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ELECTRONIC CITATION: 2000 FED App. 0381P (6th Cir.)
File Name: 00a0381p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

ELIZABETH and CLIFFORD KEMP,
Plaintiffs-Appellants,

v.

MEDTRONIC, INC.,
Defendant-Appellee.

No. 99-3720

Appeal from the United States District Court
for the Southern District of Ohio at Cincinnati.
No. 97-00103—Sandra S. Beckwith, District Judge.

Argued: May 3, 2000

Decided and Filed: November 1, 2000

Before: MOORE and GILMAN, Circuit Judges;
McKEAGUE, District Judge.*

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* The Honorable David W. McKeague, United States District Judge for the Western District of Michigan, sitting by designation.

COUNSEL

ARGUED: Gregory M. Utter, KEATING, MUETHING & KLEKAMP, Cincinnati, Ohio, for Appellants. Thomas M. Parker, ROETZEL & ANDRESS, Akron, Ohio, for Appellee. **ON BRIEF:** Gregory M. Utter, Louis Francis Gilligan, KEATING, MUETHING & KLEKAMP, Cincinnati, Ohio, for Appellants. Thomas M. Parker, Sanjay K. Varma, ROETZEL & ANDRESS, Akron, Ohio, Karen A. Carroll, ROETZEL & ANDRESS, Cincinnati, Ohio, for Appellee.

McKEAGUE, D. J., delivered the opinion of the court, in which GILMAN, J., joined. MOORE, J. (pp. 40-42), delivered a separate concurring opinion.

OPINION

DAVID W. McKEAGUE, District Judge. This appeal requires us to determine whether the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c *et seq*., to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*., preempt plaintiffs' common law and products liability tort claims alleging negligence *per se*, fraud on the Food and Drug Administration ("FDA"), and failure to warn under Ohio law. The district court found plaintiffs' claims were either preempted by the MDA or failed to present a genuine issue of material fact, and awarded summary judgment to defendant-appellee Medtronic, Inc. ("Medtronic"). For the reasons set forth below, we affirm the judgment of the district court.

I. BACKGROUND

In late December 1991, plaintiff Elizabeth Kemp was admitted to the Bethesda North Hospital Emergency Room complaining of profound dizziness, weakness, and malaise.

fatal problem is that her fraud claim on appeal is solely presented as a claim of fraud on the FDA rather than fraudulent misrepresentations to her.

In sum, I disagree with the majority's theory regarding the claim of fraud on the FDA but agree nonetheless with the conclusion that that claim must be dismissed. I agree with the conclusion that the negligence per se claim raised by Kemp is preempted because of the particular nature of her claim. I agree that we need not address the issue of whether § 360k preempts a claim of breach of a duty to warn patients of risks discovered after FDA approval of a device.

Cardiac testing revealed complete atrioventricular block. In order to regulate Mrs. Kemp's heartbeat, on January 2, 1992, doctors surgically implanted a Model 4004M pacemaker and lead, manufactured by defendant Medtronic, Inc.

More than three years later, in June 1995, Mrs. Kemp began experiencing recurrent dizziness and fainting spells, attributable to the failure of her Model 4004M pacemaker lead to properly regulate her heartbeat. Then, on June 4, 1995, Mrs. Kemp fainted while in the garage of her home and fell to the concrete floor. As a result of her fall, she hit her head, and awoke suffering headaches, facial pain, and neck pain. It was later determined that these symptoms were caused by bilateral subdural hematomas. These blood clots required surgery to relieve the pressure in Mrs. Kemp's skull, and even after surgery she continued to experience loss of sight, speech, and cognitive and motor capability. Consequently, Mrs. Kemp spent some three months in and out of hospitals and rehabilitation, and she continues to suffer related disorders resulting from the injuries sustained in her fall.

A. Development of the Medtronic Model 4004M

At the center of this dispute is Medtronic's Model 4004M pacemaker lead, the device implanted in Mrs. Kemp. A pacemaker lead is a medical device, used in conjunction with a pulse generator (commonly referred to as a pacemaker), that is designed to monitor and correct rhythm irregularities in the human heart. Before a new pacemaker lead may be marketed and sold to the public, the manufacturer must first receive one of various forms of governmental clearance from the FDA. In 1982, the FDA granted Medtronic an investigational device exemption from the premarket approval ("PMA") process to permit clinical trials of the Model 4003, a predecessor to the Model 4004M. Following clinical trials, Medtronic submitted the Model 4003 to the FDA for a complete PMA review. After the FDA accepted, reviewed, and evaluated the PMA application, it was referred to a panel of experts. The panel specifically compared the performance of silicone and

polyurethane as insulating materials and concluded that both options should be available to physicians. The Model 4003 ultimately received PMA approval from the FDA on July 29, 1986.

Two years later, on July 18, 1988, Medtronic submitted a PMA Supplement to the FDA for the Model 4004, which proposed several significant modifications to the Model 4003. In addition to the Model 4003 specifications already approved by the FDA, the Model 4004 PMA Supplement addressed, among others, modifications incorporating the use of insulation made of pellethane 80A polyurethane.

On October 31, 1989, Medtronic filed a PMA Supplement application for the Model 4004M lead. A bipolar lead like the Model 4004M pacemaker lead consists of an inner conductor coil, outer conductor coil, inner insulation, and outer insulation. Should the inner insulation fail, the lead may short circuit, and fail to sense the heartbeat. If such a failure occurs, then the pacemaker cannot regulate the heartbeat properly, and arrhythmia or arrest may result. Medtronic manufactured the Model 4004M using pellethane 2326-80A as inner insulation material, and designed the 4004M lead to have inner and outer conductor coils with a platinum sputter barrier coating. Medtronic represented that the addition of the platinum sputter better prevented the coils from metal-ion oxidation, a degradative process observed in earlier pacemaker models employing polyurethane insulation (such as pellethane). In its 4004M PMA Supplement, Medtronic represented that the platinum sputter functioned as a barrier between the pellethane insulation and bodily fluids, preventing direct contact and avoiding metal-ion oxidation. The addition of this platinum sputter coating constituted a manufacturing and design change necessitating the filing of a PMA Supplement with the FDA.

The FDA approved the Model 4004M PMA Supplement on March 28, 1990. Thereafter, however, an FDA inspection revealed a significant risk of failure for the 4004M lead due to degradation of the polyurethane insulating material, and in

to the FDA during the approval process raises federalism concerns. Rather than force the analysis of this claim into the preemption framework of § 360k(a) and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), I would instead focus on the peculiar nature of this claim. It appears from Kemp's appellate brief that she asserts that, because of alleged misrepresentations by Medtronic to the FDA, the FDA erroneously approved the 4004M, and she should therefore be able to recover damages on a state-law fraud claim. A determination in favor of Kemp on this fraud claim would effectively set aside the entire FDA approval process. Not only would litigants be able to explore and challenge the administrative decisionmaking process of the federal agency, but also conflicts could easily arise between the results of state-law fraud litigation and federal enforcement through federal civil and criminal penalties for false or misleading submissions to the FDA. *See, e.g.,* 21 U.S.C. §§ 331(q)(2), 333.

In any event, Kemp fails to point to any Ohio law upholding the viability of a "fraud against a federal agency" claim for damages to an individual user of a product. The case cited by Kemp, *Dutton v. Acromed Corp.*, 691 N.E.2d 738 (Ohio Ct. App. 1997), does not characterize the claim as a claim of fraud on the FDA but rather involves a claim of misrepresentation of a medical device's approval status to the affected individual. Such traditional fraud claims certainly are not preempted by § 360k(a) or by *Lohr*, which explained that "[n]othing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Lohr*, 518 U.S. at 495. Moreover, allowing a state fraud claim for misrepresentations made to the patient would not conflict with our decision in *Bailey v. Johnson*, 48 F.3d 965 (6th Cir. 1995), holding that the federal Food, Drug and Cosmetic Act does not impliedly provide a private *federal* cause of action for a violation of its provisions, since that state fraud claim would be premised on using the federal law as a behavioral standard as endorsed by the Supreme Court in *Lohr*. Kemp's

CONCURRENCE

KAREN NELSON MOORE, Circuit Judge, concurring. I agree with the majority that pursuant to our decision in *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997), the FDA's approval of the Model 4004M PMA Supplement and the FDA's conditions of approval imposed on the 4004M pacemaker lead constitute a specific federal requirement, thereby triggering the possibility of preemption under 21 U.S.C. § 360k(a) of the Kemps' state law claims to the extent that the state law claims are different from or in addition to the federal requirements.

I also agree that the specific federal requirements established by the FDA approval of the Model 4004M do not include a requirement as to the thickness or coverage of the platinum sputter barrier. Because Mrs. Kemp's negligence claim is premised on a failure of the device to achieve a uniform thickness of the platinum sputter barrier, her negligence claim is preempted; a jury could not find in favor of Mrs. Kemp on the negligence claim without imposing a requirement "different from, or in addition to" the federal requirement. 21 U.S.C. § 360k(a)(1).

I agree as well with the more general principle stated by the majority that "a claim premised on the violation of FDA requirements established for a Class III device through the PMA process is not automatically preempted." Maj. Op. ante ¶ 70. Thus as the majority recognizes, a claim for negligence per se premised on the absence of a platinum sputter barrier as required by the FDA approval would not be preempted because the state claim would not impose requirements different from or additional to the federal requirements.

The claim that Medtronic committed a fraud on the FDA by improperly failing to submit certain tests and laboratory data

October 1993, Medtronic issued a Health and Safety Alert recalling some 74,000 Model 4004M leads.

B. Procedural Posture

On January 24, 1997, Elizabeth Kemp and her husband Clifford sued Medtronic, alleging ten common law and statutory products liability tort claims under Ohio law. Moving for summary judgment, Medtronic argued all of plaintiffs' state law claims were preempted by the express preemption provision of the MDA, § 360k. The United States District Court for the Southern District of Ohio largely agreed, finding the MDA preempted plaintiffs' strict products liability claims for defective design, failure to warn, and nonconformance to representations, as well as their claims for negligent design, negligent failure to warn, breach of express and implied warranties, and fraudulent misrepresentation with respect to medical devices approved through the FDA's premarket approval process. The district court did not find that the MDA totally preempted plaintiffs' claims, however, and ruled that any claims alleging the Model 4004M deviated from FDA specifications were not preempted. The district court then permitted plaintiffs to file an amended complaint to that effect.

Accordingly, on January 19, 1999, plaintiffs filed an eight-count amended complaint. Count I of the amended complaint alleges negligence *per se* for Medtronic's failure to manufacture the Model 4004M in accordance with the FDA standards and requirements imposed by the Model 4004M PMA Supplement. Count II alleges negligence *per se* for Medtronic's failure to (1) submit an engineering change order that varied the thickness and coverage of the platinum sputter coating; (2) provide Solution A test results to the FDA; and (3) provide canine biostability test results to the FDA as required by representations in the PMA Supplement. Counts III-VII allege claims that arise in the event Medtronic manufactured a product different from that approved by the FDA. Finally, Count VIII presents a derivative claim for loss

of consortium on behalf of plaintiff Clifford Kemp, which is entirely dependent upon his wife's claims.

On January 22, 1999, Medtronic moved for judgment on the pleadings on all counts of the amended complaint except Count I, arguing that plaintiffs' claims were preempted pursuant to the analysis in the district court's January 12, 1999 order. In a separate motion filed that same day, Medtronic moved for a judicial determination of the "specific federal requirements" applicable to the Model 4004M. Ruling from the bench at a pretrial hearing, the district court granted Medtronic's motion for judgment on the pleadings on Counts II, IV, V, VI, and VII of plaintiffs' amended complaint. The district court also granted Medtronic's motion for judgment on the pleadings on Count III of the amended complaint, except to the extent that it could be read to assert a claim for strict liability for a manufacturing defect.

Addressing Medtronic's motion to determine the specific requirements applicable to the Model 4004M, the district court reviewed the Model 4004M PMA Supplement and determined that the FDA approval process established six specific requirements. In determining the sixth requirement, the district court ruled:

> The sixth requirement is that there must be a protective barrier coat between the conductor coil and the insulation, which is composed of platinum sputtering. And that appears at Pages VI-52 and VI-61.
>
> There are other specifications within the PMA Supplement. I don't think they are relevant because for the most part they relate to the electrodes and the type of steroid to be emitted and things which are not at issue in this case.
>
> I would note that Paragraphs 57 through 60 of the amended complaint allege that platinum sputtering must be consistent. And the plaintiffs allege this requirement on the basis of Medtronic's description of the coil winding process and the post winding examination of the

VI. CONCLUSION

For the foregoing reasons, we conclude that plaintiffs' claims are preempted and we **AFFIRM** the judgment of the district court. Defendant has not shown, however, good cause for continuing the seal on appellate briefs, and accordingly the seal is hereby **LIFTED**.

different requirements or requirements in addition to those required by federal regulations.”).

The statement in Count IV could also be read, however, to assert a wholly separate and distinct claim that defendant acquired information subsequent to the FDA approval of the Model 4004M and before implantation of the device that would lead a reasonable manufacturer to warn patients and the medical community. Unfortunately, plaintiffs did not attempt to resolve this ambiguity until *after* the district court had already granted defendant summary judgment on the claim, in which the court clearly construed the claim – consistent with the parties' arguments – in accordance with the former understanding and not this latter, alternative meaning.

Because plaintiffs had ample opportunity to clarify this ambiguity – both in their original complaint and their brief in opposition to defendant's first motion for summary judgment – yet failed to do so in a timely manner, it is apparent that the claim they now argue on appeal was never properly presented to the district court and is not properly addressed by this Court in the first instance. Accordingly, we need not address the preemptive effect, if any, of § 360k on a claim for breach of a manufacturer's duty under state law to warn patients or the medical community of potential risks of a particular medical device based on information obtained subsequent to FDA approval of the device. Further, because of these pleading defects, we decline to remand this issue to the district court for further proceedings.

D. Derivative Spousal Claim

In light of the foregoing analysis finding that Elizabeth Kemp's claims are preempted by § 360k of the MDA, Clifford Kemp's derivative spousal claim is similarly preempted.

> wires. But I do not see this as being a design specification.
>
> There are also allegations in Paragraph 135 that Medtronic changed the coverage and thickness requirements for the platinum sputtering. That is not a part of the PMA Supplement. The specifications regarding platinum sputtering in the PMA Supplement are very general, and it does not appear to me that the FDA required a particular level of platinum sputtering.

J.A. at 2941-42. The district court then struck paragraphs in the amended complaint alleging that Medtronic improperly altered the platinum sputter barrier, failed to provide Solution A and canine biostability test results, and failed to warn plaintiffs of defects in the Model 4004M learned after FDA approval of the 4004M PMA Supplement.

Plaintiffs' remaining claims in Counts I and III asserted negligence *per se* and strict liability, respectively, and alleged Medtronic failed to manufacture the Model 4004M according to FDA specifications. The final claim in Count VIII alleged a derivative loss of consortium claim on behalf of Clifford Kemp. Thereafter, Medtronic again moved for summary judgment, and the district court granted the motion in a written opinion dated April 30, 1999.

II. STANDARD OF REVIEW

This Court reviews a district court's grant of summary judgment de novo. *See Terry Barr Sales Agency, Inc. v. All-Lock Co., Inc.*, 96 F.3d 174, 178 (6th Cir. 1996). A motion for summary judgment should be granted “if the pleadings, deposition, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). On summary judgment, the Court views the facts and all inferences drawn therefrom in the light most favorable to the nonmoving party. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

III. ANALYSIS

This appeal presents fractious issues which have sharply divided the various circuit courts which have considered them: whether the express preemption provision of the MDA, § 360k, preempts state law tort causes of action for negligence, "fraud on the FDA," and failure to warn committed by a defendant manufacturer of a Class III device both prior and subsequent to having received FDA approval of a PMA Supplement.

In 1976, Congress enacted the Medical Device Amendments, which modified the Federal Food, Drug and Cosmetics Act to allow the FDA to regulate medical devices. The MDA divides medical devices into three categories, or classes. The most strict FDA regulation is reserved for Class III devices, defined as those which: (1) are to be used for supporting or sustaining human life or that are of substantial importance in preventing impairment of public health; or (2) present a potential unreasonable risk of illness or injury. *See* 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II). To market a Class III device within the United States, the manufacturer must either submit its product to the FDA for premarket approval ("PMA process"), or qualify for one of two exceptions to this time-intensive regulatory review. The PMA process involves close scrutiny of the device by the FDA, and approval requires that the FDA conclude that it has received "reasonable assurances of [the device's] safety and effectiveness" from the manufacturer. *Id.* § 360c(a)(1)(C). To that end, manufacturers must provide the FDA with samples of the device, an outline of the device's components, a description of the manufacturing process, copies of the proposed labels, and various other information. *See* 21 C.F.R. § 814.20(b). The FDA then reviews such submissions for an average of 1200 hours before either approving or disapproving the device. *Id*. §§ 812.1-.150; *see also Mitchell v. Collagen Corp.*, 126 F.3d 903, 905 (7th Cir. 1997).

A manufacturer may also gain regulatory clearance for a Class III device through one of two exemptions from the

the FDA and thus violated MDA amendments in its 4004M PMA Supplement submission conflicts with governing precedent in this circuit holding that no implied right of action exists for a violation of the Federal Food, Drug and Cosmetics Act. Plaintiffs cannot circumvent our prior decision by characterizing their claim as "fraud on the FDA," which we hold is preempted in accordance with the foregoing analysis.

C. Failure to Warn

Plaintiffs' inadequate warning claim is brought under Ohio Revised Code § 2307.76, which generally provides that a product is defective where the manufacturer fails to issue adequate warnings when the manufacturer knew, or reasonably should have known, of a risk of harm to the consumer. It is difficult to determine, however, the underlying basis of plaintiffs' claim as presented to the district court below. As set forth in their original complaint, Count IV is ambiguous: "At the time the Medtronic Models 4004 and 4004M leads were supplied to Plaintiffs, the products were defective as a result of Medtronic's failure to give adequate warnings, regarding polyurethane insulation, insulation failure, and lack of testing." J.A. at 39.

This statement could be read as asserting that the warnings found in the label and literature approved by the FDA for the Model 4004 and Model 4004M were inadequate under Ohio law. As noted above, however, the information submitted to and approved by the FDA in the Model 4004M PMA Supplement – including information regarding warnings and disclaimers – comprise the specific federal requirements applicable to defendant's pacemaker lead. Accordingly, to the extent that plaintiffs' claim is premised on the adequacy of the warnings reviewed and approved by the FDA, our analysis of the "fraud on the FDA" claim applies equally to the failure to warn claim, and the claim is similarly preempted. *See Martin*, 105 F.3d at 1100 ("To allow a state cause of action for inadequate warnings would impose

that permitting the "searching inquiry" of FDA internal procedures and personnel runs counter to both congressional intent and sound policy. Hence, we hold that to allow common-law suits for fraud on the FDA to go forward would permit juries to reach a different conclusion than the FDA did in approving the device in question, thereby imposing a different requirement than that required by the federal requirements. *Id*.

Finally, permitting a fraud claim premised on false representations to the FDA during the PMA process would conflict with well-established precedent that no implied private right of action exists under the FDCA. As we have previously observed:

> [T]he determination that a violation of a federal statute such as the FDCA will create state tort liability is not a matter solely of state law. A state's ability to use a federal statute violation as a basis for state tort liability and negligence per se depends on the intent of Congress, and not merely on the intent of the state. Thus, the congressional decision not to provide a private cause of action under the FDCA becomes quite important in considering the propriety of a state negligence per se action for violation of the FDCA.

In re Bendectin Litig., 857 F.2d 313-14 (6th Cir. 1988). Returning to answer this question when it was squarely before this Court, we held that no private cause of action exists for a violation of the FDCA. *See Bailey*, 48 F.3d at 967; *see also* 21 U.S.C. § 337(a) (restricting FDCA enforcement to suits by the United States); *accord In re Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 781, 788-89 (3d Cir. 1999); *PDK Lab., Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997); *Mylan Lab., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993). States are not granted any authority to enforce compliance with the specific federal requirements established by the PMA process. Any common-law suit premised on allegations that Medtronic committed fraud on

PMA process. First, the statute permits devices that are "substantially equivalent" to medical devices in existence in 1976 to be marketed and sold without PMA approval, in order not to stifle competition with technology existing at the time of the enactment of the MDA. *See* 21 U.S.C. § 360j(g)(1). This limited form of review is known as "premarket notification" or "the § 510(k) process," and averages only 20 hours of review as opposed to some 1200 hours in the PMA process. *See Martin v. Telectronic Pacing Sys.*, 105 F.3d 1090, 1095 (6th Cir. 1997); *Reeves v. Acromed Corp.*, 103 F.3d 442, 446 (5th Cir. 1997).

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. An IDE permits a manufacturer to market "a device that otherwise would be required to comply with a performance standard or to have premarket approval for the purpose of conducting investigations of that device." 21 C.F.R. § 812.1. Accordingly, a device operating under the IDE exemption need not comply with premarket approval requirements during the trial period. *See* 21 U.S.C. § 360j(g); 21 C.F.R. §§ 812-813.

Should a manufacturer merely propose to modify a Class III device that has already received approval pursuant to the PMA process, the manufacturer may submit a PMA Supplement rather than re-submitting the entire device for review. *See* 21 C.F.R. §§ 814.39, 814.80. The procedures applicable to a PMA Supplement are the same as those applicable to an original PMA, although the FDA only requires the manufacturer to provide that information necessary to support the proposed modifications. *See id.* § 814.3(g). If the FDA grants approval to a PMA application or a PMA Supplement, it does so subject to conditions described in a document entitled "Conditions of Approval." This three-page form (1) requires the manufacturer to submit proposed labeling of the device prior to marketing; (2) limits advertising to the FDA-approved labeling for the device; (3) specifies that "[b]efore making any change affecting the

safety or effectiveness of the device, [the manufacturer shall] submit a PMA Supplement for review and approval by FDA;" (4) requires the manufacturer to submit postapproval reports at one-year intervals from the date of FDA approval; and (5) requires the manufacturer to report any incidents of adverse reaction to, or known defect of, the approved device. Furthermore, the manufacturer must report to the FDA, "[a]ny significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that *could not* cause or contribute to death or serious injury but *are not* correctable by adjustments or other maintenance procedures described in the approved labeling." J.A. at 997-99 (emphasis in original).

IV. PREEMPTION PRINCIPLES

A. Express Preemption Under Section 360k

The Supremacy Clause of the United States Constitution provides that the "Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, cl.2. Hence, "state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Central to determining questions of preemption is divining Congress' intent. *Id*. at 517-18. In view of the historic importance of federalism in these areas, the states' police powers relating to public health and safety are not preempted by federal law unless Congress' intent to do so is clearly expressed. *See Hillsborough County, Florida v. Automated Medical Lab., Inc.*, 471 U.S. 707, 715 (1985). Moreover, where as here, Congress has included an express preemption provision in a statute, a court may not look beyond it to consider implied preemption. Rather, "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone*, 505 U.S. at 517.

At the center of the instant dispute lies section 360k of the MDA, which expressly preempts certain state law requirements governing medical devices:

Supreme Court. Furthermore, although tort claims for fraudulent misrepresentation have long been part of the common law, claims alleging fraud on federal agencies have never come within the "historic police powers of the States," a consideration that becomes relevant when determining the scope of preemption under §360k. *Lohr*, 518 U.S. at 495. It is one thing to note, as did the majority opinion in *Bone Screw I*, that federal law provides penalties for fraudulent statements made to government agencies. It is quite another to say that because federal law criminalizes such conduct, private litigants may bring a civil suit presenting a novel theory of liability under state common law to enforce an alleged violation of federal agency regulations. In our view, permitting plaintiffs to bring such actions does not equate to a "parallel" state law requirement as contemplated by *Lohr*; rather, such actions could conceivably impose both "different" and "additional" state law requirements in addition to the federal requirements specific to the Class III device established through the PMA process.

Initially, as noted by *Michael*, a jury presented with a common-law claim of fraud on the FDA might conclude that, but for the alleged misrepresentations made by the manufacturer, the FDA would have withheld approval of the device because it had not received reasonable assurance of the device's safety and effectiveness. To make such a showing, plaintiffs would have to adduce expert testimony from those familiar with FDA procedures, conduct discovery of FDA employees, and establish that the alleged misrepresentations rendered the device not safe and effective for its intended use. Effectively, actions for fraud on the FDA would allow individual juries to undertake a counterfactual FDA review, and conclude that the FDA would not have approved the device. However, "Congress allocated the FDA responsibility to design and manage a process which would result in approval of the safest and most effective medical devices possible. Congress also assigned the FDA the responsibility to approve or disapprove of applications to market medical devices." *Michael*, 46 F.3d at 1329. Furthermore, we agree

§ 360k. First, and most significantly, the *Michael* court concluded that permitting the claim to go forward would open a pandora's box of judicial scrutiny of FDA decision-making, which "could ultimately require that a court determine whether the information [the defendant] submitted was truthful, whether it was complete, whether FDA procedures sufficed to avoid a material misrepresentation, and whether the FDA should have or would have approved the device despite the misrepresentations." *Michael*, 46 F.3d at 1329. In short, the *Michael* court feared that district courts would be required to adjudicate claims "applying state law, [and] to perform the same functions initially entrusted to the FDA." *Id*. Secondly, the *Michael* court reasoned that to permit a fraud claim based on allegedly false representations made by a manufacturer would conflict with longstanding precedent against permitting implied causes of action for violations of the Federal Food, Drug and Cosmetics Act.[15] *Id*.; *accord Bailey v. Johnson*, 48 F.3d 965, 966 (6th Cir. 1995). Expressly relying on this two-pronged analysis, a panel of the Seventh Circuit held the plaintiff's claims for fraud on the FDA were preempted in a tersely-worded ruling, stating its belief that *Michael*'s holding on this issue maintained its vitality even after the Supreme Court's ruling in *Lohr*. *See Mitchell*, 126 F.3d at 914.

Having carefully considered the question, we are convinced that the Third Circuit's analysis in *Michael,* adopted by the Seventh Circuit in *Mitchell,* correctly states the law and that nothing in *Lohr's* holding impairs *Michael's* reasoning. As a background consideration, we note that the plaintiffs in *Lohr* did not present a "fraud on the FDA" claim before the

[15] This position has also been advanced by the Solicitor General for the United States as Amicus Curiae recommending the Supreme Court grant *certiorari* in *Buckman Co. v. Plaintiffs' Legal Committee*, *cert. granted*, No. 98-1768 (U.S. June 29, 2000) ("'fraud on the agency' claims could subject federal agencies to countless, highly intrusive inquiries into their internal deliberations").

> [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.

21 U.S.C. § 360k(a).

B. *Medtronic, Inc. v. Lohr*

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Supreme Court addressed the question whether the MDA preempts various common law tort claims. The device in *Lohr* had not undergone a PMA review, but had instead been approved pursuant to the "substantially equivalent" exception found in § 510(k). In a five to four decision, the Court held that none of the plaintiffs' common law tort claims were preempted by the MDA. *Lohr*, 518 U.S. at 501-02. Justice Stevens' plurality opinion was joined by Justices Kennedy, Souter, and Ginsburg. Justice O'Connor concurred in part and dissented in part, and her opinion was joined by the Chief Justice, and Justices Scalia and Thomas. Justice Breyer concurred in part and in the judgment, and joined five of the seven parts of Justice Stevens' opinion. Hence, the five sections of Justice Stevens' opinion in which Justice Breyer concurred (Sections I, II, III, V and VII) form the opinion of the Court in *Lohr.*

Because the MDA contains an express preemption provision, a majority of the Justices agreed that the issue devolved to determining the extent to which the MDA preempts a plaintiff's state law claims. *Id*. at 484. Furthermore, speaking for a majority of the Court in Part V, Justice Stevens concluded that the *Lohr* plaintiffs could maintain at least some state tort law actions for violations of

FDA regulations. *Id*. at 494-95. Proceeding from this point of initial agreement, however, the Justices' understanding diverged. Justice Stevens, writing for himself and three other Justices, rejected the defendant's assertion that § 360k preempts all common law suits because such claims always constitute "requirements." Stevens reasoned that the broad construction urged by defendant would "require far greater interference with state legal remedies, producing a serious intrusion into state sovereignty while simultaneously wiping out the possibility of remedy for the [plaintiffs'] alleged injuries." *Id*. at 488-89.

Justice Stevens' opinion found support in the plain language of § 360k. He reasoned that the use of the term "requirement," rather than the term "remedy," indicated that Congress intended to preempt "device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries." *Id*. at 487-88. Accordingly, the plurality concluded "that when Congress enacted § 360k, it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions." *Id.* at 489.

Reaching the opposite conclusion, Justice O'Connor wrote an opinion joined by three other Justices in dissent. In their view, a common-law duty came within the meaning of the term "requirement" as used in § 360k because common law causes of action "operate to require manufacturers to comply with common-law duties." *Id*. at 510. (O'Connor, J., concurring in part and dissenting in part). Therefore, these four Justices would hold that a "fair reading" of the statute "indicates that state common-law claims are preempted . . . to the extent that their recognition would impose 'any requirement' different from, or in addition to, FDCA requirements applicable to the device." *Id*. at 512. In stark contrast to the Justices joining Justice Stevens' opinion, the O'Connor block did not believe that the state common law had to be "specific" to be preempted. Rather, under their reasoning, common-law claims were preempted if they

Co. v. Plaintiffs' Legal Committee, *cert. granted*, No. 98-1768 (U.S. June 29, 2000).

We return to the language of *Lohr* to guide our determination whether a common-law claim for "fraud on the FDA" amounts to a state-law requirement, "different from, or in addition to," the specific federal requirements. Five Justices held in Part V of the *Lohr* decision that "[n]othing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Lohr*, 518 U.S. at 495. Hence, we must determine whether plaintiffs' claim alleging that Medtronic fraudulently obtained PMA Supplement approval from the FDA by failing to submit Solution A test results, by failing to perform canine studies, and by failing to submit laboratory tests for the Model 4004M, merely "parallels" federal requirements, or if, instead, it threatens to impose different or additional requirements, and thus is preempted.

Concluding that a requirement imposed by a cause of action for fraud on the FDA simply parallels federal requirements and thus is not preempted, the Third Circuit noted that 18 U.S.C. § 1001 makes it a crime to make a fraudulent statement to a federal agency, and that 21 C.F.R. § 807.87(j) requires every pre-market notification to contain a statement that the information contained therein is believed by the manufacturer to be truthful. *See Bone Screw I*, 159 F.3d at 823. Based on these two federal requirements, the *Bone Screw I* court concluded "the state common law relied upon [by the plaintiffs] does not impose any obligation on [defendant] inconsistent with federal law." *Id*.

Set against this analysis is the Third Circuit's holding in *Michael v. Shiley*, which the Seventh Circuit adopted after *Lohr* in *Mitchell v. Collagen Corp*. In its pre-*Lohr* decision, the *Michael* court held that permitting the plaintiff's claim for fraud on the FDA to go forward would impose a different requirement under state law, and thus was preempted by

common-law claim, the federal requirements established by the Model 4004M PMA Supplement "must be 'applicable to the device' in question . . . and 'specific' to a 'particular device.'" *Martin*, 105 F.3d at 1098. (quoting *Lohr*, 518 U.S. at 500).

The issue presented here reaches to the heart of a sharp split between the various Courts of Appeals.[14] The Seventh Circuit has steadfastly, albeit tersely, maintained that claims alleging fraud committed through representations made to the FDA during the PMA process are preempted even after the Supreme Court's holding in *Lohr*. *See Mitchell*, 126 F.3d at 914 ("We continue to believe that this issue was decided correctly by the Third Circuit in *Michael v. Shiley, Inc.*"). In stark contrast, the Eleventh Circuit in *Goodlin* has held that no preemption of any state-law claims flows from FDA approval of a PMA Supplement, and the Third Circuit's decision in *Bone Screw I* held that state-law claims alleging fraud on the FDA are not foreclosed in light of the Supreme Court's decision in *Lohr*. *See Goodlin*, 167 F.3d 1381-82; *Bone Screw I*, 159 F.3d at 829. Recognizing the significance of the issue for thousands of plaintiffs across the country, the Supreme Court recently granted *certiorari*, limited to the following question: "Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices." *Buckman*

[14] Count VII of plaintiffs' original complaint does not explicitly allege that Medtronic fraudulently obtained approval of the Model 4004M by presenting false information to the FDA. Rather, plaintiffs merely claim that Medtronic misrepresented the Model 4004M to plaintiffs and their physicians. To prove the falsity of Medtronic's representation as required under the third element of the claim, however, plaintiffs must establish that the Model 4004M was falsely represented to be safe and effective – the very determination made by the FDA in granting PMA approval. Consequently, although plaintiffs' Count VII claim does not expressly allege "fraud on the FDA," such a claim is necessarily implied in plaintiffs' allegations.

imposed obligations "different from, or in addition to," any requirement of federal law. *Id*. ("The statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists.").

Justice Breyer, concurring in part and in the judgment, nevertheless explicitly agreed with Justice O'Connor's interpretation that certain common law causes of action could constitute state "requirements" that would conflict with federal "requirements" and thus be preempted. To hold otherwise would invite anomalous consequences, reasoned Justice Breyer, who set forth a hypothetical to illustrate his analysis:

> Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the "2-inch" agency regulation, pre-empts the state "1-inch" agency regulation, why would it not similarly pre-empt a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that the use of a more than 1-inch wire is negligent)? . . . .
>
> Consequently, I believe that ordinarily, 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 504-05.

The various courts of appeals that have confronted issues of preemption arising under the MDA have struggled mightily with *Lohr's* language in the effort to discern its holding. Part V of Justice Stevens' opinion, however, in which Justice

Breyer concurred, provides helpful guidance.[1] First, both "[t]he ambiguity in the statute – and the congressional grant of authority to the agency on the matter contained within it – provide a 'sound basis' for giving substantial weight to the agency's view of the statute." *Id.* at 496. Second, in attempting to determine what common law duties constituted preempted "requirements," the Court took pains to explain that:

> it is impossible to ignore [the Act's] overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest . . . . The statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations.

Id. at 499.

Consequently, those circuit courts that have considered the question of the preemptive effect of § 360k of the MDA have translated *Lohr's* emphasis on the FDA regulations to focus on whether (1) the FDA has established specific counterpart regulations or other specific federal requirements; that are (2) applicable to a particular device; and thus (3) make state regulations different from, or in addition to, the specific FDA requirements. *See Mitchell,* 126 F.3d at 910*; accord In re Orthopedic Bone Screw Products Liability Litig.* 159 F.3d 817, 822 (3d Cir. 1998)("*Bone Screw I*"); *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1371 (11th Cir. 1999). However, state or local requirements that merely "affect

[1] When no single rationale commands the agreement of five Justices of the Supreme Court, "the holding may be viewed as that position taken by those Members who concurred in the judgment on the narrowest grounds." *Marks v. United States*, 430 U.S. 188, 193 (1977). Hence, Justice Breyer's concurrence takes on heightened significance in interpreting *Lohr's* holding.

Litig., 159 F.3d 817, 821-22 (3d Cir. 1998)(*Bone Screw I*), *cert. granted*, No. 98-1768 (U.S. June 29, 2000), which concluded that "*Lohr* overrules everything in *Michael* that would prevent a plaintiff from pursuing a cause of action for fraudulent misrepresentation based on common law principles." *Bone Screw I*, 159 F.3d at 825 (footnote omitted). Similarly, plaintiffs cite *Dutton v. Acromed Corp*., 691 N.E.2d 738, 742 (Ohio Ct. App. 1997), and argue that the district court's reliance on *Klein* is misplaced. *Dutton* held that *Klein* does not survive the Supreme Court's holding in *Lohr*, and concluded that the plaintiff's fraud on the FDA claim was not preempted by the MDA.

Medtronic initially responds by arguing that Ohio law does not recognize a common-law cause of action for alleged fraud on a federal agency. Moreover, Medtronic contends that the district court properly extended our decision in *Martin* to find preemption. Medtronic rejects the holding of the Third Circuit in *Bone Screw I*, which it characterizes as a minority position adopted by no other circuit court, and urges us to hold with the Seventh Circuit in *Mitchell* that the earlier Third Circuit decision in *Michael* maintains its vitality even after the Supreme Court's decision in *Lohr*. Alternatively, Medtronic contends that the principle of implied conflict preemption dictates that we hold plaintiffs' fraud on the FDA claim to be preempted.

Under Ohio law, a claim of fraudulent misrepresentation requires a plaintiff to prove the following elements: "(a) a representation or, where there is a duty to disclose, concealment of a fact, (b) which is material to the transaction at hand, (c) made falsely, with knowledge of its falsity, or with such utter disregard and recklessness as to whether it is true or false that knowledge may be inferred, (d) with the intent of misleading another into relying upon it, (e) justifiable reliance upon the representation or concealment, and (f) a resulting injury proximately caused by the reliance." *Cohen v. Lamko, Inc*., 462 N.E.2d 407, 409 (Ohio 1984) (per curiam). Once again, to preempt this

barrier with a uniform 500 angstroms in thickness. Because the specific federal requirements applicable to the Model 4004M contain no thickness requirement, a jury verdict in plaintiffs' favor on plaintiffs' negligence *per se* claims would amount to a state requirement "different from, or in addition to," the federal requirements. It follows that plaintiffs' negligence *per se* claims are preempted. Consequently, we affirm the judgment of the district court in regard to this issue.

B. Fraud on the FDA

Count VII of the original complaint is entitled "Fraudulent Misrepresentation," and alleges "Medtronic, through its uniform course of conduct in the advertising, promotion, and sale of the [Model 4004M] leads, knowingly and purposely represented to the consumers of the product and to the medical community that the leads were fit for their intended purposes, would function without defect, and were appropriate for use in persons with heart conditions requiring pacemakers."[12] J.A. at 42. In their brief, however, plaintiffs characterize this claim as "Fraud on the FDA," and argue the district court erred by relying on *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir. 1995), and *Klein v. Biscup*, 673 N.E.2d 225 (Ohio Ct. App. 1996), to find this claim was preempted by federal law.[13] As argued, plaintiffs' claim is similar to the fraud on the FDA claim presented to a panel of the Third Circuit in *In re Orthopedic Bone Screw Product Liability*

[12] Plaintiffs' original complaint thus alleges that Medtronic fraudulently misrepresented the Model 4004M *to plaintiffs and their physicians*. As argued before the district court and on appeal, however, plaintiffs purport to have claimed that Medtronic fraudulently obtained FDA approval by failing to submit Solution A test results, canine test results, and other laboratory data prior to receiving FDA approval.

[13] In its ruling, the district court expressly relied on both *Michael* and *Klein*, and also noted that our decision in *Bailey*, 48 F.3d at 968, supported its conclusion that state-law claims for fraud on the FDA are preempted. J.A. at 1370-71.

devices" are not preempted if such regulations are not "requirements applicable to a device" within the meaning of the MDA.

C. Specific Federal Requirements

Hence, as a threshold matter, we must first determine whether the FDA has established specific federal requirements applicable to the Model 4004M pacemaker through the PMA process. Plaintiffs draw our attention to the recent decision of the Eleventh Circuit Court of Appeals in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), which addressed this exact issue on nearly indistinguishable facts. In *Goodlin*, the Eleventh Circuit held that FDA approval of a PMA Supplement does not establish federal requirements specific to the device. Defendants flatly disagree, arguing that our decision in *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997), holding that IDE approval constitutes specific federal requirements, applies *a fortiori* to the PMA process.

In *Martin*, we confronted the question whether common law and statutory tort claims brought under Ohio law were preempted by FDA approval for a Class III device granted under the IDE exemption. The plaintiff in *Martin* filed suit after her implant – an experimental device that combined the functions of a defibrillator, a cardioverter, and a pacemaker – malfunctioned. *See id.* at 1092. The plaintiff then brought five claims under Ohio tort law for the injuries that she suffered. In a unanimous opinion affirming the district court's grant of summary judgment to the defendant, this Court noted that, "unlike the general federal requirements discussed in *Medtronic*, the regulations governing investigational devices are essentially device specific." *Id.* at 1097. The *Martin* court further observed that "*there are no specific regulations governing pacemakers like the one at issue; however, the application and approval process under the IDE is device specific*." *Id.* (emphasis added). Reasoning that the extensive review process undertaken by the FDA explored "the methods, facilities, and controls used for

manufacture of the device," *Martin* went on to affirm the district court's ruling that the plaintiff's manufacturing defect, design defect, inadequate warning, supplier liability and derivative spousal claims were preempted by § 360k. *Id*. With regard to the plaintiff's claim for nonconformance to express representations, *Martin* found the plaintiff waived the claim by failing to properly address the argument to the district court. *See id*. at 1100-01.

Defendant contends the same logic that guided this Court in *Martin* compels a finding that the FDA's approval of the PMA Supplement for the Model 4004M lead established device-specific requirements, because PMA Supplement approval (and the underlying PMA approval) is even more difficult to obtain than IDE approval. Vehemently disagreeing, plaintiffs cite *Goodlin* and argue the PMA Supplement application process generally, and the 4004M PMA Supplement process particularly, do not establish federal requirements specific to the device.[2] Because the Eleventh Circuit tackled the issue presented here on largely indistinguishable facts in *Goodlin*, and held none of the plaintiff's claims were preempted, we now consider the *Goodlin* analysis in relation to the instant case.

Like Elizabeth Kemp, Lisa Goodlin was implanted with a Medtronic Model 4004M pacemaker lead to regulate her heartbeat. Following receipt of the October 1992 Health and Safety Alert letter issued by Medtronic at the instigation of the FDA, Goodlin elected to have her pacemaker removed as a precaution. Although her pacemaker did not demonstrate

[2]In an opinion predating the Supreme Court's 1996 decision in *Medtronic, Inc. v. Lohr*, a panel of the Ninth Circuit reversed a grant of summary judgment in favor of a defendant manufacturer of a Class III device that had undergone PMA approval. Focusing upon the regulations promulgated by the FDA, the Ninth Circuit opined that PMA approval does not constitute a "*specific* requirement applicable to a *particular* device" under 21 C.F.R. § 808.1(d), and held § 360k of the MDA does not preempt state common law tort claims of general applicability. *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459-60 (9th Cir. 1995) (emphasis in original).

virtually unchanged i.e., dimensions, flexural and electrical properties. Therefore, the performance of the leads will not change as a result of this sputtering process." J.A. at 2886. Based on this language, included in a withdrawn application, plaintiffs contend Medtronic represented that the thickness of the platinum sputter barrier for the Model 4004M pacemaker lead was a uniform 500 angstroms.

Again, plaintiffs rely on statements that are inapplicable to the Class III device in question, the Model 4004M. Most significantly, the Model 4003M PMA Supplement was voluntarily withdrawn by Medtronic, and thus never received FDA approval necessary to establish federal requirements. As we held in Part IV(d), *supra*, it is the PMA Supplement, coupled with the conditions of approval set forth in the FDA's approval letter, that establishes the specific federal requirements for a Class III device. The PMA Supplement for the Model 4003M, a unipolar lead, cannot reasonably be deemed to establish the requirements for the Model 4004M, a bipolar lead. Furthermore, the Model 4003M was not in the Model 4004M's chain of development; rather, the proposed modification adding the platinum sputter was submitted in 1991, after the approval of the Model 4004M in 1988. Hence, any reference contained in the withdrawn Model 4003M PMA Supplement cannot serve to establish requirements applicable to the Model 4004M, established through its PMA Supplement.

Having carefully scrutinized the record, our initial observation is confirmed: Medtronic represented that the Model 4004M would contain a platinum sputter barrier, but did not represent that the barrier would have a particular thickness. The specific federal requirements established by FDA approval of the Model 4004M PMA Supplement thus contain a requirement that the Model 4004M have a barrier of platinum sputter, and a claim for negligence *per se* premised on the lack of such a barrier would not be preempted. As pled and argued by plaintiffs, however, Medtronic was negligent in failing to manufacture a product that had a platinum sputter

rejected the notion that the § 510(k) approval process establishes specific federal requirements for a device. *Lohr*, 518 U.S. at 493. By contrast, the clear implication of the holding in *Martin* and the express import of our decision today is that FDA approval pursuant to a PMA Supplement establishes specific federal requirements for the device in question. Thus, we focus on the representations Medtronic made in the Model 4004M PMA Supplement which established its specific federal requirements to the exclusion of other submissions.[9] Accordingly, any representations made in the September 28, 1987, 4016A premarket notification, which did not receive FDA-approval, are inapplicable to the FDA-approved Model 4004M which received FDA approval after undergoing the PMA process.

The second submission plaintiffs rely on to establish a thickness requirement for the Model 4004M is the voluntarily withdrawn 1991 PMA Supplement for the Model 4003M.[10] On November 19, 1991, Medtronic submitted a PMA Supplement when it decided to modify the Model 4003M to incorporate a platinum sputter barrier.[11] In an attachment to this submission, Medtronic states, "[t]he sputtering process deposits only 500 angstroms of platinum on the conductor coil. Therefore, the physical properties of the coil are

[9] Of course, the Model 4003 PMA, the ancestor of the Model 4004M, also established requirements applicable to the Model 4004M under our analysis, but any such requirements are not at issue here.

[10] Medtronic wrote to voluntarily withdraw its PMA Supplement for the Model 4003M on December 10, 1992, and the FDA acknowledged such withdrawal on December 18, 1992. *See* 21 C.F.R. § 814.44(g)(3); J.A. at 2877.

[11] The Medtronic Model 4003M, as PMA-approved on June 23, 1989, is a unipolar polyurethane pacing lead with a conductor coil that was not barrier coated. Medtronic submitted a PMA Supplement specifying the addition of a barrier coat of platinum sputter on November 19, 1991. J.A. at 2883.

any indication of failure, Goodlin brought suit against Medtronic claiming negligent design and strict products liability under Florida common law. The district court ruled the MDA preempted Goodlin's claims, because the FDA had approved the Model 4004M through the PMA process, and granted summary judgment to Medtronic. On appeal, a panel of the Eleventh Circuit reversed the judgment of the district court. *See Goodlin*, 167 F.3d at 1368-69.

Parsing the Supreme Court's decision in *Lohr*, the *Goodlin* court inquired whether "the FDA's PMA process, which produces a finding that the manufacturer has provided the reasonable assurances of safety and effectiveness necessary to market the device, translates into the necessary imposition of a 'specific requirement.'" *Id.* at 1375. After reviewing the PMA process, the *Goodlin* court concluded that PMA approval "represents only a finding that the manufacturer's proposal to market a device has reasonably assured the FDA of the device's safety and effectiveness" and that "[d]espite the specificity and considerable rigor of [PMA review] . . . neither the FDA's actual review of a device and its supporting information nor the agency's eventual approval of the device imposes any ascertainable requirement upon the device." *Id.*

In line with *Goodlin*, plaintiffs argue that in the absence of specific requirements, FDA approval of a PMA Supplement should not be granted preemptive effect. Plaintiffs further assert the issuance of a form approval letter setting forth generic "Conditions of Approval" does not mean that the FDA has established specific requirements applicable to the design and manufacture of the Model 4004M. Indeed, plaintiffs note that the FDA has never promulgated federal regulations regarding the manufacture of pacemaker leads. Plaintiffs also disagree that the FDA involvement in the PMA Supplement process is as involved as that in the IDE

application, and thus propose that the Court distinguish *Martin* on this rationale.[3]

We are not persuaded by plaintiffs' arguments, and respectfully disagree with the conclusions drawn by the panel of the Eleventh Circuit in *Goodlin*. Most importantly, *Goodlin*'s conception of what constitutes a "requirement" is irreconcilable with our analysis in *Martin* holding that IDE approval establishes specific federal requirements for the device in question. Although the IDE process imposes no "ascertainable substantive prerequisite for approval," this Court in *Martin* explained that the application and approval process under the IDE is a device-specific requirement that nevertheless has preemptive effect. *See Martin*, 105 F.3d at 1097. Our analysis comports with that advanced by the Seventh Circuit, which has held that "PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling" and is "specific to the product." *Mitchell*, 126 F.3d at 913; *accord Martin*, 105 F.3d at 1097.

Moreover, although the IDE process and the PMA process are not identical, a comparison of the governing regulations reveals no material differences.[4] Furthermore, the PMA

[3]Plaintiff offers the affidavit of Charles H. Kyper, Director of the Premarket Approval Staff from 1981-1990. Kyper avers that:

> A PMA Supplement application is not reviewed with the same rigor as a PMA. Review of a PMA Supplement is much like a review of a 510(k) application in that both focus on the change being presented and assume the accuracy of information being presented and assume the accuracy of information presented in prior submissions. Typically, reviews of PMA Supplement applications are allocated 1/7th the time allocated for a PMA.

J.A. at 311.

[4]In fact, the *Martin* court found it significant that under the IDE process, the FDA required information regarding "the methods, facilities, and controls used for manufacture . . . of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can

4004M PMA Supplement by Medtronic's statement in the Model 4004M PMA Supplement concerning the sputter barrier that, "[t]he Model 4016A pacing lead also incorporated these improvements." J.A. at 606.

We are utterly unconvinced that a statement in the Model 4004M PMA Supplement which merely points out that the addition of a platinum sputter barrier was incorporated in an earlier, unrelated model pacemaker is sufficient to establish a requirement for the Model 4004M. As a background consideration, the text from the Model 4004M PMA Supplement that plaintiffs claim incorporates the 4016A premarket notification is not placed in full context. After describing the modifications over the Model 4003, the Model 4004M PMA Supplement states in summation: "Therefore, two improvements incorporated into the Models 4004/4504 are: [b]arrier coating the conductor coils with platinum, and [t]hermal annealing tubing in an inert atmosphere (e.g., argon or nitrogen)." *Id*. at 605-06. The text goes on to state that "[t]he Model 4016A pacing lead also incorporated these improvements." *Id*. at 606. Combining these references, plaintiffs maintain they amount to a representation that the Model 4004M PMA Supplement incorporates all of the specifications submitted with the Model 4016A premarket notification.

Given the differences between the Model 4016A and the Model 4004M, plaintiffs' argument fails to persuade us. Underscoring the specious nature of plaintiffs' claim is the fact that the Model 4016A was merely judged substantially equivalent pursuant to the § 510(k) process, and was not reviewed and approved pursuant to the PMA process.[8] *Lohr*

[8]Medtronic submitted its § 510(k) notification for its Model 4016A bipolar transvenous lead on September 28, 1987. The Model 4016A was a modification of the Model 4016 which was judged substantially equivalent to leads marketed prior to May 28, 1976, pursuant to the § 510(k) process on August 29, 1985. J.A. at 774.

plaintiffs repeatedly assert, but rather called for a range of 300 to 700 angstroms in thickness.[7]

Furthermore, nowhere in the Model 4004M PMA Supplement do we find that Medtronic made an express representation as to the thickness or coverage of the platinum sputter barrier. Apparently recognizing this glaring impediment to the success of their claims, plaintiffs nevertheless contend that Medtronic made binding representations as to the thickness of the platinum sputter barrier in submissions made to the FDA both prior and subsequent to the July 15, 1988 Model 4004M PMA Supplement.

First, plaintiffs contend Medtronic represented to the FDA that the thickness of the platinum sputter barrier would be 500 angstroms over 100% of the conductor coils in the premarket notification to the Model 4016A, a pacemaker not in the chain of development of the Model 4004M. Indeed, the Model 4016A was given FDA clearance pursuant to a § 510(k) premarket notification, rather than FDA approval pursuant to the PMA process. In answer to an FDA inquiry regarding the effect of platinum sputter on the weight distribution of the lead in the Model 4016A during its premarket notification process, Medtronic represented that because "the thickness of the platinum coating is only 500 Angstroms (Å), it is unlikely that it changes the weight distribution throughout the lead, thereby affecting electrode stability." *Id.* at 852. Plaintiffs next point to mathematical calculations that plaintiffs interpret as calling for 100% of the conductor coils to be sputtered at a thickness of 500 angstroms. Plaintiffs argue that these representations were incorporated into the Model

[7] At oral argument, we explicitly asked plaintiffs to identify in the record what they contended established a thickness requirement for the platinum sputter barrier. In response, plaintiffs cited Medtronic's internal deviation authorization and engineering change order. J.A. at 986-90; 991-93. These pages do not contain any reference to the coverage of the barrier.

Supplement for the Model 4004M is composed of more than a hundred-page submission, and like the PMA, if the FDA ultimately grants approval to the modification in question, it means that the FDA has "received reasonable assurances of [the device's] safety and effectiveness." 51 Fed. Reg. at 26355. The FDA does not reach such a conclusion in approving a device pursuant to the IDE exemption, which by its very nature exists to permit experimental devices to be implanted to gather data in human trials. Hence, we agree with the district court's analysis that "preemption analysis regarding products approved through the PMA process is fully applicable to products approved through the PMA Supplement process." J.A. at 1369.

Plaintiffs further fail to adduce any evidence suggesting that a device approved pursuant to the PMA Supplement process, which builds upon the rigorous PMA process, receives any less scrutiny than does a device exempted from PMA approval under the IDE exemption process that was found to constitute specific requirements in *Martin*. Rather, plaintiffs' expert merely avers that a PMA Supplement is not reviewed with the same rigor as a PMA. This distinction is readily understandable because a PMA requires review of a previously unapproved device that does not qualify for exemption either as substantially equivalent to devices extant in 1976 or as an IDE. By contrast, a PMA Supplement proposes changes to a device that has already received rigorous review and approval during the original PMA

make a knowledgeable judgment about the quality control used in the manufacture of the device." *Martin*, 105 F.3d at 1097 (quoting 21 C.F.R. § 812.20(b)(2)) (internal quotation marks omitted). Similarly, a PMA applicant is required to submit information regarding "[t]he methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device." 21 C.F.R. § 814.20(b)(4)(v).

process. Hence, because the FDA has already made a determination as to the safety and effectiveness of the underlying device in the original PMA, it can evaluate only the proposed modifications presented in the PMA Supplement while relying on its earlier approval of the original device.

Finally, plaintiffs' argument that the FDA has never promulgated specific regulations governing pacemakers produces a result contrary to our understanding of *Lohr*'s holding. Under both plaintiffs' proposed analysis and under *Goodlin*, no cause of action involving any Class III device approved pursuant to the PMA process would ever be preempted because the FDA merely approves or disapproves the device in question, and does not set forth the basis for its decision. Hence, according to plaintiffs' position, preemption under § 360k would be exceedingly rare. Motivating Justice Breyer's refusal to join Part VI of Justice Stevens' opinion in *Lohr*, however, was his lack of conviction that "future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.'" *Lohr*, 518 U.S. at 508. (Breyer, J., concurring in part and concurring in the judgment). Indeed, we agree with Justice Breyer that, in enacting § 360k, Congress intended the preemption of some state-law causes of action, an intent given effect by this Court's *Martin* ruling. Following the logic of *Martin*, then, we hold that FDA approval of the Model 4004M PMA Supplement, taken together with the conditions of approval imposed on the device by the FDA, constitutes a specific federal requirement applicable to the device.

D. Specific Requirements Applicable to the Model 4004M

Having determined that the FDA's approval of the Model 4004M constitutes a specific requirement invoking preemption under § 360k, we must next determine what specific requirements are imposed by the FDA's approval of the Model 4004M PMA Supplement. Before the district court, the parties stipulated that the determination of the FDA

We agree with the result reached by the district court with respect to plaintiffs' negligence *per se* claims, yet we do so for different reasons. While we agree with plaintiffs that a claim premised on the violation of FDA requirements established for a Class III device through the PMA process is not automatically preempted, we nevertheless conclude that the district court properly granted summary judgment to Medtronic on plaintiffs' claims as presented, because we find that the specific federal requirements established by FDA approval of the Model 4004M PMA Supplement do not include a requirement as to the thickness or coverage of the platinum sputter barrier. To permit a jury to find Medtronic negligent for failing to manufacture the Model 4004M with a platinum sputter barrier of uniform 500 angstroms thickness would be to impose a requirement different from and in addition to those established by the FDA. It follows that plaintiffs' negligence *per se* claims are preempted.

Our review of the record leaves us firmly convinced that plaintiffs' argument that the Model 4004M PMA Supplement included a specification that the platinum sputter coat would be a uniform 500 angstroms thick represents at best a tenuous assertion and, at worst, an outright mischaracterization of the record. Both in their briefs and in oral argument, plaintiffs repeatedly asserted that the Model 4004M specifications, as originally designed, called for a platinum sputter barrier a "uniform 500 angstroms thick." Plaintiffs' statements find no support in the record. Indeed, we find that the record flatly contradicts plaintiffs' position. Instead of calling for a uniform thickness of 500 angstroms, the ECO (engineering change order) reveals that the original coating specification provided, "[c]oating thickness shall be 500 ± 200 angstroms," and that Medtronic modified the design to call for "100 to 1000 angstroms over a minimum of 85% of the wire circumference." J.A. at 993. Therefore the original specification was not for a uniform 500 angstroms as

To preempt these claims, the federal requirements must be "'applicable to the device' in question . . . and 'specific' to a 'particular device.'" *Lohr*, 518 U.S. at 500; *see also Martin*, 105 F.3d at 1098. To determine whether plaintiffs' negligence *per se* claims are preempted, however, we must first determine whether the specific requirements established by FDA approval of the Model 4004M PMA Supplement establish a requirement as to the required thickness and coverage of the platinum sputter barrier.

Addressing Count I, the district court granted summary judgment to Medtronic, ruling that any claim that the platinum sputtering may have failed to prevent insulation failure constitutes a claim for design defect, and is therefore preempted. The district court further ruled that neither the Model 4003 PMA nor the Model 4004M PMA Supplement required Medtronic to manufacture the Model 4004M lead with a particular thickness of platinum sputtering, and that if plaintiffs' common law claims asserted otherwise, they would constitute a requirement "different from, or in addition to," the non-specific federal requirement. Accordingly, such claims would be preempted. With respect to Count II, the district court granted defendant's motion for summary judgment on grounds of preemption, relying on our decision in *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995), which held no private cause of action exists for a violation of the Federal Food, Drug and Cosmetics Act.

In support of the district court's judgment, Medtronic makes three arguments. First, Medtronic contends it manufactured the Model 4004M lead in conformance with FDA requirements. Second, Medtronic argues that under Ohio law, an action for negligence *per se* can only be predicated on a statutory violation. Third, Medtronic asks us to affirm on the ground that plaintiffs' negligence *per se* claims seek to circumvent the intent of Congress and should be preempted as impermissible attempts to create private causes of action for alleged violations of the Food, Drug and Cosmetics Act.

specifications applicable to the 4004M pacemaker lead was a matter of law for the court's determination. At a hearing on the issue, the district court ruled that six specifications were determined by the FDA during the PMA Supplement process for the 4004M lead.[5]

Although Medtronic does not appeal from the district court's decision, it argues on appeal that the FDA's "PMA approval" and the "Conditions of Approval," taken together, comprise the FDA's administrative response to Medtronics' PMA Supplement, establishing the specific federal requirements for the Model 4004M. As part of the PMA process, Medtronic submitted a detailed request for approval of a specific device of a particular design, using particular manufacturing processes and labels. Once approved, Medtronic concedes that the design, manufacturing processes, and labels may not be modified without further FDA approval, unless the modifications do not affect the device's safety or effectiveness. *See* 21 C.F.R. § 814.39. Thus, Medtronic argues it is the totality of the design, manufacturing processes, and labeling – when coupled with the prohibition against modifying them – that represents the specific federal requirement "applicable under [the MDA] to the device." 21 U.S.C. § 360k(a)(1).

We agree. The district court's attempt to parse the relevant requirements from Medtronic's PMA application and PMA

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[5] The district court identified six requirements that it believed were directly applicable to plaintiffs' claims, summarized as follows:
(1) The lead must have four polyurethane tines; (2) the conductor coils must be made of MP35N nickel alloy; (3) the lead must have polyurethane insulation; (4) the conductors must be constructed from MP35M nickel alloy, .005 inches in diameter and sputter coated with platinum; (5) the insulation must be made of 2363-80A polyurethane, of specified thicknesses; and, (6) there must be a protective barrier coat between the conductor coil and the insulation which is composed of platinum sputtering.
See J.A. at 2941-42.

Supplement, while an admirable effort to discern the relevant portions of the voluminous submissions to the FDA concerning the Model 4004M, does not comport with the actual PMA approval process that *Martin* (impliedly) and *Mitchell* (explicitly) relied upon to hold that the PMA process establishes specific federal requirements for a Class III device. It is true that in granting approval for a Class III device, the FDA does not set forth the reasons justifying its decision. Impliedly, however, the FDA has relied upon both the PMA submission approved for the original Class III device and the PMA Supplement providing specific information on the proposed modification in question. These specific submissions form the basis of the FDA's approval of the PMA Supplement. Thus, we conclude the specific requirements applicable to the Model 4004M include the entire relevant PMA and accompanying PMA Supplement, rather than certain portions thereof. In the case of the Model 4004M, then, the information submitted to and approved by the FDA in both the Model 4003 PMA and as modified by the Model 4004M PMA Supplement comprise the specific federal requirements applicable to Medtronic's Model 4004M pacemaker lead.

V. PLAINTIFFS' CLAIMS

A. Negligence Per Se

Having determined that the specific requirements for the Model 4004M are established by the July 15, 1988, Model 4004M PMA Supplement combined with the conditions of approval set forth by the FDA, we turn to take up plaintiffs' particular claims in light of the above analysis to determine whether they impose state-law requirements "different from, or in addition to," federal requirements. Counts I and II of plaintiffs' first amended complaint allege negligence *per se* for failure to comply with the FDA requirement to manufacture and sell the Model 4004M Pacemaker as FDA approved. In Count I, plaintiffs generally allege Medtronic failed to manufacture the Model 4004M as required by the

FDA and thus sold a misbranded and/or adulterated product. Count I further alleges that Medtronic's failure to manufacture the Model 4004M pacemaker lead as required by the FDA resulted in insulation failure, which proximately caused Mrs. Kemp's injuries.

Building on Count I, Count II alleges that Medtronic was required by the conditions of approval set forth in 21 C.F.R. § 814.84 to seek FDA approval for any change affecting the "safety and effectiveness of the device." Plaintiffs contend that Medtronic violated the conditions of approval for the Model 4004M pacemaker lead and 21 C.F.R. § 814.84 by failing to submit to the FDA a March 1989 deviation authorization and engineering change order concerning the coverage of platinum sputter coating over the conductor coils, by failing to provide results of canine biostability tests, and by failing to provide data from clinical devices or laboratory studies involving the 4004M.

Before the district court, plaintiffs elected to distill Counts I and II down, focusing solely on Medtronic's alleged failure to manufacture the Model 4004M pacemaker lead in conformance with the FDA-approved 4004M PMA Supplement specifications, and alleging that such failure constituted negligence *per se.* The essence of plaintiffs' argument is that Medtronic failed to coat the lead with a uniform 500 angstroms of platinum sputtering, resulting in the sale of a misbranded or adulterated product.[6] Before us, plaintiffs merely contend that under *Lohr*, a negligence *per se* claim survives any application of preemption under § 360k.

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[6] In their response to defendant's motion for summary judgment on March 9, 1999, plaintiffs characterized their claims as follows:

> Plaintiffs' negligence *per se* and strict liability claims focus solely on Medtronic's failure to manufacture the Model 4004M pacemaker with a "protective barrier coat of [sic] between the conductor coil and the insulation, which is composed of platinum sputtering."

J.A. at 2801.