Legal Backgrounder

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FEDERAL PREEMPTION OF STATE TORT SUITS AVAILABLE FOR "PMA" MEDICAL DEVICES

by

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New product development is an essential ingredient to sustained profitability for medical device manufacturers. Because constant product innovation is the central strategy for seizing and maintaining market share in crowded product fields, medical device manufacturers place a premium on the celerity and facility by which they can negotiate the various obstacles to commercialization, including the sanctioning of new products by the federal Food and Drug Administration ("FDA").

FDA Approval of New Medical Products. The Medical Device Amendment Act of 1976 (the "MDA") governs the FDA's approval process for new medical devices. Congress enacted the MDA in response to mounting consumer and regulatory concern regarding the safety and effectiveness of medical devices. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). The MDA sets forth a comprehensive regulatory scheme that categorizes new products into three classes based on their complexity and relative danger to consumers, with a differing level of FDA scrutiny being placed on products by class. The most risky — Class III[1] — requires a "rigorous" application process for FDA approval, the goal of which is to provide "reasonable assurance" that the product is "both safe and effective." *Medtronic*, 518 U.S. at 477. This application process, known as the pre-market approval ("PMA") process, requires detailed submissions by the manufacturer regarding the design, safety, and testing of the proposed product and thousands of hours of FDA time in review and analysis of those submissions. *Id*. As might be expected, the PMA process presents a time consuming and somewhat expensive obstacle in the path of medical device manufacturers' goal of rapid commercialization of new products.

The § 510(k) Shortcut to FDA Approval. The provisions of the MDA, however, provide a shortcut to manufacturers desiring to circumvent the rigorous PMA process by providing exceptions to

[1]A Class III device is one that "presents a potential unreasonable risk of illness or injury" or otherwise is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C).

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the PMA requirements. In what has become the most significant exception to manufacturers, the MDA exempts devices from the PMA process that are demonstrated to be "substantially equivalent" to a pre-existing device already on the market. *Medtronic*, 518 U.S. at 478.

This exception, which has become known as "the § 510(k) process," offers a cheaper and more expedient method for manufacturers to obtain FDA approval of new products, *id*., and has become the preferred method for obtaining FDA approval for new devices. In contrast to the PMA process, a § 510(k) application imposes only a limited review focusing not on the safety and effectiveness of the new product, but rather on whether the product is "substantially equivalent" to an existing product on the market. *See id*. In the seven years following the passage of the MDA, 90% of all new Class III medical devices were approved through the § 510(k) process.[2] By 2003, less than one percent of new product applications were pursued through the more rigorous PMA process,[3] with the vast majority of manufacturers choosing the § 510(k) route. The attraction of the § 510(k) process to manufacturers is clear: "it requires little information," "it gets processed very quickly," and "it rarely elicits a negative response from the FDA"[4]

The* Medtronic *Case and its Pregnant Inference. In addition to the § 510(k) exception, an additional provision of the MDA is critically important to medical device manufacturers. In § 360k, Congress preempted the States from regulating medical devices that are specifically regulated by the FDA:

> **§ 360k. State and local requirements respecting devices**
> (a) General rule
> Except as provided in subsection (b) of this section, no 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. . . . 21 U.S.C. § 360k.

This provision, as stated, preempts states from establishing "requirements" related to the safety or effectiveness of medical devices that are different from, or would add to, the federal FDA requirements. By the late eighties, device manufacturers began to test the scope of this provision, asserting that it necessarily preempts state common law tort and products liability claims concerning medical devices regulated under the MDA.[5] The critical issues concerning the interpretation of this provision in this regard were: (1) whether a state common law jury verdict awarding damages could constitute a state "requirement;" and (2) whether the FDA process for approving new devices establishes a device-specific "federal requirement" that would trigger the preemption of later common law design defect claims for that very same device.

In 1996, the United States Supreme Court issued a plurality decision in *Medtronic, Inc. v. Lohr*, addressing the scope of preemption under § 360k. Justice Stevens announced the Judgment of the

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[2] *See Medtronic*, 518 U.S. at 479. Between 1976 and 1983 nearly 1,000 of 1,100 Class III devices were submitted through the § 510(k) process.

[3] The § 510(k) applications "dwarfed" those filed under the PMA process at a ratio of 9,872 to 54. *Horn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004).

[4] *Id.* at 478 (quoting Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 516 (1988)).

[5] *See, e.g., Mitchell v. Iolab Corp.*, 700 F. Supp. 877, 879 (E.D.La. 1988) (state tort law not pre-empted by the MDA); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1331 (7th Cir. 1992) (MDA did preempt certain types of state law tort claims).

Court, with Justices Kennedy, Souter and Ginsberg joining. Justice Breyer issued a concurring opinion that joined in the Judgment and certain parts of Justice Stevens' opinion. Justice O'Conner filed a separate opinion concurring in part and dissenting in part, in which Justices Rehnquist, Scalia, and Thomas joined. *Medtronic,* 518 U.S. 473. Cobbled together from this splintered decision, the Supreme Court held, in relevant part, that: (1) a state common law jury verdict could possibly constitute a state "requirement" under the MDA preemption provision;[6] but that (2) even if it did, the § 510(k) approval of a device does not create a corresponding federal "requirement" concerning the safety or effectiveness of that device so as to trigger preemption of subsequent design defect lawsuits. *Medtronic*, 518 U.S. at 492. The Court noted that the § 510(k) approval process is "focused on equivalence, not safety" and thus bears no imprimatur on the safety or adequacy of the device design. *Id*. at 493. However, this latter finding of the Court, when highlighted with the Court's lengthy dicta regarding the more "rigorous" safety oriented PMA process, *id*. at 477-79, left a pregnant inference in the Court's holding that had the device in question been approved through the full PMA process, the Court's decision may have come out differently.

Horn v. Thoratec Corp. ***and Other Post-Medtronic Decisions***. In August of 2004, the U.S. Court of Appeals for the Third Circuit seized upon the inference contained within the *Medtronic* decision and found that the MDA preempts common law design defect products liability claims where the accused device was FDA approved through the PMA process. In *Horn v. Thoratec Corp.*, the Third Circuit distinguished the *Medtronic* decision principally on the basis of the difference between the PMA process and the § 510(k) process. *Horn v. Thoratec Corp*., 376 F.3d 163, 169 (3d Cir. 2004). Unlike the pacemaker at issue in *Medtronic* that had been approved through the § 510(k) process, the heart pump at issue in *Horn* received FDA approval following the full PMA process. *See id*. Relying heavily on an *amicus* position by the FDA that highlighted the thoroughness and safety-oriented purpose of the PMA process,[7] the Third Circuit found that PMA approval constitutes a specific federal requirement concerning, among other things, the design of the product in question.[8] The Third Circuit, agreeing with prior decisions from the Fifth, Sixth, Seventh, and Eighth Circuits, found that "PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards, and labeling that is specific to the product" and thus preempts any state law civil claims regarding alleged defects or inadequacies in those areas.[9]

Implications on Future Litigation and New Product Development. The decision in *Horn v. Thoratec*, and comparable decisions from the Fifth, Sixth, Seventh and Eighth Circuits, obviously offer medical device manufacturers protection from certain types of products liability claims for devices approved by the FDA through the PMA process. Specifically, the most common forms of products

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[6]*See Medtronic*, 518 U.S. at 492 ("§ 360k simply was not intended to preempt *most* . . . general common-law duties enforced by damages actions") (J. Stevens, Kennedy, Souter, and Ginsburg) (emphasis added); 518 U.S. at 503 ("the MDA will *sometimes* preempt a state-law tort suit) (J. Breyer, concurring) (emphasis added); 518 U.S. at 510 ("state common-law damages actions do impose 'requirements'") (J. O'Conner, Scalia, and Thomas, concurring in part, dissenting in part).

[7]*See id*. at 167. The FDA *Amicus Curiae* brief took the position that "'[a] pre-market notification submitted under Section 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate to the FDA that the device is safe and effective.'" *Id*. (quoting FDA *Amicus Curiae* letter).

[8]*See id.* at 169-73. The Court cited to the ten years of live animal and human cadaver testing that had been a part of the heart pump's PMA testing regimen, the subsequent seven years of clinical trials, and the numerous FDA inquiries and manufacturer responses required during the interim approval process. *See id*. at 169-70.

[9]*Id.* at 170. *See also Martin v. Medtronic, Inc*. 254 F.3d 573, 584 (5th Cir. 2001); *Kemp v. Medtronic, Inc*., 231 F.3d 216, 226-27 (6th Cir. 2000); *Mitchell v. Collagen Corp*., 126 F.3d 902, 913 (7th Cir. 1997); *Brooks v. Howmedica, Inc*., 273 F.3d 785, 795-96 (8th Cir. 2001). The Eleventh Circuit, however, has held that the PMA process does not create a specific federal requirement that would not preempt state civil tort liability for defective design. *See Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1377 (11th Cir. 1999).

liability claims — those based on allegations of defective design and failure to warn[10] — are preempted under the *Horn* line of cases. Likewise, under this line of cases, derivative design defect claims under the Uniform Commercial Code's implied warranty of merchantability and fitness for an intended purpose are also preempted because those claims necessarily challenge "the standards of design and manufacture of the products."[11] However, not all products liability claims are preempted, even under the *Horn* line of cases. First, claims based on *manufacturing* defect rather than *design* defect remain viable to the extent that the accused product was manufactured or fabricated differently from its approved design. *See, e.g., Davenport v. Medtronic, Inc*., 302 F. Supp. 2d 419, 434 (E.D.Pa. 2004). Likewise, products liability claims premised on a manufacturer's failure to abide by FDA regulations or other requirements established in the PMA process with respect to the design or labeling of the product are also outside of the scope of preemption. *Medtronic*, 518 U.S. at 495.

But by far, the claims that are preempted — those alleging design defect and failure to warn — are the most common, probably because they lend themselves more easily to establishing *prima facie* validity based on expert opinion testimony. In other words, it is very likely easier for a prospective plaintiff to find a credentialed expert to opine that there is a safer design or a more thorough warning, than it is to establish the necessary evidence to demonstrate that a given product deviated in some way from its otherwise-safe design. For medical device manufacturers, litigation costs from design defect cases continue to mount, in part because they are natural companion claims in medical malpractice actions. In many cases, device manufacturers are forced into lawsuits as cross-claim defendants because medical malpractice defendants tend to defend themselves by blaming their patient's injury on the design of the medical equipment utilized.

Thus, even in products liability cases with little merit, medical device manufacturers are subject to significant costs merely from the expense associated with litigation. Moreover, where liability depends on expert opinion, resolution by summary judgment is ordinarily very difficult to obtain. Settlement costs are thus often incurred, even in marginal cases, to avoid the risk of uncertainty implicit in a jury verdict. The ability to end a products liability lawsuit, as a matter of law, at the inception of the litigation based on preemption is a valuable arrow in the manufacturer's quiver — potentially eliminating both litigation and settlement costs for certain products.[12]

The litigation savings alone from averted products liability actions provide ample incentive to medical device manufacturers to consider the PMA process for new product development, rather than abbreviated § 510(k) process, especially for products that, by their nature, are more prone to lawsuits. In many cases, the savings from the elimination of post-approval litigation may fully mitigate, or even surpass, the additional expense incurred from pursuing PMA approval. Moreover, while some critics deride the *Horn* line of cases for denying consumers a remedy for legitimate products liability injuries, this criticism overlooks a significant macro-level benefit to the public from the operation of the preemption provision. If additional economic incentives realized from preemption compel medical device manufacturers to rely on the rigorous PMA process as the primary product approval process, rather than the perfunctory § 510(k) process, the public will necessarily be benefited in the long run because more new products, on the whole, would be subject to greater FDA scrutiny and, thus, should be considerably safer.

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[10]*See Kemp*, 231 F.3d at 236. To the extent the failure to warn claim is based on the label and literature approved by the FDA through the PMA process, the claims are preempted. *See id*.

[11]*Mitchell v. Collagen Corp*., 126 F.3d 902, 915 (7th Cir. 1997); *but see In re St. Jude Medical, Inc*., MDL 01-1396, 2004 U.S. Dist. LEXIS 148, at *39-40 (D. Minn. Jan. 5, 2004) (UCC implied warranty claims are not pre-empted by the MDA).

[12]Even where only some of the products liability claims are preempted, if the design defect and failure to warn claims are removed by preemption, the case becomes necessarily harder to maintain and its settlement value decreases.