

**United States Court of Appeals
FOR THE EIGHTH CIRCUIT**

No. 00-1188

Carol Jean Brooks,	*	
	*	
Appellant,	*	
	*	Appeal from the United States
St. Luke's Hospital,	*	District Court for the
	*	District of Minnesota
Intervenor below,	*	
	*	
v.	*	
	*	
Howmedica, Inc., a Delaware	*	[PUBLISHED]
Corporation, Division of Pfizer Hospital	*	
Products Group, Inc.; Pfizer, Inc.;	*	
Howmedica International, Ltd.,	*	
	*	
Appellees.	*	

Submitted: October 18, 2000

Filed: January 10, 2001

Before MURPHY, HEANEY, and BYE, Circuit Judges.

BYE, Circuit Judge.

This appeal requires us to assess the preemptive power of the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (codified in various

sections of 21 U.S.C. and 26 U.S.C.), in view of the Supreme Court's recent decision in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

BACKGROUND

In the late 1960s, defendants Howmedica, Inc., Pfizer, Inc. and Howmedica International, Ltd. (together, "Howmedica") developed a product called "surgical Simplex[®] P Radiopaque bone cement" ("Simplex"). Surgeons employ Simplex in a variety of orthopedic procedures, including joint, hip, knee, shoulder and elbow replacement surgeries, and the repair of bone fractures.

Simplex consists of two components: a colorless liquid and a powder. Prior to surgery, the liquid and powder ingredients are mixed together, forming an amorphous mass. That mass quickly hardens into a cement-like substance that bonds tissues and bones. The mixing process releases a potentially harmful chemical byproduct, methyl methacrylate vapors. Nurses and surgical technicians who mix the Simplex components often inhale those methyl methacrylate vapors.

Howmedica submitted Simplex to the Food and Drug Administration (FDA) for marketing approval on February 8, 1971. Howmedica provided the FDA with a wealth of safety information concerning Simplex: details of animal studies; manufacturing and quality control procedures; identification of possible side effects; results of clinical trials; summaries of surgical cases and post-operative complications; long-term carcinogenicity and toxicity studies; and the results of investigational use by 67 physicians in 1508 hip replacements involving 2800 preparations of the bone-cement.

The FDA subjected Simplex to the New Drug Application (NDA) process. As part of the NDA process, the FDA scrutinized Howmedica's proposed labeling and packaging for Simplex. The FDA reviewed, and in many instances rewrote, language to be included on Simplex's package (and its insert) explaining how to use the bone

cement. FDA doctors met with Howmedica representatives on several occasions to discuss the content of Simplex's label and inserts. The FDA also informed Howmedica that Simplex would not be approved until the FDA had seen the actual printed labels and the final Simplex package insert. Each Simplex label, and every word included in the package insert, was scrutinized by FDA doctors and representatives.

The FDA formally approved Simplex for marketing on October 7, 1971. In subsequent years, the FDA required modifications to Simplex's labels and package inserts. In 1973, in response to a rat-study, the FDA recommended revising the warning section of the label; Howmedica revised the label accordingly. In 1976, doctors released a study observing operating room personnel's response to Simplex. In response to that study, the FDA required Howmedica to send out a "Dear Doctor" letter, cautioning physicians to use Simplex carefully, and referring doctors to the package insert warnings.

In 1965, Carol Brooks began work as a licensed practical nurse in Duluth, Minnesota. Between 1978 and 1981, she worked at St. Mary's Hospital in Duluth. At St. Mary's, Brooks regularly mixed bone cement for use in surgical procedures. In late 1983, Brooks left St. Mary's and joined the staff at St. Luke's Hospital in Duluth.

Brooks worked almost exclusively in the orthopedic surgery department at St. Luke's. During her first year on the job, she mixed bone cement for an average of four cases per week. Brooks's bone cement mixing duties increased steadily thereafter. In 1992, she assisted surgeons in approximately 10 operations per week requiring the use of bone cement. In virtually all such operations, Brooks mixed the bone cement herself, or she was positioned nearby as another nurse mixed the cement.

In 1989, Brooks began to cough frequently at work. Her persistent cough worsened and, in 1991, she was diagnosed with asthma. Brooks's doctor attempted to find the cause of her asthma, but he could not pin down its precise etiology.

Brooks's doctor even phoned Howmedica to inquire about Simplex's components. Though the doctor was unable to conclude that Simplex was the cause of Brooks's asthma, he restricted her exposure to Simplex at work. In 1992, Brooks suffered an acute asthma attack at work, and was thereafter restricted from exposure to Simplex. Brooks left work in 1995, unable to do her job. She has been diagnosed with occupational asthma. Her doctors now attribute its cause to her repeated exposure to methyl methacrylate vapors, a Simplex byproduct.

On March 19, 1997, after her illness prevented her from working, Brooks commenced a products liability action against Howmedica. In particular, Brooks contended that Howmedica had negligently failed to warn her of the danger of contracting occupational asthma by inhaling methyl methacrylate vapors during the process of mixing the liquid and powder components of Simplex. In addition, Brooks claimed that Howmedica failed to comply with FDA labeling regulations. After more than a year of discovery, Howmedica moved for summary judgment. Both sides filed affidavits, many of which explained the medical and technical issues in the case. The district court ultimately granted Howmedica's motion, and entered judgment adverse to Brooks. Brooks now appeals from that judgment.

DISCUSSION

We review de novo a district court's grant of summary judgment by applying the same standard as the district court. See Treanor v. MCI Telecomm. Corp., 200 F.3d 570, 573 (8th Cir. 2000). Summary judgment is appropriate when the evidence — viewed in the light most favorable to the nonmoving party — demonstrates that there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986).

A. Brooks's Failure-to-Warn Claim

Brooks alleged that Howmedica failed to warn her of the risk of contracting asthma through repeated exposure to methyl methacrylate vapors. The district court ruled that Howmedica was entitled to summary judgment because Brooks's state-law failure-to-warn claim was preempted by federal law. We reverse.

The MDA contains an express preemption provision that governs federal preemption of state law with respect to medical devices:

[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).

The Supreme Court recently analyzed the meaning and scope of § 360k preemption in Lohr. The plaintiff in Lohr suffered a complete heart block that required emergency surgery after her Medtronic pacemaker failed. She filed suit against Medtronic alleging products liability causes of action stemming from the failure of the company's Model 4011 pacemaker lead. After considering the nature and scope of § 360k preemption, the Supreme Court held that none of Lohr's Florida law causes of action were preempted.

Lohr clarified several aspects of § 360k preemption, but the Court's fractured holding has troubled the lower federal courts. See, e.g., Kemp v. Medtronic, Inc., 231

F.3d 216, 224 (6th Cir. Nov. 1, 2000) (“The various courts of appeals that have confronted issues of preemption arising under the MDA have struggled mightily with Lohr’s language in the effort to discern its holding.”). Justice Stevens favored very narrow preemption; he wrote a plurality opinion for four Justices. See Lohr, 518 U.S. at 474-503 (Stevens, J., joined by Kennedy, Souter and Ginsburg, JJ.). Justice O’Connor favored far broader federal preemption, and wrote a partial concurrence and partial dissent for four Justices. See id. at 509-14 (O’Connor, J., joined by the Chief Justice, and Scalia and Thomas, JJ.). Justice Breyer agreed with portions of both opinions, and with Justice Stevens’s overall result, but wrote a separate opinion. See id. at 503-508 (Breyer, J.). From this, then, we must divine the Supreme Court’s intentions.

All nine Justices agreed that § 360k’s reference to state “requirements” included common law tort actions. See Lohr, 518 U.S. at 486-91 (Stevens, J.), 504-505 (Breyer, J.), 510 (O’Connor, J.). Justices Stevens and Breyer then parted company from Justice O’Connor’s foursome. Justices Stevens and Breyer argued that courts’ interpretation of § 360k should be “informed by” the FDA’s own regulations explaining § 360k. See id. at 495-97 (Stevens, J.), 505-507 (Breyer, J.). Justice O’Connor bitterly dissented from the Court’s decision to look to the FDA’s preemption regulations for guidance. See id. at 509 (O’Connor, J.) (decrying the decision as “bewildering and seemingly without guiding principle”). Notwithstanding Justice O’Connor’s opinion for four Justices, however, a majority¹ of the Court sought assistance from FDA regulations in interpreting § 360k’s preemptive force.

The FDA preemption regulation provides that “state requirements are pre-empted ‘only’ when the FDA has established ‘specific counterpart regulations or . . . other specific requirements applicable to a particular device.’” Id. at 498 (quoting

¹Cf. Vasquez v. Hillery, 474 U.S. 254, 261 n.4 (1986) (explaining that the amalgamated view of five Justices forms the holding of the Court).

21 C.F.R. § 808.1(d)). The FDA regulation also states that § 360k “is not intended to pre-empt ‘State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices.’” Id. at 499 (quoting 21 C.F.R. § 808.1(d)).

Justice Stevens — joined by Justice Breyer in this portion of the plurality opinion — proceeded to interpret § 360k in view of that FDA preemption regulation. Justice Stevens’s analysis divided the overarching preemption question into three distinct steps. Each step focused on a separate aspect of the preemption analysis: the state requirement, the federal requirement, and a thoroughgoing comparison of the two requirements. See Lohr, 518 U.S. at 500.

Preemption analysis begins with an examination of the putative state “requirement” described in § 360k(a). Only state laws specific to the medical device in question, or general state laws that have “the effect of establishing a substantive requirement for a specific device,” Lohr, 518 U.S. at 500, may be preempted. Whether the state law is specific or general, the state law must relate to the safety or effectiveness of the device. See 21 U.S.C. § 360k(a)(2).

Second, a specific federal requirement must govern the medical device at issue. “[F]ederal requirements must be ‘applicable to the device’ in question, and, according to the regulations, pre-empt state law only if they are ‘specific counterpart regulations’ or ‘specific’ to a ‘particular device.’” Lohr, 518 U.S. at 500.

Third, if both such state and federal requirements exist, they must be compared using traditional principles of conflict² preemption. This comparison is the heart of the

²Although conflict preemption principles loom large in the Court’s analysis, *field* preemption does not animate § 360k preemption analysis. Five Justices concluded that

analytical framework. If state and federal laws render a medical device manufacturer's compliance with both impossible, then federal law preempts state law. See id. at 501 (Stevens, J.) (explaining that § 360k "protects" specific federal regulations from interference by potentially contradictory state requirements), 507-508 (Breyer, J.). In addition, if state law necessarily impedes the fulfillment of Congressional objectives, federal law preempts state law. See id. at 501 (Stevens, J.) (explaining that most general common law claims would not "impede the ability of federal regulators to implement and enforce specific federal requirements"), 507-508 (Breyer, J.).

The statute and regulations, therefore, 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.

Id. at 500 (Stevens, J.).

Congress did not create an exhaustive or pervasive scheme of federal regulation that would supplant state tort law altogether. See Lohr, 518 U.S. at 491 (Stevens, J.) ("There is, to the best of our knowledge, nothing in the hearings, the Committee Reports, or the debates suggesting that any proponent of the [MDA] legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices."), 508 (Breyer, J.) ("I can find no . . . indication that either Congress or the FDA intended the relevant FDA regulations to occupy entirely any relevant field."). Justice O'Connor's opinion, in contrast, would have held that the FDA's extensive labeling requirements occupied the field, thereby preempting failure-to-warn claims and other common law claims, but Justice O'Connor failed to command the vote of five Justices on this point. See id. at 514 (O'Connor, J.).

With this tripartite scheme in mind, we turn our attention to the respective state and federal laws, and their compatibility.

1. State Requirement

Brooks claimed that Howmedica failed to warn her of the dangers of exposure to methyl methacrylate vapors while mixing Simplex. Brooks argues that a common law failure-to-warn claim is generic, and therefore cannot constitute a “specific” state requirement subject to federal preemption.

We agree with Brooks that Minnesota failure-to-warn claims are generic in the sense that such claims apply to a wide range of products. *Cf.*, e.g., Kallio v. Ford Motor Co., 407 N.W.2d 92, 99-100 (Minn. 1987) (motor vehicle); Germann v. F.L. Smithe Machine Co., 395 N.W.2d 922, 924-25 (Minn. 1986) (hydraulic press); Frey v. Montgomery Ward & Co., Inc., 258 N.W.2d 782, 787-88 (Minn. 1977) (space heater); Marcon v. Kmart Corp., 573 N.W.2d 728, 730-32 (Minn. Ct. App. 1998) (plastic snow sled). But this conclusion doesn’t resolve the more difficult question framed in Lohr: may an otherwise generic common law claim act as a device-specific requirement by virtue of the claim’s application to a particular product?

Five Justices in Lohr indicated that generic common law claims could be preempted, though such claims aren’t device-specific in the abstract. Those Justices (through the opinions of Breyer and O’Connor, JJ.) concluded that, in application, a common law judgment adverse to a medical device manufacturer would force compliance in much the same fashion as a state’s enactment of regulations or other positive law specific to the medical device at issue. Justice Breyer stated that “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.” Lohr, 518 U.S. at 504-505 (Breyer, J.). Justice O’Connor’s partial concurrence echoed

Justice Breyer’s sentiment that common law tort actions frequently act as state “requirements,” as described in § 360k. See id. at 510-11 (O’Connor, J.); see also id. at 500 (Stevens, J.) (allowing for the remote possibility that general state requirements could sometimes be preempted).

A judgment favoring Brooks would provide precisely the sort of specific state-law mandate, or requirement, envisioned by Justices Breyer and O’Connor. If a jury found Howmedica liable for failing to warn Brooks and others of Simplex’s asthma-inducing propensity, then the resulting judgment against Howmedica would effectively require Simplex to bear more expansive labeling detailing the risk of contracting asthma from exposure to chemical byproducts in the mixing process. Thus we find that Brooks’s state law failure-to-warn claim would have the effect of a specific state law requirement, the first step in the preemption triad.

2. Federal Requirement

We turn now to the second stage of the analysis, the specific federal requirement. We have previously held that the premarket approval (PMA) process to which new medical devices are subjected “is a specific [federal] requirement for a device within the meaning of 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(d).” Martello v. Ciba Vision Corp., 42 F.3d 1167, 1169 (8th Cir. 1994) (citations omitted). Although Martello was decided before Lohr, we are confident that Martello’s holding survives Lohr, at least in this respect. Lohr did not address the preemptive power of the PMA process; instead, Lohr focused on a different (and far less stringent) approval process, the substantial equivalence, or § 510(k) process. See Lohr, 518 U.S. at 480. Lohr’s conclusion that *less* rigorous federal review doesn’t preempt state common law claims fails to resolve whether *more* rigorous federal review would preempt a state common law claim — the question we face.

The Supreme Court of Rhode Island, facing the same situation, answered the question in terms that apply equally well in this case.

We think rather than expressing entirely generic concerns of safety, the FDA has expressed explicit concerns toward [Simplex]. We conclude that the premarket approval process constitutes a specific federal interest as contemplated in Medtronic [v. Lohr] and that, therefore, the FDA approval served to impose strict FDA [warning and labeling] requirements upon the defendant.

Fry v. Allergan Medical Optics, 695 A.2d 511, 516 (R.I. 1997).

Our conclusion is buttressed by the considered views of the Sixth and Seventh Circuits, both of whom have recently explained that the PMA process may be considered specific federal regulation. See Kemp, 231 F.3d at 225-28 (dictum); Mitchell v. Collagen Corp., 126 F.3d 902, 911 (7th Cir. 1997) (“[T]he PMA process . . . can constitute the sort of specific federal regulation of a product that can have preemptive effect.”); but see Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1374-77 (11th Cir. 1999) (concluding that the PMA process is “conceptually distinct” from specific federal regulation of medical devices).

Of course, Simplex was not actually reviewed under the PMA process. When Howmedica developed Simplex in the late 1960s, and submitted Simplex to the FDA in 1971, PMA review had not yet been fashioned by the FDA. But the FDA *did* test and review Simplex under the older New Drug Application (NDA) process, the precursor to the FDA’s post-1976 PMA process.

As part of the NDA process, the FDA scrutinized Howmedica’s proposed labeling and packaging for Simplex. The FDA reviewed and recrafted language that appeared on Simplex’s package and package insert. FDA doctors also met with Howmedica representatives to discuss the content of Simplex’s labels and warning

inserts. Prior to Simplex’s release into the market, the FDA reviewed each label, and every word, included in Simplex’s package label and package insert. This federal review process constitutes “specific” regulation; the full might of the FDA’s regulatory power was brought to bear upon a single product, Howmedica’s Simplex.

Although the PMA process is arguably more rigorous than the older NDA process, the purpose of both processes is identical: to ensure that medical devices are reviewed for safety in advance of their release into the marketplace. As Howmedica points out, PMA is the functional equivalent of the old NDA approval process. Consequently, a medical device subject to NDA review ought to receive the same protection afforded a PMA-reviewed device.

Brooks disputes the fact that the PMA and NDA processes are functional equivalents. But even if we assumed the truth of Brooks’s contention — something we are disinclined to do — Simplex is deemed to have been PMA-approved by operation of law. See 21 U.S.C. §§ 360e(b)(1)(A), 360j(l)(3)(A); 21 C.F.R. § 888.3027 (establishing, in combination, that drugs reclassified as devices in 1976 — such as Simplex — are considered PMA-compliant). As a result, we are not persuaded by Brooks’s argument.

As we explained above, Martello holds that a PMA-compliant medical device has been subjected to specific federal regulation. Because Simplex was subjected to a PMA-equivalent approval process (NDA), and because Simplex is deemed “PMA-compliant” by virtue of federal regulations, Martello applies. Simplex was subject to specific federal regulation.

3. Comparing Federal and State Requirements

Having established the existence of pertinent state and federal requirements, we must now compare those requirements. Following the Supreme Court’s lead, we

search for (1) outright incompatibility between the state and federal requirements, or for (2) state laws that defeat the purpose of federal law or Congressional intent. Justice Stevens’s comparison between the Lohr plaintiff’s common law claims and applicable federal requirements focused on both these paths to preemption. See Lohr, 518 U.S. at 501.

Justice Stevens suggested that state regulations that complement federal regulations, i.e., those that peacefully coexist without imposing conflicting duties upon manufacturers, would not yield to § 360k’s preemptive reach. Justice Stevens analogized complementary state requirements to “local fire prevention regulations” and to “zoning codes,” neither of which requires manufacturers to avoid compliance with federal health requirements enunciated in the MDA. See id. at 501-502.

In addition, state requirements that duplicate federal requirements pose no threat to federal law, and thus will not be preempted. Only state requirements that *differ* from federal law, see 21 U.S.C. § 360k(a)(1), and those that are *divergent* from federal law, see 21 C.F.R. § 808.1(d), require preemption. See Lohr, 518 U.S. at 496-97 (Stevens, J., joined by Breyer, J.) (“The regulations promulgated by the FDA expressly support the conclusion that § 360k ‘does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.’”) (quoting 21 C.F.R. § 808.1(d)(2)); id. at 513 (O’Connor, J.) (“Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.”) (italics in original). Thus a state law that provides a remedy for violation of FDA regulations, for example, doesn’t impose a burden on manufacturers that is “different from” federal law. See Lohr, 518 U.S. at 495.

Howmedica argues that the FDA’s labeling requirements for Simplex are inconsistent with a hypothetical adverse judgment on Brooks’s state-law failure-to-warn claim. Howmedica professes that it is powerless to alter Simplex’s packaging or warning insert, and hence it couldn’t comply with both a state-law judgment and the

federal labeling regulations. In effect, while the state-law judgment would require Howmedica to *add* to its labeling and package insert, it asserts, federal regulations would require Howmedica *not to add* to its labeling and package insert. Howmedica submits that this Catch-22 epitomizes the need for, and importance of, § 360k preemption.

Howmedica's argument suffers from a fatal defect: the argument misstates a critical premise. FDA regulations do not in fact mandate that Simplex's labeling and package inserts remain frozen in their 1971-approved state. The regulations require only that Howmedica provide no less information and warning than the 1971-approved labeling. Howmedica is free to provide more information, and more detailed warnings, to consumers. See 21 C.F.R. §§ 814.39(d)(2)(i) (authorizing medical device manufacturers to change labels to "add or strengthen a contraindication, warning, precaution, or information about an adverse reaction"), (d)(2)(ii) (permitting "[l]abeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device").

Howmedica's assertion that the 1971 labeling on Simplex is set in stone by virtue of FDA regulations is wrong. See Lohr, 518 U.S. at 497 n.16; Connelly v. Iolab Corp., 927 S.W.2d 848, 854 (Mo. 1996) ("Nothing in [the FDA] regulations prohibits Iolab from adding a warning to the label regarding unreasonably high complication rates."). An adverse judgment on Brooks's failure-to-warn claim would not, as Howmedica posits, force Howmedica to choose between complying with FDA regulations and the state law judgment. Nothing prohibits Howmedica from increasing the warnings and information it provides to consumers and health practitioners on Simplex's package and package insert.

Likewise, a judgment adverse to Howmedica on Brooks's failure-to-warn claim wouldn't interfere with Congressional intent or FDA policy. The FDA's *raison d'etre* is to review new medical devices to ensure that the devices are moderately safe before

they are released into the marketplace. We struggle to imagine how a common law judgment requiring greater warnings would interfere with that purpose. Brooks’s counsel captured the essence of this point when he remarked at oral argument that “FDA regulations create floors, not ceilings.” A common law judgment against a manufacturer such as Howmedica would raise the floor, not puncture the ceiling.

Because Howmedica could have added language warning consumers of asthma risks associated with exposure to Simplex without running afoul of federal requirements, Howmedica doesn’t face a Catch-22. Howmedica could comply with both an adverse state-law judgment and FDA regulations. Accordingly, preemption is inappropriate in this instance. The district court erred in granting Howmedica’s motion for summary judgment on Brooks’s failure-to-warn claim.

At first blush, there appears to be tension between our holding and the language of § 360k. We hold that § 360k does not preempt a failure-to-warn action that might, if successful, require Howmedica to *add to* Simplex’s warnings. Section 360k forbids state requirements that are “different from, or in *addition to*” federal law. 21 U.S.C. § 360k(a)(1) (emphasis added). The apparent tension is illusory, however, because (as the Supreme Court explained in Lohr) § 360k doesn’t really mean what it says.

Justice Breyer demonstrated the folly of reading § 360k’s “different from, or in addition to” language literally: every state requirement would then be preempted because, in some small or obscure way, every such state requirement could be deemed different or additive. See Lohr, 518 U.S. at 505 (Breyer, J.) (“Congress must have intended that courts look elsewhere for help [i.e., beyond the words in § 360k] as to just which federal requirements pre-empt just which state requirements, as well as just how they might do so.”). Justice Breyer sought refuge in “basic pre-emption principles,” id. at 508, the twin notions of conflict and field preemption, see id. at 508-509. Justice Stevens likewise acknowledged the importance of conflict preemption analysis as a reprieve from § 360k’s ambiguity. See id. at 503 (Stevens, J.).

The best illustration of Justices Stevens and Breyer’s reliance upon conflict preemption to the exclusion of § 360k’s very language comes from Justice O’Connor’s separate opinion. Justice O’Connor dissented precisely on this point; she would have interpreted § 360k literally, as preempting each and every state law “different from, or in addition to” federal law.

If § 360k’s language is given its ordinary meaning, it clearly pre-empts any state common-law action that 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. . . .

The plurality’s reasons for departing from this reading are neither clear nor persuasive. . . . The Court holds that an FDCA “requirement” triggers pre-emption only when a conflict exists between a specific state requirement and a specific FDCA requirement applicable to the particular device.

Lohr, 518 U.S. at 511.

Under Justice O’Connor’s view, Brooks’s failure-to-warn claim would certainly be preempted as an “additional” state requirement. But Justice O’Connor failed to garner four additional votes for her position. Thus her opinion demonstrates, by negative implication, that five other Justices interpreted § 360k’s ambiguous language to require conflict preemption analysis. The conflict preemption analysis we undertook with respect to Brooks’s case reveals no tension between her failure-to-warn claim and FDA labeling requirements.

B. Failure to comply with FDA regulations claim

Sometime after the pleadings were filed, Brooks began to assert that Howmedica had violated, or had failed to comply with, FDA regulations. We are mindful of our liberal pleading rules, see, e.g., Fed. R. Civ. P. 8(a)(2), (e)(1), as well as the Supreme Court's acknowledgment in Lohr that such claims often arise late in the life of a products liability action, see Lohr, 518 U.S. at 494-95. As a result, we construe Brooks's complaint to raise a "negligence per se" claim based upon Howmedica's alleged violation of FDA regulations. Lohr makes clear that this type of state-law claim against a medical device manufacturer would not be preempted. See id. at 495-96. Howmedica concedes as much.

Minnesota law recognizes a common law action for negligence per se stemming from a defendant's violation of FDA regulations. See Femrite v. Abbott Northwestern Hosp., 568 N.W.2d 535, 539 & n.4 (Minn. Ct. App. 1997). Femrite requires a plaintiff, such as Brooks, to prove both that she "belongs to the class of persons that the regulation is intended to protect," id. at 539, and that the defendant in fact violated the applicable FDA regulations, see id. at 542. The latter question is one of law, appropriate for disposition on summary judgment. See id. ("Considering these FDA documents, and the record as a whole, we conclude as a matter of law that the physicians' implantation of the screw devices in appellants' surgeries was a permissible "off-label" use not in violation of FDA regulations."); cf. Bammerlin v. Navistar Int'l Transp. Corp., 30 F.3d 898, 900 (7th Cir. 1994) ("The meaning of federal regulations is not a question of fact, to be resolved by the jury after a battle of experts. It is a question of law, to be resolved by the court.") (citations omitted).

We have no doubt that Brooks belongs to the class of persons whom the FDA intends to protect by promulgating labeling regulations. Brooks, like many nurses and surgical technicians, was regularly exposed to Simplex and its concomitant chemical

byproducts. FDA labeling regulations are designed to promote safe and effective use of medical devices such as bone-cement. Howmedica cannot seriously contest Brooks's membership in the protected class.

Despite proving membership in the protected class, however, Brooks's claim founders on the second element — violation of FDA regulations. As we explained above, Howmedica fully complied with the FDA's labeling requirements at the time that Simplex was approved for use in 1971. In the intervening years, Howmedica altered Simplex's package and package insert to accommodate changes recommended by the FDA. As Howmedica indicated in its briefs, every word on the Simplex package and package insert has been formally approved by the FDA. It is folly to suggest, therefore, that Howmedica violated FDA regulations in labeling Simplex. As the district court pointed out, Brooks neglected to develop any support in the record (or in her argument) that Howmedica violated FDA regulations.³ We have scoured the record and the pertinent case law independently and located no additional support for Brooks's claim.

Because Brooks has not demonstrated any violation of FDA labeling requirements, her Minnesota-law negligence per se claim fails as a matter of law. We therefore affirm the district court's summary judgment in favor of Howmedica as to this aspect of Brooks's complaint.

³Brooks points to two affidavits and reports from expert witnesses trained in toxicology and safety engineering to support her claim that Howmedica violated FDA regulations. These reports are insufficient to entitle Brooks to prevail. Assuming for argument's sake that Brooks's experts would be qualified to opine that Howmedica violated FDA regulations, cf. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147-49 (1999) (holding that all forms of expert testimony must be subjected to Daubert's relevance-and-reliability inquiry), the fact remains that Brooks's experts *did not* opine to this effect. These experts' affidavits and reports fail even to mention the pertinent FDA regulations.

DISPOSITION

We reverse the district court's judgment that Brooks's state-law failure-to-warn claim is preempted by federal law. We affirm the court's judgment in favor of Howmedica as to Brooks's claim that Howmedica neglected to comply with federal regulations. We remand the matter for further proceedings consistent with our opinion.

MURPHY, Circuit Judge, dissenting.

I agree with part of the court's opinion, but I respectfully dissent from the discussion in section A.3. and the conclusion that Brooks' failure to warn claim is not preempted by federal law.

Simplex, the product on which Brooks' lawsuit is based, is regulated by a comprehensive set of federal requirements. It is thus unlike the pacemaker in Lohr which had no federal requirement specific to the product. See Lohr at 493-94. The Lohr pacemaker passed through a substantial equivalency process instead of the NDA process which Simplex underwent. See id. at 480. During the NDA process the FDA reviewed, and in some instances drafted, every word of the product labeling for Simplex. This labeling cannot be changed without FDA approval. In the case of Simplex, unlike for the Lohr pacemaker, "the Federal Government [] weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved . . . , and implemented that conclusion via a specific mandate on manufacturers or producers." Id. at 501.

A state requirement of general applicability will be preempted under the MDA if there is a federal requirement specific to the device and if the state requirement has the effect of imposing a substantive requirement on the device different from, or in addition to, the federal requirement. See id. at 500. The failure to warn claim brought

by Brooks seeks to impose a substantive requirement on Simplex because if it were to prevail, Howmedica would need to add warnings about the effects of inhaling methyl methacrylate vapors during the mixing process in order to escape tort liability in Minnesota. This would be in addition to federal requirements since the labels reviewed and drafted by the FDA do not include these warnings. Thus, the substantive requirement sought by the failure to warn claim would be in addition to the federal requirement specific to Simplex, and the claim is preempted. This conclusion is consistent with results in other federal circuit courts which have concluded that common law failure to warn claims are preempted by the MDA when the device has been approved after a PMA or NDA review. See Kemp v. Medtronic, Inc., 231 F.3d 216, 236-37 (6th Cir. 2000); Mitchell v. Collagen Corp., 126 F.3d 902, 907, 913 (7th Cir. 1997), cert. denied, 523 U.S. 1020 (1998); cf. Papike v. Tambrands, Inc., 107 F.3d 737, 741-42 (9th Cir. 1997) (failure to warn claim preempted by FDA labeling regulations regarding toxic shock syndrome), cert. denied, 522 U.S. 862 (1997). But see Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1377 (11th Cir. 1999) (failure to warn claim did not impose a substantive requirement).

In spite of the clear language of the statute which provides for preemption of any state requirement "different from, or in addition to, any requirement applicable under this chapter to the device," 21 U.S.C. § 360k(a), the court says that Congress did not "really mean" the language be taken literally because it was concerned about safety. The legislative history shows, however, that the preemption provision was included within the MDA because of congressional concern that "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." H.R. Rep. No. 853, 45 (1976). In respect to Simplex, the FDA worked closely with Howmedica and thoroughly reviewed and approved the warning labels. To permit state requirements to be added to those imposed by the federal government would frustrate congressional intent because it could result in conflicting labeling requirements in

various states, confusion, and unwarranted expense to manufacturers and developers of medical devices.

Since the failure to warn claim in this case falls within the scope of the preemption provision of the MDA, I would affirm the judgment of the district court.

A true copy.

Attest:

CLERK, U.S. COURT OF APPEALS, EIGHTH CIRCUIT.