

Recent Developments In Medical Device Preemption Law

By David M. Gossett

A patient is diagnosed with heart disease; a pacemaker is implanted. Years later, she experiences internal bleeding, which she asserts is the result of a malfunction in the device. She has surgery again and a new pacemaker is successfully implanted, but she is incapacitated for several months as a result of having had to undergo a second round of surgery. A classic situation for tort liability?

In fact, no. As many people learned for the first time this past summer—when the issue was featured in a front-page story and a lead editorial in the *New York Times*, and Congressman Maurice Hinchey publicly attacked then-Chief Counsel of the FDA Dan Troy over the agency’s involvement in such cases¹—in many instances federal law preempts state-law tort suits against the manufacturers of medical devices such as pacemakers. Courts have been divided over the existence and scope of that preemption, but several recent cases have helped to clarify its

scope. In particular, an important Third Circuit decision finding federal law to be preemptive may finally have put to rest the argument that there is no express preemption of tort suits in the medical-device context. Rather—as a couple of district court cases from the past year demonstrate—the real question is *which* state-law claims are preempted. Plaintiffs’ attorneys and defense counsel will surely spar over the answer to that question for years to come, but these recent decisions help tee up the issue well.

A. Some Background On Federal Regulation Of Medical Devices

In 1976, Congress enacted the Medical Device Amendments (“MDA”), 21 U.S.C. § 360c *et seq.*, to the Food Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.* The MDA vastly expanded the authority of the FDA to regulate medical devices.

Under the MDA, medical devices are divided into three categories, or classes. Class I devices, such as elastic bandages or sterile examination gloves, pose little or no risk of illness or injury, and are “subject

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only to minimal regulation.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) (citing 21 U.S.C. § 360c(a)(1)(A)). Class II devices, such as powered wheelchairs or surgical drapes, “are potentially more harmful,” and manufacturers of such devices “must comply with federal performance regulations known as ‘special controls.’” *Id.* (quoting 21 U.S.C. § 360c(a)(1)(B)). Finally, Class III devices, the most strictly regulated—and the focus of this article—are “devices that either ‘presen[t] a potential unreasonable risk of illness or injury,’ or which are ‘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.’” *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)). Class III devices include pacemakers, heart valves, prostheses, breast implants, bone screws and the like.

Before a manufacturer can market a Class III medical device it must obtain the FDA’s approval. There are three distinct routes to such approval. The primary method is the so-called “premarket approval,” or “PMA,” process, in which “the manufacturer must provide the FDA with a ‘reasonable assurance’ that the device is both safe and effective.” *Id.* (citing 21 U.S.C. § 360e(d)(2)). As the Supreme Court has noted, this is a “rigorous” process, under which “[m]anufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.” *Id.* In fact, the FDA and manufacturers frequently confer extensively during the PMA process, with manufacturers repeatedly modifying their applications to address agency concerns.

Class III devices can also obtain preclearance through two exceptions to the PMA requirement. First, devices can be sold if they are cleared under the so-called 510(k) process, 21 U.S.C. § 360(k), which allows a manufacturer to sell a device that is “substantially

equivalent” to a device that predates the MDA. (This prevents manufacturers of preexisting devices from monopolizing the market for such devices.) Second, “devices representing innovative technology may be marketed under an investigational device exemption (‘IDE’), an experimental regimen that allows for unapproved devices to be utilized in human trials.” *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000) (citing 21 U.S.C. § 360j(g)). No new Class III device can be sold without one of these three forms of preclearance from the FDA.

B. Preemption Under The MDA

At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being “stifled by unnecessary restrictions.” H.R. Rep. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the “undue burden[]” imposed by differing state regulation by including in the MDA a “general prohibition on non-Federal regulation.” *Id.* at 45. That general prohibition, which also serves to safeguard the uniformity of the federal regulatory scheme, broadly provides that no State may impose “any requirement” relating to the safety or effectiveness of a medical device that “is different from, or in addition to, any requirement applicable...to the device” under federal law. 21 U.S.C. § 360k(a). The FDA’s implementing regulation provides:

State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.

21 C.F.R. § 808.1(d).²



David Gossett

David Gossett is a partner in the Washington, DC office of Mayer, Brown, Rowe & Maw LLP, where he specializes in Supreme Court and appellate litigation. He has litigated federal preemption issues in a range of fields, including medical devices, automobiles, pesticides, railroads, and tobacco, and represented device manufacturers in a number of the cases discussed in this article. Mr. Gossett received his J.D., with High Honors, from the University of Chicago.

C. Medtronic v. Lohr

Although no one disputes that Section 360k(a) is an express preemption provision, there has been a great deal of debate about the meaning of this statute. Much of the problem can be traced to the Supreme Court's fractured decision in *Lohr*. In that case, the Court found there to be no preemption of certain state-law tort suits where the device at issue had been approved by the FDA under the 510(k) substantial-equivalence process. That much is clear. The implications of this decision, however, have been far from obvious to courts and commentators.

The best way to understand the Supreme Court's opinion in *Lohr*, as well as the lower-court cases that have attempted to interpret *Lohr*, is to focus separately on two distinct issues: (1) What **federal** actions count as "requirement[s]" that preempt state law; and (2) What **state** actions count as "requirement[s]" that are pre-empted by federal law.

First, the federal (preempting) side of the equation. Focusing on the FDA's implementing regulation, the *Lohr* Court held that only "specific" federal requirements applicable to a device are preemptive under the MDA. See 518 U.S. at 500-01. (In dissent, four Justices disagreed with this specificity gloss, noting that the statute makes no mention of specificity. *Id.* at 512 (O'Connor, J., concurring in part and dissenting in part).) According to the majority, the 510(k) process, under which the FDA must approve the sale of a device but in so doing does not review the safety or efficacy of that device, does not impose specific requirements and thus does not lead to federal preemption.

Second, the state (preempted) side of the equation. The majority in *Lohr* held that state requirements "of general applicability" are not preempted unless they have "the effect of establishing a substantive requirement for a specific device." *Id.* at 500 (internal quotation marks omitted). The Justices vehemently disagreed over whether state-law tort suits would be preempted under this standard. In his majority opinion, Justice Stevens stated that it would be "rare indeed" for a common-law suit to lead to a specific requirement, and thus to be preempted. *Id.* at 502-03. But despite the fact that this is technically part of the majority opinion, five justices in *Lohr* **specifically** disagreed with this statement. In particular, Justice O'Connor's dissenting opinion (for four justices) argued forcefully that common-law suits necessarily impose "requirements" on manufacturers: "[state] regulation can be as effectively exerted through an award of damages as through some form of preemptive relief." *Id.* at 509-10 (O'Connor, J., concurring in part and dissenting in part) (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality op.)) (brackets in *Lohr*). Justice Breyer—who signed on to the relevant section of Justice Stevens' majority opinion—disavowed this aspect of that opinion in his concurring opinion, explaining that he "basically agree[d]" with Justice O'Connor on this point. 518 U.S. at 503 (Breyer, J., concurring). As Justice Breyer noted, "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *Id.* at 504.

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D. Preemption Since Lohr

Confused yet? If so, you are in good company; the lower courts have been, too. But things have become much clearer in the last few years. The actual holding in *Lohr* is relatively straightforward: the mere fact that a Class III medical device has been approved for sale by the FDA under the 510(k) process does not give rise to any design requirements that are preemptive. Since *Lohr*, MDA preemption litigation has largely focused on Class III devices approved through the PMA (and occasionally the IDE) process. Most—though not all—courts have found there to be express preemption of at least some state-law tort claims for devices approved for sale through these processes.

Turning to the federal side of the equation, the vast majority of courts have found that PMA approval and the resultant bar on changes to a FDA-approved device create specific federal requirements that preempt conflicting state common-law

damages actions.³ This is entirely consistent with *Lohr*, in which the Court discussed the “rigorous” nature of the PMA process and compared the 510(k)-process requirements (which the Court found to be “important but entirely generic concerns”) and the PMA process (which focuses on “the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements”). See *Lohr*, 518 U.S. at 501.

On the state side of the occasion, there is even more uniformity that state-law damages claims must be preempted by divergent federal requirements.⁴ Given the five votes for this position in *Lohr*, this, too, seems to be a largely unassailable conclusion—although plaintiffs’ attorneys do continue to dispute it.

E. Enter the FDA

Although most cases after *Lohr* have found there to be preemption of common-law damages claims against manufacturers of devices approved through the PMA process, plaintiffs continued to bring such claims, and found support for their arguments in a somewhat unlikely source—the FDA itself. For a number of years, the government took the position that 21 U.S.C. § 360k(a) does not preempt state tort claims concerning FDA-approved devices. See, e.g., *U.S. Amicus Br., Smith Indus. Sys., Inc. v. Kernats, cert. denied*, 522 U.S. 1044 (1998) (No. 96-1405).

Last year, however, the FDA reversed that position. Twice in the past year—in *Murphree v. Pacesetter*, No. CT-005429-00-3 (Cir. Ct. Tenn., 13th Judicial Dist.), and *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d

Cir. 2004)—the government filed briefs arguing that, at least with respect to devices approved via the PMA process, most state-law tort claims are preempted. (The brief in *Horn* is available on Westlaw, at 2004 WL 1143720.)

This change in position has not been without controversy, of course. As I mentioned in the introduction to this article, Congressman Hinchey has embarked on a crusade against this new position. (His website, noted above, contains a wide range of letters and press releases on the subject.) Further change seems unlikely, however—and the agency’s new position is already having an effect. The second of its *amicus* briefs was relied on heavily by the Third Circuit in its recent decision finding claims against the manufacturer of a device approved through the PMA process to be preempted.

F. Horn v. Thoratec Corp.

This past summer, the Third Circuit joined the growing chorus of courts to hold PMA approval preempts common-law tort claims. See *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004). *Horn* involved tort claims arising out of the death of a patient, which apparently occurred when a suture on a HeartMate heart pump that had been implanted in him wore out, allowing an air embolus to travel to his brain. There was no dispute that the design of that suture had been approved by the FDA during the PMA process. Accordingly, the district court entered summary judgment for the defendant manufacturer on the basis of federal preemption. The plaintiff appealed to the Third Circuit.

In the early 1990s, the Third Circuit held that the PMA process preempted state tort suits. See

Gile v. Optical Radiation Corp., 22 F.3d 540 (3d Cir. 1994); *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir. 1995). Those decisions predated *Lohr*, however, and thus the plaintiff in *Horn* argued that these were no longer good authority.

The court of appeals disagreed. It explained that the PMA process “imposed requirements that were specifically applicable to the HeartMate.... [The FDA] imposed *mandatory conditions*—created through a decades-long process of correspondence, clinical testing and device alteration—pertaining to the HeartMate’s manufacturing, packaging, storage, labeling, distribution and advertising.” *Horn*, 376 F.3d at 170 (emphasis in original). Focusing on Justice Breyer’s concurring opinion in *Lohr*, the court also held that state common-law damages actions were the types of “requirements” that can be preempted under Section 360k(a). *Id.* at 173-77. In reaching these conclusions and finding the plaintiff’s claims to be preempted, the Third Circuit relied heavily on the FDA’s position, which the agency had explained in an *amicus* brief at the request of the court. See *id.* at 170-73, 177-79.

It is far too soon to tell whether *Horn* will be the final word on the existence of express preemption in the PMA context, of course—but given this decision there can be no doubt that it will be harder in the future for plaintiffs’ attorneys to argue that there is no preemption.

G. What Types Of Claims Are Preempted By Section 360k(a)?

Even if Section 360k(a) does preempt certain common-law tort claims, however, that is by no means the end of the analysis. As

two recent district court decisions demonstrate, even assuming the MDA's preemption provision preempts **some** state-law claims, it is important to focus on a plaintiff's **specific** claims, which may or may not be preempted.

As some courts have begun to recognize, the critical language in a preemption analysis is that Section 360k(a) preempts only state-law claims that would impose a requirement that "is **different from, or in addition to,**" any requirement imposed by federal law. 21 U.S.C. § 360k(a) (emphasis added). Thus, a state usually is free to impose liability on a manufacturer for selling a product that does not comply with federal law—and in particular, for selling a device that in some way violates the requirements imposed through the PMA process.

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A recent case out of Pennsylvania demonstrates this point well. *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419 (E.D. Pa. 2004), involved an implanted Activa tremor-control device used to treat Parkinson's disease, which had gone through the PMA process. The district court had no trouble finding PMA approval to be preemptive as a general matter (see *id.* at 431-32), but explained that this "does not end the inquiry." *Id.* at 432. Rather, the court analyzed the plaintiff's claims one by one, to see whether liability under each specific claim would impose a "different" or "addition[al]" (21 U.S.C. § 360k(a)) requirement on the manufacturer.

In this case, the court found some, but not all, of the plaintiff's claims to be preempted. In particular, the court found the plaintiff's implied-warranty-of-merchantability claim to be preempted (302 F. Supp. 2d at 434), but found his manufacturing-defect and express-warranty claims not to be preempted (*id.* at 432-33). Given the details of those claims, the court's analysis seems entirely correct.

For example, the plaintiff's specific "strict product liability and negligent manufacturing claims [were] based on the theory that the Activa system implanted in him **did not satisfy PMA/FDA standards.**" *Id.* at 433 (emphasis added). Were a device manufacturer to sell a device that did not meet the requirements created by that device's PMA—either because the manufacturer changed the design of the device or because the device contained a manufacturing defect that led it to not comply with the approved design—then state-law liability would not be based on a different state-law requirement but rather on evidence

that the device violated **federal** requirements. Similarly, the plaintiff's express warranty claim was based on a "Limited Warranty" provided to him, and the court explained that liability for a breach of that express warranty would be based on requirements created "by the warrantor and not imposed by state law." *Id.* at 433.⁵

Steele v. Depuy Orthopaedics, Inc., 295 F. Supp. 2d 439 (D.N.J. 2003), similarly analyzed the specific claims raised by a plaintiff one by one. This case involved an artificial knee joint used to treat osteoarthritis. Here again, the district court found FDA approval through the PMA process to be preemptive (*id.* at 451-53), but then analyzed the specifics of the plaintiffs' claims. As in *Davenport*, the plaintiffs in this case also raised state-law negligence and strict-liability claims. But unlike *Davenport*, the court here found those claims to be preempted. Why? Because whereas in *Davenport* those claims were based on the assertion that the manufacturer had violated requirements imposed under federal law, here, those claims were based on second-guessing the design that had been approved by the FDA. As the court noted, underlying the claims in this case was plaintiffs' "conten[tion] that the [device] was unsafe for its intended purpose and unreasonably dangerous to users. If successful, those claims would require a jury to conclude that the FDA's determination of safety and efficacy of the device was insufficient." *Id.* at 454-55. The court also found breach-of-implied-warranty claims to be preempted, but found state-law breach-of-express-warranty and fraudulent-concealment claims not to be preempted on the

ground that they did not impose additional requirements on the manufacturer. *Id.* at 455-57.

These two recent cases reflect the future of products-liability litigation against the manufacturers of Class III devices approved under the PMA process. Unlike earlier courts, which tended to think of preemption as an all-or-nothing inquiry, in the future courts are likely to get involved in very specific inquiries into the nature of the plaintiff's claim. Take a plaintiff claiming that her device was manufactured in a defective manner. The appropriate inquiry is, in what way? Is the plaintiff complaining about an aspect of the manufacturing process that had received FDA approval? If so, her claim is preempted. Is she instead asserting a negligent manufacturing claim, or, to take an extreme example, a claim that in the process of making her specific device a disgruntled employee intentionally contaminated

the manufacturing line? Such claims would almost certainly not be preempted, as they rely on a failure to follow specifications approved by the FDA during the PMA process. In other words, in the future, the devil will be in the details.

H. A Potential Monkey Wrench?

One final caveat must be mentioned, however, which leaves everything I've said above slightly open to question. On January 10, 2005—shortly after the submission date for this issue of *Products Liability*—the Supreme Court is scheduled to hear oral argument in *Bates v. Dow Agrosciences LLC*, No. 03-388, to consider the scope of preemption of state tort claims under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.* The Court likely will focus narrowly on FIFRA, of course, but one never knows. Stay tuned!

1. See Robert Pear, *In a Shift, Bush Moves to Block Medical Suits*, N.Y. TIMES, July 25, 2004, § 1, at 1; Editorial, *Blocking Medical Product Suits*, N.Y. TIMES, Aug. 1, 2004, § 4, at 10; <http://www.house.gov/hinchey/issues/fda.shtml> (last visited 1/9/2005).

2. This article focuses only on express preemption under 21 U.S.C. § 360k(a). It is worth noting, however, that in certain circumstances claims against a device manufacturer may also be preempted under principles of "implied" or "conflict" preemption. For example, in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court held that fraud-on-the-FDA claims are impliedly preempted by federal law. Similar implied-preemption arguments can be and sometimes are made in the context of other claims against device manufacturers, but space constraints mandate that this article be limited to express preemption.

3. See, e.g., *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001), *cert. denied*, 534 U.S. 1078 (2002); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997); *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998); *Fry v. Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996); see also *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) (en banc) (Class III device approved under New Drug Application ("NDA") process before 1976, which is therefore deemed to have been approved under PMA process, protected by preemption), *cert. denied*, 535 U.S. 1056 (2002). But see *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999); *Weiland v. Teletronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999); *In re St. Jude Medical, Inc.*, No. MDL 01-1396 JRTFLN, 2004 WL 45503 (D. Minn. Jan. 5, 2004).

4. See, e.g., *Brooks*, 273 F.3d at 796; *Martin*, 254 F.3d at 580-81; *Kemp*, 213 F.3d at 224; *Mitchell*, 126 F.3d at 913-14; *Papike v. Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376-77; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117-18. But see *Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997).

5. Despite finding only some of the plaintiff's claims to be preempted, the *Davenport* court nonetheless entered judgment in favor of the defendant, determining that the plaintiff had failed to meet his burden under the summary judgment standard and thus, could not go forward on any of his non-preempted claims. *Id.* at 435-42.