



Sales Reps in the OR

By Edward W. Gerecke
and David J. Walz

A new beat
to an old tune.

The Hunt for Non-Preempted Claims

Suing a drug and device manufacturer's representative has always been a popular tactic. After all, such lawsuits offer one of the best ways to destroy diversity jurisdiction and keep a case out of federal court. Making a sales representa-

tive a defendant and not just a fact witness, at least until the one-year removal deadline, also increases defense costs and complicates discovery about training, product promotion, and physician interaction.

Events in medical device cases during recent years have only increased the allure that these claims hold for the plaintiffs' bar. The United States Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), was the catalyst. *Riegel* covers devices approved under the premarket approval process and addresses preemption under the Medical Device Amendments of 1976 (MDA) to the Food, Drug, and Cosmetic Act (FDCA). *Riegel* decided that the MDA preempted state law claims that impose requirements relating to safety or effectiveness that are "different from, or in addition to" federal requirements. As a result, claims against manufacturers of devices approved under the premarket approval process are far more difficult to plead, let alone prove.

Riegel specifically declined, however, to reach the issue of "parallel claims" that are "premised on a violation of FDA regulations." *Id.* at 1011. Such claims may survive preemption arguments. Thus, the post-*Riegel* battle focuses on whether a plaintiff can state a viable parallel claim. Plaintiffs have had little luck pleading many such claims against manufacturers directly. Courts around the country have dismissed many claims as preempted. Other cases have met a similar fate upon summary judgment.

In response, plaintiffs have increasingly turned their attention to sales representatives in the hunt for claims that will survive preemption arguments. Depending on the circumstances, representatives may interact with physicians on highly patient- or case-specific bases. With many devices, representatives may provide technical support to a surgeon in the operating suite. Actions by representatives offer rich, possible targets for creative plaintiffs' lawyers



■ Edward W. Gerecke is a shareholder and David J. Walz is an associate in the Tampa, Florida, office of Carlton Fields. Mr. Gerecke's practice involves product liability and mass tort litigation, with a particular focus on pharmaceutical and medical device litigation. He is a member of DRI's Drug and Medical Device Steering Committee. Mr. Walz's practice focuses on product liability claims, primarily pharmaceutical litigation and the defense of actions involving prescription and over-the-counter products. He is a member of the DRI Young Lawyers Publications Subcommittee and the Florida Defense Lawyers Association.

seeking to evade *Riegel*. As a result, plaintiffs' attorneys are leaving no stone, and virtually no claim, no matter how novel, unturned in their search for claims against manufacturers' representatives that will defeat *Riegel*'s preemption holding.

Troublesome Cases Exist

Plaintiffs do have authority supporting

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their arguments. *Adkins v. CYTYC Corp.*, No. 4:07CV00053, 2008 WL 2680474 (W.D. Va. July 3, 2008), is probably the most problematic case. In *Adkins*, a manufacturers' representative attended the plaintiff's surgery and "advised and directed [the surgeon] on the proper way to measure the size of [the plaintiff's] uterus and to test the integrity of her uterine wall, which is necessary before using the device." *Id.* at *1. Later measurements, after the plaintiff suffered injuries during the procedure, indicated not only that the presurgery measurements were incorrect, but that the correct measurements would have "preclude[d] use of the device." *Id.*

The plaintiff alleged an agency theory of liability against the manufacturers for the "negligent warnings or instruction of the surgeon by defendants' [] representative." *Id.* The claim alleged that the representative had a duty to ensure that the device worked correctly and that the surgeon followed proper procedures for using the device. The plaintiff claimed that the representative breached that duty when the surgeon incorrectly measured the uterus while "relying on the representations of the corporate agent... for how to perform the measurement." *Id.*

While the court dismissed the product liability claims against the manufacturers, it declined to dismiss the claim related to the representative's actions, stating that the

"claim is not governed by *Riegel*'s preemption holding." *Id.* at *2. The reasoning that the court applied is particularly troubling:

The FDA does not regulate interactions between corporate representatives and physicians on-site at a particular surgery, and where it does not mandate special physician training for a drug, it does not specify how such an interaction at surgery must be performed. These localized situations are traditional matters for the common law, not the FDA's regulatory approval process. Such a claim does not challenge the design, manufacture, and labeling of the [] device so as to implicate *Riegel* preemption, but rather challenges negligence by a corporate agent acting as a *de facto* physician's assistant during a surgical procedure.

Id. at *3.

Thus, under *Adkins*, a representative's actions are essentially unregulated activities falling wholly outside the *Riegel* holding's realm. If a court follows the reasoning in *Adkins*, then it appears that virtually any claim based upon a representative's actions might survive preemption.

Another problematic case is *William Beaumont Hosp. v. Medtronic, Inc.*, No. 09-CV-11941, 2009 WL 2849546, at *7 (E.D. Mich. Aug. 31, 2009). In *William Beaumont*, the plaintiffs claimed that the manufacturer's representative sent a free sample to the wrong hospital department. Although recognizing that "[the defendant] correctly argues that any claim by [plaintiffs] premised on an inadequate warning label is preempted by the [MDA]," the court carved out an exception based upon the representative's action:

Plaintiffs' claim alleging joint liability is premised on [the defendant's] alleged negligence in sending free samples to an anesthesiology department at a hospital and holding the samples out for use in a refill procedure, when in fact one of the samples was not intended for such use and should not have been sent to an anesthesiology department. Plaintiffs do not allege a failure to adequately warn claim.... The adequacy of the label is not the basis for [the plaintiffs'] allegations of [the defendant's] negligence.

Id.

In effect, the representative's error placed the claim beyond *Riegel* preemp-

tion. As with *Adkins*, reasoning along these lines makes it difficult to understand how a state law claim implicating a representative would ever impose requirements "different from, or in addition to" federal requirements.

A Study in Theories of Liability and Preemption

Armed with the authority discussed above, plaintiffs have the incentive to allege a slew of theories against manufacturers' representatives in the hopes that at least one theory might stick just enough to bypass *Riegel*. The facts and resulting claims in *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270 (M.D. Fla. 2009), offer an example and are useful in examining the types of theories presented in cases that deal with preemption.

In *Wolicki-Gables*, one of the plaintiffs, Linda Wolicki-Gables, suffered from chronic pain and chose to have a pain pump implanted to deliver pain medication directly into her spinal canal. The pump had two modes of operation: (1) a continuous-infusion function that delivered pain medication in a slow, continuous release; and (2) a bolus function that allowed a physician to inject a bolus, a single, larger quantity of medicine, directly into the spinal canal. The manufacturer's representative attended the implant procedure and delivered the pain pump. For more than one year, the pump functioned properly.

Then, during a routine test, Ms. Wolicki-Gables' physician concluded that the pump's bolus function might not be working as expected. The physician contacted the same manufacturer's representative and scheduled a revision procedure to replace the pump. Before that procedure, Ms. Wolicki-Gables executed an informed consent form and specifically refused to consent to the admission of "persons required for technical support to the room in which the procedure [was] performed." *Id.* at 1278. In the same form, Ms. Wolicki-Gables also refused to "consent to the disposal of any tissues or body parts... removed in accordance with customary practice" and wrote in, with her initials, "We want old pump." *Id.*

Unaware of the consent form, the manufacturer's representative attended the revision procedure. During the procedure, the

physician cut a catheter connector between the pump and the spinal canal, after which the bolus function worked properly. The doctor replaced only that catheter connector and reimplanted the original pump. Absent “a request to save or test the part,” the surgical facility typically discarded parts as surgical waste. *Id.* According to the plaintiffs, the representative told them that he was in the operating room during the procedure, took the removed catheter connector with him afterward, and returned it to the manufacturer for testing. Also according to the plaintiffs, the representative later informed them that, in accordance with policy, the manufacturer destroyed the removed catheter connector after testing. Two weeks after the revision procedure, Ms. Wolicki-Gables lost feeling in her legs and developed transverse myelitis.

Against that factual backdrop, the plaintiffs amassed an array of negligence-based theories against the representative. First, the plaintiffs claimed that the representative owed a duty to instruct and educate the physician about the pain pump. Second, they alleged that the representative had a duty to ensure that the product was working properly before its implantation. Third, the plaintiffs alleged that the representative had a duty to verify informed consent to his presence in the operating room. Fourth, the plaintiffs alleged that the representative had a duty to verify that plaintiffs consented to disposal of the removed part.

In addition to those direct claims, the plaintiffs, the Wolicki-Gables, opposed the *manufacturer’s* preemption arguments for summary judgment by targeting *only the representative*. The plaintiffs theorized that the representative “should have disallowed the replacement of the connector” only. *Id.* at 1283. Or, the representative should have “suggested replacement of the [complete] pump system.” *Id.* The plaintiffs argued that replacing the connector only, rather than the pump and all catheters and connectors, was not a FDA-approved and authorized use. Therefore, the manufacturer, “through the presence of [the representative] at the [revision] surgery... was directly involved in ‘off-label’ use of the subject product, having provided the replacement connector to [the physician] at that time.” *Id.*

The court rejected all of those theories and held that under *Riegel*, the MDA preempted every claim against the manufacturers—strict liability, negligence, and vicarious liability—and the claim for negligence against the representative. In addressing the argument that the representative should have intervened in the procedure, the court held that it knew of no evidence establishing that the representative had a duty to affirmatively tell the physician while the physician was performing surgery that the physician should not replace only the catheter connector.

On the off-label theory, the court noted that the FDA does not regulate the practice of medicine, and a physician may lawfully “vary the conditions of use from those approved in the package insert.” *Id.* at 1283. The court reasoned that the FDA does not distinguish between on-label and off-label uses. Regarding the representative specifically, the court recognized that the Food, Drug, and Cosmetic Act prohibits off-label promotion, but no private right of action exists to enforce the act. In any event, “a complete absence of evidence” existed as to any claim that, by attending and observing the revision procedure, the representative engaged in “‘off-label’ marketing and promotion.” *Id.* at 1292.

The court’s preemption holding hinged upon the reasoning that a jury could find liability even if the manufacturers followed and complied with all FDA regulations and practices for the device. Hence, the claims imposed requirements “different from, or in addition to” the FDA requirements. Significantly, while the bulk of the preemption analysis focused on the claims directly against the manufacturer, the court adopted the same reasoning and reached the same conclusion regarding the negligence claim against the representative and the accompanying vicarious liability claims.

None of the factual allegations against the representative affected the holding about preemption or amounted to a parallel claim, including the allegations regarding informed consent and the device’s removal. Indeed, the court’s further analysis of those claims and additional reasons for granting summary judgment were only alternative holdings. Instead, the court determined that all of the claims related to the rep-

resentative involved “different from” or “additional” requirements.

In this respect, *Wolicki-Gables* counters the view taken in *Adkins*. The representative-specific claims in *Wolicki-Gables* were in some instances virtually the same as those in *Adkins*: the plaintiffs in both cases argued that the representative owed a duty to instruct or educate the physician and a duty to ensure that the device functioned properly. In other instances, the *Wolicki-Gables* claims were far broader than those in *Adkins*, encompassing consent and spoliation. Yet, regardless of the claims’ breadth, all of the Wolicki-Gables’ claims were preempted. The end result of *Wolicki-Gables* is that, if a state law claim seeks to impose liability for a representative’s actions, but nothing in those actions results in federal regulatory compliance transgressions by the manufacturer or representative, then the state law claim seeks to impose different or additional requirements than those mandated by federal law, and it is preempted.

Additional Defense Arguments

The *Wolicki-Gables* court took a straightforward approach and simply compared the nature of the state law liability and whether it could coexist with complete FDA compliance. While that approach is useful, additional defense arguments exist that build more directly upon *Riegel* and the MDA.

The Reasoning Followed by Cases Such as *Adkins* Is Inconsistent with *Riegel*

The essence of cases such as *Adkins* is that the FDA generally does not regulate physician-representative interaction during surgery. That reasoning ignores several important points. Fundamentally, the FDA *does* regulate manufacturer’s representatives through the premarket approval process. When the FDA approves a medical device under premarket approval, the FDA approves not only the device’s design, manufacturing, and labeling, but also considers whether and how to regulate other areas. As a condition of approval, the FDA may impose various other requirements on the device’s sale and distribution. *See* 21 U.S.C. §360j(e)(1)(B) (The Secretary may impose “such other conditions” on the “sale, distribution, or use” of the device as the Secretary deems appropriate). Those “other condi-

tions” may include training, instructional, or tutorial requirements for physicians that require a representative’s participation or guidance. In turn, those requirements may be set forth in the premarket approval letter and the device’s labeling. For example, regarding devices approved in 2010 alone, the FDA’s website indicates several approval letters stating that “[t]he device is

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further restricted under section 515(d)(1)(B)(ii) of the [FDCA] insofar as the labeling must specify the specific training or experience practitioners need in order to use the device.” See <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm202715.htm> (last accessed on September 20, 2010). The labeling for those devices then states that the physician must attend training conducted by the representative. See *id.* Thus, the FDA makes regulatory choices relating to a representative’s actions and any state law claim that a representative should have conveyed different or additional “other conditions” is preempted.

Similarly, premarket approval imposes specific labeling requirements. See *Riegel*, 128 S. Ct. at 1004–05. “The premarket approval process includes review of the device’s proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, §360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, §360e(d)(1)(A).” *Id.* Therefore, any state law claim that a representative should have communicated other instructions or warnings to a physician is an attempt to impose a requirement “different from, or in addition to” the federal requirements.

Overall, then, if the FDA regulates representatives to the extent of requiring certain

conduct in some situations and choosing not to impose specific requirements in other situations, then a plaintiff’s attempt through a tort claim to require any other conduct must impose a “different from” or “additional” requirement. A court cannot deem that claim “parallel” to federal requirements.

This point recognizes that the federal preemption of claims under *Riegel* is broad and extensive. *Riegel* preemption covers all tort claims related to the “safety and effectiveness” of devices approved under the FDA’s premarket approval process. Notably, *Riegel* covers “all actions” “with respect to” a device. The Court stated:

The MDA provides that no State “may establish or continue in effect *with respect to a device... any requirement*” relating to safety or effectiveness that is different from, or in addition to, federal requirements. The [plaintiffs’] suit depends upon [state law] “continu[ing] in effect” general tort duties “with respect to” [defendant’s device]. Nothing in the statutory text suggests that the pre-empted state requirement must apply *only* to the relevant device, or only to medical devices and not *to all products and all actions in general.*

Riegel, 128 S. Ct. at 1010 (last emphasis added).

Preemption under *Riegel* also applies expansively to the range of liability theories pursued by plaintiffs. *Riegel* means that the MDA not only preempts claims for strict liability and breach of implied warranty, but a wide range of negligence-based claims, including “negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the [device].” *Id.* at 1006. Even tort claims related only slightly to a device itself are preempted under *Riegel*.

For example, claims that impose “state-law requirements of general import, which regulate a medical device only incidentally, are subject to federal pre-emption in the same way as those state-law requirements which specifically target the device in question.” *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at *7 (M.D.N.C. Aug. 5, 2009). Any other application is contrary to the MDA because “the fact that a state-law ‘requirement’... may regulate a medical device only incidentally

[is] too slight a distinction to merit excluding that requirement from preemption under the MDA, especially given the ‘unusual breath’ [sic] of the language Congress used in drafting the MDA, which is to be interpreted ‘expansively.’” *Id.*

This view of preemption as covering “all actions” regarding a device encompasses not only the actions typically alleged against representatives who have had surgical interaction, but some of the more novel claims, such as off-label use and failure to report adverse events, as well. Regarding off-label allegations, they should fail because that use still falls within MDA preemption when devices have been approved under the FDA’s premarket approval process. See, e.g., *Cornett v. Johnson & Johnson*, 2010 WL 2867811, at *17, *20 (N.J. Super. A.D. July 23, 2010) (holding that off-label use is regulated by the FDA premarket approval process and the FDCA and noting that *Riegel* itself involved an off-label use); *Wheeler v. DePuy Spine, Inc.*, No. 06-21245, 2010 WL 1539855, at *4 n.3 (S.D. Fla. Mar. 9, 2010) (rejecting the argument “that [d]efendant failed to comply with conditions of the PMA by permitting usage of two discs in a patient”).

Likewise, allegations that a representative failed to report adverse events should not negate preemption. Rather, those allegations should fail for the same reasons that similar allegations against manufacturers fail. See, e.g., *Heisner v. Genzyme Corp.*, No. 08-C-593, 2009 WL 1210633, at *2 (N.D. Ill. Apr. 30, 2009) (failure to report information to the FDA is not a “defect”); *Lake v. Kardjian*, 874 N.Y.S.2d 751, 755 (N.Y. Sup. Ct. 2008) (alleged failure to comply with “reporting requirements does not constitute a ‘parallel claim’... because such an allegation would merely be an attempt to recast plaintiff’s state law claims as violations of federal statutes”).

Favorable Decisions in Analogous Contexts Support Broad Preemption

In many instances, the case against a manufacturer’s representative really boils down to a claim for “failure to train my physician.” Courts hold those claims preempted. For example, in *Mattingly v. Hubbard*, No. 07CI12014, 2008 WL 3895381 (Ky. Cir. Ct. July 30, 2008), the court held failure-to-train-the-physician claims preempted as

a requirement “in addition to” the FDA’s requirements. The plaintiff “argue[d] that his negligence claims are unaffected by *Riegel* since they relate to [the defendant’s] training of physicians rather than its FDA approval for or manufacturing of the [device].” *Id.* While noting the argument that “claims of negligent failure to train physicians properly is separate from the FDA approval process,” the court rejected the plaintiff’s reasoning and held instead “that such a claim would nonetheless impose an additional substantive requirement for a specific device.” *Id.* In fact, “[g]eneral tort duties of care... directly regulate the device itself” and “such requirements are preempted.” *Id.*

Even before *Riegel*, courts held such claims preempted. In *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 931 (5th Cir. 2006), the plaintiff claimed “that the material [that the defendant] supplied to train in the use of the [device] were [sic] inadequate.” Nonetheless, the court held that the claims were preempted because “[t]o permit a jury to decide [] claims that information, warnings, and training material the FDA required and approved through the PMA process were inadequate under state law would displace the FDA’s exclusive role and expertise in this area and risk imposing inconsistent obligations.” *Id.*

Thus, casting a plaintiff’s allegations as failure-to-train or failure-to-instruct

claims provides another route to secure preemption. As in *Mattingly* and *Gomez*, imposing liability against a representative constitutes a different or additional requirement beyond anything required by the FDA. Hence, courts should hold those claims preempted.

A Plaintiff Still Must Sufficiently Plead the Claim

Finally, as a fallback position even if *Adkins* applies, a plaintiff still must meet the pleading requirements under *Iqbal* and *Twombly*. Although the *Adkins* court concluded that *Riegel* did not apply to the claims against the manufacturer’s representative, the court dismissed those claims anyway, albeit with leave to amend. The court reasoned that the complaint lacked “any facts that explain what [d]efendants’ representative did or failed to do as part of his alleged duty,” so that nothing “more than mere suspicion of a cognizable right of action” existed. *Adkins*, 2008 WL 2680474, at *3. Pleading only “that defendants’ agent failed to ‘take the necessary steps’ to protect [the plaintiff] from the [] device” was insufficient because it left the “necessary steps... entirely to the imagination of the [c]ourt.” *Id.*

Therefore, even under *Adkins*, a plaintiff still must pass an initial hurdle. *Adkins* settled and was dismissed before the plaintiff filed an amended complaint, so the case offers no guidance on what allega-

tions against the representative would be sufficient. Nonetheless, challenging such claims at the pleadings stage regarding whether they allege sufficient facts against the representative specifically may be the key to defeating representative-based claims when a court seems inclined to follow *Adkins* on preemption. Indeed, as *Riegel* preemption develops, courts have grown accustomed to addressing preemption issues at the motion-to-dismiss stage. See, e.g., *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 789 (D. Minn. 2009); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282–84 (E.D.N.Y. 2009). Thus, even if a preemption argument does not apply to the representative under *Adkins*, a court may still be ready to examine the pleading of that claim while considering and dismissing other claims.

Conclusion

No matter how many claims a plaintiff might allege involving a manufacturer’s representative, under whatever factual allegations and asserting whatever theories of liability, those claims almost inevitably attempt to impose some requirement that is “different from, or in addition to” federal requirements. The claims also almost invariably challenge some action “with respect to” the device. As a result, no matter how novel the claim itself, under *Riegel* federal law should preempt it. 