June 1, 2004

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

Re: *Horn v. Thoratec Corp.*, No. 02-4597
Argued December 11, 2003

Dear Ms. Waldron:

Appellant Barbara Horn submits this letter brief pursuant to the Court's letter of May 20, 2004, directing the parties to respond to the May 14 letter brief filed by the Department of Justice on behalf of the Food and Drug Administration ("FDA").

INTRODUCTION

The FDA's letter brief addresses the question whether the common-law product liability claims alleged in this case are expressly preempted by section 360k(a) of the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act. Reversing a position that the FDA has held for many years, and in conflict with the FDA's own regulation, the letter brief argues that when the agency grants premarket approval ("PMA") to a medical device, product liability claims for design defect,

manufacturing defect, and failure to warn, based on strict liability or negligence, are expressly preempted by section 360k(a).

Appellant Barbara Horn offers this brief to make three points. First, as set forth in Ms. Horn's reply brief (at 14), the FDA's long-standing position that section 360k(a) does *not* preempt damages claims was based on a 1978 regulation issued through notice-and-comment rulemaking, was developed outside the context of litigation, and was consistently maintained for more than two decades. Both because the position stated in the letter brief contradicts the FDA's prior view, and because it is inconsistent with the FDA's own regulation, the brief is entitled to no weight.

Second, although *Medtronic v. Lohr* requires a "careful comparison" between the allegedly preemptive federal requirements and the allegedly preempted state requirements, the letter brief argues in generalities, avoiding any discussion of the regulatory history of the HeartMate or the state-law claims at issue here.

Third, the FDA's policy arguments run counter to the reality of the 28 years in which federal device regulation has co-existed with state-law product liability suits.

ARGUMENT

I. The Letter Brief Is Not Entitled To Weight Because The FDA Has Altered Its Long-Standing Position On The Preemptive Scope Of Section 360k(a) And Because The Letter Brief Is Inconsistent With An Existing FDA Regulation.

A. By its own admission (at 3, 28, 30), the FDA's letter brief reverses the agency's longstanding view on the preemptive effect of section 360k(a) on state-law damages claims. The FDA's newfound position contradicts not only the argument it made to the Supreme Court in *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1407 (excerpt attached as addendum to Aplt. Opening Br.), but also its previous construction of its regulation, to which the Supreme Court majority gave substantial weight in *Medtronic, Inc. v. Lohr*. *See* 518 U.S. 470, 496-97, 498-99 (1996); *id.* at 505-06 (Breyer, J., concurring). For this reason, "[a]lthough generally 'an agency's construction of its own regulations is entitled to substantial deference,' *Lyng v. Payne,* 476 U.S. 926, 939 (1986), no such deference is appropriate here." *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000); *see United States v. Mead Corp*., 533 U.S. 218, 228 (2001) (degree of deference due to government depends on, among other things, consistency and formality of government's position); *cf. Maislin Indus. v. Primary Steel, Inc.,* 497 U.S. 116, 131 (1990) ("Once we have determined a statute's clear meaning, we adhere to that determination under the doctrine of *stare decisis*, and we

judge an agency's later interpretation of the statute against our prior determination of the statute's meaning.").

The FDA's about-face parallels the situation before the Supreme Court in *Shanklin*. There, the Court considered whether the Federal Railroad Safety Act preempted the personal injury claims of a plaintiff injured at a railroad crossing. The Federal Highway Administration ("FHWA") filed an amicus brief urging the Court to hold that the plaintiff's claims were not preempted. Finding preemption, the Supreme Court looked to its decision in *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658 (1993), which interpreted the scope of preemption under the Act. In *Easterwood*, the Court had "adopted the FHWA's own understanding of the application of . . . a regulation that the agency had been administering for 17 years." *Shanklin*, 529 U.S. at 355. Because in *Shanklin* the agency's amicus brief "contradict[ed] the agency's own previous construction," on which the Court had relied in the prior case, the Court gave the agency's new view no deference. *Id.* at 356.

Arguing that its about-face should not affect the weight accorded to its view, the FDA (at 27) quotes *Medtronic*'s statement that "Congress has given the FDA a unique role in determining the scope of § 360k's preemptive effect." 518 U.S. at 596. That statement, however, was made in the course of explaining why the FDA's interpretation of section 360k(a) as set forth in the agency's preemption *regulation*

warranted substantial weight—not as a basis for giving weight to the agency's amicus brief. *Id.* at 495-96 ("The FDA regulations interpreting the scope of § 360k's pre-emptive effect support the Lohrs' view, and our interpretation of the pre-emption statute is substantially informed by those regulations.").

B. The letter brief is, in fact, inconsistent with the FDA's existing preemption regulation, 21 C.F.R. § 808.1(d). Section 808.1(d) states that preemption is limited to instances in which the FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device" or class of devices. The regulation also states 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." *Id.* § 808.1(d)(1).

The FDA has never questioned the continued viability of these regulations. Although it quotes part of section 808.1(d) in the introduction to the argument (at 13), the letter brief neither discusses the regulation nor explains how its new view is consistent with it.

The FDA acknowledges (at 13, 14-15) that both its regulation and *Medtronic* limit preemption to instances in which the agency has established a "specific counterpart regulation or other specific requirement" for the product. It then states (at 16-17) that PMA constitutes a specific federal requirement because, once the FDA has approved a product for marketing, the approved "attributes are fixed in place, as they can be materially changed only with FDA approval." Yet the same was true of the 510(k) device at issue in *Medtronic*. Although the FDA is correct that its premarket review is less extensive when a manufacturer seeks marketing permission pursuant to section 510(k) as opposed to PMA, the requirements imposed on the manufacturer after the FDA grants permission are quite similar. Either way, the manufacturer cannot generally alter the device's design before obtaining the FDA's permission. 21 C.F.R. § 814.39(d) (PMA); *id.* § 807.81(a)(3)(i) (510(k)). Either way, the same prescription device labeling regulations apply, *id.* § 801.109, and either way, the same good manufacturing practice regulations apply. *Id.* Part 820.

By focusing on differences in the route to marketing, the FDA fails to address the requirements actually imposed on manufacturers once their products reach the market, and thus fails to distinguish *Medtronic*. Because the post-marketing requirements are the ones under which a manufacturer is operating at the time of the events giving rise to a product liability suit, it is those requirements that are relevant

to the preemption analysis introduced by the FDA in its regulation and adopted by the *majority* opinion (and in Justice Breyer's concurrence) in *Medtronic*.

In addition to a device-specific federal requirement, Part V of the majority opinion in *Medtronic* (in which Justice Breyer joined) relied on the FDA's regulation to hold that preemption also requires a counterpart state requirement specific to devices. 518 U.S. at 500, 502. As in *Medtronic*, the claims in this case are based on state-law duties of general applicability, not requirements specific to devices. Avoiding this prong of the agency's own regulation and the *Medtronic* majority opinion, the FDA's letter brief (at 18) states that Ms. Horn's claims are preempted because five Justices stated that a standard imposed by state tort law can constitute a preemptive requirement. Yet the FDA makes this argument only by ignoring the majority's holding (in which Justice Breyer expressly concurred) that preemption under section 360k(a) requires *specificity* on both the federal and state-law sides of the preemption analysis. *See* 518 U.S. at 500, 501 (majority opinion); *id.* at 504-05 (Breyer, J., concurring). Not only does the FDA's letter brief fail to identify any device-specific (that is, heart-pump-specific) requirement on the federal side of the analysis, it simply ignores the "specificity" issue on the state-law side entirely. As was true of the state-law clams at issue in *Medtronic*, the generality of the design, manufacturing, and labeling claims alleged by Ms. Horn "leaves them outside the

category of requirements that § 360k envisioned to be 'with respect to' specific devices," and thus outside section 360k(a)'s preemptive scope." *Id*. at 502.[1]

In sum, because the agency has done an about-face on this issue, and because the Supreme Court relied on the agency's prior views to interpret the scope of section 360k(a), the FDA's letter brief is entitled to no deference.

II. Although Under *Medtronic* And FDA Regulations Preemption Is Premised On "Specificity," The Letter Brief Fails To Address Any Specific Requirement Or Facts Pertinent To The HeartMate.

In *Medtronic*, the Supreme Court held that both section 360k(a) and the FDA regulation, 21 C.F.R. § 808.1(d), "require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." 518 U.S. at 500. The FDA's letter brief offers no such "careful

---

[1]The Supreme Court majority explained: "[T]he general state common-law requirements in this case were not specifically developed 'with respect to' medical devices. Accordingly, they are 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. The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce." *Medtronic*, 518 U.S. at 501-02.

comparison." In fact, the argument section of the brief never mentions the HeartMate or any specific aspect of Ms. Horn's claims. Those specifics are important, however, for her claims are grounded in large part on aspects of the HeartMate's design and labeling that were not considered in the PMA process and were not the subject of any requirements imposed through it. For example, nothing in the PMA process forbade Thoratec from warning that the heart pump should not be installed if the sutures would face upward, toward the sternum. As the FDA (at 11) concedes, for Thoratec to have provided such a warning, either by changing the label pursuant to 21 C.F.R. § 814.39(d)(2)(i) or (ii), and/or via a Dear Doctor letter, would not have run afoul of any specific federal requirement. *See Medtronic*, 518 U.S. at 497 n.16 (noting that 21 C.F.R. § 814.39(d)(1) & (2) allow manufacturer unilaterally to change labels of PMA devices). Indeed, doing so would have been consistent with the manufacturer's obligation to update labeling to make "changes that add or strengthen a contraindication, warning, [or] precaution" and "that add or strengthen an instruction that is intended to enhance the safe use of the device." 21 C.F.R. § 814.39(d)(2)(i)-(ii); *see also* Aplt. Opening Br. at 35-39; Aplt. Reply at 8, 10-11.

III. The FDA's New View Is Inconsistent With The Purpose Of The Medical Device Amendments.

The FDA briefly argues that its new position promotes public policy. The agency recently made a similar argument in another case involving preemption of state-law claims, and the response of the court in that case is fully applicable here.

> 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.

In re Paxil Litigation, 2002 WL 31375497 at *1 (C.D. Cal. Oct. 18, 2002).

The FDA also states (at 23) that Ms. Horn's position "would largely nullify" section 360k(a). This statement is incorrect. Under Ms. Horn's view, section 360k(a) would still apply where the FDA has issued device-specific requirements, as it has for some devices (*see* Aplt. Reply at 23 (citing examples)), and where a state seeks to issue counterpart requirements directed at those devices. In this case, Ms. Horn does not rely on any device-specific requirements. Accordingly, at this point, there is no basis for preemption under section 360k(a).

Finally, the agency's suggestion that federal regulation provides consumers more protection than state tort systems not only ignores instances of indisputable

regulatory failure (*e.g.*, the Guidant stent device, the Bjork-Shiley heart valve, the Vitek jaw implant, the Bard heart catheter), but it compares apples to oranges. The agency overlooks a key distinction: Injured patients cannot seek compensation through the regulatory system. State-law product liability suits are the sole means for compensation when medical devices injure or, as in Mr. Horn's case, kill the patients who use them. For this reason, the Supreme Court has observed that Congress can and does rationally preempt state regulatory efforts, while at the same time leaving in place state-law systems for compensating individuals injured by federally-regulated products and industries. *See*, *e.g.*, *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) ("perfectly rational for Congress not to pre-empt common-law claims" when preempting state positive law because common-law claims "perform an important remedial role in compensating accident victims"); *English v. General Electric Co.*, 496 U.S. 72, 87-90 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Prior to enactment of the MDA, individuals could seek redress for injuries caused by medical devices through state-law damages actions. Indeed, when Congress enacted the Food, Drug, and Cosmetic Act in 1938, it specifically rejected a proposal to include a private right of action for damages caused by faulty or unsafe products regulated under the Act on the ground that such a right of action already existed under state common law. *See*, *e.g.*, Hearings Before Subcomm. Of Comm. On

Commerce on S. 1944, 73d Cong., 2d Sess. 400, 403 (1933); Adler & Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 924 & n. 130 (1995) ("Congress rejected a provision in a draft of the original FD&C providing a federal cause of action for damages because 'a common law right of action [already] exists'") (quoting legislative history).

In 1976, Congress enacted the MDA in the wake of the Dalkon Shield tragedy, which killed and injured many women, many of whom then sued the device's manufacturer. *See* S. Rep. No. 94-33, at 1-2 (1975), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1070-71; *Medtronic*, 518 U.S. at 476. Yet in enacting the MDA, Congress said nothing to indicate that it disapproved of these suits or that it was seeking to immunize manufacturers from such suits in the future.

The FDA's position here is particularly extraordinary given that Congress expected that 510(k) devices would be phased out, as the FDA would call for PMA for *all* class III devices within just a few years. *See* 21 U.S.C. § 360c(c)(2)-(3) (requiring prompt classification of devices and making devices presumptively class III); H.R. Conf. Rep. 94-1090, at 56-57 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1103, 1107-09; *Medtronic*, 518 U.S. at 479 ("Congress anticipated that the FDA would complete the PMA process for Class III devices relatively swiftly."). Class III devices

are the riskiest and most likely to cause injury.[2] Thus, under the FDA's new reading of the MDA, Congress intended to immunize from damages suits the manufacturers of the devices those most likely to cause serious harm, the very devices that prompted Congress to act and that provided the impetus for the MDA's regulatory cornerstone: the PMA process.

The notion that, in 1976, in a bill sponsored by Senator Edward Kennedy, Congress intended to effect tort reform on the large scale suggested by the FDA's brief, and without any specific discussion of such an intent, is not credible. *See Silkwood*, 464 U.S. at 251 ("Congress would [not], without comment, remove all means of judicial recourse for those injured by illegal conduct."). Because "'the purpose of Congress is the ultimate touchstone' in every pre-emption analysis," *Medtronic*, 518 U.S. at 485 (citation omitted), the FDA's new position must be rejected.

[2]As explained in Ms. Horn's Opening Brief, Class III devices are those for which the controls provided for class I and class II devices cannot provide reasonable assurance of safety and effectiveness for human use and that either operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose a potentially unreasonable risk to patients. 21 U.S.C. § 360c(a)(1)(C); *see* 21 C.F.R. § 860.3(c)(3).

CONCLUSION

For the reasons stated above and in appellant's opening and reply briefs, 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,

Allison M. Zieve
Brian Wolfman
Public Citizen Litigation Group
1600 20th Street, NW
Washington, DC 20009
(202) 588-1000

John M. Humphrey
Rieders, Travis, Humphrey, Harris,
Waters & Waffenschmidt
161 W. Third Street, P.O. Box 215
Williamsport, Pennsylvania 17703-0215
(570) 323-8711

Counsel for Appellant Barbara Horn

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of June, 2004, I served the foregoing LETTER 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:

Alan Untereiner
Robbins, Russell, Englert, Orseck & Untereiner
1801 K Street, NW, Suite 411
Washington, DC 20006

Peter Maier
Department of Justice
Civil Division
601 D Street, NW, Room 9012
Washington, DC 20530-0001

Robert Weiner
Arnold & Porter
555 12th Street, NW
Washington, DC 20004

Daniel G. Jarcho
McKenna Long & Aldridge
1900 K Street, NW
Washington, DC 20006

_____
Allison M. Zieve