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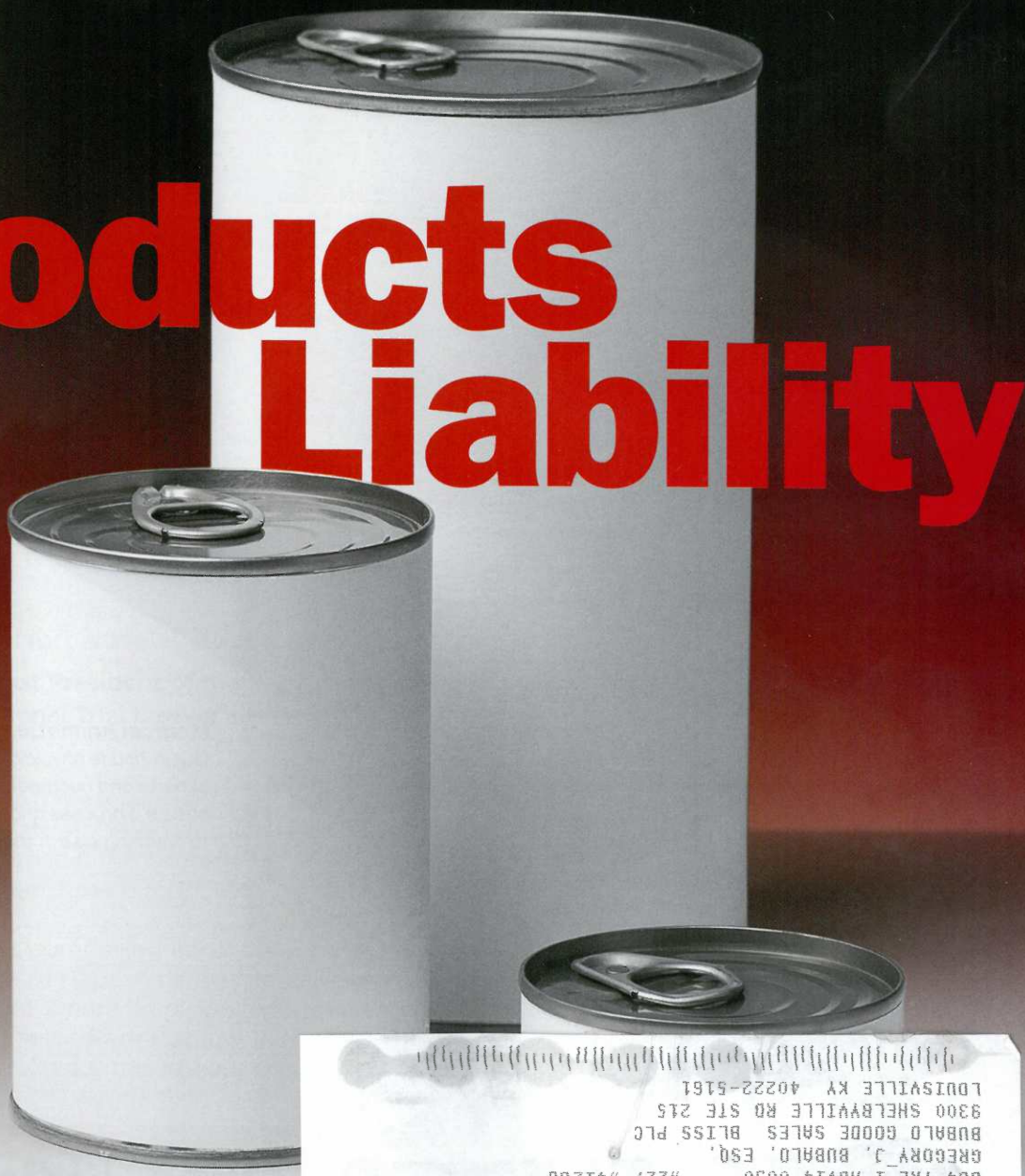

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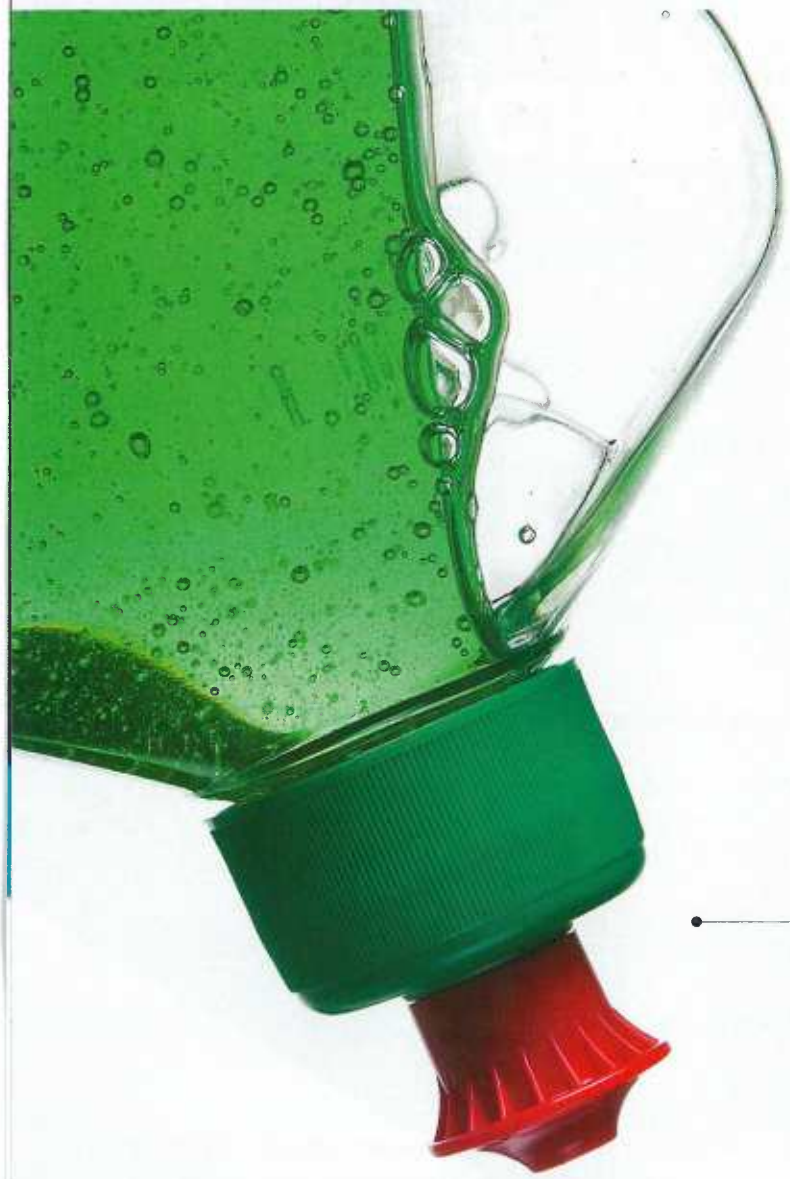

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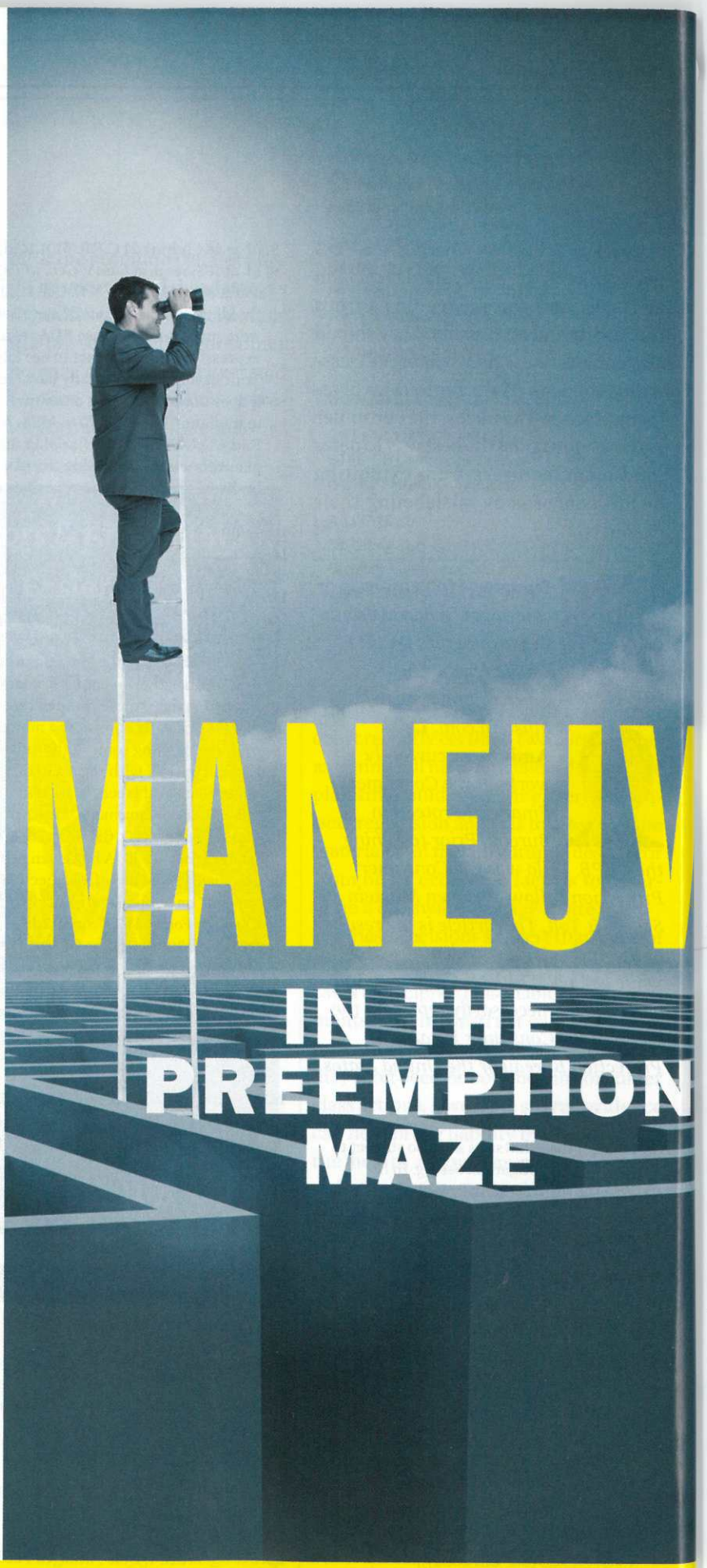


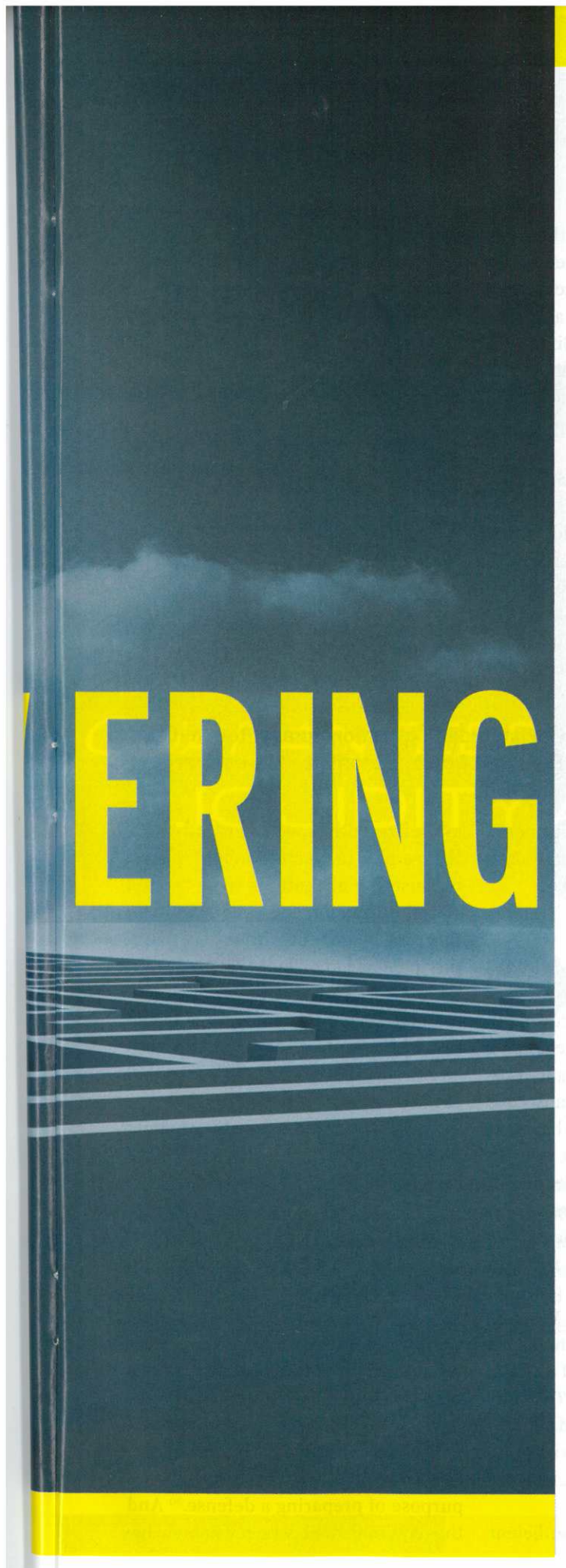
MANEUVERING IN THE PREEMPTION MAZE

A 2008 Supreme Court decision left a trail of problems for plaintiff attorneys bringing medical device cases. Start prepping for the defense's motion to dismiss before you even file the complaint.

Some of the world's largest drug and device makers have faced billions of dollars in criminal fines for promoting, marketing, and selling their products "off label"—for uses the FDA has not approved. Medtronic, Inc., is one of these companies, and injuries from its Infuse bone graft device have spurred hundreds of lawsuits across the country.

These lawsuits allege traditional state law claims for injuries caused by Medtronic's off-label marketing. The facts supporting these common law theories of recovery are parallel with Medtronic's repeated violations of FDA regulations and the Federal Food, Drug, and Cosmetic Act prohibiting such off-label marketing. So it strains credulity that Medtronic claims immunity based on the Medical Device Amendments of 1976 (MDAs) express preemption provisions[1] as applied in *Riegel v. Medtronic, Inc.*, where the U.S. Supreme Court held that state law claims challenging the safety and effectiveness of a device receiving FDA premarket approval were preempted.[2] Although victims of Medtronic's scheme have had some notable victories,[3] Medtronic has had some alarming successes.[4] To get through the labyrinth of *Riegel* and preemption, you need to start preparing for the defendant's

By || **Gregory J. Bubalo and Leslie M. Cronen**



WAVEBREAK/GETTY IMAGES

arguments even before you file the complaint. Here are some guideposts to help you draft a complaint and survive the inevitable pre-answer motion to dismiss.

In 1996, Medtronic began clinical studies of bone morphogenetic protein (BMP), a purified protein used to treat bone and cartilage defects, to try to grow bone between vertebrae for use in spinal fusion surgeries. Medtronic hoped BMP would eliminate the need to use the patient's own bone (usually taken from the hip) to stimulate bone growth.

The company anticipated that BMP would be used in all types of common spinal fusion surgery. But in 1999, one part of the clinical trial was halted when 75 percent of patients undergoing posterior approach surgery (incision from the back) grew excess bone pressing against the spine and nerve roots, which could potentially lead to serious injuries. As a result, BMP was considered safe and effective for only a very limited type of surgery: anterior lumbar interbody fusion, where the BMP is inserted through an incision in the stomach into the front of the spine, with a specially designed surgical cage to prevent excess bone growth.

In 2002, Medtronic obtained premarket approval for Infuse as a Class III device consisting of two components: BMP soaked into a collagen sponge (BMP sponge) that is inserted into the second component, the LT-Cage, a hollow, titanium cylinder. Although the sales market for the device was supposed to be limited based on its approved use, up to 85 percent to 90 percent of its sales were for off-label uses.[5] A June 2011 issue of *Spine Journal* revealed a pattern of injuries caused by Infuse's off-label uses,[6] resulting in consumers filing hundreds of lawsuits in federal and state courts, primarily in Kentucky, Missouri, and Tennessee. Medtronic's primary defense has been to move to dismiss all these cases based on preemption under *Riegel*.

In 1996, Charles Riegel underwent a coronary angioplasty to dilate a blocked artery in his heart after a heart attack. His doctor used the Evergreen balloon catheter—a Class III device that received FDA premarket approval—but the approved label contraindicated such a use with patients having diffuse or calcified stenosis, like Riegel. The catheter ruptured, and Riegel was placed on life support and underwent bypass surgery. Riegel and his wife filed a products liability lawsuit against Medtronic based on violations of New York law. The district court granted Medtronic summary judgment, and the Second Circuit affirmed.

In affirming the dismissal of Riegel's state law claims, the Supreme Court formulated two basic questions to determine whether a state law products liability claim must be dismissed based on the MDA's express preemption provisions. The first question is: Has the federal government established requirements applicable to a particular medical device or "device-specific" requirements?[7] Preemption cannot apply if no such regulatory requirements exist. Second, if device-specific requirements exist, do the plaintiffs' claims impose duties on the defendant different from or in addition to those under federal law?[8] State law claims that do not contain different or additional requirements are

parallel claims and are not preempted.[9] But the "contours of the parallel claim exception were not addressed in *Riegel* and are as-yet ill-defined."[10]

Venue Challenges

Without more definite guidance from the Supreme Court, results have varied greatly among U.S. courts, from finding all the plaintiffs' claims preempted[11] to finding none preempted.[12] And some courts have declined to preempt claims based on the first step of *Riegel*, concluding that no device-specific requirements attach to off-label Infuse promotion.[13] Others have reached the same conclusion but based on parallel claims.[14]

Eleventh Circuits have been the most restrictive to plaintiffs by requiring that the defendant must violate device-specific requirements to assert a parallel claim.[21] In contrast, the Fifth, Sixth, and Seventh Circuits have ruled that parallel claims may be based on violations of generalized federal requirements applicable to all medical devices.[22]

Despite this conflict, the Supreme Court recently denied certiorari in a case interpreting *Riegel*.[23] After Medtronic filed its cert petition in that case, U.S. Solicitor General Donald Verrilli submitted an amicus brief discussing how most courts incorrectly apply the first step of the *Riegel* analysis and wrongly conclude that any device-specific requirements impose across-the-board preemption—a position favorable to plaintiffs.[24]

Medtronic has argued that even if diversity jurisdiction does not exist, federal questions presented in its preemption defense justify federal jurisdiction, despite Supreme Court authority to the contrary.

Plaintiffs laboring to overcome preemption will need to fight for their choice of forum. As a general rule, state courts have been more favorable to plaintiffs; they still apply notice pleading[15] and may not have been influenced by the Supreme Court's decisions in *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal*, which collectively require a heightened pleading standard of factual plausibility for claims to survive a motion to dismiss.[16] Infuse cases illustrate how desperate defendants are to stay out of state court. Medtronic has argued that even if diversity jurisdiction does not exist, federal questions presented in its preemption defense justify federal jurisdiction, despite Supreme Court authority to the contrary.[17] Most courts have rejected this argument,[18] although Medtronic has had some success.[19] Plaintiffs have found forums in state courts to proceed based on a lack of diversity.[20]

The various circuits have diverse views of *Riegel*, which has contributed to venue challenges. The Eighth and

Crafting the Complaint

Riegel preemption generally cannot be avoided if you file only pro-forma products liability causes of action and include bare-bones factual allegations. You must anticipate the defendants' pre-answer motion to dismiss. You must have detailed knowledge of the facts based on publicly available sources that you can access prelitigation; applicable federal statutory and FDA regulatory provisions; and case law interpreting *Riegel* and preemption. For instance, we recently filed a master complaint for a group of 43 Infuse cases pending in the Western District of Tennessee.[25] The complaint is 188 pages long and contains 101 exhibits to ensure compliance with the *Twombly* and *Iqbal* plausibility standard. Nevertheless, Medtronic probably will argue that the complaint has insufficient detail to withstand *Riegel*.

How can plaintiffs obtain sufficient detail before discovery, especially when the bulk of the facts are in the defendants' or third parties' possession? Our master complaint was based on publicly available documents,[26] but there are other possibilities to consider.

Alleging fraud or misrepresentation. Fraud in selling Infuse has been generally accepted as a parallel claim that will not be preempted. But alleging fraud with "particularity" has been a heavy burden. In *Lawrence v. Medtronic, Inc.*, a Minnesota court dismissed all causes of action that were parallel to off-label marketing allegations, finding them preempted.[27] However, the court dismissed the fraud actions without prejudice with leave to amend "with the requisite particularity," partly because the allegations were "stated upon information and belief, signaling that they [were] not within [the] plaintiffs' personal knowledge."[28] Particularity in *Lawrence* required the plaintiffs to personally know the details of the fraud before any discovery. With such an extreme rule, you may face an uphill battle in some jurisdictions.

Plaintiffs may not be able to meet *Lawrence*'s particularity standards early in litigation, before discovery. On its face, the particularity rule is similar among state and federal courts—most courts require who, what, when, and where. But courts apply that rule inconsistently. Some have found complaints contained sufficiently particular allegations of fraud,[29] but those same allegations were deemed insufficient in *Lawrence*. The more liberal interpretation applies the rule of particularity to give only fair notice to the defendants for the purpose of preparing a defense.[30] And the requirement of personal knowledge

appears nowhere in Fed. R. Civ. P. 9(b) or in equivalent state civil procedure rules.

When pleading fraud claims, you often can obtain the specific details you need with a little legwork, such as interviewing witnesses or uncovering information from public sources. However, in medical and products liability cases, like Infuse, the misrepresentations are seldom made directly to the plaintiff. They usually are made to the doctors who were misinformed about the drug's true risks when advising the plaintiff and recommending a treatment. Interviewing the prescribing doctor before filing your complaint is ideal, but frequently, this is impossible because of time restraints or prescribing doctors' reluctance to speak to an attorney without a subpoena. In such cases, allegations based on "information and belief" should be sufficient to give the defendant notice of the claim. In *Lawrence*, it was not. In those circumstances, it is vital for you to argue to the court that discovery is necessary before ruling on a motion to dismiss, because knowledge is either in the defendants' or third parties' sole possession, inaccessible presuit to the plaintiff.

The need for discovery. In the past, some plaintiffs disclaimed the need to conduct discovery in opposing defendants' pre-answer motions to dismiss.[31] Many times, however, the defendants possess information those plaintiffs needed to make their case, because under federal law, much of the information disclosed in the premarket approval process for the device is confidential.[32] Formal discovery is often necessary to fill in the details of your clients' claims. As a result, courts frequently must consider matters outside of the pleadings, which, under Fed. R. Civ. P. 12(d), places the pre-answer motion to dismiss within the orbit of summary judgment. Rule 12(d) recognizes that "parties must be given a reasonable opportunity to present all the material that is pertinent to the motion."[33] Rule 56(d) further solidifies Rule 12(d) by allowing the court to defer ruling on the motion until the parties can conduct discovery. Many state courts have held that a pre-answer motion to dismiss in a complex case, without discovery, in and of itself precludes dismissal,[34] especially considering that "federal preemption is an affirmative defense upon which the defendants bear the burden of proof."[35] Pursuant to Rule 12(d), we have asked courts to delay ruling on pre-answer motions to dismiss before allowing discovery, especially if such discovery can be specifically targeted.

FDA regulatory experts can help you craft the sections of the complaint that should be devoted to explaining the applicable regulations.

Federal regulations and experts. We strongly suggest consulting FDA regulatory experts before filing the complaint, although it is costly. They can help you craft the sections of the complaint that should be devoted to explaining the applicable regulations, including how these regulations apply to the case. For instance, our Infuse master complaint contained a detailed explanation of why the device's premarket approval requirements are not applicable to the device's separate components. Only the first Infuse component, the BMP sponge, was implanted into the plaintiffs, so Medtronic was promoting a device different and distinct from Infuse. The FDA defined and approved Infuse as a combination device, and completely different FDA regulations apply to its separate components.[36] These allegations support our contention that the first step of *Riegel* could not be satisfied, because the premarket approval restrictions do not apply solely to the separate Infuse components.

Parallel Claims

You must cite specific federal regulatory requirements in your complaint showing how the alleged state law claims will not expand the defendants' duties beyond their federal boundaries. For instance, negligence claims can be based on duties of care and reasonableness found within the confines of federal law.[37] In *Sadler v. Advanced Bionics, Inc.*, a federal district court held that duties of care under Kentucky law to test a product before marketing a design change run parallel to federal duties prohibiting marketing such changes contrary to the design the FDA specifically approved during the premarket approval process.[38] The court recognized that Kentucky products liability actions (both for strict liability and negligence) may be based on duties of care and reasonableness evidenced through federal law and FDA regulations.[39]

Sadler shows the error in other cases where the courts preempted all state law claims based on the assumption that the premarket approval process's federal prohibitions against off-label promotion are "not genuinely equivalent to the

MORE ON MEDICAL DEVICES AND PREEMPTION

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AAJ LITIGATION GROUP
Medtronic Infuse
www.justice.org/litgroups

LITIGATION PACKET
Preemption: A Changing Landscape
www.justice.org/litigationpackets

AAJ EDUCATION PROGRAM
Medtronic Infuse 2014 Annual Convention Program
www.PlaybackAAJ.com

state law requirements . . . [because] it is possible to violate the state law requirement while complying with the federal requirement and vice versa."[40] As the court reasoned in *Sadler*, if the duties under state law are restricted to federal regulatory requirements, it is impossible to be liable under state law but not to violate federal requirements. Most states allow proof of a violation of a safety statute or ordinance to be admitted as proof of negligence.[41] In *Sadler*, the jury was restricted to finding negligence under Kentucky law only to the extent FDA regulations were also violated.

Facing pre-answer motions to dismiss in medical device cases is not easy, but it's a battle that can be won by taking the right path—through the eye of the needle that has become federal preemption.

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Notes

1. 21 U.S.C. §360k(a) (2012).
2. 552 U.S. 312, 321–26 (2008).
3. *See e.g. Hornbeck v. Medtronic, Inc.*, 2014 WL 2510817 at **3–5 (N.D. Ill. June 2, 2014); *see also Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977 (D. Ariz. 2013); *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868 (N.D. Cal. 2013); *Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069, 1096–99 (D. Ore. 2013).
4. *See e.g. Hawkins v. Medtronic, Inc.*, 2014 WL 346622 (E.D. Cal. Jan. 30, 2014); *Kashani-Matts v. Medtronic, Inc.*, 2013 WL 6147032 (C.D. Cal. Nov. 22, 2013); *Ledet v. Medtronic, Inc.*, 2013 WL 6858858 (S.D. Miss. Dec. 30, 2013); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206 (W.D. Okla. 2013); *Dawson v. Medtronic, Inc.*, 2013 WL 4048850 (D.S.C. Aug. 9, 2013).
5. *See* Emily Jane Woo, *Recombinant Human Bone Morphogenetic Protein-2: Adverse Events Reported to the Manufacturer and User Facility Device Experience Database*, 12 Spine J. 894–99 (Oct. 2012); *see also* John Carreyrou & Tom McGinty, *Medtronic Surgeons Held Back, Study Says*, Wall St. J. (June 29, 2011).
6. Eugene J. Carragee, Eric L. Hurwitz, & Bradley K. Weiner, *A Critical Review of Recombinant Human Bone Morphogenetic Protein-2 Trials in Spinal Surgery: Emerging Safety Concerns and Lessons Learned*, 11 Spine J. 471 (June 2011).
7. *Riegel*, 552 U.S. at 319.
8. *Id.* at 321–22.
9. *Id.* at 330.
10. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010).
11. *Caplinger*, 921 F. Supp. 2d 1206.
12. *McDonald-Lerner v. Neurocare Assocs., P.A.*,