medical devices that were on the market by 1976. The second exception applies to devices that are substantially equivalent to Class I, II, or III devices that were already approved by the FDA and were on the market before 1976.

The 510(k) Process

A manufacturer of a medical device can obtain an FDA clearance indicating that the device in question is a substantial equivalent. This is accomplished through a notification process commonly known as the 510(k). In contrast to the PMA process, the 510(k) process merely requires the manufacturer to notify the FDA of its intent to market the medical device at least 90 days prior to its introduction to the market and to explain the device's substantial equivalence to a pre-1976 device (which is known as a predicate device). By this means, a Class III device that is substantially equivalent to a predicate device may be placed on the market by satisfying the less-stringent 510(k) process. The tension between the PMA and 510(k) processes is at the center of the federal regulatory preemption debate. Section 360k of the MDA contains this specific preemption provision:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

In 1996, the U.S. Supreme Court addressed the regulatory preemption of medical devices in the landmark decision of *Medtronic, Inc.* v. *Lohr*.[3] The Court held that state claims regarding the negligent design of a Class III device marketed under 510(k) were not preempted. Central to the Court's holding was the fact that the device was marketed under the limited review of 510(k) as opposed to the more rigorous PMA process.

Where Does Preemption Begin?

Lohr left several questions unanswered, the most important of which is whether the rigorous PMA process imposes a specific requirement that preempts state tort claims. Since *Lohr,* the majority of cases have concluded that if consumer safety is the central concern, as it is with Class III devices, the PMA process imposes specific requirements that preempt state tort claims.[4]

In *Steele* v. *Collagen,* which involved Class III collagen injections, the California Court of Appeal held: "[S]tate requirements in the form of standards of care or behavior are preempted…if they are different from or in addition to the specific federal requirements arising from the PMA process."[5] However, the court reversed summary judgment in favor of the defendant because the defendant had made no attempt to show that it had complied with the PMA process.

In 2002, in *Gilleon* v. *Medtronic USA, Inc.,* the Ninth Circuit addressed preemption in the context of a Class III stent used for abdominal surgery.[6] The court held, "To the extent plaintiffs' claims seek to impose liability even though the…device at issue…complies with the design approved by the FDA…and to the extent plaintiffs' claims are based on alleged failures to warn, or inadequate warnings, arising from the warnings and labeling approved by the FDA, those claims…are preempted."

Courts that found against preemption have done so on the basis that the PMA process provides no device-specific regulations. In *Lakie* v. *Smithkline Beecham,* the district court for the District of Columbia held that because the PMA process for denture adhesives does not constitute a "specific federal requirement," it does not trigger federal preemption.[7] Also, in *Sowell* v. *Bausch & Lomb, Inc.,* the New York appellate court came to the same conclusion in a ruling that was concerned with extended wear

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contact lenses.[8]

Additionally (although the issue was not addressed by the *Lohr* Court), Class II devices have been held to be preempted if device-specific regulations have been promulgated by the FDA. In *Papike* v. *Tambrands, Inc.*, the Ninth Circuit held that the plaintiff's state claims were preempted because tampons, although a Class II rather than a Class III device, have been the subject of several specific FDA regulations mandating warnings for toxic shock syndrome.[9]

Proposition 65

However, in *Committee of Dental Amalgam Manufacturers* v. *Stratton*, the Ninth Circuit held that Section 360k did not preempt a claim under Proposition 65, California's Safe Drinking Water and Toxic Enforcement Act.[10] The court found that dental amalgam is both a Class I and II device because of its component parts of mercury and amalgam alloy. Since Proposition 65 is a general law of applicability and it is not specific to any one product, the court held that the warning requirements under Proposition 65 do not constitute a specific requirement.

Based upon a survey of current law, what appears to be the crucial issue is whether the device was marketed under the PMA process or whether the FDA articulated specific requirements. Thus, as a general rule, Class I and II devices with no specific FDA requirements, as well as Class III devices marketed under the 510(k) process, will not be preempted from state actions. Class II devices with attendant FDA special requirements, and Class III devices marketed under the PMA process, will generally be preempted from state regulations. However, since the U.S. Supreme Court has not fully addressed the scope of preemption under the MDA, these issues remain unclear. ■

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[1] 21 U.S.C. §§360c-l.
[2] 21 U.S.C. §§301 *et seq.*
[3] Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2246 (1986).
[4] Martin v. Medtronic, 254 F. 3d 573 (5th Cir. 2001) (pacemaker); Kemp v. Medtronic, 231 F. 3d 216 (6th Cir. 2000) (pacemaker); Mitchell v. Collagen Corp., 126 F. 3d 902 (7th Cir. 1997) (collagen implants); Brooks v. Howmedica, Inc., 273 F. 3d 785 (8th Cir. 2001) (bone cement); Lake v. TPLC, 1 F. Supp. 2d 84 (D. Mass. 1998) (pacemaker); Fry v. Allergan Med. Optics, 695 A. 2d 511 (R.I. 1997) (artificial eye lens).
[5] Steele v. Collagen Corp., 54 Cal. App. 4th 1474, 1489 (1997).
[6] Gilleon v. Medtronic USA, Inc., 2002 U.S. Dist. LEXIS 20154, at *2-3, 18-19 (N.D. Cal. Aug. 28, 2002).
[7] Lakie v. Smithkline Beecham, 965 F. Supp 49, 53-54 (D. D.C. 1997).
[8] Sowell v. Bausch & Lomb, Inc., 656 N.Y.S. 2d 16, 21 (App. Div. 1997).
[9] Papike v. Tambrands, 107 F. 3d 737 (9th Cir. 1997).
[10] Committee of Dental Amalgam Mfgs. & Dists. v. Stratton, 92 F. 3d 807, 813-14 (9th Cir. 1996).