**PUBLISHED**

# UNITED STATES COURT OF APPEALS

## FOR THE FOURTH CIRCUIT

SHERRY ANN WALKER, Individually and as Administratrix of the Estate of Arnold Leroy Walker, Jr.,

*Plaintiff-Appellant*,

v.

MEDTRONIC, INCORPORATED, a Minnesota corporation,

*Defendant-Appellee*,

and

MEDTRONIC USA, INCORPORATED, a Minnesota corporation,

*Defendant.*

No. 10-2219

Appeal from the United States District Court
for the Southern District of West Virginia, at Charleston.
David A. Faber, Senior District Judge.
(2:07-cv-00317)

Argued: November 8, 2011

Decided: January 25, 2012

Before DUNCAN, WYNN, and DIAZ, Circuit Judges.

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Affirmed by published opinion. Judge Duncan wrote the majority opinion, in which Judge Diaz joined. Judge Wynn wrote a dissenting opinion.

## COUNSEL

**ARGUED:** Christopher Brinkley, MASTERS LAW FIRM, LC, Charleston, West Virginia, for Appellant. Andrew E. Tauber, MAYER BROWN, LLP, Washington, D.C., for Appellee. **ON BRIEF:** David M. Gossett, Brette L. Steele, MAYER BROWN, LLP, Washington, D.C., for Appellee.

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## OPINION

DUNCAN, Circuit Judge:

Appellant Sherry Walker appeals from the district court's holding that her common law tort claims against Medtronic, Inc. are preempted by the Medical Device Amendments of 1976 ("MDA"), as interpreted by *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). Walker argues that, because the device in question allegedly failed to operate in accordance with the terms of its premarket approval, her claims parallel federal requirements and therefore should avoid preemption. In light of Walker's concession that the device was designed, manufactured, and distributed in compliance with the terms of its premarket approval, given by the Food and Drug Administration ("FDA") as required under the MDA, however, we are compelled to affirm.

The exclusive provisions of the FDA regulatory process recognize only one mechanism for the creation of an enforceable requirement governing the ongoing performance of a medical device, and that is through the establishment of a formal performance standard. Walker concedes that no such performance standard was created here. This concession makes clear that her common law claims seek to impose requirements above and beyond those of the FDA, thus bringing them within the category expressly preempted by the MDA. To hold otherwise would be to undermine the balance Con-

gress struck when it enacted the MDA, in which it determined that the benefit to the many of bringing potentially lifesaving, but risky, medical devices to the public following the rigorous process of FDA approval outweighed the cost to the few of preempting common law claims based on different standards.

## I.

### A.

In 1976, Congress passed the Medical Device Amendments, 21 U.S.C. § 360c et seq., in order to "impose[ ] a regime of detailed federal oversight" to govern medical devices. *Riegel*, 552 U.S. at 316. It did so in response to mounting concern following the highly publicized controversy surrounding the Dalkon Shield intrauterine device, which "demonstrated the inability of the common law tort system to manage the risks associated with dangerous devices." *Id.* at 315. As such, Congress intentionally "swept back some state obligations" in favor of uniform federal regulation. *Id.* at 316.

To that end, the MDA includes a provision expressly preempting state regulation of medical devices. It states in relevant part:

> [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 MDA also establishes three classes of medical devices, organized according to the level of oversight required to ensure their safety. Class I devices are those for which general controls, such as labeling requirements, "are sufficient to provide reasonable assurance of [their] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(A)(i). They include such things as "elastic bandages and examination gloves" and are "subject to the lowest level of oversight." *Riegel*, 552 U.S. at 316. Class II devices include "such devices as powered wheelchairs and surgical drapes," *id.*, and are subject to heightened oversight mechanisms, such as "performance standards [and] postmarket surveillance," 21 U.S.C. § 360c(a)(1)(B).

Class III devices require the highest level of federal oversight. Class III devices are those for which the general controls regulating Class I devices and the specific controls that regulate Class II devices are deemed insufficient to ensure safety and effectiveness, and that are either useful in "supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or that "present[ ] a potential unreasonable risk of illness or injury." *Id.* at § 360c(a)(1)(C). Because of the risks associated with them, Class III devices are required to go through premarket approval "to provide reasonable assurance of [their] safety and effectiveness." *Id.*

"Premarket approval is a rigorous process." *Riegel*, 552 U.S. at 317 (internal quotation marks omitted). To obtain premarket approval, a device manufacturer must submit to the FDA full reports of all investigations relating to the device's safety or effectiveness; a "full statement of the components, ingredients, and properties and of the principle or principles of operation" of the device; a full description of the manufacturing methods and the facilities and controls used for the device's manufacturing; references to any performance standards applicable to the device; samples of the device and any

component parts; examples of the proposed labeling for the device; and other information as requested. 21 U.S.C. § 360e(c)(1). This typically requires a "multivolume application." *Riegel*, 552 U.S. at 317.

The FDA reviews these applications, approving only those it has determined provide reasonable assurance of a device's safety and effectiveness. It "spends an average of 1,200 hours reviewing each application." *Id.* at 318. If the FDA deems it necessary, it may refer an application to a panel of experts "for study and for submission . . . of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation." 21 U.S.C. § 360e(c)(3). The FDA's final grant of premarket approval is based on "weighing any probable benefit to health from the use of [a] device against any probable risk of injury or illness from such use." *Id.* at § 360c(a)(2)(C). "It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Riegel*, 552 U.S. at 318.

The FDA may condition its grant of premarket approval upon certain requirements. Significantly for our purposes, the FDA may require that a device meet certain performance standards if it "determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360d(a)(1).

The establishment of a performance standard is a formal process specifically governed by the MDA. It requires publication of a notice of proposed rulemaking in the Federal Register setting forth justification why the performance standard is necessary, "proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate," and invitation for comments from interested persons.[1] *Id.* at § 360d(b)(1)(B). Following the expira-

[1]The FDA may also "recognize . . . an appropriate standard established by a nationally or internationally recognized standard development organization" by publishing such a standard in the Federal Register. 21 U.S.C. § 360d(c)(1)(A).

tion of the comment period and consideration of the comments submitted therein, the FDA must promulgate a regulation establishing a formal performance standard and publish it in the Federal Register. *Id.* at § 360d(b)(3)(A). When the FDA establishes a performance standard for a Class III device, it does so as a precursor to the grant of premarket approval. 21 C.F.R. § 861.1(b)(3).

Once premarket approval has been granted, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing process, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319. To gain FDA approval of a proposed change, the manufacturer must submit a supplemental application describing the change in detail and summarizing the findings supporting the change. 21 U.S.C. § 360e(d)(6)(A)(i). A premarket approval application supplement is "evaluated under largely the same criteria as an initial application." *Riegel*, 552 U.S. at 319.

The FDA continues to oversee Class III devices after the grant of premarket approval. Manufacturers must report to the FDA when an approved device "may have caused or contributed to a death or serious injury" or malfunctioned in a way that would make it likely to do so in the future. 21 U.S.C. § 360i(a)(1). They also must periodically inform the FDA about data from clinical studies or scientific literature related to the device. 21 C.F.R. § 814.84(b). "The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." *Riegel*, 552 U.S. at 319-20.

B.

The device at issue here is a Model 8627-18 SynchroMed EL Programmable Pump (the "SynchroMed pump"), which was designed, manufactured, and distributed by Medtronic.

The SynchroMed pump is a component part of the SynchroMed Infusion System, a method of delivering medication designed for patients who require chronic infusions of drugs. Specifically, the system delivers medication directly into the space surrounding the spinal cord. It accomplishes this through implantation of the SynchroMed pump in the patient's abdominal area and implantation of a catheter in the patient's interspinal space. The SynchroMed pump is connected to the catheter and programmed to deliver a controlled amount of medication at the dosage and frequency prescribed by a physician.

The SynchroMed pump is undisputedly a Class III device with respect to which the FDA granted premarket approval. The FDA originally approved Medtronic's application for the SynchroMed pump in 1988; it subsequently granted premarket approval to application supplements in 1994 and 1999. It is further undisputed that neither the FDA's initial grant of premarket approval nor its later approvals of supplemental applications were subject to any requirement that the SynchroMed pump comply with a formal performance standard pursuant to § 360d.

In relevant part, the FDA's March 18, 1999 approval letter stated that the SynchroMed pump had been modified by "extend[ing] down" the flow range "to 0.048 ml/day from 0.098 ml/day, while maintaining the delivery accuracy of ±15%." J.A. 93. It also noted the "[c]hange to the labeling for . . . new delivery accuracy (0.048 ml±15%)." *Id.*

The Technical Manual for the SynchroMed pump—which was approved by the FDA during the premarket approval process and is distributed along with the device—likewise specified that "[t]he flow accuracy of the SynchroMed EL pump, measured at the catheter tip, is within ±15 percent of the programmed flow rate." J.A. 153. It qualified this statement, however: "[T]he accuracy of the SynchroMed EL Infusion System depends on how closely procedures are followed.

Noncompliance with implant and refill procedures, as well as other human factors, may cause the observed accuracy of the system to vary by ±25 percent." *Id.*

The Technical Manual contained other warnings about the risks associated with use of the SynchroMed pump. Of significance here, it stated:

> Improper use of implanted, programmable infusion pumps could result in drug overdose. Users must comply with product instructions for initial pump preparation, programming, implantation, initial filling, refilling, and injecting into the side catheter access port (if present) of the pump. Technical errors may result in a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug overdose.

J.A. 107. It further noted that possible pump complications included a "[c]hange in flow performance characteristics, due to component failure or changes over time, which may result in . . . overinfusion of the drug [or] drug overdose." J.A. 109. Finally, it included the following special notice:

> The pump and catheter are implanted in the extremely hostile environment of the human body. This environment places severe demands on their design and function. . . . Reasons for failure of the pump or catheter include, but are not limited to: body rejection phenomena; change in performance characteristics due to component changes or failures; unusual physiological variations in patients; medical complications; complete or partial catheter occlusion; catheter dislodgement; catheter leakage; catheter breakage; migration; or erosion of the pump. In addition, despite the exercise of all due care in design, component selection, manufacture, and testing prior to sale, the pump and catheters may be

> damaged before, during, or after implantation by improper handling or filling; by drugs or uses not described in this technical manual; or by other intervening acts. Consequently, no representation or warranty is made that failure or cessation of function of the pump or catheters will not occur, or that the body will not react adversely to their implantation.

J.A. 114.

C.

In May 2003, physicians implanted the SynchroMed pump in Arnold Walker, appellant Sherry Walker's late husband, for the purpose of delivering medication to treat his chronic back pain. It is undisputed that the pump functioned for approximately two years.

On June 9, 2005, Arnold died from—according to his death certificate—"[c]ombined hydromorphone, hydrocodone, diazepam, and venlafaxine intoxication."[2] J.A. 29. During Arnold's autopsy, the SynchroMed pump was removed and placed in a bag, where it continued to dispense hydromorphone. Walker's expert, Dr. Harry Milman, later analyzed the contents of the pump and the bag and concluded that, based on the programmed hourly infusion rate at which the medication was to be dispensed, 568 mg of hydromorphone were unaccounted for. Milman opined that, prior to Arnold's death, the SynchroMed pump had malfunctioned and overinfused the unaccounted for hydromorphone into Arnold's body. He concluded that this overinfusion by the SynchroMed pump was the cause of death.[3]

[2]At the time of Arnold's death, he was being treated orally with hydrocodone, diazepam, and venlafaxine. The only medication he was receiving via the SynchroMed Infusion System was hydromorphone.

[3]Medtronic vigorously contests Walker's theory that an overinfusion by the SynchroMed pump caused her husband's death. It recognizes, how-

D.

On May 18, 2007, Walker filed a diversity suit against Medtronic in the United States District Court for the Southern District of West Virginia. She alleged that the SynchroMed pump had malfunctioned, resulting in Arnold's death from a lethal overdose of medication. In her complaint, she asserted three common law causes of action: negligence, strict liability, and breach of warranty. She sought compensatory and punitive damages, attorney's fees, costs, and pre- and post-judgment interest.

On April 21, 2008, following the Supreme Court's decision in *Riegel*, Medtronic moved for summary judgment, arguing that Walker's claims were preempted. The district court denied the motion without prejudice, finding that there was a dispute of fact regarding whether the SynchroMed pump in question complied with the terms of its premarket approval. The court recognized, however, that Walker's original complaint did not allege a claim that would survive *Riegel*'s preemption analysis. Consequently, it informed her that she could amend the complaint to correct the deficiency.

Walker filed an amended complaint on October 29, 2008. In her amended complaint, she asserted the same three causes of action but alleged for the first time that "the pump failed to comply and operate in terms of its Pre-Market Approval." J.A. 40.

The parties then engaged in discovery to determine whether the SynchroMed pump complied with the terms of is premar-

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ever, that this factual dispute is irrelevant to the question of whether Walker's claims are preempted by the MDA. Because when reviewing a grant of summary judgment, we "view[ ] the facts in the light most favorable to the nonmoving party," we recount the facts here in the light most favorable to Walker. *See Nat'l City Bank of In. v. Turnbaugh*, 463 F.3d 325, 329 (4th Cir. 2006).

ket approval. During discovery, Medtronic produced reports establishing that the particular SynchroMed pump implanted in Arnold Walker had been tested prior to implantation and had been determined to be in compliance with its premarket approval terms.

On October 29, 2009, following discovery, Medtronic filed a renewed motion for summary judgment. It argued that because discovery had demonstrated that the SynchroMed pump was designed, manufactured, and sold in accordance with its premarket approval, Walker's claims were preempted by the MDA as interpreted by *Riegel*. Walker opposed the motion. She did not dispute that the pump was designed, manufactured, and sold in accordance with its premarket approval. Rather, she asserted, as she does here, that her claims fell within the exception for parallel claims articulated in *Riegel*. Specifically, she argued that the pump had failed to adhere to the plus or minus 15 percent specification included in the premarket approval materials and, that by failing to administer medicine within these parameters, it had violated the terms of its premarket approval.

The district court granted Medtronic's renewed motion for summary judgment. It reasoned that because Walker conceded that the SynchroMed pump was designed, manufactured, and sold in accordance with its premarket approval terms, her claims did not parallel federal requirements. It also determined that, because the plus or minus 15 percent flow accuracy rate referenced in the SynchroMed pump's premarket approval application was not a formal performance standard, failure to adhere to the specification was not a violation of the premarket approval. As such, the district court concluded that all of Walker's common law tort claims were preempted by the MDA.

## II.

On appeal, Walker again asserts that her common law tort claims are not preempted by the MDA because they fit within

the narrow exception for parallel claims the Supreme Court carved out in *Riegel*. We review the district court's finding of preemption de novo. *Equal Rights Ctr. v. Niles Bolton Assocs.*, 602 F.3d 597, 600 (4th Cir. 2010). Here, we first discuss *Riegel* and its effect on common law tort claims based on the failure of FDA-approved medical devices. We then analyze Walker's claims in light of *Riegel*.

A.

In *Riegel*, the Supreme Court considered whether a plaintiff's common law claims based on the failure of a Class III medical device were precluded by the MDA's express preemption clause, which preempts state requirements "different from, or in addition to" requirements applicable under federal law. 552 U.S. at 321 (quoting 21 U.S.C. § 360k(a)(1)). To answer this question, it engaged in a two-part inquiry. 552 U.S. at 321-22. First, the Supreme Court examined "whether the federal government ha[d] established requirements applicable to" the device in question. *Id.* at 321. It specifically found that "[p]remarket approval . . . imposes 'requirements' under the MDA." *Id.* at 322. This is because "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323. Therefore, because all Class III devices are required to undergo the premarket approval process, federal requirements exist with respect to all Class III devices.

Second, the *Riegel* Court considered whether the plaintiff's common law claims imposed any requirements that were "different from, or in addition to" these federal requirements and "relate[d] to the safety or effectiveness of the device or to any other matter included in a requirement of the device." *Id.* (quoting 21 U.S.C. § 360k(a)). It first recognized that common law liability necessarily implies that the defendant had a

legal duty and that "a liability award 'can be, indeed is designed to be, a potent method of governing conduct and controlling policy.'" *Id.* at 324 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992)). Common law duties, it went on to hold, therefore ordinarily constitute state requirements. *Id.* It further observed that "[s]tate tort law that requires [a device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Id.* at 325.

In sum, the Supreme Court held that the terms of a Class III device's premarket approval constitute federal requirements and that a common law tort claim premised on different or additional requirements is preempted by the MDA. Applying this framework to Riegel's case, it concluded that her claims against Medtronic were preempted.

The Supreme Court did recognize one situation in which a plaintiff's common law claims would not be preempted under the MDA: when "state duties . . . 'parallel,' rather than add to, federal requirements." *Id.* at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). This situation occurs when claims are "premised on a violation of FDA regulations." *Id.* Because Riegel only raised the argument that her claims paralleled federal requirements for the first time before the Supreme Court, it declined to consider the claim.

B.

Here, Walker contends that her common law tort claims parallel the federal requirements imposed by the SynchroMed pump's premarket approval. She argues that the plus or minus 15 percent specification included in Medtronic's premarket approval materials became a part of the federal requirements governing the device. Because the SynchroMed pump allegedly infused an amount of medication outside of these parameters, her argument follows, it violated the terms of the

premarket approval. Walker has, however, made concessions that are fatal to her claim.

Walker concedes that the SynchroMed pump was designed, manufactured, and distributed in compliance with the terms of the FDA's premarket approval. She concedes that the plus or minus 15 percent specification is *not* a formal performance standard. And she acknowledges, as indeed she must, that unless her claims parallel federal requirements as opposed to imposing more stringent ones, they are preempted under the MDA as interpreted by *Riegel*.

1.

We first note that this appeal is not about whether the plus or minus 15 percent flow accuracy specification set forth in Medtronic's premarket approval application constitutes a formal performance standard (although, as we explain, it does not). The issue before us is whether Walker's claims are preempted by the MDA, as interpreted by the Supreme Court in *Riegel*, which provides a rigorous, comprehensive, and exclusive framework that precludes state law tort claims that seek to impose different or higher standards upon federally approved devices. Whether the plus or minus 15 percent specification is a formal performance standard is pertinent because only such a performance standard could create the type of binding requirement that would make Walker's claims impose requirements parallel to, as opposed to more restrictive than, those imposed by the FDA. Thus, the status of the plus or minus 15 percent specification informs our resolution of the ultimate question posed by this appeal: whether Walker's claims are preempted by the MDA.

Simply because the majority recognizes that the plus or minus 15 percent specification does not create an ongoing requirement, however, we do not state, or even suggest, that the flow accuracy specification is a "mere aspirational figure," as the dissent asserts. *Post* at 20. To the contrary, it informs

the medical community of the results the device is likely to achieve under optimal circumstances. It also imposes consequences when a SynchroMed pump does not meet the specification. Specifically, Medtronic is required to report any such malfunction to the FDA for consideration in its ongoing evaluative process.

Instead, the majority simply concludes what is incontrovertible under FDA regulations: the only mechanism for creating a binding, ongoing performance requirement is the creation of a performance standard. And Walker does not dispute that, here, the plus or minus 15 percent specification is not a performance standard. As such, it cannot bear the weight the dissent would assign to it. Indeed, if we were to treat the flow rate as a requirement, we would be imposing a heightened standard beyond that of the FDA—which is impermissible under *Riegel*. Moreover, as we have noted, such a holding would upend the carefully calibrated construct Congress created in the MDA, balancing the potential rewards of such devices following the rigorous process of FDA approval against the cost of preempting common law claims based on standards different than those imposed by the FDA.

2.

*Riegel* held that, because of the congressional balance reflected in the MDA, a plaintiff's state law cause of action based on injuries caused by a Class III medical device could only survive if the alleged malfunction also violated a federal requirement. Because the SynchroMed pump's premarket approval application makes it clear that ongoing adherence to the plus or minus 15 percent flow accuracy specification was not a requirement,[4] Walker's claims based on the device's alleged failure to adhere to the specification must fail.

[4]With respect for the dissent's suggestion to the contrary, we note that the opinion of one Medtronic employee, expressed during a deposition, regarding whether an overinfusion of the SyncrhoMed pump would constitute a violation of the device's premarket approval has no bearing on the question of whether the *FDA* conditioned its premarket approval of the device upon ongoing adherence to the plus or minus 15 percent flow rate.

As discussed above, the FDA may promulgate formal performance standards to which a device must adhere as a condition of its premarket approval. *See* 21 U.S.C. § 360d. The process of creating a formal performance standard requires adherence to specific procedures. *See id.* at § 360d(b). Because the plus or minus 15 percent specification here was not a formal performance standard, however, Walker cannot claim that ongoing adherence to it was a requirement of the SynchroMed pump's premarket approval.

That ongoing adherence to the plus or minus 15 percent specification was not a requirement of the device's premarket approval is further demonstrated by the FDA approval letter and the FDA-approved Technical Manual.[5] As noted above, the approval letter referred to the plus or minus 15 percent specification as a measure of "delivery accuracy"; it in no way conditioned the device's approval on maintaining this metric. J.A. 93. To the contrary, the letter contained a number of specific "Conditions of Approval." J.A. 94. These detailed, inter alia, restrictions on advertising and reporting requirements. They did *not* include the plus or minus 15 percent specification—or any sort of performance standard.

[5]We do not necessarily disagree with the dissent's assertion that "the FDA's [premarket] approval and the Conditions of Approval, taken together, . . . establish[ ] the specific federal requirements for" a Class III device. *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 228 (6th Cir. 2000). That a specification is included in a device's premarket approval application, however, does not indicate that the specification imposes a binding requirement for the life of the device—at least not without clear indication by the FDA through promulgation of a formal performance standard. Here, it is undisputed that the SynchroMed pump at issue was designed, manufactured, and sold in compliance with the terms of its premarket approval—including the plus or minus 15 percent specification. As we explain, without an express statement in the FDA's approval materials that the SynchroMed pump was subject to an ongoing requirement that it never deviate from the plus or minus 15 percent specification, any attempt to impose one through civil tort liability would impose additional requirements in violation of the MDA as interpreted by *Riegel*.

Further, the Technical Manual, also approved by the FDA, contained a number of warnings making it clear that the plus or minus 15 percent specification was subject to many variables. It specifically stated that human error,[6] technical error, or component failure could result in a change in flow accuracy. It also clearly listed "overinfusion" and "drug overdose" as possible consequences of device malfunction. J.A. 109. Finally, the Technical Manual contained a general warning about the inherent risks of implanting a device in the "extremely hostile environment of the human body." J.A. 114.

In short, nothing in the SynchroMed pump's premarket approval application—which was approved in its entirety by the FDA—purported that the device would always dispense medication within the range of the plus or minus 15 percent flow accuracy. Instead, the plus or minus 15 percent specification reflects the SynchroMed pump's output under optimal conditions, but subject to numerous qualifiers that disclose the possibility of infusion outside this range. To the extent that Walker interprets the plus or minus 15 percent specification as a guarantee of performance, she seeks to impose a more demanding standard than that of the FDA, rather than a parallel one.

On this record, we agree with the district court that "[a]n alleged deviation from manufacturing performance specifications for a device that has received premarket approval is not the same thing as noncompliance with the FDA or its regulations." *Walker v. Medtronic, Inc.*, No. 2:07-00317, 2010 WL 4822135, at *5 (S.D. W. Va. Nov. 24, 2010). To the contrary, because Walker's argument would require that the SynchroMed pump *never* deviate from its programmed flow rate by more than plus or minus 15 percent, and the terms of the

[6]It should be noted that nothing in our preemption discussion precludes a state tort claim against a physician who improperly implants the pump or otherwise negligently causes it to malfunction. Walker has not, however, made any such allegation here.

device's premarket approval do not contemplate this result, she is actually contending that the device should have been designed differently. Stated another way, given that the SynchroMed pump's premarket approval specifically included language detailing the possibility of deviation from the plus or minus 15 percent specification, it necessarily follows that any design that eliminated the possibility of such variation would be "different from, or in addition to" the design approved by the FDA. *See* 21 U.S.C. § 360k(a)(1). As the *Riegel* court noted, however, "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." 552 U.S. at 323. A common law tort claim that presupposes a Class III device should have been designed in a manner other than that contemplated by its premarket approval is therefore expressly preempted by the MDA as interpreted by *Riegel*. *Id.* at 324-25.

We note that, in granting premarket approval, the FDA did precisely what the dissent would have it do: it evaluated, through a rigorous process, the safety and reliability of the device at issue. It also recognized, however, that the device's safety and reliability cannot be guaranteed indefinitely in the "extremely hostile environment of the human body," where myriad other factors external to the device are brought to bear (although the device at issue here did function in such an environment, without dispute, for approximately two years). J.A. 114. It is Walker's attempt to transform a *design specification*, which the FDA recognizes the device will not always function in accordance with, into an actionable guarantee, that seeks to impose an additional requirement as precluded under *Riegel*.

The consensus of the federal courts post-*Riegel* supports our conclusion. Specifically, numerous district courts have held that common law tort claims based on the failure of

devices that were designed, manufactured, and sold in accordance with the terms of their premarket approval were preempted under *Riegel*. *See, e.g.*, *Rankin v. Boston Scientific Corp.*, No. 09-177-KSF, 2010 WL 672135, at *4 (E.D. Ky. Feb. 19, 2010) ("Boston Scientific received premarket approval for the Maverick Balloon at issue in this case. The fact that the Maverick Balloon allegedly failed during normal use does not override the clear language of § 360(a) or the Supreme Court's ruling in *Riegel* that the plaintiffs' claims are preempted by federal law."); *Banner v. Cyberonics, Inc.*, No. 08-0741, 2010 WL 455286, at *4 (D.N.J. Feb. 4, 2010) ("[I]f the FDA approves a manufacturing process and the defendant-manufacturer conforms with it, a device thereby produced that nevertheless does not function as intended does not give rise to liability."); *Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301, 306 (E.D. Pa. 2009), *aff'd*, 388 F. App'x 169 (3d Cir. 2010) (unpublished) ("To avoid federal preemption, a plaintiff must make some showing that the medical device was not manufactured in accordance with FDA standards."); *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1095 (D. Minn. 2008) ("Because plaintiff's claims are not based on a breach of the MDA as enforced by the FDA, the claims are not grounded in state laws that 'parallel' federal requirements. Thus, plaintiff's claims are preempted."). Neither Walker nor the dissent point to any case law, nor have we found any, in which a court has reached a contrary conclusion.

Because the SynchroMed pump was undisputedly designed, manufactured, and distributed in compliance with its FDA premarket approval, and Walker's common law claims exceed or differ from, rather than parallel, federal requirements, we hold that each of her specific claims for negligence, strict liability, and breach of warranty is preempted.

III.

For the foregoing reasons, the judgment of the district court is

*AFFIRMED*.

WYNN, Circuit Judge, dissenting:

This case boils down to a choice of whether the Federal Drug Administration's ("FDA") specification that a potentially deadly medical device, an internally implanted pump, "maintain[ ] the delivery accuracy of ±15%" (J.A. 93) is a requirement, or whether it is a mere aspirational figure. Because I believe that the accuracy rate specification is indeed a requirement, and because the medical device's failure to meet that requirement underlies Plaintiff Sherry Walker's state law tort claims, I would hold that her claims are not preempted under *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). I therefore respectfully dissent.

In *Riegel*, the Supreme Court expressly stated that state tort suits are preempted only to the extent that they impose requirements "different from, or in addition to" the requirements imposed by federal law. 552 U.S. at 321. The Supreme Court affirmed a Second Circuit opinion that emphasized at the outset that

> our preemption analysis is quite limited in scope, affecting the small universe of cases resting on claims alleging liability despite a [premarket]-approved device's adherence to the standards upon which it secured FDA premarket approval. We take care to explain that we do not hold that all state tort claims as to [premarket]-approved devices are preempted. Thus, *tort claims that are based on a manufacturer's departure from the standards set forth in the device's approved [Pre-Market Approval] application*—such as the Riegels' negligent manufacturing claim—*are not preempted.*

*Riegel v. Medtronic, Inc.*, 451 F.3d 104, 106 (2d Cir. 2006) (emphasis added).

The Supreme Court established a two-step analysis for determining if state-law claims are preempted. First, a court

must determine whether "the Federal Government has established requirements applicable to" the particular medical device. *Riegel*, 552 U.S. at 321. Claims involving a Class III medical device with Pre-Market Approval automatically clear step one of the analysis because the Pre-Market Approval process establishes specific requirements applicable to the particular device. *Id.* at 322-23. In the second step, a court must determine whether the state law claims are based on requirements "different from or in addition to" the federal requirements relating to safety and effectiveness. *Id.* at 323 (quotation marks omitted).

In my view, Walker's suit clears both of these hurdles. The Medtronic SynchroMed EL Infusion Pump ("Pump") at issue in this case is undisputedly a Class III device with specific requirements. The first *Riegel* step is therefore met. Further, the Pre-Market Approval established a plus or minus 15 percent delivery accuracy requirement for the internally-implanted Medtronic SynchroMed EL Infusion Pump ("Pump"). Walker's suit is based on the Pump's failure to meet that requirement. Indeed, she proffered evidence, which we must take as true for summary judgment purposes, that her husband, Arnold Walker, died because the Pump delivered an extreme overdose of 258 percent of his prescribed medicine dosage. Walker's suit therefore does not impose additional or different requirements but rather parallels the pre-existing federal requirements for the Pump. I therefore do not believe that her suit is preempted under *Riegel*.

The majority casts the Federal Drug Administration's ("FDA") requirement that the Pump "maintain[ ] the delivery accuracy of ±15%" (J.A. 93) as a mere aspirational figure, i.e., what "the device is likely to achieve under optimal circumstances." *Ante* at 15. I cannot agree. And, apparently, neither would the FDA. In an amicus brief filed in *Horn v. Thoratec Corp.*, 376 F.3d 163 (2004), in which the Third Circuit addressed whether state claims were preempted, the FDA stated that "the agency's approval of this [Class III] device

through *the PMA process does impose specific requirements for* its design, manufacturing, *performance*, labeling, and use." Brief for the United States as Amicus Curiae at 15, *Horn v. Thoratec Corp.*, 376 F.3d 163 (2004) (No. 02-4597), 2004 WL 1143720, at *15 (emphasis added). Further, "in reviewing a PMA, FDA considers in great depth and detail the *performance* and design *specifications*, methods of manufacture, labeling, and indications for use of a proposed medical device." Amicus Br. at 16. Nowhere in its 31-page brief did the FDA even *mention* the words "performance standard." Nevertheless, the FDA repeatedly made clear that it can and does exact performance specifications and requirements in the ordinary course of the Pre-Market Approval process—which is precisely what we have in this case.

The FDA underscored that "*although FDA does not itself design any medical devices, through the PMA approval process it certainly establishes 'specific requirements' applicable to a 'particular device' because the specifications for that device's* design, *performance*, manufacture, labeling, and use *are approved by the agency based on what the applicant submits*. See *Kemp v. Medtronic, Inc.*, 231 F.3d at 216." *Id.* at 16 (emphasis added). And, notably, "*FDA does not, and has never, used notice-and-comment regulations*"—and formal performance standards are just such regulations, as the majority recognizes—"*to approve individual products or to establish product-specific requirements for* manufacture, *performance*, labeling, and use. Rather, a PMA order is better conceptualized as an individual adjudication that imposes 'specific requirements' on the device." *Id.* at 23-24 (emphasis added).

Accordingly, the accuracy rate at issue here is a requirement for the Pump per the Pre-Market Approval. The accuracy rate of "delivery accuracy of ±15%" is included twice in the PMA approval, which itself was based on information that Medtronic provided and that included the figure. J.A. 93-94. Medtronic itself argued in a previous appeal before the Sixth

Circuit that "the FDA's [Pre-Market] [A]pproval and the Conditions of Approval, taken together, . . . establish[ ] the specific federal requirements for the" device at issue. *Kemp*, 231 F.3d 216, 228 (6th Cir. 2000) (quotation marks omitted). The Sixth Circuit agreed with Medtronic's position—and so do I. *See id.*; *see also Horn*, 376 F.3d at 171 ("The FDA, when PMA approval is granted, imposes federal requirements based on the highly detailed and prescriptive nature of the PMA process and the approval order that results from it."). Indeed, even in this litigation, Medtronic conceded that an overinfusion of medication above 15 percent would violate the Pump's Pre-Market Approval. Medtronic's corporate representative for purposes of this case, Patrick L. Johnson, Regulatory Affairs Director for the Medtronic Neurological Business, testified in his deposition as follows:

> Q: Okay. Let me rephrase it then. Assuming there are no procedural errors, the physician hasn't done anything wrong and Mr. Walker's pump has been used within the environmental conditions that are spelled out in the technical manual and the pump because of a system complication, a system error overinfuses Mr. Walker by more than 15 percent, that would be a violation of the PMA approval for this pump, would you agree with that?
>
> A: That would be a reasonable statement, yes.

S.J.A.[1] 248 (objection to form omitted). That is precisely what Walker is claiming.[2]

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[1]Certain case materials containing confidential medical information relating to Arnold Walker were filed under seal. While this deposition excerpt is found in the sealed joint appendix, it does not pertain to confidential medical information.

[2]I also note that even Medtronic's appellate counsel conceded at oral argument that delivery of more than plus or minus 15 percent of the appropriate dosage of medicine would constitute a Pump "malfunction."

The majority notes that "neither the FDA's initial grant of premarket approval nor its later approvals of supplemental applications [for the Pump] were subject to any requirement that [the Pump] comply with a formal performance standard pursuant to § 360d." *Ante* at 7. The majority then goes on, however, to assert, without citation to any support, that "only such a performance standard could create the type of binding requirement that would make Walker's claims impose requirements parallel to, as opposed to more restrictive than, those imposed by the FDA." *Ante* at 14. I cannot agree that the absence of a formal performance standard for this Class III device frees the manufacturer from accountability for ensuring that its device performs as approved, including with regard to the approved accuracy rate.

It is instructive to consider what a formal performance standard is. "Medical devices are developed individually, but classes of products with similar features can sometimes benefit from a uniform standard of safety and effectiveness. These are the Class II devices." James T. O'Reilly, 1 *Food & Drug Admin.* § 18:18 (3d ed. 2011). Performance standards are a form of special control that may be instituted when "[t]he FDA . . . make[s] a finding that a performance standard is necessary to provide reasonable assurance of the device's safety and efficacy." *Id.* (quotation marks omitted).

Notably, however, to obtain Pre-Market Approval, a Class III device manufacturer must always "provide[ ] reasonable assurance that the product is safe and effective under the conditions of use for which it is labeled . . . ." *Id.* at § 18:50. This is echoed in 21 C.F.R. § 860.7, the regulation dedicated to the "[d]etermination of safety and effectiveness[,]" which equates the establishment of performance standards for Class II devices with the Pre-Market Approval of Class III devices. The regulation states:

> *In determining the safety and effectiveness of a device for purposes of* classification, establishment

> of performance standards for class II devices, and *premarket approval of class III devices, the Commissioner and the classification panels will consider the following, among other relevant factors*:
>
> (1) The persons for whose use the device is represented or intended;
>
> (2) The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;
>
> (3) The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and
>
> (4) *The reliability of the device.*

21 C.F.R. § 860.7(b) (emphasis added).

Stated differently, as part of *every* Pre-Market Approval for a Class III device (in contrast to a Class II device, where these concerns come into play specifically in establishing formal performance standards), the FDA must evaluate "safety and effectiveness" by considering, among other things, "[t]he reliability of the device" and the device's potential injury versus potential benefit. *Id.* Given that even the FDA equates a safety and effectiveness determination, including consideration of device reliability, in Pre-Market Approvals for Class III devices with performance standards for Class II devices,[3] I cannot agree with the majority that "[b]ecause the plus or minus 15 percent specification here was not a formal performance standard, . . . Walker cannot claim that ongoing adher-

[3]I of course recognize that the FDA "*may*" (and therefore necessarily need not) establish a performance standard for Class III devices "as a condition to premarket approval . . . ." 21 C.F.R. § 861.1(b) (emphasis added).

ence to it was a requirement of the [Pump's] premarket approval." *Ante* at 16. Indeed, it seems illogical that the FDA would place more exacting performance requirements on Class II devices such as "surgical drapes" (*Riegel*, 552 U.S. at 316) than on Class III devices such as "replacement heart valves, implanted cerebella stimulators, and pace-maker pulse generators," for which "a less stringent classification would provide [no] reasonable assurance of safety and effectiveness . . . ." *Id.* at 317.

Nor do I believe that Medtronic's inclusion of various warnings in its Pre-Market Approval materials neuters the "maintaining the delivery accuracy of ±15%" requirement. Those warnings address, e.g., potential component failure, conditions under which the device might malfunction (such as at high altitudes), and human error. Those general warnings do not change the fact that the specific plus or minus 15 percent accuracy rate requirement is twice stated in the FDA's two-page Pre-Market Approval letter, which, per Medtronic, establishes a device's requirements. *See Kemp*, 231 F.3d at 228. Further, Medtronic has not alleged that any number of the things addressed by the warnings are in play here (e.g., Medtronic does not contend that Arnold Walker went hiking in the Himalayas).

To be sure, it cannot be said that, under my analysis, device manufacturers must achieve perfection. Indeed, "the delivery accuracy of ±15%" itself recognizes that manufacturers may be given some margin for error. The FDA accepted that margin, based on Medtronic's Pre-Market Approval application, to be plus or minus 15 percent. Perhaps potential liability for incidents that occur outside of that 30 percent margin for error is simply a cost of doing business. The ramifications of holding anything else are indeed serious. If manufacturers are not held accountable for having their devices perform as approved by the FDA, they will have little incentive to ensure that potentially deadly devices function properly. For example, if Walker's factual contentions are true (and we must presume

that they are in reviewing summary judgment against her (*Nat'l City Bank of In. v. Turnbaugh*, 463 F.3d 325, 329 (4th Cir. 2006))), the Pump, which was approved with a dosage accuracy rate of plus or minus 15 percent, instead infused her husband with 258 percent of the appropriate medication dosage, and this extreme overdose killed him. I fail to see why—in the absence of clear congressional instruction to the contrary—the Walkers alone should bear the burden of this malfunction.

My view is bolstered by the general presumption against preemption of state law claims. As this Court articulated in a 2008 opinion, "we begin our consideration with the basic premise that 'Congress did not intend to displace state law.' *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). . . . The presumption against preemption has particular force in the areas of public health and safety that have traditionally been regulated by the states. *See Pinney v. Nokia, Inc.*, 402 F.3d 430, 457 (4th Cir.), *cert. denied*, 546 U.S. 998 (2005)." *City of Falls Church v. Fairfax Cnty. Water Auth.*, 272 F. App'x 252, 256 (4th Cir. 2008) (unpublished). Particularly when viewed through this lens, I fail to see how Walker's claims are preempted.[4]

Of course, whether or not Walker can prevail on her claims remains a very open question. But at stake today is not whether Walker should win or Medtronic should be held liable. The question before us is simply whether Walker may pursue her state law tort claims in light of the FDA's regula-

[4]The majority appears to turn the presumption *against* preemption on its head when it asserts "That a specification is included in a device's premarket approval application, however, does not indicate that the specification imposes a binding requirement for the life of the device—at least not without clear indication by the FDA through promulgation of a formal performance standard." *Ante* at 16 n.5. Under the majority's analysis, then, in clear contradiction to precedent, we assume preemption, i.e., additional requirements via state tort suits, absent clear indication to the contrary. With this, I cannot agree.

tion of the Pump. I believe that she should be able to do so. Accordingly, I respectfully dissent.