UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 95-31080

EDWARD A. LEWIS, et al.,

Plaintiffs-Appellants,

versus

INTERMEDICS INTRAOCULAR, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Eastern District of Louisiana
(Nos. 93-CV-7, 93-CV-403, 93-CV-404, 93-CV-405, 93-CV-407)

April 9, 1997

Before BARKSDALE, EMILIO M. GARZA, and BENAVIDES, Circuit Judges.

PER CURIAM:*

At issue, in the light of the Supreme Court's recent decision concerning preemption under the Medical Device Amendments of 1976, ***Medtronic, Inc. v. Lohr***, ___ U.S. ___, 116 S. Ct. 2240 (1996), is a pre-***Medtronic*** summary judgment granted Intermedics Intraocular, Inc., on the basis of such preemption. We **REVERSE** in **PART** and **VACATE** and **REMAND** in **PART**.

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* Pursuant to Local Rule 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in Local Rule 47.5.4.

I.

Under the Medical Device Amendments of 1976 (MDA) to the Food, Drug and Cosmetic Act, Pub. L. No. 94-295, 90 Stat. 539 (codified in scattered sections of 21 U.S.C.), all medical devices intended for human use are subject to regulation by the Food and Drug Administration (FDA). ***Id.*** at 539 (Preamble to MDA). The MDA classifies devices into three categories based on the amount of regulatory control needed to ensure their safety and effectiveness. 21 U.S.C. § 360c; H.R. Conf. Rep. No. 1090, 94th Cong., 2d Sess. 51, *reprinted in* 1976 U.S.C.C.A.N. 1070, 1103.

Class I devices are subject only to general controls, such as good manufacturing practices regulations, labeling requirements, and prohibitions on misbranding. 21 U.S.C. § 360c(a)(1)(A); 21 C.F.R. §§ 801.1-.150, 820.1-.198.

Class II devices are more complex and potentially more hazardous; they are subject to more special controls, such as postmarket surveillance and the promulgation of specific performance standards. 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. §§ 861.1-.38.

Class III devices are those used in sustaining human life or that present a potential unreasonable risk of injury; they require premarket approval by the FDA before commercial distribution. 21 U.S.C. §§ 360c(a)(1)(C), 360e; 21 C.F.R. §§ 814.1-.84. In this process, a manufacturer must submit a detailed application to the

FDA, including such information as known or published about the device, samples of the device, proposed labeling, and description of manufacturing methods. 21 U.S.C. § 360e(c); 21 C.F.R. § 814.20. The FDA then typically refers the application to a panel of experts to study the safety and effectiveness of the device. 21 U.S.C. § 360e(c)(2); 21 C.F.R. § 814.40. Action must be taken on the application within six months. 21 U.S.C. § 360e(d)(1)(A); 21 C.F.R. § 814.40.

There are, however, two major exceptions to the rule of premarket approval. First, Class III devices that are "substantially equivalent" to devices already on the market before the effective date of the MDA (28 May 1976) may be commercially distributed without premarket approval. 21 U.S.C. § 360e(b)(1). In a process known as "premarket notification", the maker of the device applies to the FDA for a "substantial equivalence" determination. ***Id.*** § 360(k). This procedure is known colloquially as the "§ 510(k) process" for the original section number in the Food, Drug and Cosmetic Act. *See* MDA § 4(a)(9), 90 Stat. at 580 (amending Food, Drug and Cosmetic Act, ch. 675, § 510, as added by Drug Amendments of 1962, Pub. L. No. 87-781, § 302, 76 Stat. 790, 794 (1962)); *see also* ***Medtronic,*** 116 S. Ct. at 2247.

Second, Class III devices that receive an investigational device exemption (IDE) may be tested on humans without premarket approval. 21 U.S.C. §§ 360e(a), 360j(g); 21 C.F.R. §§ 813.1-.170.

With an IDE, information about the device and its effect on humans is collected through clinical study groups. This information can then be used in an application for premarket approval. To obtain an IDE, the sponsor of an investigatory study (often the device manufacturer) must submit an application to the FDA, which must approve or reject it within 30 days. 21 C.F.R. §§ 813.20, 813.30. The sponsor must also submit an investigatory plan, describing aspects of the proposed study such as expected results, expected duration, and patient population, which an institutional review committee must approve. ***Id***. §§ 813.20(b)(6)-(7), 813.25, 813.42.

At issue is an intraocular lens, a Class III medical device used to replace the natural lens of the eye. Intermedics Intraocular, Inc. designs and manufactures these lenses; in 1982, it received an IDE from the FDA to study a particular lens. In its investigational plan, Intermedics divided its clinical studies into three groups: a trial investigation group, an expanded core investigation, and an adjunct investigation. The trial group and core group (an expansion of the trial group) contained a relatively small number of patients (100-500), who were monitored several times a year for approximately two years. On the other hand, the adjunct group contained an unlimited number of patients, who were given only two postoperative visits. Each patient was to sign a consent form, a copy of which was included with the application. Data collected from the trial and core groups was submitted by

investigators (ophthalmologists) to Intermedics; data from the adjunct group was not.

In the 1980s, Edward A. Lewis and the four other plaintiffs-appellants were each implanted by the same doctor with at least one Intermedics' Model 44B intraocular lens in conjunction with cataract extraction surgery. Plaintiffs were part of Intermedics' adjunct study group.

Each Plaintiff brought suit in Louisiana state court in 1993, alleging that complications developed, such as extreme pain, removal of the lens, injuries to the eye, and blindness. They presented state law claims for failure to obtain informed consent; strict liability; design and manufacturing defects; failure to warn; breach of express and implied warranty; fraud, misrepresentation, and concealment of information; and failure to follow FDA regulations.

Intermedics removed the actions to federal court; they were consolidated for purposes of discovery. Intermedics moved for summary judgment on the ground that each claim was preempted.

The district court granted summary judgment on that basis on all but the failure to obtain informed consent claim. (Each Plaintiff denies being aware of the 44B's experimental nature or of his participation in any clinical study group, let alone an adjunct group.) And, as for the informed consent claim, on interlocutory appeal, our court rendered judgment for Intermedics. ***Lewis v.***

Intermedics Intraocular, Inc., 56 F.3d 703, 706-08 (5th Cir. 1995) (Louisiana does not recognize claim against manufacturer for failure to obtain informed consent). The district court then entered final judgment on the other claims.

II.

We are tasked with applying the MDA's preemption provision to the claims at hand. As stated at 21 U.S.C. § 360k(a):

> [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.

(Pursuant to § 360k, the term "State" will include any of its political subdivisions.) ***Medtronic,*** the Court's only decision addressing preemption under the MDA, charts a narrow course. Because the majority shifts on several key sub-issues, that opinion must be analyzed meticulously.

A.

Medtronic concerned a defective implanted heart pacemaker lead manufactured by Medtronic pursuant to an FDA § 510(k) determination of substantial equivalence. ***Medtronic***, 116 S. Ct. at 2248. The recipient of the device presented claims for strict liability; negligent design, manufacture, assembly, and sale; failure to warn;

and violation of FDA regulations. ***Id.*** Medtronic urged preemption under § 360k because: (1) the § 510(k) process and the regulations governing good manufacturing practices and labeling constituted federal "requirements" applicable to the lead; (2) States cannot maintain additional or different "requirements" relating to safety or effectiveness; and (3) the common-law tort claims constituted such additional or different requirements. ***Id.*** at 2248-49.

A divided Supreme Court (three opinions) held that none of the claims were preempted. ***Id.*** at 2254-58. The separate opinions reflect the continuing division in the Court over statutory construction: whether to look to a statute's plain words, as opposed to looking to legislative history or some other source, for a statute's meaning. As discussed *infra*, there are three different majorities for sub-issues on the deference to be given the FDA regulation on the scope of § 360k; the necessary specificity of the federal "requirements" for § 360k; and the frequency with which state common-law duties will equal state "requirements" for § 360k's purposes.

Justice Stevens announced the judgment of the Court and wrote an opinion joined in full by three other justices (Kennedy, Souter, Ginsburg) and in part by one (Breyer). He began by contrasting the roles played by the States and the Federal Government in the field of health and safety: the States have an historical and prominent role in "protecting the health and safety of their citizens", these

being “primarily, and historically, ... matters of local concern” for which “the States traditionally have had great latitude under their police powers to legislate”; but, “in recent decades the Federal Government has played an increasingly significant role” in this arena such as the approval of new drugs. ***Id.*** at 2245-46 (internal quotation marks and brackets omitted). The MDA was enacted “[i]n response to the mounting consumer and regulatory concern” over the injuries resulting from the failure of newly introduced medical devices. ***Id.*** at 2246.

Concerning the scope of § 360k preemption, Justice Stevens stated that, “[a]lthough our analysis of [its] scope ... must begin with its text ... [our] interpretation is informed by two presumptions about the nature of pre-emption.” ***Id.*** at 2250 (citation omitted). “First, because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action”; in other words, “we start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress”; and this “approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety.” ***Id.*** (citations and internal quotation marks omitted). And, “[s]econd, our analysis of the scope of the statute’s pre-emption is guided by our oft-repeated comment ...

that 'the purpose of Congress is the ultimate touchstone' in every preemption case"; this purpose, or intent, is found primarily in the language of the preemption section and its surrounding "statutory framework", but "[a]lso relevant ... is the structure and purpose of the [Act] as a whole, ... as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the [Act] and its surrounding regulatory scheme to affect business, consumers, and the law." ***Id.*** at 2250-51 (internal quotation marks and brackets omitted).

Justice Stevens then rejected Medtronic's contention that any state common-law claim is a state "requirement" preempted by the plain language of § 360k. ***Id.*** at 2251. He concluded that Congress intended § 360k primarily to preempt "device-specific" positive law enacted by state governmental and administrative bodies, not general common-law duties. ***Id.*** at 2252-53. He found no evidence in the legislative history that Congress intended to completely immunize device manufacturers from state common-law liability. ***Id.*** This is especially so because passage of the MDA indicated congressional concern that the industry needed "more stringent regulation", ***id.*** at 2251 (citing Preamble to MDA, 90 Stat. at 539), yet the MDA does not provide expressly for a private action and there is "no suggestion that the Act created an implied private right of action." ***Id.*** This "legislative history also confirm[ed his] understanding that § 360k simply was not intended to pre-empt

most, let alone all, general common-law duties enforced by damages actions", with the result "that at least some common-law claims against medical device manufacturers may be maintained after the enactment of the MDA." ***Id.*** at 2253.

Because Justice Stevens found "the language of [§ 360k] not entirely clear", and because "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect", his "interpretation of the pre-emption statute [was] substantially informed by" the "FDA regulations interpreting the scope of § 360k's pre-emptive effect". ***Id.*** at 2255; 21 C.F.R. § 808.1. Under the FDA regulation, preemption occurs only when "specific [federal] requirements applicable to a particular device" make "divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements", 21 C.F.R. § 808.1(d); and, state requirements of "general applicability" are not preempted unless they have "the effect of establishing a substantive requirement for a specific device". ***Id.*** § 808.1(d)(1),(6)(ii); *see* ***Medtronic***, 116 S. Ct. at 2256-57 & n. 18. Justice Stevens noted also that, as stated in § 360k, state requirements must also relate to either the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the Act. ***Medtronic***, 116 S. Ct. at 2257; *see* 21 U.S.C. § 360k(a)(2). Consequently, in Justice Stevens' view, § 360k is a very narrow provision that will

rarely preempt state requirements, especially common-law duties. *See* ***Medtronic***, 116 S. Ct. at 2251-53, 2257-58. "[G]iven the critical importance of device-specificity in our (and the FDA's) construction of § 360k, it is apparent that few, if any, common-law duties have been pre-empted by this statute." ***Id.*** at 2259.

Under these principles, Justice Stevens concluded that the defective design claims were not preempted. ***Id.*** at 2254-55. The § 510(k) determination that the device (pacemaker lead) was "substantially equivalent" to pre-MDA devices did not equal FDA approval of the device on safety and effectiveness grounds. ***Id.*** at 2254. The § 510(k) process focused more on equivalence, not safety, and it did not "require" the lead to "take any particular form for any particular reason". ***Id.***

Likewise, the manufacturing and labeling claims were not preempted. ***Id.*** at 2256-58. Regulations governing good manufacturing practices and labeling were not specific enough because they applied to all medical devices, not just the pacemaker lead. ***Id.*** at 2258. They reflected "generic concerns about device regulation generally" and did not impose a "specific mandate" on manufacturers. ***Id.*** In addition, the state requirements (in that instance, common-law duties) were not developed specifically "with respect to" medical devices and hence were too general to be preempted; such requirements were "not the kinds of requirements that Congress and the FDA feared would impede the ability of

federal regulators to implement and enforce specific federal requirements." ***Id.***

Finally, the claims based on violations of federal regulations were not preempted. ***Id.*** at 2255-56. Having earlier stated, as noted, that the MDA does not create a private action against manufacturers, ***id.*** at 2251, Justice Stevens explained: "Nothing 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." ***Id.*** at 2255 (emphasis added). Such a remedy is simply not an "additional" or "different" requirement, ***id.***, and the FDA regulation interpreting § 360k supported this conclusion. ***Id.*** at 2256; *see* 21 C.F.R. § 808.1(d)(2) (state requirements "equal to, or substantially identical to" federal requirements are not preempted). In fact, such state requirements would not be preempted even if they required showing violation of the federal regulations *plus* another factor, such as negligence because

> such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirements. While such a narrower requirement might be 'different from' the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another

> reason for manufacturers to comply with identical existing 'requirements' under federal law.

Medtronic, 116 S. Ct. at 2255.

Justice Breyer concurred in the judgment, agreeing that none of the claims were preempted; but, he joined only part of Justice Stevens' opinion, because he found § 360k to be broader in scope than the plurality suggested, in large part because he was in general agreement with the position taken by Justice O'Connor on this point in her separate opinion -- he read the term "requirements" in § 360k to encompass state tort actions. ***Id***. at 2259-62 (Breyer, J., concurring). As he explained, similar language in a preemption provision of a different statute, addressed by the Court in ***Cipollone v. Liggett Group, Inc.***, 505 U.S. 504 (1992), "'easily' encompassed tort actions because '[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief.'" ***Medtronic***, 116 S. Ct. at 2259 (Breyer, J., concurring) (quoting ***Cipollone***, 505 U.S. at 521). In Justice Breyer's view, a "requirement" includes "legal requirements that grow out of the application, in particular circumstances, of a State's tort law." ***Id***. Therefore, he

> believe[s] 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. It is possible that

> the plurality also agrees on this point, although it does not say so explicitly.

Id. at 2260 (Breyer, J., concurring).

But, for deciding whether the claims in issue were preempted, Justice Breyer, like Justice Stevens, relied on the FDA regulation interpreting § 360k. ***Id.*** at 2260-61 (Breyer, J., concurring). He did so because he found § 360k "highly ambiguous"; concluded, therefore, that Congress "must have intended that courts look elsewhere for help as to just which federal requirements pre-empt just which state requirements, as well as just how they might do so"; stated that the "Court [had] previously suggested that, in the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect"; and, moreover, found quite relevant that "the FDA has promulgated a specific regulation designed to help" -- 21 C.F.R. § 808.1(d). ***Medtronic,*** 116 S. Ct. at 2260 (Breyer, J., concurring).

Looking to that regulation, he concluded that only specific federal requirements, applicable to a particular device, could preempt state requirements. ***Id.*** at 2260-61 (Breyer, J., concurring) ("regulation's word 'specific' does narrow the universe of federal requirements that the [FDA] intends to displace at least some state law"). Because he agreed with Justice Stevens that the federal regulations applicable to Medtronic's pacemaker lead "even

if numerous, are not 'specific' in any relevant sense", he found none of the claims preempted. ***Id.*** at 2261 (Breyer, J., concurring).

In addition, Justice Breyer invoked principles of "conflict" and "field" preemption to support his conclusion, explaining that federal requirements preempt state requirements only if there is an actual conflict between the two or if federal regulation in a field is so pervasive as to leave no room for States to participate; he found neither. ***Id.*** On the other hand, as noted, one of the two reasons given for not joining Justice Stevens' opinion in full was because Justice Breyer was "not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare'". ***Id.*** at 2262 (Breyer, J., concurring).

Justice O'Connor, joined by the Chief Justice and Justices Scalia and Thomas, concurred in part and dissented in part. She agreed with Justice Breyer that state common-law claims were one type of state "requirements" and therefore could be preempted by § 360k. ***Id.*** at 2262-63 (O'Connor, J., concurring in part and dissenting in part). She disagreed, however, that the FDA preemption regulation was entitled to any deference, especially in the light of § 360k's plain and explicit meaning. ***Id.*** at 2263 (O'Connor, J., concurring in part and dissenting in part).

Accordingly, Justice O'Connor would not utilize the more narrow construction of § 360k found in the FDA regulation and,

therefore, would not amend § 360k's "clear" meaning by adding, as found in the regulation, "a requirement of specificity" to the "any requirement" language in § 360k. ***Id.*** As a result, Justice O'Connor doubtless would find preemption more often than either the plurality or Justice Breyer. ***Id.***

Turning to the claims, Justice O'Connor concluded that those for design defect and violation of FDA regulations were not preempted: as for the former, the § 510(k) substantial equivalence process only ensures "equivalenc[e], and places no 'requirements' on a device"; as for the latter, a state claim "seek[ing] to enforce ... [a] requirement [under the Act] does not impose a requirement that is 'different from, or in addition to'" federal requirements. ***Id***. at 2263-64 (O'Connor, J., concurring in part and dissenting in part). In explaining why a state law claim seeking damages for violations of federal requirements was not preempted, she stated:

> To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.

Id. at 2264.

On the other hand, Justice O'Connor concluded that the manufacturing and labeling and the failure to warn claims were preempted, because there were extensive federal regulations on

these points applicable to the device and the common-law claims at issue would compel compliance with requirements different from, or in addition to, those required by the Act. ***Id.***

Medtronic, therefore, produced a narrow majority on the standard for determining whether a state law claim is preempted under § 360k. Five justices agreed that deference to the FDA regulation on the scope of § 360k was appropriate. ***Id.*** at 2257-58 (plurality opinion); ***id.*** at 2260-61 (Breyer, J., concurring).

Medtronic produced a different majority, however, for how often such preemption probably would occur. As noted, only Justice Stevens and the three justices who joined his opinion in full concluded that preemption of a state law claim would be rare, on the basis that state common-law duties are usually too general to satisfy § 360k and its corresponding regulation, 21 C.F.R. § 808.1(d). ***Medtronic***, 116 S. Ct. at 2258-59 (plurality opinion). The balance of the Court (Justice Breyer, together with Justice O'Connor and the three justices who joined her opinion) would find preemption more often, on the basis that state common-law duties are "requirements" under § 360k. ***Id.*** at 2258-59 (Breyer, J., concurring); ***id.*** at 2262-63 (O'Connor, J., concurring in part and dissenting in part).

But, these five justices did not agree on the necessary specificity of the federal requirements for § 360k preemption; as discussed, Justice Breyer would require a greater level of

specificity than the other four justices. Therefore, as dictated by ***Medtronic***, a § 360k preemption question will be resolved, in most cases, by focusing primarily on any applicable federal regulations.

In sum, a state law claim is preempted pursuant to § 360k only under the following conditions: (1) there is a *specific* federal requirement, usually a regulation, applicable to a particular device; (2) there is a state requirement (statute, regulation, ordinance, or common-law duty, *see* 21 C.F.R. § 808.1(b)) maintained with respect to the device that is related to safety and effectiveness or to any other matter included in a requirement applicable to the device under the Act, ***id***.; and (3) the state requirement is different from, or in addition to, the federal requirement. Accordingly, as Justice Stevens noted, courts will have to undertake a most "careful comparison" of the federal and state requirements to determine state law claim preemption *vel non*. ***Medtronic***, 116 S. Ct. at 2257-58.

Based on our reading of ***Medtronic***, we conclude that this preemption analysis applies regardless of the class of the device and of whether it is made available through premarket approval or through the two exceptions to it: § 510(k) (as in ***Medtronic***) or an IDE (as here). Mindful of the delicate balance in ***Medtronic***, we turn to the claims at issue.

B.

Plaintiffs' major contention is that, because they were participants in an adjunct study, preemption does not apply to any of their claims. They point to the MDA and the regulations on intraocular lens IDEs and assert that only well-controlled core study groups are contemplated. Citing an internal product bulletin, they maintain that Intermedics simply used the adjunct group as a guise to commercially distribute thousands of untested, unapproved lenses to ophthalmologists. Because IDEs are intended to enable manufacturers to develop information on safety and effectiveness, *see* 21 U.S.C. § 360j(g)(2)(A); 21 C.F.R. § 813.1(a), Plaintiffs maintain that Intermedics' actions were outside the scope, and at odds with the purpose, of the regulations, meaning Intermedics should not be entitled to whatever preemptive protection those regulations afford.

As support, Plaintiffs cite the conclusion in ***Medtronic*** that the § 510(k) process did not preempt the state tort claims in issue there because the process focused primarily on equivalence, not on safety or effectiveness. Like the § 510(k) process, they maintain, an adjunct study is not concerned with safety or effectiveness but is simply a way to enable manufacturers to avoid premarket approval. They also point to statements by the FDA expressing concern that manufacturers would use IDEs as "subterfuge for commercial distribution of ... lenses" and contemplating that

consumers could look to tort law for protection, because "[it is] not the duty of the FDA to protect sponsors or investigators from lawsuits by subjects". 42 Fed. Reg. 58874-75, 58881 (1977).

In response, Intermedics maintains that adjunct studies are a by-product of a congressional mandate to make intraocular lenses reasonably available to physicians. It points to a provision in the MDA that the FDA shall make IDE regulations governing certain devices "applicable in such a manner that the device[s] shall be made reasonably available to physicians". 21 U.S.C. § 360j(l)(3)(D)(iii). The MDA legislative history makes clear that this provision applies only to intraocular lenses. H.R. Conf. Rep. No. 1090, 62-63 ("This new provision applies solely to the intraocular lens ....").

In addition, Intermedics cites an FDA Commissioner's statements at a congressional hearing that the FDA established a dual (core-adjunct) study system to investigate intraocular lenses in response to the above quoted language in the MDA. *See Cataract Surgery: Fraud, Waste, and Abuse: Hearing Before the Subcomm. on Health and Long-Term Care of the Select Comm. on Aging*, 99th Cong., 1st Sess. 206-10 (1985) (statement of Dr. Frank E. Young, Commissioner, FDA). It further asserts that, because the MDA allows adjunct studies, state law cannot make them illegal or prohibit them through state law claims.

On this issue, the facts of this case are unique, and we find little guidance in case law, the MDA, or the federal regulations. Pre-***Medtronic***, other federal courts addressed preemption in the IDE and intraocular lens context, but none seems to have faced this core-adjunct question. *See, e.g.*, ***Becker v. Optical Radiation Corp.***, 66 F.3d 18 (2d Cir. 1995); ***Gile v. Optical Radiation Corp.***, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); ***Slater v. Optical Radiation Corp.***, 961 F.2d 1330 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992). Post-***Medtronic***, several courts have addressed MDA preemption but, again, not in the core-adjunct context. *See, e.g.*, ***Papike v. Tambrands Inc.***, 1997 WL 74338 (9th Cir. Feb. 20., 1997); ***Martin v. Telectronics Pacing Sys., Inc.***, 105 F.3d 1090 (6th Cir. 1997); ***Reeves v. Acromed Corp***., 103 F.3d 442 (5th Cir. 1997); ***Duvall v. Bristol-Myers-Squibb Co.***, 103 F.3d 324 (4th Cir. 1996); ***Sanders v. Optical Radiation Corp.***, 92 F.3d 1181 (4th Cir. 1996) (table); ***Committee of Dental Amalgam Mfrs. and Distribs. v. Stratton***, 92 F.3d 807 (9th Cir. 1996), *cert. denied*, 65 U.S.L.W. 3369 (U.S. Jan. 13, 1997) (No. 96-705); ***Berish v. Richards Medical Co.***, 937 F. Supp. 181 (N.D.N.Y. 1996); ***Armstrong v. Optical Radiation Corp.***, 50 Cal. App. 4th 580 (Cal. Ct. App. 1996); ***Connelly v. Iolab Corp.***, 927 S.W.2d 848 (Mo. 1996) (en banc).

In addition, the MDA, the general IDE regulations, and the lens IDE regulations do not mention adjunct studies. Intermedics

cites regulations it says support a dual (core-adjunct) clinical study system, but none of the cited regulations supports its assertion. *See* 21 C.F.R. §§ 813.25(a)(7),(8); 813.30(c)(4),(6). In fact, the only specific references we find to adjunct studies are the FDA commissioner's statements and in Intermedics' investigatory plan. In any event, Plaintiffs ask us to hold as a matter of law that adjunct studies are not concerned with safety and effectiveness; and are therefore outside the scope of an IDE; and are therefore not shielded by § 360k from common-law liability.

We cannot agree with Plaintiffs' interpretation. First, we are not convinced that adjunct studies are outside the scope of the MDA or the regulations. It is impossible to overlook the fact that Intermedics' investigatory plan includes an adjunct study group that will be monitored less than the core study group and that this plan was approved by the FDA. Also, we refuse to engraft onto the MDA or applicable regulations a judicially-created distinction between core and adjunct studies, especially when there is no clear congressional intent on the question. The statements cited by Plaintiffs do evidence a concern about adjunct studies; but, that is all they evidence. Second, ***Medtronic*** provides the test for *all* claims of MDA preemption, regardless of whether the device in question has been made available to the public pursuant to premarket approval, a finding of substantial equivalence, or an IDE. Whether Plaintiffs' claims are preempted turns on the device-

specificity of the federal and state requirements at issue, not whether the claim arose out of an adjunct or a core study.

By the same token, however, we do not agree with Intermedics that the FDA's approval of its investigatory plan, thereby permitting an adjunct study group, provides blanket preemption of Plaintiffs' claims. ***Medtronic*** makes clear that, for § 360k preemption, specific federal requirements must conflict with specific state requirements. Finding no statute or regulation that even mentions adjunct groups, let alone mentions them in connection with intraocular lenses or other ophthalmological devices, we refuse to conclude that Intermedics is "required" by federal law to conduct its IDE studies using a core-adjunct system. In addition, Plaintiffs' claims are not premised solely on the fact that they were adjunct patients.

The preemption question simply cannot be resolved on the basis of the core-adjunct distinction. Instead, as mandated by ***Medtronic***, a careful (indeed, most painstaking) analysis must be made of each claim. Except for the violations of FDA regulations claim, discussed *infra*, and because of the claims presented, the issues raised, and the changes effected by ***Medtronic,*** this analysis must be performed first by the district court, after the parties are permitted to supplement the summary judgment record and sharpen and clarify the claims, bases and sub-issues for each. *See* ***Sanders***, 1996 WL 423124, at *1-2 (concerning § 360k preemption *vel*

non, and in light of ***Medtronic,*** holding negligence *per se* claims for violations of FDA regulations not preempted but remanding remaining state law claims for reconsideration).

C.

Plaintiffs' claim that Intermedics violated FDA regulations, based on allegations that Intermedics failed to follow the regulations governing lens IDEs, including failing to recall the device, with the result that the safety of the lens was not adequately tested or investigated. Plaintiffs point to ***Medtronic***, in which state tort claims imposing duties parallel to the federal requirements were held not preempted. ***Id.*** at 2255-56.

Notwithstanding the clear adverse holding in ***Medtronic,*** Intermedics contends that these violation-of-FDA-regulations claims are preempted because, as discussed, the Food, Drug and Cosmetic Act does not provide a private right of action to enforce such violations, a matter solely within the discretion of the FDA. Intermedics points to ***Merrell Dow Pharmaceuticals v. Thompson***, 478 U.S. 804, 810 (1986), in which the Supreme Court assumed, without deciding, that there was no private right of action in the Food, Drug and Cosmetic Act.

These claims are not preempted. The ***Medtronic*** Court was unanimous (and explicit) in holding that state law claims providing a remedy for violations of FDA regulations were not preempted under § 360k. *See* ***Medtronic***, 116 S. Ct. at 2255-56 (plurality opinion);

id. at 2260-61 (Breyer, J., concurring); ***id.*** at 2264 (O'Connor, J., concurring in part and dissenting in part); 21 C.F.R. § 808.1(d)(2). As discussed *supra*, the Court reasoned that, if state law paralleled federal requirements, the state claim would impose requirements that were equal or substantially identical to, rather than different from or in addition to, the federal requirements, even if the State required a plaintiff to prove that the violations were the result of negligence. ***Medtronic***, 116 S. Ct. at 2255-56. The MDA preemption regulation supports this interpretation. 21 C.F.R. § 808.1(d)(2).

Intermedics' reliance on ***Merrell Dow*** is misplaced. It simply held that a state law claim premising liability on violation of a federal regulation (*i.e.*, negligence *per se*) did not present a federal question, meaning that a district court would not have 28 U.S.C. § 1331 subject matter jurisdiction. ***Merrell Dow***, 478 U.S. at 812-17. In other words, federal courts could not "create" a federal cause of action by treating a state tort claim, for which an FDA regulation violation was a component, as one that arose under federal law. Nothing in ***Merrell Dow*** prevents a federal court from hearing a state law claim (assuming, of course, it otherwise has jurisdiction) that premises liability on violation of an FDA regulation. Plaintiffs' state law claims premising Intermedics' liability on violations of FDA regulations are not preempted.

III.

Accordingly, we **REVERSE** the summary judgment as to the violation of FDA regulations claim; **VACATE** the summary judgment as to the remaining claims; and **REMAND** for further proceedings consistent with this opinion.

REVERSED IN PART, VACATED IN PART, AND REMANDED