Exhibit B

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May 14, 2004

Marcia Waldron, Clerk
United States Court of Appeals for the Third Circuit
21400 United States Courthouse
601 Market Street
Philadelphia 19106-1790

Re: *Horn v. Thoratec (No. 02-4597)*

Dear Ms. Waldron:

This letter-brief is being filed on behalf of the United States as *amicus curiae*, in response to this Court's letter of February 27, 2004. After briefing and oral argument by the parties, the Court requested the views of the United States Food and Drug Administration ("FDA") on the following issue:

> With respect to the Thoratec Heartmate, which was reviewed by FDA, are state common law claims of design defect, labeling, strict liability, negligence, and failure to warn preempted by § 360(a) of the Medical Device Amendments to the Food, Drug and Cosmetic Act?

As explained in this letter, the United States believes that Section 521(a) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 360k(a), does preempt these state common law claims because they would impose a requirement different

from, or in addition to, the requirements imposed by FDA in granting pre-market approval to the Thoratec HeartMate.[1] The Government believes that this view is compelled in order to achieve Congress's important public health protection purposes, carried out through FDA's implementation of the FDCA.

I. Interests of the United States

The United States has a strong interest in the preemption question before the Court, and appreciates the fact that the Court has sought our views.

In this case, the Court must determine whether federal law preempts claims brought under Pennsylvania common law alleging defects in the design, manufacture, labeling, and warnings pertaining to a Class III medical device that was approved by FDA in 1994, after undergoing the agency's pre-market approval process. Because FDA is responsible for regulating the safety and effectiveness of medical devices, and the conditions for their design, manufacture, performance, labeling, and use, the United States has a substantial stake in ensuring that state common law tort judgments do not interfere with implementation of this important federal scheme. As we explain below, we believe that, in the FDCA, Congress provided that FDA pre-market approval for a new medical device preempts state law tort judgments that do

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[1] Although the Court's letter refers to the preemption provision as codified at Section 360(a), it actually appears at 21 U.S.C. § 360k(a).

not merely effectuate the regulation of that device imposed by the agency. A contrary rule would undermine overall public health protection.

We acknowledge that, as the briefs filed by the private parties reveal, this position represents a change for the United States. In an *amicus* brief filed in the Supreme Court in 1997, at the Court's invitation in *Smiths Industries Medical Systems, Inc.* v. *Kernats, cert. denied*, 522 U.S. 1044 (1998) (No. 96-1405), the Government stated that 21 U.S.C.§ 360k(a) does not preempt a state tort law claim concerning an FDA-approved device. We explain in this letter-brief that, based on further analysis of the relevant legal and policy issues by FDA, the agency charged with administering the MDA and implementing its preemption provisions - - as well as the recent rulings by several courts of appeals and state courts- - the Government has instead determined that state tort claims such as those raised here are indeed preempted with respect to FDA-approved devices. This change in views has not been taken lightly, and we assure the Court that the filing of this letter taking this position has been authorized by the Solicitor General.

II. Nature of The Case

This letter-brief is predicated on the following understanding of this case, drawn from the parties' briefs.

Plaintiff, the executrix of the estate of her late husband, Daniel Ray Horn, brought this suit against Thoratec Corporation, formerly known as Thermo Cardiosystems, Inc. ("TCI") for negligence, strict liability, and breach of warranty. TCI made a device called the HeartMate Implantable Left Ventricular System ("HeartMate") , which was implanted inside Mr. Horn, who was awaiting a heart transplant. As explained below, the HeartMate is a Class III medical device that received pre-market approval from FDA in 1994, following the agency's extensive investigation into the device's safety and effectiveness.

Mr. Horn experienced difficulties with the device and died shortly after undergoing exploratory surgery to determine the cause of his medical problems.

Plaintiff's allegations in her complaint focus upon one aspect of the design and manufacture of the HeartMate, a screw ring that attached the elbow of the device to the body of the heart pump and that was secured to the device by a suture. Plaintiff presented state tort claims sounding in strict liability, negligence, and breach of warranty and fitness for intended use. These claims rested on allegations of defective design, defective manufacture, and failure to warn. More specifically, plaintiff makes two main claims: first, that TCI should have employed a design to prevent the screw rings used to hold the device in place inside the patient's chest from becoming disconnected (plaintiff asserted that TCI overlooked better alternatives to the design

it chose); second, that TCI should have issued warnings to doctors, through either revisions in the product labeling or correspondence to health care professionals (commonly called "Dear Doctor letters"), against using the device if the suture as placed in the device packaging would face the patient's sternum.

TCI moved for summary judgment on the ground that FDA's approval of the device for marketing under the 1976 Medical Device Amendments to the FDCA ("the MDA"), which are codified at 21 U.S.C. §§ 360c-360k, expressly preempted plaintiff's state law claims, which sought to impose requirements different from, or in addition to, requirements imposed through the agency's pre-market approval process. Plaintiff has appealed the district court's grant of summary judgment.

III. Statutory and Regulatory Background

The contours of the underlying statutory scheme governing FDA regulation of medical devices, and the practice under that scheme, are crucial in understanding the preemption issue here. In enacting the MDA, Congress established a comprehensive plan for regulation by the Department of Health and Human Services ("HHS") of medical devices. HHS has delegated this task to FDA.

A. The MDA creates three classes of medical devices, which receive different levels of regulation. Class III medical devices are those: (1) for which there is insufficient information to determine that general controls and special controls are

adequate to provide reasonable assurance of safety and effectiveness; and (2) that are purported or represented to be for a use in supporting or sustaining human life, or for use of substantial importance in preventing impairment of human health, or that present a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C). Class III devices are subject to the most stringent regulatory controls of all device classes.

B. Under the MDA, the manufacturer of a Class III medical device must obtain FDA's approval of a premarket approval application (a "PMA") before marketing the device in interstate commerce (unless the device is not subject to the PMA requirement). 21 U.S.C. § 360e.

A manufacturer seeking the necessary FDA approval must submit an application containing full reports of clinical investigations, whether adverse or supportive, known to or that should reasonably be known to the applicant, and that concern the safety or effectiveness of the device. 21 U.S.C. § 360e(c)(1)(A); 21 C.F.R. § 814.20(b)(8)(i). The manufacturer's application must contain a full statement of the components, ingredients, properties, and principles of operation of the device. 21 U.S.C. § 360e(c)(1)(B). It must include a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, the device. 21 U.S.C. § 360e(d). The

PMA must identify, discuss, and analyze any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to, or that should reasonably be known to, the applicant from any source, foreign or domestic, including information derived from investigations other than those proposed in the application and from commercial marketing experience. 21 C.F.R. § 814.20(b)(8)(ii). Even unpublished information must be included in the PMA if it is possessed or reasonably obtainable by the applicant, if requested. 21 C.F.R. § 814.20(b)(8)(iii).

The PMA must also include specimens of the labeling proposed to be used for the device. 21 U.S.C. § 360e(c)(1)(F). The proposed labeling must provide "adequate directions for use." 21 U.S.C. § 352(f). FDA by regulation has defined this to mean "directions under which the layman can use a device safely" for its intended use. 21 C.F.R. § 801.5. Because a prescription device, by definition, cannot be used safely by a layperson without professional supervision, FDA regulations afford an exemption from the statutory requirement of adequate directions for use for a prescription device whose labeling includes "any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended * * * ." 21 C.F.R. § 801.109(c).

In reviewing a PMA, FDA scientists carefully evaluate all of the data and information submitted by the manufacturer, which must be periodically updated during the review process, to assure the continuing completeness of the application. 21 C.F.R. § 814.37. FDA may request additional information as necessary to provide a complete and accurate picture of the product, and may supplement the expertise of its in-house scientific personnel with advice from scientific advisory committees of outside experts. 21 C.F.R. §§ 14.171, 814.20(b)(13). FDA regulations also specifically authorize FDA to evaluate the device's safety and effectiveness using information other than that submitted by the applicant. 21 C.F.R. § 814.45(c).

C. The agency's approval of a PMA reflects its conclusion that there is a "reasonable assurance of safety and effectiveness" of the device under the conditions set forth in the labeling for the product. 21 U.S.C. § 360e(d). In addition, PMA approval means that FDA has determined that the proposed labeling for the device complies with the detailed labeling requirements set forth in 21 C.F.R. parts 801 and (if applicable) 809, and is neither false nor misleading. 21 U.S.C. § 360e(d); 21 C.F.R. § 814.45. Preparation of a PMA and FDA's process of reviewing a PMA constitute a massive undertaking. The agency's review process for a PMA is thorough and scientifically rigorous, generally taking an average of 1,200 hours of review time by the agency. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

Class III devices are also subject to an additional set of conditions of approval, imposed by FDA pursuant to the "restricted device" provisions of the FDCA. FDA can declare a device "restricted" if, because of its potential for harmful effect or the collateral measures necessary to its use, restrictions are necessary for there to be reasonable assurance of safety and effectiveness. Restrictions on sale, distribution, or use may be imposed by notice-and-comment rulemaking. 21 U.S.C. § 360j(e). Restrictions on sale or distribution may also be imposed as conditions of PMA approval. 21 U.S.C. § 360e(d)(1)(B); 21 C.F.R. § 814.82. Designation of a device as "restricted" triggers other provisions of the Act – most notably, provisions governing the content of advertising. 21 U.S.C. § 352(q), (r). The vast majority of devices covered by approved PMAs are also "restricted" devices.

The bases for FDA's PMA approval for a device include the circumstances specified in the proposed labeling under which the device meets the statutory safety and effectiveness standard, the design characteristics of the device as submitted to FDA, any conditions of approval for the device identified by FDA through the PMA process, and the conditions determined by FDA to be necessary if the device is a restricted device. Conditions of approval are conveyed to the applicant by the agency

in an approval order, which takes the form of a letter. 21 C.F.R. § 814.44. As the approval order states, violation of any of these conditions automatically invalidates the approval. See 21 C.F.R. § 814.82(c).

Once FDA approves a Class III medical device, the holder of the approval may not change the design of the device in a manner affecting its safety or effectiveness without FDA approval. 21 U.S.C. § 360e(d)(6).

In other words, and of considerable significance here, after FDA approves a PMA for a medical device, the applicant generally may not make changes affecting the device's safety or effectiveness without the FDA's approval of the change, through a PMA supplement. 21 C.F.R. § 814.39. If a manufacturer changes a device in a manner that affects its safety or effectiveness without FDA approval, its distribution of the altered product is unlawful. 21 C.F.R. § 814.80.

FDA considers revisions proposed in a PMA supplement using the same type of rigorous scientific process utilized for review of original PMAs. 21 U.S.C. § 360e(d)(6)(A); 21 C.F.R. § 814.39. Changes to the design of a device that affect safety or effectiveness are approved only if nonclinical data demonstrate that the modification creates the intended additional capacity, function, or performance of the device, and if clinical data provide a reasonable assurance of safety and effectiveness for the changed device under the conditions in the labeling. 21 U.S.C.

§ 360e(d)(6)(B). FDA is authorized to "require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness." *Ibid.*

Certain labeling changes that enhance safety without a corresponding effectiveness impact are eligible for implementation without prior FDA approval. And, some manufacturing changes are also accorded special treatment. 21 U.S.C. § 360e(D)(6); 21 C.F.R. § 814.39. Even under these circumstances, the agency may disapprove a change after it has been implemented. Because all other changes that could affect safety and effectiveness require FDA approval, manufacturers have substantial incentives to obtain FDA agreement before a change is implemented.

D. Most medical devices do not undergo the FDA pre-market approval process that covered the HeartMate. Class I and II devices are not subject to the PMA requirement. Also, in general, a Class III medical device is not subject to the PMA requirement if it was marketed prior to the MDA's enactment (21 U.S.C. § 360e(b)(1)(A)), and a regulation requiring submission of PMAs has not been issued for the device, or if it is "substantially equivalent" to a predicate device. A predicate device may be either one marketed prior to the MDA's enactment or one "substantially equivalent" to a device marketed prior to the statute's enactment. 21 U.S.C. § 360j(1).

A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a pre-market notification to the agency in accordance with Section 510(k) of the FDCA. 21 U.S.C. § 360(k). A device found to be "substantially equivalent" to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a PMA). A pre-market notification submitted under Section 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate to FDA that the device is safe and effective. See *Lohr*, 518 U.S. at 478-79 ("The § 510(k) notification process is by no means comparable to the PMA process").

The number of medical devices that receive PMA review each year is dwarfed by the number of those that are marketed pursuant to cleared section 510(k)s. In fiscal year 2003, for example, original PMAs represented only 54 of the 9,872 major submissions received. The previous fiscal year, original PMAs accounted for 49 of 10,323 total submissions.[2]

E. The HeartMate is a Class III medical device. A PMA was submitted for the device in March 1992, and, after an extensive analysis, FDA approved it in September 1994, and subsequently published a notice of the approval.[3] See 61 Fed.

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[2]Office of Device Evaluation, Center for Devices and Radiological Health, ODEFY03 Annual Report 17 (http://www.fda.gov/cdrh/annual/fy2003/ode/2003.pdf).

[3]At the time FDA approved the HeartMate in 1994, the agency published approvals in the Federal Register. Such notices advised interested persons of the

Reg. 51712 (October 3, 1996). FDA subsequently approved multiple PMA supplements for the HeartMate, covering a variety of changes to the conditions of approval relating to labeling, manufacturing, and design.

IV. Plaintiff's Causes of Action Are Preempted by Federal Law

The preemption issue here turns on the express preemption clause in the MDA., which reads:

> [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). Under interpretive regulations issued by FDA, "state or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device." 21 C.F.R. §808.1(d).

As we demonstrate, FDA imposed such requirements through the PMA process. The manufacturer generally cannot make changes in the design, labeling, or

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right to request a formal hearing or a review of the application. See 21 U.S.C. § 360e(g). Currently, FDA provides initial notice of a PMA approval on the internet, and publishes a quarterly list of devices receiving PMA approval in the Federal Register. 21 C.F.R. § 818.44.

manufacturing processes specified in the PMA that affect safety and effectiveness without FDA approval.

A. The Supreme Court's ruling in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), provides the starting point today because the Court there considered whether state tort law claims with respect to a medical device marketed under the Section 510(k) clearance process were preempted. Thus, the Court examined the bounds of Section 360k(a), although in a different context than in the case at bar. Justice Stevens' opinion in *Lohr* reflected the views of four Justices, and Parts I, II, III, V, and VII of the opinion, in which Justice Breyer joined, constitute the opinion of the Court. See 518 U.S. at 508 (Breyer, J., concurring).

In ruling against preemption in that setting, the *Lohr* Court explained that "federal requirements reflect[ing] important but entirely generic concerns about device regulation generally, [are] not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." 518 U.S. at 501.

In his separate opinion concurring in the *Lohr* judgment, Justice Breyer further reasoned that, given FDA's regulation implementing Section 360k(a), state requirements are preempted under the MDA where FDA has established specific counterpart regulations or other specific federal requirements applicable to a

particular device, and a state requirement is different from, or in addition to, the specific FDA requirements. 518 U.S. at 507 (Breyer, J., concurring).[4]

B. Under this analytical framework, the MDA preempts plaintiff's claims here. Although FDA has issued no specific counterpart regulation for the HeartMate, the agency's approval of this device through the PMA process does impose specific requirements for the product, including requirements for its design, manufacturing, performance, labeling, and use. In approving the PMA for the HeartMate, FDA considered a variety of factors, such as the risk–benefit profile of the product, the nature of the medical conditions the product is intended to treat, and the availability of alternative therapies. See 21 U.S.C. 360e(d). In the words of *Lohr*, 518 U.S. at 501, this is a case "in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular set of case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers."

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[4] Most federal courts of appeals applying *Lohr* have found this to be the analysis endorsed by the Court. See *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001); *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001), *cert. denied*, 535 U.S. 1056 (2002); *Mitchell* v. *Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); *In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817, 822 (3d Cir. 1998).

As explained earlier, in reviewing a PMA, FDA considers in great depth and detail the performance and design specifications, methods of manufacture, labeling, and indications for use of a proposed medical device. 21 C.F.R. § 814.20. When FDA approves a PMA, it does so following a thorough review of a substantial scientific record. The approval perforce embodies the agency's conclusion that there is a "reasonable assurance of safety and effectiveness" of the device. 21 U.S.C. § 360e(d).

FDA's approval of the specific device as covered by the PMA governs that device with respect to labeling, manufacturing, design, distribution, sale, and use. In addition, as the agency's approval orders state, and consistent with 21 C.F.R. § 814.80, a device that does not comply with conditions of approval established through the PMA process is adulterated or misbranded and subject to seizure or other FDA enforcement action. See App. A-216.

Hence, although FDA does not itself design any medical devices, through the PMA approval process it certainly establishes "specific requirements" applicable to a "particular device" because the specifications for that device's design, performance, manufacture, labeling, and use are approved by the agency based on what the applicant submits. See *Kemp* v. *Medtronic, Inc.*, 231 F.3d at 216. And, those attributes are fixed in place, as they can be materially changed only with FDA

approval. As noted above, if a manufacturer materially changes the design or labeling of a device without FDA approval, distribution of the altered product is unlawful. 21 C.F.R. § 814.80.

This resolution of the PMA process and its future impact fit well within the common definition of "require," which is: "2. To call for as fitting; demand. 3. To impose an obligation on; compel. 4. To command, order." *The American Heritage Dictionary* (2d Coll. Ed. 1982). As a condition of marketing the HeartMate, FDA plainly imposed obligations on its manufacturer.

C. The second part of the proper analysis under Section 360k(a) requires determining whether the state law tort claim involves a requirement different from, or in addition to, the specific federal requirements established through the PMA process. Here, plaintiff seeks to impose liability based on asserted flaws in the design, labeling, and manufacture of the HeartMate as approved by FDA despite the fact that it complied with FDA requirements. Thus, plaintiff does attempt to impose a requirement different from FDA. This conclusion is shown by part of Justice O'Connor's opinion in *Lohr*, concurring in part and dissenting in part on behalf of four Justices, and joined by Justice Breyer as a fifth Justice for this portion. See 518 U.S. at 503-04.

The four Justices agreeing with Justice O'Connor made a majority for the conclusion that state tort law judgments do impose a requirement for purposes of preemption under the MDA when a common law action "would impose a requirement different from, or in addition to, that applicable under the FDCA – just as it would pre-empt a state statute or regulation that had that effect." 507 U.S. at 511. As Justice O'Connor also observed, Justice Breyer reached the same conclusion: " * * * 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." 507 U.S. at 504-05 (emphasis added).

There is no allegation that the HeartMate's design, labeling, or methods of manufacture deviated from those set forth in the PMA approved by FDA. Accordingly, any finding of liability based upon TCI's failure to satisfy a standard different from those approved by FDA in the PMA process would necessarily rest upon an implicit requirement that this device be designed, manufactured, or marketed in a way that differs from the way approved by FDA. In light of the conclusion of five Justices in *Lohr*, such a holding would constitute a common law requirement "different from, or in addition to, the specific FDA requirements." *See Kemp* v. *Medtronic*, 231 F.3d at 232; *Brooks* v. *Howmedica, Inc.*, 273 F.3d at 796; *Mitchell*

v. *Collagen Corp.*, 126 F.3d at 913; *Michael* v. *Siley, Inc.*, 46 F.3d 1316 (3d Cir. 1995).

Moreover, the conclusion by five Justices in *Lohr* that the legal standard embedded in a state tort law judgment would constitute a "requirement" for purposes of Section 360k(a) is significant for an additional reason. Such a "requirement" would stem from the application by a court of a general common law duty to a specific device, such as the HeartMate. If such state law judgments constitute device-specific "requirements" for the purposes of Section 360k(a), then clearly so also does FDA's application to a specific device of the general obligation to ensure that a Class III medical device meets the federal standards of safety and efficacy.

Thus, because five Justices have concluded that a state common law tort judgment is a "requirement" under Section 360k(a), surely an FDA decision approving a PMA and the design, manufacture, and labeling attributes of the HeartMate similarly establishes a "requirement" under that provision as well.

D. While the decision in *Lohr* thus establishes the framework for applying Section 360k(a), the ruling by the majority there that Section 510(k) clearance by FDA does not preempt state common law tort judgments does not provide the answer in this case, because, as the Supreme Court itself observed, the Section 510(k) procedure is quite unlike the PMA process. That Court emphasized that the PMA

approval process "is by no means comparable" to the Section 510(k) clearance process. 518 U.S. at 478.

As previously noted, under the Section 510(k) process, FDA "clears" a new medical device as substantially equivalent to a predicate device. As the Supreme Court observed, this process focuses upon "equivalence, not safety." 518 U.S. at 493. And under FDA's regulations, Section 510(k) clearance does not denote official approval of the device. 21 C.F.R. § 807.97.

In contrast to the Section 510(k) review process, which typically requires an average of only twenty hours to complete *(Lohr*, 518 U.S. at 479), PMA approval is far more rigorous, requiring an average of 1,200 hours. *Id.* at 518 U.S. at 477. Unlike a Section 510(k) clearance, which only determines whether two products are substantially equivalent, PMA approval consummates an exhaustive inquiry into the risks and efficacy of a device. *Buckman Co.* v. *Plaintiffs Legal Comm.*, 531 U.S. 341, 348 (2001).

In *Lohr*, not surprisingly, the Court premised its holding against preemption on the fact that the device had been cleared only through the Section 510(k) process, a "limited form of review." *Lohr*, 518 U.S. at 478. A manufacturer may change the design and labeling of a Section 510(k)-cleared device as long as it continues to be substantially equivalent to its predicate. 21 C.F.R. § 807.81. In direct contrast to the

PMA regime, FDA does not "approve" changes to a Section 510(k)-cleared device. Rather, the manufacturer simply has to demonstrate that its device is still substantially equivalent to its predicate. Moreover, the range of changes that a manufacturer can make to a cleared device with getting prior authority from FDA is broader than for an approved device. A manufacturer of a cleared device must submit a Section 510(k) notice to FDA only for changes that "could significantly affect safety or effectiveness of the device," or that represent a "major change." in the intended use of the device. 21 C.F.R. § 807.81.

Thus, agency actions and responsibilities in the Section 510(k) and PMA processes are quite different. For the latter, in stark contrast to the former, after a very lengthy process involving thousands of pages of documentation and many hours of expert analysis, and often including substantial give-and-take between the agency and the manufacturer, FDA approves a new device, including detailed specifications for its design, manufacture, performance, labeling, and use. Any of these specifications may be changed in way that affects safety and effectiveness only with FDA's authorization.

E. After issuing its decision in *Lohr*, the Court granted, vacated, and remanded to the Sixth and Seventh Circuits, to consider, whether the PMA process was sufficiently different from the Section 510(k) process to warrant a different outcome.

See *Mitchell v. Collagen Corp.*, 518 U.S. 1030 (1996) (granting certiorari, vacating judgment, and remanding for consideration in light of *Lohr*); *Martin v. Teletronics Pacing Sys., Inc.*, 518 U.S. 470 (1996) (same).

After reconsidering the issue of the preemptive effect of the PMA process in light of the Supreme Court's analysis in *Lohr*, both of those Circuits adhered to their prior position, finding that the FDA's approval of a PMA for a device indeed preempted different state requirements. *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); *Martin v. Teletronics Pacing Sys., Inc.*, 105 F.3d 1090 (1996) (same).

Every court of appeals to address this precise issue since *Lohr* – including the only Circuit to support plaintiff's no-preemption position – has treated the matter as undecided by *Lohr*. See *Goodlin v. Medtronic*, 167 F.3d 1367, 1371 (11th Cir. 1999); *Mitchell* v. *Collagen Corp.*, 126 F.3d. at 907 (finding it "important to stress that the factual situation before the Court in [*Lohr*] was substantially different from the one before us today"; *Lohr* "dealt with the scope of the preemption provision of the MDA in the context of the expedited 'substantially equivalent' process, not the full PMA process"); *Kemp v. Medtronic*, 231 F.3d. at 221, 227; *Martin* v. *Medtronic*, 254 F.3d at 580.

F. The view that plaintiff's claims here are preempted is consistent with the language and purpose of Section 360k(a).

We note first that plaintiff's contrary position would largely nullify this section. Congress well knew when it adopted the MDA that FDA does not design medical devices. Rather, Congress charged FDA with reviewing devices developed by manufacturers to ensure that they are safe and effective. If the agency had to specify the design of a device for there to be express preemption, "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 * * *." *Kemp v. Medtronic*, 231 F.3d 216, 227 (6th Cir. 2000). However, "motivating Justice Breyer's refusal to join Part VI of Justice Stevens' opinion in *Lohr* * * *. was his lack of conviction that 'future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.'" *Ibid.* If MDA preemption depended upon FDA itself imposing the design of a device in a regulation, preemption would be exceedingly rare, effectively reading the preemption provision out of the statute. To give effect to the words of the statute, FDA must be able to impose "requirements" without the agency developing devices in the first instance.

We second emphasize that the requirements imposed by FDA approval of a PMA are no less effective because the design has been proposed by the manufacturer. FDA can impose requirements by rule or order, regardless of whether or not the requirements were initially suggested to the agency by an outside party. FDA does

not, and has never, used notice-and-comment regulations to approve individual products or to establish product-specific requirements for manufacture, performance, labeling, and use. Rather, a PMA order is better conceptualized as an individual adjudication that imposes "specific requirements" on the device. Although the PMA approval order does not itself expressly reiterate all of the specific features the device's design, labeling, and manufacturing processes must have, it specifically approves as a matter of federal law those features as set forth in the application and binds the manufacturer to produce and market the product in compliance with the specifications as approved by FDA.

We also certainly recognize that Section 518 of the FDCA (21 U.S.C. § 360h) authorizes FDA to order a manufacturer to issue a warning to health care professionals or device users to repair or replace a device, to refund the cost of a device, or to recall a device. Subsection (d) of this section states that compliance with any such order "shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account." 21 U.S.C. § 360h(d).

Although this provision recognizes that manufacturers may be found liable in state tort actions, we believe, by virtue of the preemption provision, that the liability

contemplated is for actions alleging that a manufacturer failed to follow the requirements of an approved PMA. As the Supreme Court unanimously found in *Lohr*, "[w]here a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is 'different from, or in addition to,' requirements under federal law * * *. Section 360k does not preclude States from imposing different or additional remedies, but only different or additional requirements." *Lohr*, 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part).

G. There are very strong public policy considerations that support the Government's view that PMA approval by FDA preempts a state common law tort suit that would, if successful, impose liability when a manufacturer is doing only what FDA approved.

State common law tort actions threaten the statutory framework for the regulation of medical devices, particularly with regard to FDA's review and approval of product labeling. State actions are not characterized by centralized expert evaluation of device regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population – the central role of FDA – sometimes on behalf of a single individual or group of individuals. That individualized

redetermination of the benefits and risks of a product can result in relief – including the threat of significant damage awards or penalties – that creates pressure on manufacturers to add warnings that FDA has neither approved, nor found to be scientifically required, or withdrawal of FDA-approved products from the market in conflict with the agency's expert determination that such products are safe and effective. This situation can harm the public health by retarding research and development and by encouraging "defensive labeling" by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments. [5]

The Government's assessment of the potential impact of common law suits of this kind on the FDA's ability to perform its role is plainly entitled to deference. In

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[5]We also note that the FDCA device regulation scheme offers far more immediate protection for consumers from design flaws than does the tort system. Manufacturers must report injuries associated with a device to FDA. Where an adverse event "necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health" manufacturers must report the event to FDA within five days. 21 CFR § 803.53(a). FDA can then evaluate the nature of the adverse event and determine whether it was caused by a flaw in the device. If FDA were to find that a device flaw is causing injury and presents an unreasonable risk of substantial harm to the public health, the agency may order the manufacturer to notify health care professionals, patients, or others about the flaw, or to repair, replace, or recall the device. This system allows FDA to take immediate action to protect the public health. In stark contrast, the tort system normally takes years to reach resolution, and the resolutions it reaches are often not consistent with the broader risk-benefit calculus the agency makes.

assessing the preemptive effect of a statute or administrative action, the views of the agency charged with administering that statute are entitled to great weight. See *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000). "In addition, Congress has given the FDA a unique role in determining the scope of § 360k's preemptive effect." *Medtronic, Inc.* v. *Lohr*, 518 U.S. at 495-96. The fact that an agency has changed its views does not affect the primacy of its role or the fact that its views merit deference.

Further, when a manufacturer fails to report injuries associated with its device or the safety issue is otherwise attributable to the manufacturer's misconduct, FDA has ample authority to take action, as recognized in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341, 347-48 (2001). For example, last year, Endovascular Technologies (EVT) pled guilty to charges relating to a failure to report widespread, serious adverse events associated with one of its devices and knowingly and intentionally misleading FDA about device malfunctions. EVT agreed to pay a total of $92.4 million to settle civil and criminal charges. As this example illustrates, FDA has the tools necessary to protect the public health, with due consideration for the need to encourage appropriate use of medical devices.[6]

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[6]Plea Agreement, United States v. Endovascular Technologies, Inc., No. CR 02-0179SI(N.D.Cal.June12,2003(availableathttp://www.usdoj.gov/usao/can/press/assets/applets/2003_06_12_Endovascular_plea.pdf).

H. Plaintiff's opening brief asserts that the Government has previously taken the position that state law is not preempted under facts like those presented here. Plaintiff relies chiefly upon statements that appeared in an *amicus curiae* brief opposing certiorari filed in December 1997. That brief was filed in *Smiths Industries Medical Systems, Inc.* v. *Kernats, cert. denied*, 522 U.S. 1044 (1998) (No. 96-1405). There, the Government stated that PMA approval does not impose specific federal requirements for purposes of preemption under the MDA. Plaintiff also cites statements in an *amicus* brief filed by the United States in *Lohr*, which includes an explanation why Section 360k(a) approval does not impose a federal requirement that can form the basis for preemption.

Further, the position presented in the United States' *amicus* filing in *Kernats* does not reflect FDA's current views. The Government's earlier position that PMA approval does not impose a specific federal requirement reflected two underlying points. First, it rested upon the proposition that a PMA reflects a design, production method, and labeling proposed by the manufacturer and that FDA's approval of a privately devised design therefore does not convert the features of that design into federal requirements even though it carries legal consequences for the manufacturer. This proposition does not adequately account for the highly detailed and prescriptive nature of the PMA process and the approval order that results from it.

The Government's brief in *Kernats* also suggested that, because the PMA process represents FDA's endorsement of a minimum standard, PMA approval should not displace state common law that may provide additional protection to consumers. This suggestion does not take sufficient account of the state-of-the-art risk management principles that FDA currently follows. In recent years, FDA has recognized that more risk minimization does not necessarily yield greater public health benefits. Risk minimization measures, such as labeling warnings and market withdrawal, may actually present substantial disadvantages. More warnings can discourage appropriate product use. Market withdrawal can deprive patients of a useful therapeutic product. Therefore, FDA review of a PMA focuses not only on identifying the risk minimization appropriate for the device, but also on ensuring that the measures selected do not present their own public health disadvantages. By imposing additional risk minimization measures, state co-regulation may disrupt the careful balancing performed by FDA in the PMA process. Moreover, as we have pointed out, a manufacturer generally may not deviate from the specifications in the PMA concerning device design, fabrication, and labeling. Given this important restriction, the PMA approval does not simply establish minimums that manufacturers of Class III medical devices may choose to exceed. In fact, a PMA approval sets a ceiling as well as a floor.

Although the views stated here differ from the views that the Government advanced in 1997, those new views reflect a reasoned analysis. And, as the Supreme Court has made clear, because an agency's initial view "is not carved in stone," a revised agency statutory interpretation is entitled to deference even if it represents a break with prior interpretations *Rust* v. *Sullivan*, 500 U.S. 173, 186 (1991); *Motor Vehicle Manufacturers Association* v. *State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 41-42 (1983).

The change in governmental policy here also reflects in part the decisions applying *Lohr* issued by the federal courts in the seven years since that case was decided. Since 1997, three circuits have held that approval through a PMA constitutes a federal requirement that may have a preemptive effect under the MDA. *See Martin* v. *Medtronic, Inc.*, 254 F.3d 573 ; *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216; *Mitchell* v. *Collagen Corp.*, 126 F.3d 902. The Government now believes that the position stated in this letter-brief is a better implementation of the statutory scheme.

V. Conclusion

For these reasons, the United States believes that this Court should affirm the district court's dismissal of this action. The district court concluded that FDA had established specific federal requirements for the HeartMate through the PMA process because the agency's approval reflected a determination that the device was safe and

effective. That approval required TCI to sell the product only in the form approved by FDA, and to obtain further regulatory approval from the agency if it wished to make any material change to the device. The district court also concluded that plaintiff's state common law tort action would impose requirements on the product that differed from, or were additional to, those imposed through the PMA process, which had culminated in the agency's determination that the device was safe as designed. These rulings are correct, and this Court should make clear that the types of claims here are preempted under federal law.

Respectfully submitted,

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