No. 02-4597

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BARBARA HORN,

Plaintiff-Appellant,

v.

THORATEC CORP.,

Defendant-Appellee.

On Appeal from the United States District Court
for the Middle District of Pennsylvania

REPLY BRIEF OF APPELLANT BARBARA HORN

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INTRODUCTION

Relying on the majority opinion in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and supported by the long-held views of the Food and Drug Administration ("FDA"), Ms. Horn demonstrated in her opening brief that the preemption provision of the Medical Device Amendments ("MDA"), 21 U.S.C. § 360k(a), does not preempt her damages claims against Thoratec Corp. ("TCI"). In response, appellee TCI urges this Court to follow a pre-*Medtronic* case, *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir. 1995), the reasoning of which is inconsistent with the Supreme Court's decision. At the same time, TCI downplays the *majority* opinion of the Supreme Court in *Medtronic*, instead relying on an amalgam of views expressed in minority opinions and ultimately elevating the opinion of a single concurring Justice above the opinion of the five-Justice majority. TCI also exaggerates the significance of the premarket approval ("PMA") process. Along the way, TCI's brief misrepresents Ms. Horn's arguments and the views of the FDA, thereby setting up straw men that it then proceeds to knock down. TCI's effort notwithstanding, the decision of the district court holding that the MDA preempts Ms. Horn's damages claims should be reversed.

ARGUMENT

I. MS. HORN'S CLAIMS ARE NOT EXPRESSLY PREEMPTED.

A. Premarket Approval Imposes No Device-Specific Requirements That Preempt Ms. Horn's Damages Claims.

1. TCI spends many pages rebutting the notion that PMA has no pre-emptive effect. Ms. Horn, however, has not made that contention. The question is not whether PMA can be preemptive. The question is what does PMA preempt, that is, what state requirement is the counterpart to a federal PMA applicable to a particular device? The answer is: a state PMA requirement for that same device. A state requirement that a heart pump receive state premarket approval prior to marketing would address the same topic, at the same level of specificity as a federal requirement that a heart pump receive PMA from the FDA, and would thus be preempted.[1]

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[1] Although in *Michael*, 46 F.3d 1316, this Court considered whether PMA imposed device-specific requirements, other courts that considered the preemptive effect of PMA pre-*Medtronic* have agreed that the Supreme Court's decision drew their prior cases into question. *See*, *e.g.*, *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (re-examining circuit precedent in light of *Medtronic*, ultimately upholding prior decision); *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1376 n.16 (11th Cir. 1999) (re-examining circuit precedent in light of *Medtronic*, ultimately reversing prior decision); *Haidak v. Collagen Corp.*, 67 F. Supp. 2d 21, 23-24 (D. Mass. 1999) (rejecting as inconsistent with *Medtronic* prior First Circuit precedent finding PMA preempts damages claims); *see also Mitchell v. Collagen Corp*., 518 U.S. 1030 (1996) (vacating and remanding decision involving PMA device in light of *Medtronic*). Thus, *Michael* is not binding here, and this Court must address the issue presented anew.

This conclusion is demonstrated by the various references in TCI's brief to FDA statements concerning the reach of section 360k(a). For example, in the 1978 Federal Register notice cited by TCI (at 38), the FDA explained that state and local PMA requirements are preempted by the FDA's PMA requirements. 43 Fed. Reg. 18661, 18664 (1978). Accordingly, in 1980, the FDA explained that California could continue to require a state PMA before allowing a particular device to be marketed in California until the FDA established a "counterpart" requirement for that device, that is, until the date on which the FDA either determined that the device did not require PMA at all or the FDA determined that the device could not lawfully be marketed without a federal PMA. 45 Fed. Reg. 67321, 67323 (1980).

Likewise, in the portion of the 1980 Federal Register notice cited by TCI (at 39), the FDA explains that federal good manufacturing practice requirements preempt different or additional state good manufacturing requirements. And in the 1996 advisory opinion cited by TCI (at 40), the FDA explained that requirements imposed on over-the-counter HIV test kits preempted requirements "different from or in addition to *specific counterpart* requirements imposed on that *particular* device" by the FDA. Addendum to TCI Br. at 3a (emphasis added). For example, the FDA allowed the test kits to be purchased by consumers over-the-counter and mailed directly from the consumer to the laboratory for processing, but New York law would have allowed

laboratories to test kits only when forwarded by licensed health professionals. Because the state device-specific requirements would have differed from the federal device-specific requirement, those state provisions were preempted. *Id.* at 2a.[2]

Thus, preemption under section 360k(a) looks for device-specific counterparts. This understanding of the preemptive scope of PMA is consistent with the presumption against preemption, with *Medtronic*, 518 U.S. at 500-01 (majority); *id.* at 505 (Breyer, J., concurring), and, as illustrated by the examples above, with the long-held views of the FDA.[3]

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[2] The FDA's PMA Manual states that PMA shows that a specific device, manufactured through a specific process, is safe and effective, and that FDA approval is required for changes that affect the safety and effectiveness of PMA devices. PLAC Br. at 18 (citing Manual). This discussion is consistent with the agency's statements that PMA imposes requirements, but it does not address the question what "specific counterpart" requirements are thereby preempted. That question is addressed in the agency's Federal Register statements, discussed above.

[3] TCI states (at 53) that the presumption against preemption should not apply because the Supreme Court has recently criticized it. However, the cases that TCI cites do not support that statement. As TCI admits, in *Sprietsma v. Mercury Marine*, 123 S. Ct. 518, 526 (2002), the Court did not reject the presumption. It simply found *no* preemption without mentioning the presumption. In the other two cases cited, *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and *United States v. Locke*, 529 U.S. 89 (2000), the Court did not apply the presumption because the cases arose in areas of historic federal, not state, concern. *See Buckman*, 531 U.S. at 347-48; *Locke*, 529 U.S. at 107-08. In contrast, compensation for individuals injured by medical devices is a matter of historic state concern, as shown by the Supreme Court's endorsement of the presumption in *Medtronic*. *See* 518 U.S. at 485.

In reality, the Supreme Court has repeatedly confirmed the validity of the (continued...)

2. Having first misstated Ms. Horn's view on whether PMA has any preemptive effect on any state requirements, TCI then misunderstands Ms. Horn's, and the FDA's, views on the need for specificity. Ms. Horn is not suggesting that state law is preempted only when that law was developed with respect to a particular device. Rather, preemption under section 360k(a) looks for *counterpart* federal and state requirements. Thus, the existence of one federal device-specific requirement does not preempt all state requirements applicable to that device. The federal requirement preempts only the counterpart state requirement. To use Justice Breyer's example, a federal regulation that hearing aids must have two-inch wires would preempt a state requirement that hearing aids have a one-inch wire, *Medtronic*, 518 U.S. at 505; but that federal regulation would not preempt state rules regarding packaging of hearing aids.

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[3](...continued)
presumption. As Justice Thomas stated just last month, "If a federal statute is ambiguous with respect to whether it pre-empts state law, then the presumption against pre-emption should ordinarily prevent a court from concluding that the state law is pre-empted." *Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 123 S. Ct. 1855, 1876 n.4 (2003) (Thomas, J., concurring). *See*, *e.g.*, *Medtronic*, 518 U.S. at 485, 494 (majority opinion); *New York Conference of Blue Cross and Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654-55 (1995) (unanimous opinion); *CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658, 663 (1993); *id.* at 1745 (Thomas, J., concurring in part and dissenting in part); *Cipollone v. Liggett Group*, 505 U.S. 504, 516, 518 (1992) (plurality); *id.* at 532-33 (separate opinion); *cf. U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 871 n.12 (1995) (Thomas, J., joined by Rehnquist, C.J., O'Connor, J., and Scalia, J., dissenting); *see also* Horn Br. 17-20 (citing cases).

Accordingly, the federal requirement that a device cannot be marketed without federal PMA would preempt a state requirement that the device undergo state PMA but would not preempt state rules regarding other aspects of that device. Product liability claims for design or manufacturing defect or failure to warn are not counterpart requirements to a PMA; such claims simply do not address the same topic (marketing approval). They are therefore not preempted by the federal PMA process.

3. The design of the HeartMate originated with TCI and was not mandated by any federal requirement. TCI nonetheless argues (at 31) that PMA somehow converts the manufacturer's choice of design into a federally required design. Medtronic made a similar argument in *Medtronic*. Although that case involved a device marketed under a finding of substantial equivalence, not PMA, the FDA's response to that argument is fully applicable here:

> There is an additional reason why the defective-design claims would not be preempted by a substantial equivalence determination, even if it were deemed tantamount to the determination of safety and effectiveness required for premarket approval. Neither the FDCA nor the FDA's regulations prescribe criteria for the design of devices. The design of devices originates with its manufacturer. Even if design specifications could be characterized as "requirement[s]" in some sense, once the FDA clears the device under Section 510(k), they are not "requirement[s] *applicable* to the device *under th[e Act]*." 21 U.S.C. 360k(a)(2) (emphasis added); see also 21 U.S.C. 360k(a)(1). Instead, the specifications are applicable to the device as a result of the voluntary decision of a private party, the manufacturer, to introduce the device into the market with a design of the manufacturer's choosing. That federal

> law attaches a consequence to such private decisions does not convert them into federal "requirements." Cf. *American Airlines, Inc. v. Wolens*, 115 S. Ct. [817,] 824 [1995].

Brief for the United States as Amicus Curiae in *Medtronic v. Lohr*, S. Ct. No. 95-754, 1996 WL 118035, at *20-*21 (filed Mar. 15, 1996) (underlined emphasis added; italics in original).

Thus, FDA approval neither required TCI to market the heart pump nor mandated a particular design for the product. A-225. Put differently, the FDA's 1994 marketing approval of a heart pump that used sutures to hold the components in place did not, in the language of section 360k(a), "require" that the heart pump use sutures. The fact that TCI now markets a very similar heart pump with self-locking screws in lieu of sutures, A-276, further demonstrates that no federal requirement mandates the use of sutures in these devices.

Indeed, TCI has changed the design of the HeartMate several times since its approval. *See* Horn Br. at 12; App. A-235, 240, 244, 249, 259, 276. Although FDA regulations required TCI to obtain FDA authorization for those changes, the same was true with respect to the device at issue in *Medtronic*. *Compare* 21 C.F.R. § 814.39 (manufacturer must submit PMA supplement before making any change that affects safety or effectiveness of PMA device), *with* 21 C.F.R. § 807.81(a)(3)(i) (manufacturer must submit new 510(k) application before making any change that affects safety

or effectiveness of 510(k) device). In fact, much as TCI relies on 21 C.F.R. § 814.39 here, Medtronic relied in the Supreme Court on the corresponding section 510(k) regulation, 21 C.F.R. § 807.81(a)(3)(i).[4] Yet the Supreme Court unanimously rejected the argument that the design-defect claim was preempted. *Medtronic*, 518 U.S. at 492-94 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

In addition, one aspect of Ms. Horn's complaint is the fact that the device implanted in her husband had sutures that lay on top of the pump, which caused the suture to rub against the sternum until the suture broke. In this regard, Ms. Horn does not allege that all TCI HeartMate heart pumps are defective, but that the particular pump implanted in her husband was defective. Not even TCI has claimed that marketing approval required a suture that lay on top of the heart pump; and the record shows that TCI did not even communicate with the FDA regarding whether the suture would lay on top of, on the side of, or underneath the screw ring. Surely there can be no preemption of a claim that an individual HeartMate was defective because of a feature that was not intrinsic to the product, but instead relates to how one such product was situated in the body after implantation.

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[4] *See* Brief for Petitioner Medtronic in *Medtronic v. Lohr*, S. Ct. Nos. 95-754, 95-886, 1996 WL 88789 at *27-*28 (Mar. 1, 1996); Reply Brief for Petitioner Medtronic in *Medtronic v. Lohr*, S. Ct. Nos. 95-754, 95-886, 1996 WL 180309, *13-*14 (Apr. 16, 1996).

4. Ms. Horn's opening brief pointed out that the labeling requirements applicable to PMA devices, codified at 21 C.F.R. § 801.109, are the same requirements applicable to section 510(k) devices and that the Supreme Court in *Medtronic* rejected the manufacturer's argument that these general requirements preempt failure-to-warn claims. TCI's response is, first, to try to avoid the import of the regulation. Thus, TCI declares (at 55) that Ms. Horn waived reliance on section 801.109 and any argument based on it because she did not make this specific point in the district court. However, section 801.109, and *Medtronic*'s treatment of it, cannot be so easily side-stepped. To be sure, this Court will not consider *issues* raised for the first time on appeal. *Gass v. Virgin Islands Telephone Corp.*, 311 F.3d 237, 246 (3d Cir. 2002).[5] But Ms. Horn is not raising a new issue. Below, she argued both that federal requirements do not preempt her labeling (or other) claims and that *Medtronic* supported her argument. Highlighting a particular paragraph of the *Medtronic* opinion is not raising a new "issue." *See also Nelson v. Adams USA, Inc*., 529 U.S. 460, 469 (2000) (issue preservation "does not demand the incantation of particular words;

[5] This rule is based in large part on the concern that, where an issue was not raised in the district court, the parties will not have developed an adequate factual record. *Gass*, 311 F.3d at 246. Here, of course, all facts relevant to Ms. Horn's point are in the record.

rather, it requires that the lower court be fairly put on notice as to the substance of the issue.").

Turning to the merits of this point, TCI has little to say. First, TCI points out (at 56) that labeling was one of the items that the FDA reviewed during the PMA process, whereas the labeling of the pacemaker lead at issue in *Medtronic* was not subject to PMA review. Proposed labeling, however, is part of the section 510(k) submission at issue in *Medtronic*. *See* 21 C.F.R. § 807(e). Moreover, TCI's statement does not address Ms. Horn's point: Once the products were on the market, both the TCI heart pump and the Medtronic pacemaker lead were subject to identical labeling requirements, embodied in 21 C.F.R. § 801.109. The Supreme Court found that those requirements did not preempt the Lohrs' failure-to-warn claims. They therefore cannot preempt Ms. Horn's failure-to-warn claim.

Next, pointing to the HeartMate's labeling, TCI claims that its device was subject to more extensive labeling requirements than are set forth in federal regulations because the labeling contains many statements that are specific to the product. The same could be said, however, for the labeling of every class III device, including the pacemaker lead at issue in *Medtronic*. Put simply, TCI has failed to identify a single federal labeling requirement applicable specifically to heart pumps as a class or to the HeartMate in particular, and it has failed to distinguish the labeling

requirements applicable to its device from the labeling requirements applicable to products such as the one at issue in *Medtronic*.

Ms. Horn has also argued (at 38-39) that her failure-to-warn claims are not preempted to the extent that they challenge TCI's failure to provide a warning outside of the product labeling. Here, a Dear Doctor letter would have been a permissible, non-labeling vehicle for informing doctors about the risk of implanting a HeartMate when the suture would face the patient's sternum. Again, TCI (at 56) first tries to sidestep this point by arguing waiver. Again, Ms. Horn is not raising a new issue, but further developing arguments previously made with respect to the issue of whether her failure-to-warn claim is expressly preempted. *See Nelson*, 529 U.S. at 469-70; *see also Beech Aircraft v. Rainey*, 488 U.S. 153, 174 (1988) (no waiver of objection where, although argument not explained "as thoroughly as ideally might be desired," counsel "substantially satisfied requirement that court be on notice as to his concern"). And TCI's assertion that Ms. Horn's complaint does not allege that the company should have provided warnings through means other than labeling is simply wrong. The complaint alleges that TCI "fail[ed] to provide warnings as to the reasonably foreseeable defects in the product . . . " and "fail[ed] to provide adequate instructions to physicians. . . ." App. A-38 (¶¶ 19(i), (j)). The complaint no more limits these

allegations to warnings via labeling than it does to warnings via Dear Doctor letters or other forms of communication.

Finally, citing to three cases, TCI declares that courts have rejected similar arguments in cases under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), which contains a provision expressly preempting state "labeling and packaging" requirements. *See* 7 U.S.C. § 136v(b). TCI neglects to mention that there is substantial controversy regarding whether that provision preempts claims based on failure to warn by means other than labeling. *See*, *e.g.*, *Chemical Specialties Manufacturers Ass'n v. Allenby*, 958 F.2d 941, 946 (9th Cir. 1992) (no preemption of such claims); *New York State Pesticide Coalition v. Jorling*, 874 F.2d 115, 119 (2d Cir. 1989) (same); *Macrie v. SDS Biotech Corp*., 630 A.2d 805, 813 (N.J. Super.) (same), *certif. denied*, 636 A.2d 522 (N.J. 1993). Therefore, even assuming that FIFRA's preemption provision is relevant here, it does not help to resolve the matter.

B. Ms. Horn's State-Law Claims Would Not Impose Requirements That Have Any Specific Federal Counterpart.

Turning to the state-law side of the analysis, TCI first argues (at 43-44) that Justice Breyer's concurrence in *Medtronic* focused on the federal side of the question and, therefore, that Ms. Horn is wrong to read *Medtronic* as requiring specificity on the state side. In effect, TCI is asking this Court to disregard the Supreme Court's

majority opinion and to treat the one-Justice concurrence as the opinion of the Court. That plea is flatly wrong and must be rejected. *Medtronic* contains only one judgment of the Court, a majority opinion joined by five Justices. That majority opinion, and only that opinion, establishes the precedent. As discussed throughout Ms. Horn's opening brief, that precedent requires a finding of no preemption in this case.

Moreover, TCI's theory is based on the faulty premise that Justice Breyer's concurrence is inconsistent with his joinder in the majority opinion. Justice Breyer's separate opinion reflects his view that preemption occurs in cases of direct conflicts between specific state and federal requirements. *See* 518 U.S. at 503-04. His example—where a federal regulation (not merely federal approval) requires a two-inch hearing aid wire but state law requires a one-inch hearing aid wire—is device specific and presents a situation where the state requirement is a precise counterpart to the federal requirement. That is, the two requirements address the same matter: the length of a hearing aid wire. *Id.* at 504. Thus, contrary to TCI's contention, Justice Breyer's concurrence, like the majority opinion in which he joined, requires specificity on both the federal *and* the state sides of the preemption equation. Accordingly, even if *Medtronic*'s precedent were established by Justice Breyer's concurrence rather than by the majority opinion, that precedent would still require specificity for both the federal and the counterpart state requirements.

C. The FDA's Longstanding Views, As Reflected In A Binding Regulation, Support A Finding Of No Preemption Here.

TCI struggles throughout its brief to portray the FDA's views on express preemption as helpful, or at least as not harmful, to its argument. Yet the consistency of the FDA's statements over the past 25 years cannot be obscured. In briefs, in advisory opinions, and, most importantly, in regulations and regulatory commentary, the FDA has repeatedly expressed views entirely at odds with those of TCI and the district court.

To begin with, the FDA has stated in a regulation, issued in 1978 pursuant to notice-and-comment rulemaking, that preemption is limited to instances where the FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device" or class of devices. 21 C.F.R. § 808.1(d). FDA regulations also state that section 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirements relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1). The FDA has never questioned the continued viability of these

regulations, and the *Medtronic* majority gave those regulations substantial weight. 518 U.S. at 496-97, 498-99; *see also id.* at 505-06 (Breyer, J., concurring).

Subsequent to the issuance of section 808.1(d), the FDA has several times applied the regulation in the context of state-law claims. In 1984, in an advisory opinion that relied on section 808.1(d), the FDA stated that the legislative history of the MDA offered no suggestion that Congress intended to preempt state rules or requirements with respect to legal remedies available under state judicial systems. Brief for the United States as *Amicus Curiae* in *Medtronic*, 1996 WL 118035, at *14; Porter, *The Lohr Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7, 9 (1997) (FDA's then-chief counsel describing FDA's views on scope of § 360k(a)). Then, in 1995, the FDA filed two amicus briefs in damages actions arising from injuries caused by medical devices, in one case a PMA device and in the other a section 510(k) device. In both cases, the FDA argued against preemption. *Id.* at 10. And in 1996, the FDA filed its amicus brief in *Medtronic*, in which the agency made clear that "it consistently had construed the term 'requirement' to refer to substantive, but not remedial, provisions." *Id.* As the agency later stated: "FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection." *Id.* at 11.

Finally, in a certiorari-stage amicus brief in *Smith Industries Medical Systems v. Kernats*, filed in the Supreme Court in 1997, the FDA specifically argued that PMA does not preempt "state law standards of care or common law duties respecting medical devices." Addendum to Horn Br. at 7a. Addressing design claims in particular, the FDA explained: "Because FDA has not imposed specific substantive requirements on [the design of the device] in the course of the review process, that design does not represent a specific federal requirement that preempts state common law requirements." *Id.*

TCI (at 49-50) tries to blur the clarity of the FDA's views by suggesting that the position in the *Kernats* brief was dependent on a proposed rule, which was pending at the time the brief was filed and later withdrawn. However, as is readily apparent from the amicus brief, *see* Addendum to Horn Br. at 6a-8a, the agency's discussion of the merits did not even mention the proposed rule. Rather, the proposed rule was discussed as a separate reason why the ruling below was not "cert-worthy," a reason entirely independent of the FDA's four pages of argument about why the ruling below correctly held that PMA did not preempt damages claims. *Id.* at 8a. The FDA nowhere claimed that the proposed rule buttressed or even affected its views on the merits.

The two-page excerpt from the amicus brief of the United States in *American Cyanimid Co. v. Geye* (*see* PLAC Br. at 2a-3a) does not suggest that the FDA has altered its views. To begin with, an amicus brief filed by the Solicitor General's office in a case involving FIFRA cannot possibly override the views of the FDA as set forth in a binding regulation implementing the MDA. In any event, the brief in *American Cyanimid* is consistent with the FDA's longstanding view that state law may be preempted under section 360k(a) when it imposes specific requirements that are "different from or in addition to" federal requirements, but that the generality of common-law claims typically leaves them outside the preemptive scope of section 360k(a). *See* Addendum to Horn Br. at 7a (US Br. in *Kernats*). This position is the one adopted by the Supreme Court majority in *Medtronic*. 518 U.S. at 500-02.

The FDA's view that section 360k(a) does not preempt damages claims is set forth in a 1978 regulation issued through notice-and-comment rulemaking, was developed outside the context of litigation, and has been consistently maintained for more than two decades. The agency's regulation and its application of that regulation in lawsuits involving injuries caused by PMA devices is thus entitled to considerable weight here. *United States v. Mead Corp*., 533 U.S. 218, 228 (2001) (degree of deference due to government depends on, among other things, consistency, formality, and thoroughness of government's position).

II. MS. HORN'S CLAIMS ARE NOT IMPLIEDLY PREEMPTED.

Damages actions for personal injuries caused by medical devices and FDA regulation have co-existed for 27 years. Damages actions have co-existed with federal regulation of drugs for 75 years. Without citing a single instance in which a verdict for a plaintiff injured by a device or a drug has undermined federal regulation, TCI and its amici argue that, even if section 360k(a) does not expressly preempt Ms. Horn's damages claims, the Food, Drug, and Cosmetic Act impliedly preempts her claims. Their theory is that state law conflicts with federal law because it asks jurors to second-guess the FDA concerning the safety and effectiveness of the HeartMate. This bold grab for judicially-created immunity from tort liability should be rejected.

1. The FDA authorized the marketing of the medical device at issue in *Medtronic v. Lohr*; the FDA has authorized the marketing of every other new medical device lawfully sold in the United States since 1976, and the FDA has authorized the marketing of every new drug lawfully sold in the United States since 1938. *See* 21 U.S.C. § 355. Yet under TCI's implied preemption theory, no product liability action could be maintained against a manufacturer for injuries caused by any drug or medical device lawfully sold in the United States. In the drug context, the courts have rejected that argument; and the same result is warranted here. *See*, *e.g.*, *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1176-78 & n.2 (5th Cir. 1988) (rejecting argument that

FDCA and PHSA preempt claims regarding vaccines and reviewing case law); *see also* Hearings Before a Subcomm. of the Comm. on Commerce of the U.S. Senate on S. 1944, 73d Cong., 2d Sess. 400, 403 (1933) (rejecting proposal to include private right of action for damages caused by faulty or unsafe products regulated under the FDCA on ground that such right of action already existed under state common law).[6]

Moreover, the Supreme Court has already rejected the notion that federal regulation inherently conflicts with state damages actions. In *Cipollone v. Liggett Group*, for example, seven members of the Court held that the 1965 Act expressly pre-empted state regulatory law but did not preempt common law. The Court explained:

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[6] Amicus Chamber of Commerce cites three recent FDA amicus briefs that argue for implied preemption, two in personal injury cases involving failure-to-warn claims arising from injuries caused by prescription drugs and one in a case seeking to enforce a state law that would require warnings regarding certain risks associated with over-the-counter drugs. What the Chamber neglects to mention, however, is that, thus far, the courts in all three of those cases have rejected the implied preemption argument. *See Motus v. Pfizer*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000), *appeal pending*, Nos. 02-55372, 02-55498 (9th Cir.); *In re Paxil Litigation*, 2002 WL 31375497 (C.D. Cal. Oct. 18, 2002); *Dowhal v. SmithKline Beacham*, 122 Cal. Rptr. 2d 246 (Cal. App. 2002), *appeal pending*, No. S-109306 (Cal. S. Ct.). As the court stated in *In re Paxil*:

> FDA's and [defendant]'s position vitiates, rather than advances, the FDCA's purpose of protecting the public. That is, FDA and [defendant] invite the Court to find that in enacting the FDCA for the purposes of protecting public health, Congress not only declined to provide for a private cause of action, but also eliminated the availability of common law state claims. This position contravenes common sense, *cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996), and the Court declines the invitation.

2002 WL 31375497 at *1.

"[T]here is no general inherent conflict between federal pre-emption of state [regulatory] requirements and the continued vitality of state common law damages actions." 505 U.S. at 518 (plurality); *id.* at 533-34 (Blackmun, J., concurring).

Again, in *Silkwood v. Kerr-McGee Corp.*, the Court acknowledged that the Atomic Energy Act preempted state positive law directly "regulating the safety aspects of nuclear development." 464 U.S. 238, 250 (1984). Yet the Court held that the plaintiff's state-law damages action concerning an unsafe nuclear plant, including her claim for punitive damages, was not preempted. The Court found that it would be improper to interpret federal statutes to "remove all means of judicial recourse" for those seeking compensation for injuries without a clear statement to that effect. *Id.* at 251; *see also Sprietsma*, 123 S. Ct. at 527 (unanimous opinion) ("perfectly rational" for Congress to preempt state positive law, but not "common-law claims, which—unlike most administrative and legislative regulations—necessarily perform an important remedial role in compensating accident victims").

Here, in the context of a statute containing an express preemption provision, the argument against implied preemption is even stronger than in *Silkwood*. Congress is presumed to carry out its policies through the text of enacted legislation. Thus, where it has expressly addressed preemption of state law in a particular statutory provision, as in 21 U.S.C. § 360k(a), that provision is assumed to be a "reliable indicium" of

congressional intent. *Cipollone*, 505 U.S. at 517. Although this presumption "does not . . . entirely foreclose[] any possibility of implied preemption," an "express definition of the pre-emptive reach of a statute 'implies'—i.e., supports a reasonable inference—that Congress did not intend to pre-empt other matters." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995).

In any event, this case does not present a conflict between state and federal law. A jury verdict in favor of Ms. Horn would only require TCI to pay damages to Ms. Horn. It would not require TCI to take any action inconsistent with federal requirements. *Accord Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988) ("The effects of direct regulation on the operation of federal projects are significantly more intrusive than the incidental regulatory effects of such an additional award provision. Appellant may choose to disregard Ohio safety regulations and simply pay an additional workers' compensation award if an employee's injury is caused by a safety violation."). Again—notwithstanding the grim picture painted by TCI and its amici—medical device manufacturers, the FDA, and consumers have functioned under our dual state-federal system of government without undue confusion, burden, or cost since the enactment of the medical device laws in 1976.

2. *Pokorny v. Ford Motor Co*., 902 F.2d 1116 (3d Cir. 1990), discussed at length by amicus Chamber of Commerce, does not suggest that implied preemption

applies here. In *Pokorny*, a driver's estate sued after the driver was killed in an automobile accident. The complaint alleged that the vehicle was defectively designed because it did not have an airbag, automatic seatbelts, or protective netting over the windows. First, this Court rejected Ford's argument that the preemption provision of the National Traffic and Motor Vehicle Safety Act expressly preempted Pokorny's claims. *Id*. at 1122.

Then, turning to implied preemption, this Court held that the design defect claims were impliedly preempted insofar as they sought to hold the company liable for failing to install airbags or automatic seatbelts. This conclusion turned on the existence of a federal safety standard, Standard 208, that allowed the company to choose one of several passive restraint systems, which the company had done (combined lap and shoulder belts with a warning light and buzzer). Because the federal standard had been formally addressed through a regulation, and because the agency commentary accompanying the issuance of Standard 208 revealed that "flexibility and choice [were] an essential element of the regulatory framework," *id.* at 1124, the Court found that the claims were preempted insofar as they sought to hold Ford liable for choosing one of the permissible options, as opposed to other options. In so holding, the Court relied heavily on the goals of Congress and the agency with respect to the specific topic of occupant restraint systems, as expressed in a statute, its

legislative history, and the agency discussion in the Federal Register. *Id.* at 1123-24; *see Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000) (finding conflict with Standard 208 where agency "has explained [standard's] objectives, and the interference that 'no airbag' suits pose thereto, consistently over time").

Of course, Congress has never specifically legislated with regard to the design of heart pumps (or any other medical device). Likewise, the agency has not issued any rules to address the design, manufacture, or labeling of these devices—as it has, for example, with regard to the design of certain laser devices, 21 C.F.R. § 886.4392, and the labeling of tampons, 21 C.F.R. § 801.430. In these circumstances, where no federal standard governs the "particular design said to be defective," this Court has agreed that conflict preemption does not apply. *Pokorny*, 902 F.2d at 1122 (discussing *Dawson v. Chrysler Corp*., 630 F.2d 950 (3d Cir. 1980)). Thus, this Court in *Pokorny* found *no* preemption of the claim that the vehicle was defective because it lacked protective netting over the windows. This claim, the Court explained, did not address any safety option included in Standard 208 and, accordingly, did not frustrate the flexibility intended by the agency. *Id.* at 1126 (argument that Court "should simply hold that *all* safety alternatives not included in [safety standard] are pre-empted does not persuade us"); *see also Geier*, 529 U.S. at 885 (quoting government's statement that claim that manufacturer should have chosen to install

different type of passive restraint system because of design features particular to that car would not necessarily frustrate Standard 208).

To the extent that *Pokorny* offers any analogy to his case, Ms. Horn's claims are closer to Pokorny's protective netting claim than to his airbag claim. In designing the heart pump, TCI did not choose among various federal options set forth in a regulation issued through notice-and-comment rulemaking. Rather, the choice of how to address the problem of separation of the pump's components was TCI's. As was true with regard to Ford's choice not to install protective netting, no federal objective would be frustrated by holding TCI accountable for that choice. Indeed, it would be hard to explain the FDA's consistent position—in a regulation and numerous subsequent statements—against *express* preemption of damages remedies in medical device cases, without ever suggesting that such remedies are *impliedly* preempted, if those remedies conflicted with its regulations or frustrated its objectives. Thus, implied preemption does not apply here.[7]

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[7] TCI relies on a recent statement of FDA's Chief Counsel Dan Troy, made in the context of discussing personal injury cases involving prescription drugs, in which Mr. Troy stated his view that federal law preempts state-law "requirements" that "conflict with specific FDA determinations." TCI Br. 59. This statement is of no help in resolving the question presented here. To begin with, it essentially restates the framework of the MDA's express preemption provision, without offering any analysis that would help to apply it. Second, Mr. Troy's personal views cannot override the Supreme Court's decision in *Medtronic* and the FDA's binding regulations, to which (continued...)

CONCLUSION

For the reasons stated above, the decision of the district court should be reversed and the case remanded for a trial on the merits of Ms. Horn's claims.

Respectfully submitted,

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[7](...continued)
Medtronic gave considerable weight. Finally, an informal newsletter is hardly the sort of agency pronouncement that is entitled to judicial respect, especially when it is inconsistent with the views of FDA's prior chief counsel, Margaret Porter. *See* Porter, *The Lohr Decision: FDA Perspective and Position*, 52 Food & Drug L.J. at 11 ("Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection . . . ."). Accordingly, it is entitled to little weight. *See United States v. Mead Corp*., 533 U.S. at 228 (degree of deference to government depends on, among other things, formality and consistency of government's position).

CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief was prepared in proportionately spaced, 14-point type and contains 6,249 words.

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June 18, 2003

CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of June, 2003, I served the foregoing REPLY BRIEF OF APPELLANT BARBARA HORN on the parties listed below by causing two true and correct copies thereof to be placed in the U.S. mail, first-class postage prepaid, addressed as follows:

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