On Performance Standards and Preemption

Thursday, January 26, 2012

As we've mentioned before, the supposed "parallel violation claim" exception to medical device preemption has been frustratingly vague. That's because it originated in a complaint's vague language that Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) – decided on a motion to dismiss – speculated might have stated such a claim. A single paragraph of *dictum* in Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008), seemingly recognizing the exception in the course of explaining that the plaintiffs had waived it, only made things worse.

A new case, Walker v. Medtronic, Inc., No. 10-2219, 2012 WL 206036, slip op. (4th Cir. Jan. 25, 2012), is the first court of appeals case that really takes a close look at what "parallel" claims entail post-Riegel. While we'd prefer that this phantom exception not exist at all, the court's discussion keeps it tightly constrained and thus gets a thumbs up from us. Perhaps it was fitting that Walker was decided on Bexis' birthday.

Walker involved what's essentially a spinal version of a pain pump – designed to infuse a preset amount of specific drugs into the fluid that surrounds the spinal cord. It's supposed to be accurate within ± (that's "plus or minus") fifteen percent of whatever it's set for, but both the FDA's approval letter, and the FDA-approved materials that accompany the pump make clear that this fifteen percent is not some kind of absolute guarantee, but only a best estimate, and there are a lot of problems that can lead to a deviation (such deviations being reportable to the FDA as adverse events). Slip op. at 7-8, 14-15.

The pump was "undisputedly a Class III device." Slip op. at 7. Cf. Duggan v. Medtronic, Inc., ___ F. Supp.2d ___, 2012 WL 45503, at *5 (D. Mass. Jan. 10, 2012) (rejecting argument that based upon claim that not all components of different pump system weren't all originally PMAed). Thus Riegel preemption applied.

Because Walker is a product liability case, it doesn't take much to describe what happened. The decedent was taking a bunch of painkilling drugs at the same time and died from "[c]ombined hydromorphone, hydrocodone, diazepam, and venlafaxine intoxication." Slip op. at 9. Only one – hydromorphone – was being infused using the pump, so that's the one the plaintiff targeted. Plaintiff obtained some sort of "expert" who, through some unexplained process (probably assuming the pump had been filled to the brim when it wasn't) claimed there had been an overdose. Id.

Whether there was or was not an overdose was not germane to the preemption summary judgment motion. Slip op. at 9-10 n.3. That underscores why preemption is so powerful. It applies irrespective of the merits of the underlying litigation.

Trying to turn the ±15% language in the product literature into a "guarantee of performance," slip op. at 17, plaintiff argued that she had stated some sort of unpreempted "parallel" violation claim because she had some evidence that the device was outside this range. The court held that no such claim existed.

In so doing, Walker had to decide how broadly to construe the "parallel" claim loophole to preemption. Fortunately it's construction was relatively restrictive. The FDA has a formal type of specification,

called a "performance standard," under which a manufacturer must guarantee a particular level functioning upon pain of violating the Medical Device Amendments:

"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. Id. at §360d(b)(1)(B). . . . 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)."*

Walker, slip op. at 5-6 (footnote omitted) (emphasis added).

When a plaintiff, under state law, tries to take some statement, or other device attribute, that hasn't jumped through the hoops to become a "performance standard," and through litigation tries to make it into such a mandatory standard is something that's "different from or in addition to" within the meaning of the Act's preemption clause. Therefore, preemption bars the claim:

*"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 [plaintiff's] claims impose requirements parallel to, as opposed to more restrictive than, those imposed by the FDA."*

Slip op. at 14 (emphasis added). The court revisits the same point, at greater length, a little later:

*"[It] is incontrovertible under FDA regulations: **the only mechanism for creating a binding, ongoing performance requirement is the creation of a performance standard**. And [plaintiff] does not dispute that, here, the plus or minus 15 percent specification is not a performance standard. . . . [I]f 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."*

Id. at 15 (emphasis added). No formal "performance standard" – that's simple, easy to apply, and above all, rare.

The device in question was manufactured sold, etc. in full compliance with everything the FDA required, including those aspects that underlay the expected ±15% flow rate. Plaintiff did not contest that. E.g. slip op. at 16 n.5. But that expectation was not the same as a real FDA requirement that the device could not, for any reason, ever deviate from that rate. For plaintiff to use state law to convert any deviation into a "violation" that did not, in fact, exist was dissimilar from what the FDA required and therefore preempted:

"[N]othing in the [device'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. . . . To the extent that [plaintiff] 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."

Id. at 17.

As anyone reviewing the cases on our device preemption scorecard can attest, this is one version – and a rather restrictive one – of the elusive "parallel" violation claim that post-Riegel courts have adopted. While not tying the analysis explicitly to "performance specifications," numerous courts have rejected the theory that underlay the plaintiff's arguments in Walker, which is that the mere malfunction of a device somehow establishes a non-preempted violation claim. See Carrelo v. Advanced Neuromodulation Systems, 777 F. Supp.2d 303, 314 (D.P.R. 2011) ("the failure of a Class III medical device does not establish the existence of a manufacturing defect"); Haynes v. Cyberonics, Inc., 2011 WL 3903238, at *3 (N.D. Ga. Sept. 6, 2011) ("a manufacturer could comply with all FDA regulations, but nevertheless produce a product containing an unintended flaw or abnormal condition"); Timberlake v. Synthes Spine, Inc., 2011 WL 711075, at *9 (S.D. Tex. Feb. 18, 2011), ("plaintiff "must plead and prove the specific way in which Defendants' manufacturing process differed from that approved by the FDA in order to show that his manufacturing defect claim is truly 'parallel'"); Cafferty v. Cayuga Medical Center, 2011 WL 541809, at *5 (N.D.N.Y. Feb. 8, 2011) ("under the federal law governing the PMA process, there is no demand that a product be risk-free, only that its benefits, if manufactured according to specifications, outweigh its risks"; res ipsa loquitur is "refuted by Riegel"); Gelber v. Stryker Corp., 752 F. Supp.2d 328, 334 (S.D.N.Y. 2010) (preemption because plaintiffs "have not pointed to evidence of device-specific violations of federal law"); Rankin v. Boston Scientific Corp., 2010 WL 672135, at *4 (E.D. Ky. Feb. 19, 2010) ("[defendant] received premarket approval"; "that the [device] allegedly failed during normal use does not override the clear language of §360(a) or . . . Riegel"); Banner v. Cyberonics, Inc., 2010 WL 455286, at *4 (D.N.J. Feb. 4, 2010) ("FDA approves the process by which a Class III device is manufactured, but it does not guarantee that every device manufactured in that process will work"; "if the FDA approves a manufacturing process and the defendant-manufacturer conforms with it, a [malfunction] does not give rise to liability"); Ilarraza v. Medtronic, Inc., 677 F. Supp.2d 582, 588 (E.D.N.Y. 2009) ("vague and open-ended . . . regulations . . . cannot serve as the basis for a parallel claim[, s]ince these regulations are open to a particular manufacturer's interpretation"); Funk v. Stryker Corp., 673 F. Supp.2d 522, 532 (S.D. Tex. 2009) (plaintiff "essentially relies on a circular argument that because he was injured and because the device (allegedly) contained impurities, [it] therefore violated FDA regulations. Such reasoning is contrary to the holding in Riegel"), aff'd, 631 F.3d 777 (5th Cir. 2011); Williams v. Cyberonics, Inc., 654 F. Supp. 2d 301, 306, 308 (E.D. Pa. 2009) ("[t]o avoid federal preemption, a plaintiff must make some showing that the medical device was not manufactured in accordance with FDA standards"; "[w]ithout proof that the [device] did not adhere to the premarket approval, [plaintiffs'] claim must fail"), aff'd, 388 Fed. Appx. 169 (3d Cir. 2010); Miller v. DePuy Spine, Inc., 638 F. Supp.2d 1226, 1230 (D. Nev. 2009) (preemption where there is "no evidence to show that the [device] was manufactured out of conformity with the materials or manufacturing specifications approved by the FDA"); In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp.2d 1147, 1158 (D. Minn. 2009) ("In the absence of any specific requirement . . . holding [defendant] liable for such a [specific] 'defect' would impose requirements 'different from, or in addition to' those under federal law"), aff'd, 623 F.3d 1200 (8th Cir. 2010); Delaney v. Stryker Orthopaedics, 2009 WL 564243, at *6 (D.N.J. March 5, 2009) (plaintiff "does not specify in what way [device] deviated from the manufacturing process that the FDA approved"; "mere occurrence of an accident" insufficient for preemption); Clark v. Medtronic, Inc., 572 F. Supp. 2d 1090, 1094-95 (D.

Minn. 2008) ("[p]laintiff is ultimately wrong when he assumes that premarket approval guarantees the device is completely safe"; his "claims are not based on a breach of the MDA as enforced by the FDA"; "[t]hus plaintiff's claims are preempted"); In re Medtronic Sprint Fidelis Lead Products Liability State Court Litigation, 2009 WL 3417867 (Minn. Dist. Oct. 29, 2009) ("that the FDA specifically approved the design and proposed manufacturing processes" requires preemption); Colombini v. Westchester County Health Care Corp., 2009 WL 2170230, at *4 (N.Y. Sup. July 6, 2009) ("plaintiffs cite to no document from the FDA which specifically mandates [the items at issue] as the only solutions to the problems. Plaintiffs therefore have not demonstrated that they have any parallel claims") (in table at 899 N.Y.S.2d 58).

As the court in Walker observed, "[n]either [plaintiff] nor the dissent point to any case law, nor have we found any, in which a court has reached a contrary conclusion." Slip op. at 19. We haven't seen any either.

So Walker is the first appellate court explicitly to hold that the mere assertion of a device malfunction is not, at least under anything approaching ordinary circumstances, enough to establish a "parallel" violation claim. The court provides a narrow escape hatch – that a parallel claim would be established if the FDA had adopted a "performance standard" that set a particular characteristic as an absolute floor the non-attainment of which, without more, constitutes a violation. That's all well and good, but such device-specific "performance standards," if not quite as rare as hen's teeth, come close. We've only seen one even asserted in any of the post-Riegel device preemption cases we've read (and we think we've read them all). Burgos v. Satiety, Inc., 2011 WL 1327684, at *5 (E.D.N.Y. Apr. 5, 2011), and even there it wasn't sufficiently described that we could be sure such a thing actually existed.

Thus, while we'd rather not have a "parallel" requirement exception to preemption at all (they're disguised attempts at private enforcement of the FDCA, which the statute bans), if we have to have one, the articulation in Walker – requiring the presence of a "performance standard" – is the kind of bright line we can live with.