IN THE UNITED STATES COURT OF APPEALS

FOR THE FIFTH CIRCUIT

No. 92-2084

JENNIFER STAMPS,

Plaintiff-Appellant,

VERSUS

COLLAGEN CORPORATION,

Defendant-Appellee.

Appeals from the United States District Court
for the Southern District of Texas

(February 19, 1993)

Before GOLDBERG, SMITH, and EMILIO M. GARZA, Circuit Judges.

JERRY E. SMITH, Circuit Judge:

Contending that she contracted a rare autoimmune disease from being injected with defendant Collagen Corporation's ("Collagen") products, Jennifer Stamps filed suit to recover damages in state court, alleging causes of action based upon defective design, inadequate warnings, and negligent failure to warn. Collagen timely removed and thereafter moved for summary judgment. The district court found all of Stamps's state law claims to be preempted by federal law and granted summary judgment. We affirm.

I.

A.

Zyderm and Zyplast are so-called Class III medical devices regulated under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360*l*, pursuant to which the Food and Drug Administration ("FDA") classifies all medical devices in one of three categories. See 21 U.S.C. § 360c. Class I devices generally pose little or no threat to public health and safety; tongue depressors are an example. Accordingly, Class I devices are subject only to general controls on manufacturing processes.

Class II items are more complex than Class I and include such devices as oxygen masks used in anesthesiology and tampons. These may be subject to recommendations, guidelines, post-marketing surveillance, the development of patient registries, and even the promulgation of specific performance standards, should the FDA deem them a sufficient health hazard as to require strict product specifications or warnings. See 21 U.S.C. § 360c(a)(B).

Class III devices, such as Zyderm, require premarket approval ("PMA"), which process permits the FDA to determine whether a proposed product provides "reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c(a)(C). Such devices are subject to the more stringent PMA process because they "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

The PMA process requires a manufacturer to submit a detailed application to the FDA, including information pertaining to product

specifications, intended use, manufacturing methods, and proposed labeling. See 21 U.S.C. § 360e(c). The FDA refers each application to a panel of qualified experts that prepares a report and recommendation. Within six months, the FDA must either accept or reject the application. 21 U.S.C. § 360e(d).

B.

In March and April 1988, Stamps was injected with Zyderm and Zyplast, which contain processed bovine collagen that Collagen markets as an anti-wrinkle treatment for middle-aged women. A typical treatment consists of a series of injections directly under the skin, the collagen then remaining to smooth out any wrinkles or deformities on the skin's surface.

Shortly after receiving her injections, Stamps began complaining of muscle and joint pains that subsequently were diagnosed as dermatomyositis/polymyositis ("DM/PM"). DM/PM is a relatively rare autoimmune disease in which an individual's immune system identifies one's own skin and muscle tissue as foreign and attacks them. Stamps claims that Collagen's products attached to her tissues and provoked an immune response that destroyed her body tissue.

II.

In granting summary judgment, the district court likened the instant case to Moore v. Kimberly-Clark Corp., 867 F.2d 243 (5th Cir. 1989), in which we found a plaintiff's state-law-based failure-to-warn and labeling claims regarding a Class II medical

device (tampons) to be preempted, although her defective construction and design claims survived. Reasoning that collagen implants are regulated under Class III, which requires FDA pre-market approval of not just labeling and packaging, but manufacturing methods as well, see, e.g., 21 C.F.R. §§ 814.20, 814.80, the court concluded that Stamps's claims are completely preempted.

Appellant Stamps disputes the district court's interpretation of the MDA and its application of Moore, contending that the MDA neither expressly nor impliedly preempts general state tort law and that Moore must be limited to the Class II regulatory context it describes. As a final matter, Stamps argues that even if we find Moore compelling precedent in the Class III context as well, the most it can be said to require is the preemption of her defective labeling and negligent failure-to-warn claims; her products liability, fraud, and negligence per se causes of action, as in Moore, should be reinstated.

III.

The question is whether the MDA preempts Stamps's state law claims. The Supremacy Clause of the Constitution invalidates state laws that "interfere with, or are contrary to" federal law. U.S. CONST. art. VI, cl. 2. When "the field which Congress is said to have pre-empted has been traditionally occupied by the States . . . `we start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress.'" Jones v.

Rath Packing Co., 430 U.S. 519, 525 (1977) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)) (citations omitted); see also Hillsborough County v. Automated Medical Lab., 471 U.S. 707, 715 (1985) (recognizing a "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause"). Accordingly, "`[t]he purpose of Congress is the ultimate touchstone'" of preemption analysis. Malone v. White Motor Corp., 435 U.S. 497, 504 (1978) (quoting Retail Clerks v. Schermerhorn, 375 U.S. 96, 103 (1963)).

Congress's intention to preempt may be either express or implied from the statutory text. Absent an express declaration, Congressional intent to preempt state law may be inferred only if state law actually conflicts with federal law, see Pacific Gas & Elec. Co. v. Energy Resources Conservation & Dev. Comm'n, 461 U.S. 190, 204 (1983), or where the scheme of federal legislation is so comprehensive "`as to make reasonable the inference that Congress left no room for the States to supplement it.'" Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982) (quoting Rice, 331 U.S. at 230).

IV.

A.

The Supreme Court's most recent and authoritative treatment of preemption doctrine is Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992). In Cipollone, a plurality held that a lung cancer victim's suit against cigarette manufacturers alleging breach of

warranty, failure to warn, fraudulent misrepresentation, and conspiracy to deprive the public of medical information regarding smoking was not preempted by the 1965 Federal Cigarette Labeling and Advertising Act; certain of her failure to warn and fraudulent misrepresentation claims were, however, preempted by the language added by Congress to the Public Health Cigarette Smoking Act of 1969. Id. at 2625.

In Cipollone, the Court relied exclusively upon the express language of the statutory provision regarding preemption. Reasoning that "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted," the Court concluded,

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a "reliable indicium of congressional intent with respect to state authority," "there is no need to infer congressional intent to pre-empt state laws from the substantive provisions" of the legislation . . . . Therefore, we need only identify the domain expressly pre-empted by [the statute].

112 S. Ct. at 2618 (citations omitted). See also id. at 2625 (Blackmun, J., concurring) (same).

The MDA was enacted in 1976 as an amendment to the Federal Food, Drug and Cosmetic Act of 1938. Like the Public Health Cigarette Smoking Act addressed in Cipollone, it contains a provision expressly addressing its intended preemptive scope:

> [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))
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> (1) which is different from, or in addition to, any requirement applicable under this

> chapter to the device, and
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> (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) (Supp. 1992).

B.

Applying Cipollone, we reject, at the outset, Collagen's contention that we may resort to the doctrine of implied preemption to uphold the district court. The existence in the MDA of an express preemption provision precludes any such reliance.

C.

We likewise must reject Stamps's argument that Congress did not intend to preempt state tort law remedies when it enacted the MDA. Section 360k(a) speaks broadly: Any state requirement "different from, or in addition to," federal law is preempted.

Moreover, Stamps's contention that the MDA does not preempt common law tort actions is necessarily foreclosed by Moore. Implicit in our holding that certain of Moore's state law claims were preempted by the applicable FDA Class II regulations is the conclusion that Congress intended the preemption of state tort liability where such liability effectively creates a requirement "different from, or in addition to" specific federal requirements. Congress, of course, has the power so to displace state tort law remedies. See, e.g., Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311, 331 (1981) (state common law may be

preempted by federal law).

This result is fortified not merely by Moore's compatibility with the analysis pursued in Cipollone but also by the Court's determination that the language of the statute at issue there, preempting any state "requirement or prohibition," "sweeps broadly and suggests no distinction between positive enactments and common law . . . ." Cipollone, 112 S. Ct. at 2620. It would be anomalous to interpret the MDA differently from the Public Health Cigarette Smoking Act solely on the basis that while they both employ "requirement," the MDA omits "prohibition."[1] Thus, Moore correctly decided this issue; section 360k(a) also "sweeps broadly" and encompasses common law tort actions within its preemptive scope. See also Morales v. Trans World Airlines, Inc., 112 S. Ct. 2031, 2037 (1992) (finding state common law actions "relating to" airline advertising preempted by Airline Deregulation Act of 1978).

D.

Returning to Cipollone's admonition that our inquiry be guided solely by the express language of the statute's preemption provision, we glean from section 360k(a) the following analysis: A state tort cause of action will be preempted if, in the context of the particular case, it (1) constitutes a requirement different from, or in addition to, any requirement the MDA makes applicable to the device at issue and (2) relates either to (a) the safety or

[1] Indeed, the FDA regulation that parallels § 360k(a), 21 C.F.R. § 808.1(b), extends the "any requirement" language of that section to any medical device standard "having the force and effect of law (whether established by statute, ordinance, regulation, or court decision) . . . ." (Emphasis added.)

effectiveness of the device or (b) any other matter included in a requirement made applicable to the device by the MDA.[2] See also King v. Collagen Corp., 1993 U.S. App. LEXIS 432, at *12-*13 (1st Cir. Jan. 15, 1993) (applying similar test to identical product).

By this test, we find that our decision in Moore logically extends to the FDA Class III regulatory context and that Stamps's claims may be preempted under the MDA. Simply put, Texas tort liability, following Cipollone, would constitute a requirement either different from, or in addition to, a requirement)) the Class III PMA process)) that the MDA has made applicable to Zyderm and Zyplast. The second part of the analysis, involving as it does the "relates to" language of section 360k(a)(2) recently given a sweeping interpretation by the Supreme Court in Morales, 112 S. Ct. at 2037-38, is even simpler than the first. In the context of this case, Stamps's state law claims undoubtedly "relate to" either the safety or effectiveness of Zyderm and Zyplast, or to some other matter included in the PMA requirements applicable to the

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[2] The FDA's gloss on § 360k(a) poses essentially the same test:

> (d) 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 under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. There are other State or local requirements that affect devices that are not preempted by section [360k(a)] of the act because they are not "requirements applicable to a device" within the meaning of section [360k(a)] of the act.

21 C.F.R. § 808.1(d). As with administrative agencies generally, the FDA's construction of the statute is entitled to "controlling weight unless it is plainly erroneous or inconsistent with the regulation." Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945). Neither party contests the validity of the FDA's regulations pursuant to the MDA.

products.[3]

V.

Because the MDA, like the statute at issue in Cipollone, fails to "indicate that any familiar subdivision of common law claims is or is not pre-empted," Cipollone, 112 S. Ct. at 2621, we must pursue the "straightforward" inquiry commended to us by the Supreme Court: "[W]e ask whether the legal duty that is the predicate of the common law damages action constitutes" a requirement relating to the safety or effectiveness of Zyderm and Zyplast or to any other matter included in a requirement made applicable to it by the MDA. Id.

A.

We need not conduct a categorical inquiry into each cause of action pursued by the plaintiff, as did the Court in Cipollone, as Moore tells us that Stamps's inadequate labeling (paragraph IV of the original petition) and failure to warn (paragraph V) allegations are preempted by the MDA. The Class III regulatory structure, no less than that of Class II, involves the FDA in considerable oversight regarding proposed package labeling of a device.[4]

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[3] Applying the language of § 808.1(d), see supra note 2, yields the same result: The PMA process constitutes a "specific requirement[] applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements."

[4] See 21 U.S.C. § 360e(c)(1)(F) (requiring PMA application to contain samples of device's proposed labeling); 21 C.F.R. § 814.20(b)(10), (e) (same);
(continued...)

Nor can Stamps's third cause of action (paragraph VI), based upon the defective design and manufacture of Collagen's products, survive preemption, as the Class III PMA process includes FDA scrutiny and approval of these particular aspects of a device.[5]

B.

Stamps's claim that even if preemption applies to the Class

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[4](...continued)
see also 21 U.S.C. § 360e(d)(2)(A)-(B),(D) (requiring denial of PMA application for insufficient showing that the device is safe and effective "under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," or if the proposed labeling is false or misleading in any particular).

[5] See 21 U.S.C. § 360e(c)(1)(B)-(C) (requiring, in PMA application, statements and descriptions of the ingredients, components, methods, controls, and facilities used in the manufacture and processing of the device); id. § 360e(d)(2)(C) (requiring denial of application where "the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 360j(f) of this title . . ."). See also 21 C.F.R. § 814.80 ("A device may not 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.").

Moreover, § 360j(f)'s "[g]ood manufacturing practice requirements" impose further requirements upon the manufacture of Class III devices, leaving us with little doubt as to whether the MDA tolerates different or additional state requirements, respecting design or manufacture, in the form of common law products liability duties.

Lastly, we note that we have not analyzed Stamps's fraud-based cause of action in accordance with Cipollone because we are convinced that her original petition contains no adequate averment of fraud. Although the petition does state in paragraph V that "Defendant engaged in an active campaign to suppress the facts, blame the adverse reactions on some other cause, and prevent discovery of the risks associated with its products," this sentence comes sandwiched between allegations of negligence in a paragraph that concludes only that "Defendant's conduct was negligent and was the proximate cause of Plaintiff's damages." Such an allegation of fraud would not suffice under Fed. R. Civ. P. 9(b); and while Stamps is technically correct that the burden lies with the defendant to request a more definite statement under Fed. R. Civ. P. 12(e) when a pleading or allegation is too vague or ambiguous to admit of a response, we do not believe such was the case here. Paragraph V is not vague or ambiguous; it reads quite plainly as an allegation of negligence. Albeit liberal with respect to the formalities, notice pleading is yet to be distinguished from reading tea leaves. To require Collagen to move for a more definite statement in order to determine whether, when Stamps pled negligence, she in fact meant fraud, would go far towards erasing that distinction.

III context, the MDA preempts state law only to the extent that the state mandates a similar PMA process, presents a close question. In Larsen v. Pacesetter Sys., 837 P.2d 1273, 1282 (Haw. 1992), for example, the court has found that an implant patient's claims arising from the recall of a "substantially equivalent" Class III pacemaker were not preempted by the MDA, noting that "the statutes and regulations governing premarket approval set forth general procedural requirements and, therefore, do not trigger a preemption analysis under [21 C.F.R.] § 808.1(b)."[6] On this subject, the FDA has stated,

> Like all other medical device requirements, different or additional State and local [PMA] requirements are preempted when FDA establishes specific counterpart regulations or there are other specific requirements applicable to the device under the act.

43 Fed. Reg. 13,664 (1978) (emphasis added).

This passage might be construed exclusively)) to the effect that only different or additional state PMA processes are preempted

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[6] Larsen is distinguishable from the instant case in that it involved a device that passed through a less stringent Class III review process by virtue of its being "substantially equivalent" to devices already allowed to be marketed. As the court stated, "Although a determination of substantial equivalence involves a review by FDA of what is known of the safety and effectiveness of the devices, and may even include some additional clinical testing, it is not equivalent to an approval by the FDA of the device's safety and effectiveness." Larsen, 837 P.2d at 1282 (citing H.R. Rep. No. 8081, 101st Cong., 2d Sess. 14, reprinted in 1990 U.S.C.C.A.N. 6305, 6307; 21 C.F.R. § 807.97 (FDA's acceptance of claim of substantial equivalence does not denote official approval of the device)).

The instant devices are not "substantially equivalent" to marketable devices; rather, they have been subjected to the full rigor of the PMA process. While we do not rely upon this ground, one could argue that 21 C.F.R. § 807.97's explicit statement that the FDA does not officially approve "substantially equivalent" devices creates at least the presumption)) by way of the doctrine expressio unius est exclusio alterius)) that the FDA does officially approve those products it scrutinizes through the regular Class III PMA process. Such official approval, of course, strongly would imply that federal preemption is present.

when the FDA has classified a device under Class III. We believe, instead, that the emphasized language above)) added to the fact that the passage was written in response to public comments seeking clarification from the FDA as to "whether or when State and local [PMA] requirements are preempted," id.)) demonstrates that the better reading is that PMA processes are preempted in addition to any other state requirements relating to safety or effectiveness or any other MDA requirement established for the device.[7]

We believe the literal language of the statute compels this result: State requirements pertaining to the safety or effectiveness of a device, or to any other matter included in a requirement made applicable to the device by the MDA, are preempted whenever they are different from, or in addition to, any requirement imposed upon the device under the MDA. Zyderm and Zyplast, it is undisputed, are required by the MDA to undergo the FDA's stringent PMA

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[7] See Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333 (7th Cir.), cert. denied, 113 S. Ct. 327 (1992) (finding that MDA Class III devices developed under the FDA "Investigational Device Exemption" ("IDE") regulations are preempted from state tort law liability; although IDE regulations "do not specify the safe and effective design [,] they specify the procedures for determining whether the experimental design is safe and effective" and thus "are requirements relating to safety and effectiveness and they can therefore have preemptive effect"). To our knowledge, Slater and King are the only decisions by federal courts of appeals to have reached the preemptive scope of the MDA's Class III regulations, and both have reached conclusions consistent with our analysis herein. Inasmuch as we have previously determined in Moore that preemption applies in the MDA Class II sphere, extension of that holding to Class III regulations comports with logic and our understanding of the MDA regulatory scheme. Moreover, although we do not need to consult legislative history to decide this issue, we note that Senator Kennedy stated, when he introduced the MDA, that "[t]he most hazardous devices . . . would require full premarket testing and clearance before they are allowed on the market. Premarket clearance represents the highest degree of regulatory control . . . ." 121 CONG. REC. 10,688 (1975) (emphasis added); see also King, 1993 U.S. App. LEXIS 432, at *22-*28 (Aldrich and Campbell, JJ., concurring) (finding intent of Congress in enacting MDA was to provide maximum of protection available to medical device users).

process. State tort causes of action)) to the extent they relate to safety, effectiveness, or other MDA requirements)) constitute requirements "different from, or in addition to" the Class III process; they are, therefore, preempted.[8]

C.

Stamps also argues that Collagen's ability to strengthen the contraindications in its packaging and labeling proves that it could comply with both state tort law and the federal statute. In essence, Stamps argues that the MDA forms only the floor of regulation; the states are free to construct a regulatory ceiling.

We agree with Stamps that, under the Class III regulatory framework, Collagen could have strengthened its warning labels without first obtaining prior FDA approval. The "Conditions of Approval" issued with respect to Zyderm, for example, provide,

> Changes in labeling, manufacturing, sterilization, packaging, or performance of design specification which enhance safety of the device or safety in the use of the device may be placed into effect by the sponsor prior to the receipt of a written FDA approval of the supplemental PMA . . . .
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> Specific examples of changes permitted are:

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[8] Nor does the seemingly more restrictive language of § 808.1(d) compel a different result. That section provides that state and local requirements are preempted "only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act . . . " (emphasis added).

Stamps apparently reads out the latter half of this clause and points to the fact that the FDA premarket approval process is not a "specific counterpart regulation" to state tort law. We disagree with this interpretation and need look no further than the second half of the quoted clause. It is plain that § 808.1(d) poses the same test as the statute: When there exists a specific requirement applicable to a particular device under the act)) such as the MDA's PMA requirement for Zyderm and Zyplast)) additional or different state laws are preempted.

> (1) addition of warnings, contraindications, or side effects . . . .

See also 21 C.F.R. § 814.39(d)(2)(i) (permitting without prior FDA approval "[l]abeling changes that add or strengthen a contraindication, warning, precaution or information about an adverse reaction.").

We cannot agree, however, with the conclusion Stamps draws from this)) that the lack of direct conflict between the state and federal regulations compels a finding of no preemption. While we are aware that the court in Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1540-43 (D.C. Cir.), cert. denied, 469 U.S. 1062 (1984), interpreting the Federal Insecticide, Fungicide, and Rodenticide Act's ("FIFRA") similar express preemption provision, found no preemption where there was no direct conflict between the state and federal regulation, we do not believe the analysis therein applied can be said to have survived Cipollone, and was directly refuted in Morales. See Morales, 112 S. Ct. at 2038 (rejecting contention that express preemption is inappropriate where state and federal law are consistent).

In Ferebee, the court rejected Chevron's contention that FIFRA's express preemption provision, 7 U.S.C. § 136v(b), which said that states "shall not impose or continue in effect any requirements for labeling . . . in addition to or different from those required under this subchapter," required a holding of preemption of state tort liability. Instead, the court noted that Congress, although explicitly preempting state labeling "requirements," had not stated its intention to preempt state damages

actions. 736 F.2d at 1542. Yet in the statute at issue in Cipollone, Congress had not expressly declared its intent to preempt state damages actions, and the Court nevertheless found them preempted, at least in part. Thus, no such "plain statement" of congressional intent as Ferebee contemplated is required. Moreover, we reiterate our belief that no sound distinction can be drawn between the "no requirement or prohibition" language found dispositive in Cipollone and the express preemption of "any requirement" contained in the FIFRA and the MDA.[9]

D.

Finally, we acknowledge that our reading of the MDA effectively denies Stamps access to state law damages actions as a

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[9] Lastly, to the extent Ferebee can be read to import a direct conflict requirement into express preemption analysis, it runs afoul of Cipollone, where the Court stated, 112 S. Ct. at 2618, that the language of the express preemption provision alone must guide the preemption inquiry. Direct conflict, moreover, is more appropriately considered as an aspect of implied preemption analysis, particularly of that version that applies where "compliance with both federal and state regulations is a physical impossibility." See Florida Lime & Avocado Growers v. Paul, 373 U.S. 132, 142-43 (1963); Osburn v. Anchor Lab., 825 F.2d 908, 912-13 (5th Cir. 1987), cert. denied, 485 U.S. 1009 (1989) (finding no implied preemption in FDA label PMA process for new animal drugs where FDA regulations permitted manufacturer to strengthen label warnings without prior approval).

As Cipollone has clarified, resort to implied preemption analysis is inappropriate where the statute specifies the scope of its intended preemptive effect. Lastly, the MDA is different from FIFRA, although it incorporates a similar express preemption provision. And as regards the preemptive scope of the MDA, the FDA has stated,

> Congress has expressly declared that the Federal Food, Drug & Cosmetic Act preempts any State or local requirement with respect to the safety or effectiveness of a medical device that is different from or in addition to a requirement under the act applicable to the device. The test of implied Federal preemption, therefore, does not apply . . . . Under Section [360k(a)] of the act, preemption is not restricted to State requirements that directly conflict with Federal law . . . .

45 Fed. Reg. 67326, 67328 (1980).

remedy for her injuries. Stamps cites Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984), for the proposition that there is a strong presumption against preemption of state law remedies where no federal remedy exists. Like Stamps's direct conflict argument, however, this too is more appropriately addressed in the context of implied preemption.[10] That is to say, where Congress has expressly preempted state common law damages actions, as in Cipollone and the MDA, its failure to provide a federal remedy will not defeat its intent to preempt state law.[11]

VI.

In conclusion, the district court did not err in finding Stamps's state law claims completely preempted by section 360k(a). The summary judgment is AFFIRMED.

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[10] See Silkwood, 464 U.S. at 256 (rejecting suggestion that "there could never be an instance in which the federal law would pre-empt the recovery of damages based on state law," but refusing to recognize any such preemption in that case based upon implied "conflict" or "frustration" preemption); Abbott by Abbott v. American Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir.), cert. denied, 488 U.S. 908 (1988) (applying unavailability of federal remedy presumption in impled preemption context).

[11] See Lee v. E.I. DuPont de Nemours & Co., 894 F.2d 755, 757 (5th Cir. 1990) (ERISA's express preemption provision preempts state tort law despite unavailability of federal remedy); see also Slater, 961 F.2d at 1333 "(It would be a mistake to conclude that preemption in these circumstances leaves the consuming public remediless, at least if we have concern for economic substance rather than legal formality and do not suppose that the only `remedies'. . . are those that the law provides.").