

A Powerful Tool  
to Wield Early

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**A** roadmap to express and implied preemption, as well as “best practices” found to be effective, and pitfalls to avoid.

# How to Argue Medical Device Preemption

Federal preemption can be a powerful weapon in the defense practitioners’ arsenal. An early win on preemption can dispose of a case at the threshold, thereby avoiding the burdens and costs of discovery and trial. And a preemp-

tion defense, if it is effective, can secure dismissal as a matter of law in the face of unfavorable facts and sympathetic plaintiffs, regardless of whether the underlying claims are meritorious as a matter of state law. In the medical device context, courts have found preempted all sorts of state law claims, including design defect, manufacturing defect, failure to warn, breach of implied warranty, breach of express warranty, fraud, and consumer protection act claims.

Any attorney defending a product liability action brought by someone who

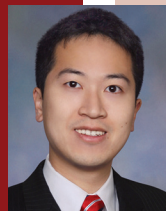
claims to have been injured by a medical device should therefore evaluate the viability of express preemption and implied preemption arguments early. These preemption doctrines can be complex and are the subject of an ever-evolving and expanding body of decisional precedent. This article offers a brief roadmap to these doctrines. It also describes both “best practices” that we’ve found to be effective, and some of the potential pitfalls we’ve learned to avoid, when arguing that federal law preempts state law claims asserted against medical device manufacturers.

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## The Basics of Express and Implied Preemption for Medical Devices

Federal preemption is nothing more—and nothing less—than the Constitution’s Supremacy Clause in action. The Supremacy Clause declares that all constitutionally valid federal laws “shall be the supreme law of the land” and that “the judges in every state shall be bound thereby, anything in the constitution or laws of any state to the contrary notwithstanding.” In other words, federal law trumps—or preempts—state law.

There are two types of preemption: express preemption and implied preemption. Express preemption arises when



Congress has adopted a statute that explicitly displaces state law. Implied preemption arises, whether or not Congress has explicitly displaced state law, when federal law occupies the entire regulatory field, leaving no place for state law, or when state law would conflict with federal law, either because simultaneous compliance with federal and state law is impossible or because state law thwarts the federal statutory scheme.

Both types of preemption are relevant in the medical device context. The Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA) contain an express preemption provision, 21 U.S.C. §360k(a), which was authoritatively construed by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 316 (2008). The FDCA also contains a no-private-right-of-action clause, 21 U.S.C. §337(a), which, the Supreme Court held in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), impliedly preempts state law actions that attempt to enforce provisions of the FDCA.

### **Express Preemption: §360k(a) and *Riegel***

Let's begin with §360k(a). The MDA, enacted in 1976, granted the FDA authority to regulate medical devices, and created a comprehensive "regime of detailed federal oversight." *Riegel*, 552 U.S. at 316. Congress sought to ensure that safe and effective innovative medical devices would be readily available to treat patients in need of life-saving or disability-averting care. Specifically recognizing the "undue burden[]" imposed by differing state regulation, Congress adopted a general "prohibition on non-Federal regulation" of medical devices by incorporating an express preemption clause into the Medical Device Amendments. H.R. Rep. No. 94-853, at 45 (1976). That provision, §360k(a), expressly preempts any claim that imposes a *state law* "requirement" with respect to a medical device that is "different from, or in addition to" a *federal* requirement imposed by the FDA.

Because it preempts all claims that would impose state law requirements "different from, or in addition to" the applicable federal requirements, and not merely those that would impose state law requirements that conflict with the fed-

eral requirements, §360k(a) has broad preemptive force. That said, it is important to note that §360k(a) does not apply to all medical devices. Rather, as interpreted by the Supreme Court in *Riegel* and an earlier case, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), §360k(a) applies only to devices designated as "Class III" devices under 21 U.S.C. §360c—*i.e.*, those that support or sustain human life or otherwise present a potentially unreasonable risk of illness or of injury—and more specifically to only those Class-III devices that have received Premarket Approval (PMA) pursuant to 21 U.S.C. §360e. By contrast, §360k(a) does not preempt claims made with respect to Class-III devices marketed pursuant to the so-called §510k process.

In what follows, then, we'll deal exclusively with Class-III devices that have Premarket Approval—what we'll refer to as PMA-approved medical devices. Only a small fraction of the Class-III medical devices that enter the market each year are approved through the PMA process. *Riegel*, 552 U.S. at 317. Such medical devices are subject to a rigorous "federal safety review" by the FDA before being sold. *Id.* at 323. As the U.S. Supreme Court explained in *Riegel*, "[t]he FDA spends an average of 1,200 hours reviewing each [premarket approval] application and grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* at 318 (internal citation omitted). To obtain FDA approval for a device via the PMA process, a manufacturer must typically submit a multi-volume application that includes "full reports of all studies and investigations of the device's safety and effectiveness"; a "full statement of the device's components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; and "samples or device components required by the FDA[]" and a specimen of the proposed labeling." *Id.* at 317–18. The FDA closely scrutinizes each premarket approval application, "weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* at 318 (quoting 21 U.S.C. §360c(a)(2)(C)).

Once a device has received Premarket Approval, the manufacturer is forbidden "to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 531 U.S. at 319. This means that a PMA-approved medical device is subject to device-specific federal requirements and that any claim is therefore expressly preempted under §360k(a) if it relies upon or seeks to impose a state law "requirement" that is "different from, or in addition to" those federal requirements. As the Supreme Court made clear in *Riegel*, *state law tort claims*, as well as explicit state regulation, can be said to impose "requirements." The Court's reasoning was straightforward: A state's "requirements" include the duties imposed by its tort law, because liability in tort is "premised on the existence of a legal duty," and a tort judgment against a medical device manufacturer necessarily establishes that the manufacturer has violated a state law obligation with respect to the device. *Riegel*, 552 U.S. at 324. *Riegel* confirmed that, by enacting §360k(a), Congress expressly preempted *any* state law claim that challenges the design, manufacturing, testing, marketing, or labeling of a PMA-approved medical device that complies with the terms of its PMA approval because success on such a claim would require a jury to determine that the device at issue should, *as a matter of state law*, have been designed, manufactured, tested, marketed, or labeled in a manner that either adds to, or differs from, the manner required by *federal law*. *Id.* at 326–27.

The takeaway point is that express preemption under §360k(a), as authoritatively construed by the Supreme Court in *Riegel*, is a powerful, broad doctrine. Congress determined that PMA-approved medical devices should not be subject to either differing or additional state law requirements. And by virtue of the Supremacy Clause, §360k(a)'s command must be obeyed by all courts, state and federal.

### **Implied Preemption: §337(a) and *Buckman***

Even when a state law claim against the manufacturer of a medical device isn't expressly preempted because it doesn't seek



to impose any different or additional state law requirements on the device, it still might be *impliedly* preempted by federal law. The Supreme Court has held that an express preemption provision does not “bar the ordinary working of conflict preemption principles.” *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000). In the specific context of the federal regu-

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latory scheme governing medical devices, there’s a statutory provision that provides a “hook” for implied preemption, 21 U.S.C. §337(a). Section 337(a) specifies that all proceedings to enforce the Food, Drug, and Cosmetic Act, of which the Medical Device Amendments are a part, “shall be by and in the name of the United States.” As the Supreme Court has stated, §337(a) “leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions” of federal law. *Buckman*, 531 U.S. at 349 n.4.

Section 337(a)’s prohibition against private enforcement actions reflects Congress’s intent that the Medical Device Amendments (and the Food, Drug, and Cosmetic Act more generally) be enforced exclusively by the federal government. The FDA has the authority to investigate violations of the Act and “has at its disposal a variety of enforcement options that allow it to make a measured response” to any wrongdoing that it uncovers. *Buckman*, 531 U.S. at 349. Those remedies include “injunctive relief, 21 U.S.C. §332, and civil penalties, 21 U.S.C. §333(f)(1)(A); seizing the device, [21 U.S.C.] §334(a)(2)(D); and pursuing criminal prosecutions, [21 U.S.C.] §333(a).” *Id.* Thus, as the Supreme Court

recognized in *Buckman*, “the federal statutory scheme amply empowers *the FDA* to punish and deter” violations of the FDCA. 531 U.S. at 348 (emphasis added).

Not only does the FDA have significant enforcement power, but it also has “complete discretion” in deciding “how and when [its enforcement tools] should be exercised.” *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). That administrative discretion is an important aspect of the federal regulatory scheme because the agency must use its authority “to achieve a somewhat delicate balance of statutory objectives.” *Buckman*, 531 U.S. at 348. Thus, as the Supreme Court recognized in *Buckman*, state law claims that seek to enforce the FDCA and its implementing regulations are impliedly preempted because they would usurp the FDA’s exclusive enforcement authority under §337(a) and thereby conflict with the federal regulatory scheme.

Taken together, express preemption and implied preemption can serve as a one-two punch knocking out plaintiffs’ state law claims. As the Eighth Circuit put it, “*Riegel* and *Buckman* create a narrow gap through which a plaintiff’s state law claim must fit if it is to escape express or implied preemption.” *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010). We’ll have more to say later about that “narrow gap,” and about how preemption arguments are most effectively presented to courts.

### Practice Pointers for the Express-Preemption Argument

Preemption makes many courts uncomfortable. They see preemption as a way for defendants to avoid liability, often in cases involving sympathetic plaintiffs. They fear a regulatory void, where without the threat of jury verdicts, manufacturers will run wild, designing unsafe products that are manufactured shoddily and marketed recklessly.

Therefore, when asserting a preemption defense, defendants should educate the court on the nature and challenges of Class III medical devices that, by definition, come with an inherent risk of failure and a potentially “unreasonable risk of injury.” In short, defendants must establish that in the context of Class III medical devices, failure and even serious injury does not equate to an actionable product “defect.”

Further, defendants should reassure the court that preemption neither absolves device manufacturers of accountability for their conduct nor jeopardizes public health by allowing unduly dangerous products to be sold. This can be done, in part, by explaining the federal government’s extensive civil and criminal enforcement powers. Defendants should also take pains to emphasize that PMA-approved medical devices aren’t like most products on the marketplace. They’re subject to a rigorous approval process by the FDA, which creates detailed federal requirements as to the design, manufacture, and labeling of such devices. Accordingly, to say that the plaintiff can’t proceed with his or her state common-law tort claims because they’re preempted under §360k(a) isn’t to give the device manufacturer a free pass. Rather, it is to say that a manufacturer who passes through one crucible (PMA approval) need not also pass through a second (state tort law). The express preemption provision in the Medical Device Amendments just reflects Congress’s considered judgment that the FDA’s *federal* safety review and the uniform *federal* regulatory regime should be the exclusive means of imposing requirements on such complex, innovative, and life-saving medical devices.

Regardless of the court’s policy preferences, this reflects Congress’s enacted policy, which courts are bound to respect. But it is also helpful to point out that this congressional policy advances public health. Before it grants Premarket Approval to a device, the FDA engages in a cost-benefit analysis in which it weighs the potential benefits of a device against its potential risks. As the Supreme Court explained in *Riegel*, juries are ill-equipped to perform the cost-benefit analysis because they “see[] only the cost[s]” of a device—that is, its potential to cause harm—and are “not concerned with its benefits” because “the patients who reaped those benefits are not represented in court.” 552 U.S. at 325.

With that preliminary observation out of the way, here’s some practical advice for presenting the express-preemption argument in a streamlined and effective way.

### The Basic Structure

One simple but effective way to organize the express preemption argument in a brief



is to start by setting forth the basic test for determining if a given state law claim is preempted, and then proceed to demonstrate that each specific claim is preempted under that test.

Begin by explaining that §360k(a) establishes a two-step procedure for determining if a state law claim is preempted. It's often effective to break out the two-part test under separate headings, especially for a court that is unfamiliar with preemption; doing so pins the plaintiff down and limits what the plaintiff can dispute without seeming foolish.

- **First**, the court must determine whether “the Federal Government has established requirements applicable to” the particular medical device. *Riegel*, 552 U.S. at 321. The key point here is that the Supreme Court has held that claims involving a medical device that has received Premarket Approval from the FDA automatically satisfy the first condition of this test for preemption. See *Riegel*, 552 U.S. at 322–23; *Walker v. Medtronic, Inc.*, 670 F.3d 569, 577 (4th Cir. 2012); *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300–01 (11th Cir. 2011).
- **Second**, the court must determine whether the state law claim would impose “requirements with respect to the device that are ‘different from, or in addition to’” *Riegel*, 552 U.S. at 322 (quoting 21 U.S.C. §360k(a)(2)). The key point here is that the Supreme Court has held that state-law claims—whether statutory or common law—do impose requirements “with respect to devices” for purposes of this express-preemption provision. *Riegel*, 552 U.S. at 327.

The crucial point to convey is that *Riegel* stands unequivocally for the proposition that §360k(a) expressly preempts any state law cause of action that would impose a requirement on a PMA-approved device that is “different from, or in addition to” the federal requirements imposed by the FDA.

Having established this fundamental point, the brief should go on to reassure the court that it would be doing nothing remarkable if it were to hold that each of the plaintiff's claims are preempted. As one court stated, since *Riegel*, “courts across the country have applied Section

360k(a) broadly, preempting all manner of claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing- and design-defect, to negligence per se.” *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (citations omitted), *aff'd*, *Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010). We've found that a string-cite of favorable authority from across the country, coupled with a more expanded discussion of the one or two best cases from the relevant jurisdiction, sets the stage well.

At this point, we typically march through each state law claim advanced by the plaintiff and cite to other cases where the same type of claim has been dismissed as expressly preempted, focusing especially on authority from the same jurisdiction. There are plenty of good cases. The biggest challenge often is making sense of the plaintiff's pleadings and breaking the complaint down into discrete pieces that can be attacked.

Incidentally, we've found that it generally isn't helpful to accept a plaintiff's categorization of claims as “strict liability” or “negligence” claims. The constituent aspects of each such claim—*e.g.*, design defect, manufacturing defect, failure to warn—should be addressed separately, even if that requires reframing or recharacterizing the plaintiff's complaint.

Anyway, let's move on the commonly asserted claims and recent authority finding each claim preempted:

- **Design defect.** Such claims are squarely foreclosed because, in order to prevail, the plaintiff necessarily would have to establish that the medical device should have a design different from that approved by the FDA through the PMA process. See, *e.g.*, *Riegel*, 552 U.S. at 320; *Walker*, 670 F.3d at 580–81.
- **Manufacturing defect.** Putting aside parallel claims (which we discuss below), claims that a device was defectively manufactured are preempted because the plaintiff would have to prove that the device should have been manufactured in a manner different from that approved by the FDA through the PMA process. See, *e.g.*, *Riegel*, 552 U.S. at 328; *Wolicki-Gables*, 643 F.3d at 1302; *Bryant*, 623 F.3d at 1207.

- **Failure to warn.** Because the labeling for a medical device is approved by the FDA through the PMA process, claims for failure to warn are preempted because they would require a finding that the medical device manufacturer should have provided different or additional warnings from those approved by the FDA. See, *e.g.*, *Riegel*, 552 U.S. at 329;

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*Wolicki-Gables*, 643 F.3d at 1302; *Bryant*, 623 F.3d at 1205. As a practical matter, we have found it helpful to lump failure-to-warn, fraud, and misrepresentation claims together in the preemption analysis, dropping a footnote (where applicable) to note that the claims sounding in fraud also fail because they have not been pleaded with sufficient particularity.

- **Breach of warranty.** Plaintiffs often assert express and implied warranty claims, alleging that a manufacturer breached promises that its device was safe and effective to use. Such claims (in contrast to express warranty claims based, for example, on a manufacturer's promise to pay a patient's unreimbursed medical costs in the event of a device malfunction) are preempted because they would require a finding that the device was not safe and effective—a finding that would contradict the FDA's conclusive determination during the PMA process that there is “a ‘reasonable assurance’ of the device's ‘safety and effectiveness.’” *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. §360e(d)). See, *e.g.*, *id.* at 320; *Bass v. Stryker Corp.*, 669 F.3d 501, 515–16 (5th Cir. 2012); *Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010).
- **Derivative claims.** Derivative claims, such as those for loss of consortium, negligent infliction of emotional distress, and



conspiracy, all of which depend on the success of a underlying claim, are also preempted. *See, e.g., Riegel*, 552 U.S. at 321; *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 237 (6th Cir. 2000).

### Debunking Plaintiff's Arguments

The Supreme Court's decision in *Riegel* doesn't give plaintiffs much room to

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argue that claims asserted against medical device manufacturers aren't preempted. But they still try. Here are seven arguments that plaintiffs like to make, and effective responses to each.

### Plaintiffs Might Invoke Pre-Riegel Caselaw

Plaintiffs may rely on pre-*Riegel* caselaw—especially cases from state courts—to deny that Premarket Approval imposes federal requirements. Or they might say that state common-law causes of action do not impose state law "requirements." The effective—and completely dispositive—response is that the Supreme Court squarely held otherwise in *Riegel*, and it's the duty of all courts to apply that precedent faithfully.

### Plaintiffs Might Try to Use Preemption Caselaw from Other Fields

Plaintiffs sometimes cite to express preemption cases decided under different statutory schemes. But express preemption depends on the precise language of the relevant statute, which, in the medical device context, is §360k(a), a provision that has been authoritatively construed in *Riegel*. That said, cases interpreting identical express preemption provisions, *i.e.*, those that employ the "different from, or in addi-

tion to" language, can sometimes be helpful for bolstering defendants' arguments. We'll talk more about this below.

### Plaintiffs Might Deny that the Device Received Premarket Approval

Sometimes the complaint doesn't say anything about whether the device that the plaintiff received is PMA-approved, and sometimes the plaintiff erroneously alleges that the device is not PMA-approved. Happily, the FDA's decision to grant Premarket Approval to a medical device is a matter of public record. In fact, the FDA even maintains an online database of premarket approvals. Therefore, defendants can easily correct plaintiffs' errors without discovery, and it's entirely appropriate for a court to take judicial notice of a device's Premarket Approval. *See, e.g., Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011).

### Plaintiffs Might Claim that the Specific Component of a Device That Failed Did Not Receive Premarket Approval

Medical devices often have complicated regulatory histories. For example, a component of the device might previously have been approved by the FDA through something other than the Premarket Approval process. Plaintiffs might say that this component wasn't PMA-approved, and that therefore preemption doesn't apply. The response is that the FDA considers a device as a whole when reviewing a Premarket Approval application, and that Premarket Approval, once granted, applies to all aspects and components of the device. *See, e.g., Gross v. Stryker Corp.*, \_\_\_ F. Supp. 2d \_\_\_, 2012 WL 876719, at \*14–15 (W.D. Pa. Mar. 14, 2012). This is true, for example, "even where a component of a premarket-approved device had previously been approved through the §510(k) process." *Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466, 471 (D. Mass. 2012). Plaintiffs cannot avoid express preemption by isolating individual components of the device.

### Plaintiffs Might Invoke the "Presumption Against Preemption"

Although often invoked by plaintiffs, the "presumption against preemption" is a red herring. While this presumption might apply in some contexts, it does not apply to state law claims that fall within the scope

of §360k(a). "When a federal law contains an express preemption clause," courts must "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *Chamber of Commerce of U.S. v. Whiting*, 131 S. Ct. 1968, 1977 (2011) (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)). In the medical device arena, Congress has spoken with utmost clarity: State law may not impose requirements that are "different from, or in addition to" the requirements imposed by federal law. Given this unambiguous language, it is not surprising that *Riegel*, the Supreme Court's authoritative interpretation of §360k(a), doesn't even mention the presumption.

### Plaintiffs Might Conflate Express Preemption with Conflict Preemption

Once a device has received Premarket Approval, the manufacturer generally can't make any changes to its design specifications, manufacturing processes, or labeling without seeking approval from the FDA. But plaintiffs will sometimes point out that, under certain circumstances, federal law does permit manufacturers to strengthen warnings pending approval of a proposed change to an earlier approved warning. 21 C.F.R. §814.39. Based on this possibility, plaintiffs will sometimes argue that a state failure-to-warn claim does not conflict with federal law because federal law does not absolutely prohibit a manufacturer from changing a device's labeling. Yet the absence of a conflict between federal and state law is irrelevant to express preemption under §360k(a), which prohibits *all* state law requirements that are different from or in addition to the federal requirements, including state law requirements that do not conflict with the federal requirements. If state law *requires* something that federal law only *permits*, such as the issuance of a stronger warning, it is an additional requirement that is plainly preempted. *See McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005).

In this connection, it is effective to point the court to the Supreme Court's recent decision in *National Meat Association v. Harris*, 132 S. Ct. 965 (2012), which—interpreting the Federal Meat Inspection Act's similarly worded express preemption provision—held that a state law claim is pre-

empted if it converts a federal “may” into a state law “must.” *Id.* at 970.

### **Plaintiffs Might Point Out that the Device Has Been Recalled**

Saying that a device has been recalled by the FDA conjures up images of a defective product—and importantly for preemption purposes, suggests (incorrectly) that the FDA has revoked the device’s Premarket Approval. For a defendant, it’s important not to run from a product recall—maybe even take it head-on in the opening brief—since it’s irrelevant for preemption purposes. A recall neither invalidates a device’s Premarket Approval nor negates the federal requirements applicable to a device with such approval. As a result, courts have repeatedly dismissed state law claims on preemption grounds in product liability cases involving recalled medical devices. *See, e.g., Bryant*, 623 F.3d at 1205 n.4; *Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1093 (C.D. Cal. 2011). Moreover, it is helpful to educate the court about what a medical device “recall” actually is. Rarely, if ever, does a “recall”—which is often referred to by regulators and medical device companies as a “correction,” a “removal,” or a “field action”—require that implanted PMA-approved medical devices be explanted from patients and sent back to the manufacturer, as the term “recall” implies.

### **Defanging the “Parallel Claim”**

*Riegel* recognized but did not analyze a narrow exception to express preemption for state law claims that genuinely “parallel,” rather than add to, federal requirements.” 552 U.S. at 330. And unsurprisingly, plaintiffs have tried mightily to cast their claims as “parallel” ones. It’s a judgment call whether and to what extent to anticipate a parallel claim argument in an opening brief. But if there’s a chance that the plaintiff will make the argument, we usually think it’s better to anticipate the issue and thereby frame the terms of the discussion.

As is often the case, the best place to start is the U.S. Supreme Court’s decisions, which explain that a state law requirement must be “identical” (*Lohr*, 518 U.S. at 495), or at least “genuinely equivalent” (*Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005)), to a pre-existing federal requirement to be considered “parallel.”

One thing to keep in mind is that, contrary to what plaintiffs sometimes argue, a state law requirement is not parallel to the federal requirements merely because it is “consistent” with the federal requirements. Although the absence of a conflict is relevant to an implied preemption analysis, it is irrelevant to the express preemption analysis because any state law requirement that is neither identical nor genuinely equivalent to a federal requirement is “different from, or in addition to” the federal requirements, even if it is “consistent” with those requirements.

It can be helpful to provide the court with an example of a valid parallel claim, so as to reassure the court that device manufacturers aren’t looking for blanket immunity. For example, if the Premarket Approval for, say, a catheter requires that the catheter be 0.25 inches in diameter, but, because of a manufacturing defect, the particular catheter implanted in the patient is only 0.1 inches in diameter, the claim would not be expressly preempted under the Medical Device Amendments and the plaintiff may be able to successfully plead a parallel claim (assuming, of course, that the narrowness of the catheter was what caused his or her injury, and that there is a genuine state law basis for the claim).

At any rate, after defining a parallel claim and giving an example of one, we’ve found it useful in our briefs to provide a crisp statement of what, in our view, are the requisite elements of a properly alleged, non-preempted parallel claim. The precise formulation will of course vary with the jurisdiction, but we think a sound default position—backed by the weight of federal appellate authority—is that the plaintiff must (1) identify a specific federal requirement applicable to the device; (2) show that the device did not comply with that specific federal requirement; (3) identify a pre-existing state cause of action that makes actionable that non-compliance; and (4) show that the deviation from the federal requirement caused his or her injuries. *See, e.g., Walker*, 670 F.3d at 580–81; *Wolicki-Gables*, 634 F.3d at 1301; *Funk*, 631 F.3d at 782; *Bryant*, 623 F.3d at 1207. And of course, each of these elements has to be alleged with the specificity and factual elaboration required under the applicable pleading standards.

Some defendants miss opportunities to push back against a plaintiff’s attempt to allege a parallel claim. At a minimum, we suggest that defendants run through the following check-list:

- Has the plaintiff actually identified a specific federal requirement (and not merely non-binding or discretionary guidance)?

**It’s important not to run from a product recall—maybe even take it head-on in the opening brief—since it’s irrelevant for preemption purposes.**

- When the plaintiff does try to establish a deviation from a federal requirement, it’s important to carefully scrutinize the evidence cited by plaintiff. For example, does the evidence presented by the plaintiff—say, a warning letter related to a facility inspection—actually relate to the plaintiff’s device? We’ve seen plaintiffs cite warning letters that concern facilities that were not involved in the production of the plaintiff’s device; batches or lots that did not contain plaintiff’s device; and time periods other than when the plaintiff’s device was constructed. Remember, plaintiff’s counsel often throw everything against the wall, hoping that something will stick. It’s the defendant’s job to demonstrate that nothing sticks.
- Consider also whether the state law requirement underlying a particular claim is in fact identical to the federal requirement allegedly violated by the manufacturer. For example, because a state law duty to warn *consumers or doctors* is not identical to the federal requirement that a manufacturer file certain reports with the FDA, a violation of the federal reporting requirement does not properly support a state law failure-to-warn claim. *See Heisner*



*v. Genzyme Corp.*, 2010 WL 894054, at \*3 (N.D. Ill. Mar. 8, 2010); *cf. Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 2576 (2011).

- Consider whether there is a pre-existing state law duty or claim or whether plaintiff is simply seeking to enforce a requirement that exists only by virtue of federal law. If there is no pre-existing state law duty or claim, then there can be no parallel claim.
- Has the plaintiff sufficiently tied the alleged federal violation to the harm that he or she allegedly suffered?

Finally, don't forget that discretion is sometimes the better part of valor. If the complaint really does do a thorough job alleging a parallel claim—and therefore the judge might be tempted to let the complaint survive a motion to dismiss—consider whether it might be better to defer the preemption arguments for a motion for summary judgment, following limited or staged discovery, where the record will be better developed. As medical device defense counsel, we should be careful not to create bad law that the rest of us will have to deal with!

### Practice Pointers for the Implied-Preemption Argument

When litigating preemption in the medical device context, it's important not to forget about implied preemption. The mere fact that Medical Device Amendments contain an express-preemption provision, 21 U.S.C. §360k(a), does not preclude operation of implied-preemption principles where appropriate. *See Geier*, 529 U.S. at 869. After all, there is both statutory and decisional authority that supports implied preemption. *See* 21 U.S.C. §337(a); *Buckman*, 531 U.S. 341. Thus, even if a claim is not expressly preempted, it might be impliedly preempted.

As previewed above, the U.S. Supreme Court held in *Buckman* that there is no “doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions” of federal law. 531 U.S. at 349 n.4. As a result, taken together, “*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state law claim must fit if it is to escape express or implied preemption.” *Bryant*, 623 F.3d at 1204. In order to avoid dismissal, a “plain-

tiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by §360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA ([because] such a claim would be impliedly preempted under *Buckman*).” *Bryant*, 623 F.3d at 1204 (internal quotation marks omitted). In other words, “[f]or a state-law claim to survive the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA.” *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

The most strategically significant use of implied preemption is knocking out the sorts of claims that are *least* vulnerable to express preemption, because they are premised on asserted violations of federal law. But implied preemption can also be used as a second basis for dismissing a state law claim, to give the presiding judge added comfort that his or her decision is correct and will not be reversed on appeal.

Consider a breach-of-implied-warranty claim that challenges the safety and effectiveness of a medical device with Premarket Approval. Such a claim is expressly preempted because success on this claim depends on a jury's finding that the device was not, in fact, safe and effective. That is, state law would require the manufacturer to have done something *different from or in addition to* the federally imposed requirements in order to honor the safety-and-effectiveness warranty—be that provide additional warnings or use a different design.

This claim also is impliedly preempted. The FDA conducts a “time-consuming inquiry into the risks and efficacy of each device.” *Buckman*, 531 U.S. at 348. The jury's finding of liability on an implied-warranty invariably would contradict the FDA's conclusive determination, via the Premarket Approval process, that the device was safe and effective, and would “[a]fter[] the balance struck by the FDA” by imposing a state law requirement “to protect safety to a greater degree” than determined to be appropriate by the agency. *Farina v. Nokia Inc.*, 625 F.3d 97, 126 (3rd Cir. 2010) (citing *Buckman*, 531 U.S. at 350–51). As the Third Circuit recognized, “[a]llowing juries to perform their own risk-utility analysis and second-guess the

[agency's] conclusion would disrupt the expert balancing underlying the federal scheme.” *Id.*

### Loose Ends

Finally, defendants shouldn't forget about traditional state law bases for dismissal just because they have a strong federal preemption argument. All too often, we see motions to dismiss that leave these arguments on the table—even when many of them complement preemption nicely. You might consider, for example:

- Is there a valid statute of limitations or statute of repose defense?
- Are there any relevant standing requirements? Consumer protection statutes, for example, sometimes require that the product be purchased by the plaintiff for household use.
- Are strict liability and implied warranty claims barred by Restatement (Second) of Torts Section 402A, cmt. k, Restatement (Third) of Torts: Products Liability Section 6(c), or any equivalent doctrine regarding “unavoidably unsafe” products as a matter of state law?
- Do warranty claims in this jurisdiction require a showing of privity?
- Have alleged misrepresentations or a purported express warranty been pleaded with sufficient particularity?
- Are there state law limitations on negligence per se? For example, state law might not recognize negligence per se claims based on violations of regulations (as opposed to statutes) or might contain a doctrine analogous to *Buckman* (*i.e.*, to the effect that negligence per se isn't recognized when it would amount to an end-run around the absence of a private right of action).

### Conclusion

Given the powerful defense tool that federal preemption can be in a medical device product liability action, it's important to consider the availability of express preemption and implied preemption arguments early on in the case assessment process. But no matter how strong the preemption arguments seem, don't leave traditional state law defenses on the table. Together, federal preemption and traditional state law defenses can often successfully knock out claims involving a medical device.