IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

BARBARA E. HORN, Executrix of the Estate of Daniel Ray Horn, Deceased,	:	
Plaintiff	:	
v.	:	No. 4:CV-00-0779 (Judge McClure)
THERMO CARDIOSYSTEMS INC.,	:	
Defendant.	:	

DEFENDANT'S REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT ON GROUNDS OF FEDERAL PREEMPTION

In our opening memorandum, we showed that plaintiff's claims in this case are expressly preempted by the MDA because, if permitted to go forward, they would impose state-law "requirements" on the design, manufacture, and labeling of the HeartMate that are plainly "different from, or in addition to" the extensive requirements imposed on that heavily regulated device by federal law. 21 U.S.C. § 360k(a). We further demonstrated that the relevant state and federal requirements are sufficiently "specific" to come within the FDA's gloss on the broad language of Section 360k(a). See 21 C.F.R. § 808.1(d). Finally, we explained that even if plaintiff's claims are not expressly preempted, they are impliedly preempted because they conflict with and frustrate the federal purposes underlying the MDA and the PMA process.

Plaintiff's response is notable for what it does not say. Plaintiff does not deny that, in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), a majority of the Supreme Court held that state tort law imposes "requirements" within the meaning of Section 360k(a). Nor does she dispute that the state-law requirements involved in this case have been specifically applied to the HeartMate LVAD and thus are subject to preemption under Section 360k(a) as that provision has been interpreted by the FDA. Indeed, plaintiff's only argument as to why the state requirements here should be spared from express preemption relies upon the so-called "presumption against preemption" as well as portions of Justice Stevens' plurality opinion in Lohr that failed to garner a majority of the Court.

On the federal side of the equation, plaintiff acknowledges the "specificity and considerable rigor of the PMA process." Plaintiff's Br. in Opposition ("Opp."), at 21. Nevertheless, she argues that PMA review — which by its very nature focuses on a single medical device — is not "specific" enough to trigger preemption. Her principal argument against express preemption, however, is that the PMA process imposes no requirements at all on a device manufacturer — a position, we note, that has been rejected by all but a tiny minority of federal and state courts, both before and after

Lohr. As for the Third Circuit's pre-Lohr decision in Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir.), cert. denied, 516 U.S. 815 (1995), plaintiff maintains that it is no longer controlling because of a later Third Circuit decision that the Supreme Court reversed. Opp. 27. As we explain below, these and other arguments made by plaintiff against express and implied preemption are meritless.

1. Although plaintiff acknowledges that her state-law claims in this case would impose "requirements" under Section 360k(a) that apply with specificity to the HeartMate, she advances a host of reasons why her claims should be spared from Congress's preemptive command. First, she notes that, according to Justice Stevens' plurality opinion in Lohr, the "requirements" referred to in Section 360k are "state and local legislative and administrative enactments," not requirements imposed by state common law. Opp. 14; see also id. at 12-13. That very argument, however, was rejected by five Members of the Court in Lohr — as plaintiff herself elsewhere concedes. See Lohr, 518 U.S. at 509 (opinion of O'Connor, J.); id. at 503-04 (opinion of Breyer, J.) (same); Opp. 14-15.

Next, plaintiff argues that it would be inconsistent with Congress's consumer-protection objective in passing the MDA "to leave the consumer without recourse" for injuries caused by medical devices. Opp. 13 (citing Lohr and Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984)). There are at least two problems with this argument. To begin with, the statute as construed in Lohr does not leave consumers without recourse: it preserves tort claims where there are no preemptive federal requirements applicable to the device, where the state requirements are identical to the counterpart federal requirements, or where the FDA has exempted a state tort statute or other law from preemption pursuant to under Section 360k(b). In addition, Congress's purpose in enacting the MDA was not unitary. Congress designed the MDA as a "balanced regulatory proposal" intended not only to endow the FDA with broad new regulatory powers aimed at protecting consumers from

unsafe and ineffective devices but also to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976). The MDA's express preemption clause, which Congress characterized as a "general prohibition on non-Federal regulation" (id. at 45), was designed to serve the latter purpose.[1]

Plaintiff also invokes 21 U.S.C. § 360h(d) — which she describes as a general "savings clause" — as evidence that Congress "expected that some tort liability" would "survive the enactment of the MDA" and as "clear evidence that Congress assumed that manufacturers would remain civilly liable for device-related defects." Opp. 14. But Congress's expectation (or assumption) is already readily apparent from its exclusion of identical state requirements from Section 360k(a) as well as from Congress's creation of an exemption power in the FDA. More importantly, as plaintiff concedes, Section 360h(d) "does not directly limit the pre-emption clause of Section 360k." Opp. 14. It is thus not a "savings clause" at all. Section 360h(d) is part of a provision that governs FDA orders directing manufacturers to notify health professionals and others of certain risks, to recall or replace devices, or to refund the purchase price of devices. It provides:

> Compliance with an order issued under this section 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) (emphasis added). By its plain terms, Section 360h(d) is limited to describing the effect of compliance with one of the various but limited FDA orders that could issue under

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[1] The plaintiffs in Buckman Co. v. Plaintiffs' Legal Committee also "relie[d] heavily on Silkwood," but the Court noted (in words equally applicable here) that Silkwood "turned on specific statutory evidence that Congress 'disclaimed any interest in [achieving its objectives] by means that fail to provide adequate remedies for those who are injured by exposure to hazardous nuclear materials.'" 121 S. Ct. 1012, 1019 (2001) (quoting Silkwood, 464 U.S. at 257) (emphasis added).

Section 360h. There is no such order in this case. Moreover, the reference to federal or state liability in Section 360h(d) is not even necessarily a reference to tort actions. It encompasses, for example, contractual liability under state law for economic loss in disputes between device manufacturers, importers, distributors, and retailers. Not surprisingly, the Supreme Court in Lohr ignored Section 360h(d), even though the Lohrs argued that it was relevant to the preemption inquiry. See Nos. 95-754, 95-886 Br. for Cross-Petitioners Lora Lohr and Michael Lohr, 1996 WL 88460, at *27-28.

Finally, plaintiff falls back on a general "presumption against preemption." Opp. 10-11. Plaintiff never explains, however, why that presumption should be given any more effect than it has already been accorded in Lohr, where (as plaintiff admits, see Opp. 15) a majority of the Court, in adopting the FDA's gloss, gave a "very restrictive interpretation" on the broad language of Section 360k(a). In any event, it is difficult to see why, in cases where Congress has elected to include an express preemption provision in a statute, courts should entertain the (obviously mistaken) assumption that Congress did not intend to disturb state authority to regulate. Perhaps for that reason, the "presumption against preemption" has been either avoided or criticized by the Supreme Court in cases since Lohr and it has been subjected to harsh criticism by legal scholars. See, e.g., Buckman, 121 S. Ct. at 1017 (declining to apply the presumption); Crosby v. National Foreign Trade Council, 530 U.S. 363, 374 n.8 (2000) (same); United States v. Locke, 529 U.S. 89, 107-08 (2000) (criticizing the presumption as "artificial" and declining to apply it); Norfolk S. Ry. Co. v. Shanklin, 529 U.S. 344 (2000) (making no mention of the presumption). See also Dinh, Regulatory Compliance as a Defense to Products Liability: Reassessing the Law of Preemption, 88 GEO. L.J. 2085, 2096-97 (2000) (arguing that the constitutional structure of federalism does not admit of a general presumption against federal preemption of state law); Nelson, Preemption, 86 VA. L. REV.

225, 235-64, 292-93 (2000) (arguing on the basis of historical analysis that a presumption against preemption is inconsistent with the text of the Supremacy Clause).

2. In our opening memo (at 23-25), we marshaled substantial evidence from the text, structure, legislative history, and regulatory interpretation of the MDA showing that the PMA process imposes federal "requirements" that trigger preemption under Section 360k(a). Plaintiff has nothing to say in response to this evidence. Neither does plaintiff offer any answer to our demonstration (id. at 20-21) that most federal and state appellate courts have ruled that PMA "[a]pproval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling" and is "specific to the product." Mitchell v. Collagen Corp., 126 F.3d 902, 913 (7th Cir. 1997), cert. denied, 523 U.S. 1020 (1998). Significantly, that majority includes the Third Circuit's pre-Lohr decision in Michael, which squarely held that PMA approval triggered express preemption of state-law tort requirements under Section 360k(a). Since Lohr did not involve a PMA device, it does not alter the holding of Michael, which is controlling here. Plaintiff's response is to cite a later Third Circuit panel's "reluctance to find pre-emption" (Opp. 27) even though that later decision was unanimously reversed by the Supreme Court in Buckman. The argument is absurd. As explained in our opening memo (at 22), other courts have had no difficulty concluding that Lohr left prior cases involving PMA devices unaffected.

In an effort to show that the PMA process does not impose preemptive federal requirements, plaintiff relies primarily on an article written by the FDA's Chief Counsel and on a proposed regulation that the FDA withdrew before it ever became final. Opp. 16, 18-19, 25 (citing Porter, The Lohr Decision: FDA Perspective and Position, 52 FOOD & DRUG L.J. 7 (1997), and 62 Fed. Reg. 65384 (1997)). For several reasons, this reliance is misplaced.

The proposed regulation is of no moment because the FDA withdrew it after receiving several highly critical comments from the public, including objections from industry groups who argued that it was beyond the FDA's authority and inconsistent with past agency interpretations of the MDA. Because the proposed regulation was withdrawn, courts have correctly ruled that it is "entitled to no weight." Dunlap v. Medtronic, Inc., 47 F. Supp. 2d 888, 897 (N. D. Ohio 1999); accord Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1375 n.15 (11th Cir. 1999) ("[W]e have given the FDA's expression of its views in this proposed rule no authoritative weight or deference."). Indeed, even before the proposed regulation was withdrawn, courts gave it little if any weight. See Easterling v. Cardiac Pacemakers, Inc., 1998 U.S. Dist. LEXIS 1361, at *2-3 (E.D. La. Feb. 6, 1998) (describing rule as neither "controlling" nor "persuasive" because it is "proposed and not final"); see also Worthy v. Collagen Corp., 967 S.W.2d 360, 375 (Tex.), cert. denied, 524 U.S. 954 (1998).[2]

Plaintiff maintains, however, that the FDA's proposed regulation is instructive because it reflects the agency's longstanding view that (a) tort law or "common law claims" will rarely be preempted under Section 360k(a), and (b) PMA approval does not impose federal requirements that trigger express preemption. See Opp. at 16, 20. In fact, neither of these views is "consistent with [FDA's] historical position on preemption." Id. at 16 n.1. The FDA's regulatory notices and

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[2] Plaintiff suggests that the FDA's proposed rule was withdrawn "because of concerns regarding its timing with respect to amendments to the MDA enacted in late 1997." Opp. 16 n.1. That explanation is incomplete. The proposal was withdrawn after the Medical Device Manufacturers Association (MDMA) complained that FDA had shared a preliminary draft with the Public Citizen Litigation Group prior to publication in the Federal Register. See 4/9/98 Letter of S. Northrup to M. Friedman, at 1-2 (Tab 1). Noting that federal regulations make it unlawful for the FDA to furnish a "draft of a notice or proposed regulation or its preamble" to any interested person unless the draft is also furnished to "all interested persons by a notice published in the Federal Register" (21 C.F.R. § 10.80(b)(2)), MDMA called for a "thorough investigation." 4/9/98 Northrup letter, at 1. The FDA later indicated that it was "tak[ing] [these] concerns seriously and [was] initiating an investigation of the issues" raised by MDMA. See 5/1/98 Letter of M. Friedman to S. Northrup, at 1 (Tab 2).

exemption practice have never recognized a distinction between state requirements that are based in the tort or common law and other kinds of state requirements. Indeed, the FDA refused to exempt from preemption (and thus found preempted) a California law forbidding fraudulent and other representations in advertising with respect to medical devices. See 21 C.F.R. § 808.55(b)(2) (hearing aids). That statute essentially embodied a tort duty under California law. Moreover, in its Lohr brief the FDA explained that it had "not heretofore taken a formal position specifically on whether the term 'requirement' in Section [360k(a)] encompasses obligations established by a State's common law of torts." Nos. 95-754, 95-886 Br. for the United States as Amicus Curiae, 1996 WL 118035, at *15 n.12 (Tab 3). The FDA went on to take such a formal position, indicating that common law duties are "requirements" subject to preemption under Section 360k. Id. at *15-19. Indeed, later in its brief the FDA provided a concrete example of a "common law standard of care" that would be preempted by the MDA. Id. at *25 n.20 (federal good manufacturing practices ("GMP") regulation requiring the heads of Quality Assurance ("QA") programs at all device manufacturers to have high school diplomas would, "in the absence of an exemption, preempt both state regulations requiring QA heads to have college degrees and a state common-law standard of care requiring that result in a particular case"). By proposing a special rule for common law requirements, the FDA in its proposed rule was thus departing from positions taken in its Lohr brief.

Equally wrong is plaintiff's suggestion that FDA has long held the view that PMA approval does not impose preemptive federal requirements. As we pointed out in our opening brief (at 22-23 n.11), the FDA's regulatory notices have expressly acknowledged that the requirement of premarket approval triggers federal preemption. In a 1978 notice, for example, the FDA, in response to several commentors who stated that it was "unclear" in the FDA's proposed regulation concerning

exemptions from preemption "whether or when State and local premarket approval requirements are preempted" (43 Fed. Reg. 18661, 18664 (May 2, 1978)), provided the following clarification:

> Like all other medical device requirements, different or additional State and local premarket approval requirements are preempted when FDA establishes specific counterpart regulations or there are other specific requirements applicable to the device under the act. For a device classified in class III under sections 513(f) and 520(l) of the act (21 U.S.C. 360c(f) and 360j(l)), the counterpart FDA requirement — the requirement that the product have premarket approval — was established by operation of the act immediately upon enactment of the Amendments on May 28, 1976. * * * Once these FDA requirements are established, different or additional State requirements are preempted.

Id. (emphasis added). As this passage indicates, the requirement of premarket approval triggers preemption under Section 360k(a). The FDA has since reaffirmed this understanding. See 45 Fed. Reg. 67321, 67322-23 (Oct. 10, 1980); 44 Fed. Reg. 19438, 19439 (Apr. 3, 1979).[3]

Equally misplaced is plaintiff's reliance on the Porter article, which contains a number of serious errors. Perhaps most remarkable is Ms. Porter's assertion, which plaintiff quotes and relies upon (Opp. 18-19), that the FDA in its Lohr brief "stated that the good manufacturing practice and labeling provisions" are not preemptive "because these are general requirements applicable to all devices, rather than specific requirements applicable to a particular device." 52 FOOD & DRUG L.J. at 10 (emphasis added). In fact, as noted above, the FDA acknowledged in its Lohr brief that the

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[3] Even if the proposed rule had not been withdrawn by the FDA, it would have been deserving of no weight because it was plainly beyond the agency's authority. FDA's avowed purpose was to resolve "confusion among the lower courts" over the scope of MDA preemption and the meaning of the Supreme Court's decision in Lohr. 62 Fed. Reg. at 65384. But the FDA has no authority to issue an interpretive rule aimed at influencing the outcome of private tort lawsuits to which the agency is not a party. An interpretive rule is a "statement[] made by an agency to give guidance to its staff and affected parties as to how the agency intends to administer a statute or regulation." Daughters of Miriam Ctr. for Aged v. Matthews, 590 F.2d 1250, 1258 (3d Cir. 1978) (emphasis added). Here, however, the agency was not illuminating how it intended to administer the MDA but rather advising the courts on how they should interpret and apply the statute. The FDA's interpretation, moreover, was contrary to the weight of judicial authority, even then. Congress plainly has not delegated to the FDA a roving commission to instruct the state and federal judiciary on the desired outcome of product liability claims.

general requirements imposed in the GMP can give rise to preemption of state requirements (as in the case of GMP educational requirements for the heads of QA programs at all device manufacturers). Nos. 95-754, 95-886 Br. for the United States as Amicus Curiae, 1996 WL 118035, at *25 n.20. Moreover, the FDA made clear:

> Our belief that GMPs ordinarily will not [be] found to preempt state tort claims is based on the "different from, or in addition to," condition for preemption in Section [360k(a)]. We do not dispute that the GMPs impose "requirement[s]" within the meaning of Section [360k(a)]. See 21 U.S.C. 333(f)(1)(B)(i) (referring to Section 360j(f), under which GMPs are promulgated, as imposing "requirements"); 21 U.S.C. 351(h) (same); 21 U.S.C. 360c(c)(2)(B) (same); 21 U.S.C. 360j(f)(2)(C) (same).

Id. at *24 n.19 (emphasis added). In like manner, FDA's argument that the general federal labeling requirements at issue in Lohr did not preempt the plaintiffs' claims focused not on the generality of those requirements but on whether they were different from the counterpart state-law requirements. Id. at *27-28. The Porter article thus misunderstands the agency's own position in Lohr.

3. Once this underbrush is cleared away, plaintiff is left with three basic arguments against express preemption. First, she maintains that the PMA process imposes no "requirements" at all because the device's design, manufacturing, and labeling originates in choices made by the manufacturer and not in mandates imposed by the agency. Second, plaintiff argues that even if the PMA process imposes requirements, those requirements are not "specific" enough to trigger preemption under the FDA's interpretation of Section 360k(a). Third, she maintains that express preemption under the MDA is limited to situations where "specific" federal requirements conflict with their counterpart federal requirements. These arguments are all unavailing.

a. There is no merit to plaintiff's argument that the PMA process does not impose any "requirements" at all because a device's design, manufacturing process, and labeling all originate in choices made by the manufacturer. Opp. 20. This argument fails for at least four reasons. First,

it has no basis in the statutory language, which "necessarily contains the best evidence of Congress' pre-emptive intent." CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993). The MDA's express preemption provision states that "any requirement applicable * * * to the device" under the MDA preempts different or additional state requirements. 21 U.S.C. § 360k(a) (emphasis added). It does not say "any requirement that originates in the FDA rather than the manufacturer."

Second, it cannot be reconciled with the fact (which plaintiff admits, see Opp. 22) that under federal law, a device that is approved for marketing through the PMA process cannot be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80; see also id. § 814.39. Put differently, the manufacturer is required to follow the design and other specifications embodied in the PMA application and approved by the FDA. Compliance is not optional. The fact that the FDA can change these requirements following the submission and approval of a PMA supplement does not make these requirements anything less than mandatory.[4]

Third, as explained in our opening memo (at 20-22), plaintiffs' argument is contrary to the substantial weight of authority holding, both before and after Lohr, that the PMA process imposes preemptive federal requirements. Indeed, if plaintiff's theory were correct, then the federal requirements imposed on investigational devices through the IDE process would also fail to trigger express preemption (since manufacturers also make choices in that context about design and other

[4] Changes to the design of the HeartMate made after PMA approval trigger a supplemental FDA review process, and the change cannot be implemented until approved by the FDA. See 21 C.F.R. § 814.39. Therefore, plaintiff's suggestion (Opp. 7-8) that post-1994 design changes somehow eliminate the federal "requirement" is inconsistent with the regulatory scheme. Simply put, FDA approval of a design change, no less than FDA approval of the original design contained in the original PMA submission, gives rise to a federal requirement.

matters). Yet numerous courts have reached the opposite conclusion. See, e.g., Chambers v. Osteonics Corp., 109 F.3d 1243, 1248 (7th Cir. 1997). Under plaintiff's view, Section 360k(a) would be reduced to a virtual nullity.

Fourth, plaintiff's approach is not even remotely administrable. It would require courts, in order to resolve preemption issues, to conduct a searching examination of the regulatory process. See Buckman, 121 S. Ct. at 1015-21 (holding impliedly preempted claim that would require intrusive inquiry into FDA's regulatory and decisionmaking processes). Notably, plaintiff's test would also have to be applied to requirements that are imposed through FDA regulations, since those too can originate in the proposal of a private party. See 21 C.F.R. §§ 10.25(a), 10.30, 10.40(a)(2).

b. Next, plaintiff argues that even if the PMA process imposes some federal "requirements," they are not specific enough to trigger preemption. Opp. 18. According to plaintiff, the federal requirements at issue here are not specific because they "apply to all products undergoing the PMA process" and not to a single type of device. Id. As explained in our opening memorandum (at 22-23 n.11), however, federal requirements that are limited to a single regulatory class of devices are specific enough to trigger preemption under the FDA's regulatory pronouncements and the available evidence of Congress's intent. Such requirements are also more limited in their applicability than the federal labeling and GMP requirements at issue in Lohr. Plaintiff has no answer to these points.

In addition, plaintiff is wrong to say that the federal requirements applicable to the HeartMate apply to all PMA products. While that could be said for the requirement to obtain PMA approval — which, as explained above, the FDA has indicated would trigger express preemption, see 43 Fed. Reg. 18661, 18664 (May 2, 1978)) — the same is not true for the design, manufacturing, and labeling requirements imposed specifically on the HeartMate as a consequence of PMA approval.

The latter requirements arise as a result of the PMA process being applied specifically to the HeartMate and only to the HeartMate. There is simply no logical difference — none — between that process of device-specific application of the PMA process on the one hand and, on the other, the process of applying generalized tort duties to specific devices in particular lawsuits (which plaintiff does not dispute gives rise to "specific" state requirements). Nor is there any difference between the requirements imposed in the "Conditions of Approval" — some of which plaintiff admits are "device specific" (Opp. 22 n.2) — and other requirements imposed on the HeartMate as a result of PMA approval. Both types of requirements have been specifically applied to the HeartMate LVAD. For all of these reasons, plaintiff's submission is lacking in merit.[5]

c. Plaintiff next argues that, under Lohr, express preemption is limited to situations where a specific federal requirement conflicts with its counterpart state requirement, which is not the case here. Opp. 17-19, 24-25. That argument is wrong at every turn. To begin with, as we explained in the portion of our opening memorandum that discussed implied preemption, the state requirements that would be imposed through plaintiff's claims do conflict with the federal requirements applicable to the HeartMate LVAD. Beyond that, plaintiff's cramped view of express preemption is wrong for at least three independent reasons. First, it relies on passages from the Lohr opinion that do nothing

[5] In its Buckman brief, the FDA gave several examples of "specific" federal requirements that "apply to a specific device or set of devices" and thus trigger preemption (Nos. 98-1768 Br. for the United States as Amicus Curiae, 2000 WL 1364441, at *12 (emphasis added)). One such example was federal requirements that apply to all medical devices containing natural rubber (21 C.F.R. § 801.437). Notably, the "natural rubber" regulation covers 43 different categories of devices, including catheters, latex gloves, tracheal tubes, balloons, orthodontic headgear, condoms, enema kits, elastic bandages, opthalmic eyeshields, irrigating syringes, surgical masks, tourniquets, water bottles, elastic binders, pistonsyringes, crutch pads, intestinal splinting tubes, and in vitro diagnostic devices. 63 Fed. Reg. 50660, 50673-50676 (1998). Moreover, FDA has estimated that these 43 categories comprise "approximately 17,600" different models of medical devices. Id. at 50676.

more than identify Congress's "overarching concern" or explain why the MDA's preemption clause (according to the FDA's interpretation) targets only those requirements that are "specific" in nature. See Opp. 12, 16-17. Second, plaintiff's reading finds no support in the language of the preemption clause itself, which plainly goes beyond implied-preemption concepts.[6] Third, it is squarely refuted by the language of Section 360k(b), which provides powerful evidence that Congress did not intend to limit express preemption to conflicting state requirements. The exemption clause permits the FDA to exempt from preemption state requirements that both are "required by compelling local conditions" and may be "compli[ed] with" without "caus[ing] the device to be in violation of any applicable [federal] requirement." 21 U.S.C. § 360k(b)(2). In other words, the MDA permits exemption of state requirements that do not conflict with federal requirements. It necessarily follows that some non-conflicting state requirements are subject to preemption under Section 360k(a).[7]

4. Finally, plaintiff advances several arguments for why her claims are not impliedly preempted. Any argument for conflict preemption, she contends, must overcome a presumption against preemption and can succeed only where there is clear evidence of a direct conflict. Opp. 28 (citing Geier v. American Honda Motor Co., 529 U.S. 861 (2000)). But it is hard to imagine a greater conflict with (and frustration of) the federal purposes underlying the MDA and the PMA process than to allow lay jurors to second-guess the considered, expert judgment of the FDA —

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[6] The preemption of state requirements that are "in addition to" applicable federal requirements on the same subject matter reaches well beyond "conflicting" state requirements. 21 U.S.C. § 360k(a). The same can be said of "different" state requirements: state requirements can be different without conflicting with, or frustrating the purpose of, applicable federal requirements. The statutory text is therefore far broader in its reach than are principles of implied preemption.

[7] Plaintiff also vaguely suggests, in passing, that her claims escape express preemption "[t]o the extent that" they seek to enforce state requirements that are identical to the applicable federal requirements. Opp. 26. While that is true in theory, plaintiff fails to identify even a single claim of hers that seeks to enforce an identical state requirement. She cannot avoid summary judgment based on pure speculation.

made after years of intense regulatory scrutiny based on reams of data — concerning the safety and effectiveness of the HeartMate's design, method of manufacture, and labeling. "To prevail" on her claims, plaintiff must prove that the HeartMate "as approved by the FDA is not safe" — a result that would "contradict[] not only the FDA's specific finding to the contrary but also the manufacturing, distribution, and labeling protocols approved by the FDA." Worthy, 967 S.W.2d at 376.

As for the presumption against preemption, the Supreme Court has made clear in several recent cases that "neither an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'" Buckman, 121 S. Ct. at 1019 (quoting Geier, 529 U.S. at 869). That logic should apply, a fortiori, in a statutory context such as this, where Congress has included an express preemption clause but declined to enact a savings clause. The implied preemption inquiry here thus should be governed by ordinary principles of implied preemption law. See Geier, 529 U.S. at 873 (in rejecting argument that proponent of implied preemption defense should bear a "special burden," explaining that such an approach "promise[s] practical difficulty by further complicating well-established pre-emption principles that already are difficult to apply").

Drawing on the Porter article and the withdrawn FDA regulation discussed above, plaintiff next argues that implied preemption should be rejected because of the "complementary role" played by tort law with respect to the federal regulatory scheme and because Congress's objective in passing the MDA was to enhance consumer safety. Opp. 28. Taking the second point first, we have already explained that Congress's goals were not unitary, contrary to plaintiff's assumption. See pages 2-3, supra. As for the supposed "complementary role" that Congress envisioned for all of tort law, that is inconsistent with Congress's express preemption of "any" state requirements that satisfy certain conditions, even if those requirements are embodied in state tort law. The "complementary" state

tort requirements that Congress singled out for preservation were those that are not "different from, or in addition to," the requirements imposed by federal law.

Lastly, plaintiff suggests that "given the nature of the test devised in Lohr," according to which there is no express preemption unless there is an "actual conflict" between state and federal requirements, the entire doctrine of implied preemption is completely superfluous and adds nothing to the express preemption clause. Under that view, Congress's real intention in enacting the broad language of Section 360k(a) was to limit the scope of implied preemption that would otherwise operate to situations where state and federal requirements are not only in conflict but also "specific" in nature. That reading is implausible, to say the least. It also is little more than a repackaged version of the argument — which the Supreme Court has rejected as "without merit" — that "implied pre-emption cannot exist when Congress has chosen to include an express preemption clause in a statute." See Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995). For the reasons set forth in our opening memorandum, plaintiff's claims are all impliedly preempted.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Alan E. Untereiner, hereby certify that true and correct copies of the foregoing Defendant's Reply in Support of Summary Judgment on Grounds of Federal Preemption was served this 17th day of April, 2001, by UPS overnight delivery, upon:

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