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September 14, 2017

Ms. Marcia M. Waldron, Clerk of the Court
U.S. Court of Appeals for the Third Circuit
21400 U.S. Courthouse
601 Market Street
Philadelphia, PA 19106-1790

Re: *Shuker v. Smith & Nephew, Inc.*, No. 16-3785

Dear Ms. Waldron:

Following oral argument, the Court issued an order inviting the federal government to file an amicus letter brief addressing the application of express- and implied-preemption principles in this case. The Food and Drug Administration (FDA) appreciates this opportunity to present views regarding matters that bear upon the national device regulatory system that Congress has tasked the agency with implementing. As explained below, the express-preemption provision of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), applies to some, but not all, of the tort claims held to be expressly preempted by the district court. To the extent these claims are not expressly preempted, they would be subject to ordinary principles of implied preemption if that issue were properly preserved in this appeal.

BACKGROUND

A. Statutory and Regulatory Background

The Federal Food, Drug, and Cosmetic Act (FDCA), as amended, provides for detailed federal oversight of medical devices. *See* 21 U.S.C. §§ 301 *et seq.*, 360c *et seq.* The extent to which medical devices are subject to federal regulation varies according to the risks they present. Devices presenting limited risks are

designated class I or II and are subject only to general controls or general and special controls, while devices presenting more substantial risks are designated class III and are generally subject to the rigorous requirements for premarket approval. *See id.* § 360c(a)(1); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476-77 (1996). A manufacturer can obtain clearance to market a device under § 510(k) of the FDCA, and does not need to obtain premarket approval, if the manufacturer demonstrates that the device is "substantially equivalent" to a lawfully marketed predicate device that did not require premarket approval. 21 U.S.C. § 360c(f)(1)(A).

For devices requiring premarket approval, FDA must determine "whether or not there is a reasonable assurance of [the device's] safety and effectiveness," and the agency relies on "the conditions of use included in the proposed labeling as the basis for" that determination. 21 U.S.C. § 360e(d)(1)(A). Once FDA grants premarket approval, the FDCA and implementing regulations generally forbid a manufacturer from making changes to a device's design specifications, manufacturing processes, labeling, or any other attribute that would affect the safety or effectiveness of the device, unless the manufacturer obtains FDA approval for the change. *Id.* § 360e(d)(5)(A)(i); *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008).[1]

The FDCA expressly preempts any state law that imposes, "with respect to a device," a "requirement" that "is different from, or in addition to, any requirement applicable under this chapter to the device" and that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). That express-preemption provision applies only when FDA has established "specific counterpart regulations or there are other specific requirements applicable to a particular device." 21 C.F.R. § 808.1(d); *see Riegel*, 552 U.S. at 322; *Lohr*, 518 U.S. at 501. The Supreme Court has held that premarket approval imposes device-specific requirements within the meaning of § 360k(a) because FDA "requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application." *Riegel*, 552 U.S. at 323. By contrast, the Court held in *Lohr* that the review conducted under § 510(k) in that case imposed no device-specific requirements, and therefore did not implicate

[1] A manufacturer may place into effect, prior to receiving FDA approval, labeling changes for a premarket approved device that "add or strengthen an instruction that is intended to enhance the safe use of the device" or similarly improve its safety. 21 C.F.R. § 814.39(d)(2)(ii).

§ 360k(a), because "FDA does not 'require' that a device allowed to enter the market as a substantial equivalent 'take any particular form for any particular reason.'" *Riegel*, 522 U.S. at 323 (quoting *Lohr*, 518 U.S. at 493). Likewise, the Court has held that federal requirements that are "applicable across the board to almost all medical devices" ordinarily have no preemptive effect under § 360k(a) because they generally reflect "'entirely generic concerns about device regulation generally.'" *Id.* at 322 (quoting *Lohr*, 518 U.S. at 501).

Even where state-law claims implicate device-specific federal requirements, § 360k(a) preempts such claims only to the extent that they impose requirements on the device that are "different from, or in addition to," those federal requirements. *Riegel*, 552 U.S. at 330. Accordingly, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* (quoting *Lohr*, 518 U.S. at 495). However, state-law claims that are not expressly preempted by § 360k(a) remain subject to implied-preemption principles. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 349, 352 (2001) ("neither an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles'") (alteration in original) (quoting *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000)).

B. Procedural Background

Defendants[2] design and manufacture medical devices for use in hip replacement and resurfacing procedures. Two of defendants' systems are implicated here. First, the R3 acetabular system is a class II device for hip replacements that consists of four main components: an acetabular cup that covers the hip socket, a polyethylene liner that rests inside the cup, a metal femoral head that replaces the ball of the thighbone, and a femoral stem that is inserted into the thighbone. FDA cleared the components of the R3 system for marketing under § 510(k) of the FDCA.

Second, the Birmingham hip resurfacing system (BHR system) is a class III device consisting of two main components: a metal acetabular cup, and a metal cap that covers the ball of the patient's thighbone. FDA granted premarket approval

[2] The complaint names both Smith & Nephew, Inc. and Smith & Nephew PLC as defendants. Because any distinctions between these entities have no bearing on the preemption analysis, the government does not distinguish between them for purposes of this brief.

for the BHR system in 2006. In 2008, FDA approved a modular version of the metal acetabular cup as a supplement to the BHR system. The modular version consists of a metal acetabular shell and a separate metal liner, which defendants named the "R3" metal liner despite the fact that the liner was not intended for use with the R3 system. Indeed, the FDA-approved labeling associated with the modular-cup supplement included a surgical technique addendum stating that, "in the US, the R3 metal liner is intended for use as part of the BHR system only." JA 42. Notwithstanding that warning, defendants issued a press release shortly after FDA approved the modular cup, announcing "the introduction of a metal liner option for its R3 Acetabular System, an advanced multi-bearing cup system used in hip replacement and resurfacing procedures." JA 43.

Plaintiff Walter Shuker underwent a right total hip replacement surgery in April 2009. His surgeon implanted several § 510(k)-cleared components of the R3 system, together with the R3 metal liner that was approved as a component of the BHR system, thereby using the metal liner in a manner not approved by FDA. JA 44. Less than two years after the operation, Shuker experienced serious complications that required additional surgeries. JA 44-45. In June 2012, defendants withdrew the R3 metal liner from the market based on a large volume of reported complications associated with its use. JA 45.

Mr. Shuker and his wife filed suit against defendants in September 2013. The second amended complaint asserts state-law claims for negligence, strict products liability, breach of express and implied warranties, fraud, and loss of consortium, focusing on the interaction between the metal femoral head of the R3 acetabular system and the R3 metal liner from the BHR system. The complaint alleges, *inter alia*, that defendants were negligent in designing and manufacturing the § 510-cleared components of the R3 system, as well as components like the R3 metal liner that would foreseeably be used with the cleared components in a dangerous manner, JA 899-900; failing to provide warnings associated with the components of the R3 system stating that they should not be used with the R3 metal liner, JA 912; and providing false and misleading advertising relating to the branding of the R3 metal liner and by suggesting that the metal liner could be used safely with the R3 system, *id.* Defendants filed a motion to dismiss and for summary judgment, urging that most of plaintiffs' claims were expressly preempted, and that the remainder were inadequately pleaded.

In March 2015, the district court granted defendants' motion in substantial part, holding that most of plaintiffs' claims were preempted by § 360k(a). The court first held that FDA's premarket approval of the R3 metal liner—even as a

component of a device different from the one in which it was ultimately used—"imposed federal requirements" with preemptive effect under § 360k(a). JA 54. The court explained that, upon FDA's approval of the BHR system, "Defendants were required to produce and market the device, including all of its constituent components, in accordance with the specifications approved by the FDA," regardless of the use to which the device or components were ultimately put. JA 54, 57. The court thus rejected plaintiffs' argument that the novel configuration of components implanted in Mr. Shuker should be regarded as a new device that had not received premarket approval and therefore did not implicate § 360k(a).

The court noted that some of plaintiffs' claims "purport to challenge the safety of the § 510(k)-cleared R3 System," rather than the metal liner itself. JA 61. But it concluded that the liner is ultimately "at the heart of each of Plaintiffs' claims," making § 360k(a) applicable. *Id.* The court explained that "[t]he only factual allegation . . . pertaining to the R3 System, as opposed to the liner, concerns the adequacy of the warnings accompanying the System," and "[a] warning against using the R3 metal liner with the R3 System . . . is undoubtedly a warning that 'relates to the safety or effectiveness' of the liner regardless of whether the warning accompanies the liner or another component." JA 62. The court thus held that such claims were also expressly preempted. *Id.*

With respect to plaintiffs' claims for off-label promotion and failure to report adverse events, the court held that the claims appeared to allege violations of federal requirements and could thus potentially be stated as parallel claims not expressly preempted by § 360k(a). JA 67 & n.24, 70. But the court concluded that plaintiffs had failed to plead sufficient facts to render those claims plausible. *See* JA 68-69, 72. The court granted plaintiffs leave to amend their complaint as to their claims for off-label promotion, JA 74, and plaintiffs filed a third amended complaint in August 2015, JA 468. On September 29, 2016, the court granted defendants' motion to dismiss the complaint with prejudice, holding that plaintiffs had again failed to plausibly allege that defendants affirmatively promoted the R3 metal liner for off-label use. JA 25-26. Plaintiffs appealed.

This Court held oral argument on June 16, 2017. On June 20, 2017, the Court issued orders directing the parties to file supplemental briefs addressing the application of implied-preemption principles in these circumstances, and inviting the government to file an amicus letter brief addressing four questions concerning the application of express- and implied-preemption principles in this case. Questions 1 and 2 ask whether and how § 360k(a) applies to state tort claims that concern a component of a device that received premarket approval when used in

combination with components that did not. Question 3 asks whether and how principles of implied preemption apply to such claims, to the extent the claims are not expressly preempted. And Question 4 invites the government to identify any practical and policy consequences of the Court's resolution of the foregoing issues. Because these questions are in many respects interrelated, the following brief sets forth the government's position in two sections, respectively addressing the application of express- and implied-preemption principles in this case.

DISCUSSION

The district court correctly held that § 360k(a) applies to a component of a premarket-approved device even when the component is put to an unapproved use. The component of the premarket-approved device is itself a "device" under the FDCA, and FDA's approval imposes device-specific requirements with respect to that component. The manufacturer generally may not deviate from those requirements without prior approval from FDA, regardless of the uses to which the component may be put by third parties. Because the component is subject to device-specific federal requirements, § 360k(a) expressly preempts any state requirements "with respect to" the component that are "different from, or in addition to," those device-specific federal requirements.

In applying § 360k(a) to plaintiffs' claims, however, the district court overlooked important limitations on that provision's preemptive reach. As noted above, where a device is subject to device-specific federal requirements, § 360k(a) preempts state requirements "with respect to" the device that are different from, or additional to, the federal requirements. But state requirements with respect to other components not subject to device-specific federal requirements fall outside the scope of § 360k(a) and are not expressly preempted. *See* 21 C.F.R. § 808.1(d).

Defendants do not appear to have raised an implied-preemption defense before the district court, and this Court ordinarily does not reach claims or defenses on appeal that were not presented or passed on below. If the Court nonetheless deems the issue to be properly before it, medical-device tort claims that are not expressly preempted remain subject to implied-preemption principles.

A. The FDCA Expressly Preempts Some, but Not All, of Plaintiffs' Claims.

1. Section 360k(a) preempts any "requirement" of state law "with respect to" a medical "device" that is "different from, or in addition to, any requirement applicable under [the FDCA] to the device" and that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" under the FDCA. The FDCA defines "device" to include, as relevant here, any "implant" that is "intended to affect the structure or any function of the body," as well as "any component, part, or accessory" of such an article. 21 U.S.C. § 321(h). Accordingly, the definition of "device" encompasses the premarket-approved BHR system, the § 510(k)-cleared R3 system, and each of the "component[s], part[s], [and] accessor[ies]" of these devices—including the R3 metal liner.

The Supreme Court has held that premarket approval of a medical device imposes federal "requirements" on the approved device within the meaning of § 360k(a), while substantial-equivalence review under § 510(k) generally does not. *Riegel*, 552 U.S. at 322-23. Premarket approval of the BHR system, including the modular cup approved as a supplement to that system, imposed device-specific requirements applicable to the R3 metal liner. Those requirements remain applicable to the liner regardless of how it is used by third parties.

As a general matter, the device-specific requirements that attach to a medical device through premarket approval apply even when the device is put to an unapproved use. Once a device receives premarket approval, the FDCA generally prohibits the manufacturer from making, without FDA permission, changes that would affect the safety or effectiveness of the device. *Riegel*, 552 U.S. at 319; *see* 21 U.S.C. § 360e(d)(5)(A)(i); 21 C.F.R. 814.39. For example, premarket approval of the R3 metal liner as part of the BHR system imposed requirements on the liner with respect to its composition, dimensions, and labeling, among other specifications. Those requirements apply irrespective of the use to which the device is ultimately put. The possibility that a physician may choose to use a device for an unapproved purpose—something the FDCA contemplates, *see* 21 U.S.C. § 396—does not authorize a manufacturer to vary the design, the manufacture, or (with limited exceptions) the labeling of the device in anticipation of that use. Such variation would violate federal law.

Consistent with the foregoing, federal courts have generally assumed that premarket approval subjects a medical device to "requirements" for purposes of

§ 360k(a) even when the device is put to an unapproved use. *Riegel* itself involved an off-label use of the device in question. Although the treating physician used the catheter at issue in a manner contraindicated by its labeling, the Court held that FDA's approval imposed device-specific requirements and that § 360k(a) therefore applied. *See* 552 U.S. at 322-23; *see also Otis-Wisher v. Medtronic, Inc*., 616 F. App'x 433, 434 (2d Cir. 2015) (similarly assuming that an approved medical device remains subject to device-specific "requirements" for purposes of § 360k(a) even when the state-law claim concerns an off-label use of the device); *Perez v. Nidek Co*., 711 F.3d 1109, 1118-19 (9th Cir. 2013) (same).

In the only federal appellate opinion to consider the question directly, the Tenth Circuit expressly held that the applicability of § 360k(a) does not turn on the use to which an approved device is put. *Caplinger v. Medtronic, Inc*., 784 F.3d 1335, 1344 (10th Cir. 2015) (Gorsuch, J.). The court explained that, "[t]extually, § 360k(a) simply does not contain [a] distinction . . . between suits addressing on- and off-label uses." *Id.* The court also rejected the suggestion that "there are no federal regulations on the subject of off-label uses" and that § 360k(a) therefore does not apply in such cases. *Id.* at 1344-45 (quotation marks omitted). Simply put, once a device receives premarket approval, it remains subject to federal requirements for purposes of § 360k(a) regardless of how it is used.

In one respect, the off-label use in this case differs from the off-label uses in *Riegel* and *Caplinger*. Here, plaintiffs claim to have been injured not by an off-label use of the approved BHR system, but by the off-label use of a single component of that system in combination with § 510(k)-cleared components of another device. While FDA did not review the safety of the R3 metal liner separate from the BHR system, this difference does not alter the express-preemption analysis. As noted above, the FDCA expressly defines "device" to "include[e] any component, part, or accessory" thereof. 21 U.S.C. § 321(h). And FDA's premarket approval of the BHR system imposed requirements specific to the metal liner that generally preclude changes to the liner's design, manufacture, and labeling without further approval by FDA. Those requirements apply equally when third parties put the liner to an unapproved use with components of another device that are subject only to clearance under § 510(k). Defendants generally may not deviate from the requirements imposed through premarket approval regardless of how the liner is used. Claims touching on those requirements therefore implicate § 360k(a) even when a component of an approved device is put to the type of unapproved use here at issue.

The conclusion that § 360k(a) applies in this context also makes sense as a matter of policy. Congress entrusted FDA with determining which device designs should be approved for marketing, as well as how approved devices should be labeled to provide medical professionals with appropriate safety information. Section 360k(a) acknowledges FDA's judgment in this respect and prevents States from pursuing competing judgments that would impose different or additional requirements on approved devices. That provision also protects manufacturers that have complied with detailed federal requirements from being subjected to liability under state law for doing what federal law required. Manufacturers must generally adhere to the specifications established through premarket approval, even if health-care practitioners subsequently exercise their judgment and employ the device for an unapproved use. *See* 21 U.S.C. § 396. Section 360k(a) preempts state requirements with respect to devices subject to device-specific federal requirements to the extent the state requirements differ from, or are in addition to, the requirements imposed by FDA.

Consistent with the foregoing analysis, several federal district courts—including the district court in this case—have held that premarket approval imposes device-specific requirements with respect to the R3 metal liner even when the liner is used off label with § 510(k)-cleared components of the R3 system. *See* JA 54; *Nagel v. Smith & Nephew, Inc.*, No. 15-927, 2016 WL 4098715 (D. Conn. July 28, 2016), *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246 (E.D.N.Y. 2014); *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395 (S.D.N.Y. 2013). These courts correctly explained that "preemption analysis is not concerned with how a particular device is used or whether there are federal requirements imposed on a particular use of the device. Rather, preemption is focused on whether there are federal requirements applicable to the device itself," and premarket approval of the BHR system imposed requirements applicable to the metal liner. *Bertini*, 8 F. Supp. 3d at 255. Accordingly, claims directed toward the design, manufacture, or labeling of the metal liner implicate § 360k(a) regardless of how the liner is used. A number of courts have reached the same conclusion in a closely analogous context, in which a single component of the Infuse bone-graft device was used on its own rather than in the approved system, holding that device-specific requirements applied to the component in those circumstances. *See, e.g.*, *Arvizu v. Medtronic Inc.*, 41 F. Supp. 3d 783, 790 (D. Ariz. 2014); *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, 1036 (D. Ariz. 2014); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1035 (D. Haw. Apr. 10, 2014); *Houston v. Medtronic, Inc.*, No. 13-1679, 2014 WL 1364455, at *4 (C.D. Cal. Apr. 2, 2014).

At the same time, other judicial decisions addressing R3 metal-liner litigation have held that, although claims directed at the metal liner itself implicate § 360k(a), claims directed at the combination of components do not. In *Lafountain v. Smith & Nephew, Inc.*, No. 14-1598, 2015 WL 3919796, at *5-6 (D. Conn. July 18, 2016), the court distinguished *Simon* and *Bertini* as involving only claims directed at the metal liner, and not claims alleging negligence with respect to the broader combination of components. *See id.* at *6. The court reasoned that, although premarket approval imposed device-specific requirements on the metal liner, the "combination of component parts" was not subject to premarket approval or other device-specific federal requirements. *See id.* Based on that understanding, the court held that, because claims concerning the combination of components were not premised on state requirements "with respect to" a device subject to device-specific requirements within the meaning of § 360k(a), such claims did not implicate that provision. In a case arising in a factually distinct context, the court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 752 (S.D. W. Va. 2014), similarly concluded that claims directed at a combination of components do not implicate § 360k(a) even when one such component received premarket approval.

Although these opinions are sometimes understood as taking a divergent view of § 360k(a)'s scope, they are correct insofar as they hold that § 360k(a) requires a court to parse a plaintiff's claims to determine whether the state-law requirements that underlie them are indeed directed at the premarket-approved component. Accordingly, in these circumstances the court must ask whether the alleged defect pertains to the metal liner—by alleging, for example, that the liner itself should have been designed, manufactured, or labeled in a manner different from the specifications established by premarket approval—or whether the claim instead alleges a defect with respect to one or more § 510(k)-cleared components. Where a plaintiff alleges violations of state requirements only "with respect to" a component that did not receive premarket approval and is not otherwise subject to device-specific federal requirements, the claim does not implicate § 360k(a).

2. Concluding that the R3 metal liner is a "device" subject to device-specific federal "requirements" even when it is used off label in combination with § 510(k)-cleared components does not complete the inquiry under § 360k(a). The Court must additionally consider, on a claim-by-claim basis, whether plaintiffs' allegations entail state requirements "with respect to" the metal liner that are "different from, or in addition to," applicable federal requirements. Claims alleging a failure to comply with state requirements with respect to devices other than the liner are not expressly preempted.

The district court erred in concluding that, "[a]lthough Plaintiffs' claims also purport to challenge the safety of the § 510(k)-cleared R3 System, the body of the Second Amended Complaint reveals that the liner is at the heart of each of Plaintiffs' claims," and all such claims are therefore subject to § 360k(a). JA 61. While it is true that plaintiffs' claims "generally concern the interaction of the R3 metal liner with the components of the R3 acetabular system," *id.*, the express-preemption analysis requires the court to further parse those claims to determine if any are directed at one or more of the § 510(k)-cleared components, rather than the liner itself. As discussed above, the § 510(k)-clearance process generally does not impose device-specific requirements on medical devices and components thereof, and state requirements with respect to such devices are thus unlikely to implicate § 360k(a). *See Riegel*, 552 U.S. at 323; *Lohr*, 518 U.S. at 493. The fact that such components were in this case used in conjunction with a premarket-approved component does not alter that analysis. Section 360k(a) preempts plaintiffs' claims only to the extent they concern device-specific requirements applicable to the metal liner itself.

Plaintiffs advance two types of claims that may concern state requirements "with respect to" the R3 system and its § 510(k)-cleared components rather than the metal liner. First, plaintiffs allege that defendants negligently failed to provide adequate warnings with the components of the R3 system cautioning against using them with the metal liner. *See* JA 886, 912. The district court acknowledged that this allegation "pertain[ed] to the R3 System, as opposed to the liner," but it nevertheless held that such a warning "'relates to the safety or effectiveness' of the liner" and is therefore preempted "regardless of whether the warning accompanies the liner or another component." JA 62 (quoting 21 U.S.C. § 360k(a)(2)). However, the labeling obligation asserted by plaintiffs in this claim is directed at the components of the R3 system, and the plaintiffs do not appear to be suggesting that defendants should be liable based on a failure to alter the labeling or other attributes of the liner itself. Because FDA did not impose device-specific labeling requirements on the R3 system components as part of the components' § 510(k) clearance, a state requirement that those components carry warnings against use with metal liners would not implicate § 360k(a). To the extent that plaintiffs' claim is predicated on such a requirement, the requirement is not one "with respect to" the R3 metal liner and the claim is therefore not expressly preempted.[3]

[3] A different question might be presented by a state warning requirement that applied specifically to the use of the R3 system's components with the R3

Similarly, to the extent that plaintiffs may be pursuing claims alleging defects in the design or manufacture of one or more of the § 510(k)-cleared components of the R3 system, such claims do not implicate § 360k(a). The district court held that plaintiffs did not state such a claim, concluding that "the Second Amended Complaint identifies the metal liner—not the femoral components—as the source of the problem" in each instance, with the exception of the labeling claim discussed above. JA 61-62. However, the Second Amended Complaint alleges that "[t]he R3 Acetabular System, both with *and without* components such as the R3 metal liner that foreseeably would be used with it," was "defective in design or formulation." JA 60 (quoting Second Amend. Compl. ¶ 141) (emphasis added; alteration in original). And plaintiffs make further allegations that might be understood to suggest a defect in a component other than the metal liner. *See* JA 887 (discussing the condition of certain components of the R3 system).

Regardless of whether claims alleging defects in the design or manufacture of the § 510(k)-cleared components of the R3 system are presented here—a question of fact on which the government takes no position—it is possible to imagine a case arising from similar factual circumstances in which the plaintiff alleges that the femoral head or another of the § 510(k)-cleared components of the R3 system was defectively designed or manufactured. Because such a claim would not be premised on state requirements "with respect to" the metal liner, it would not be expressly preempted.[4]

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metal liner in particular, rather than to the use of those components with metal liners in general. Likewise, a different question might be presented if, in connection with its approval of the BHR system, FDA had considered and rejected a warning against the use of the metal liner with the other components of the R3 system. The foregoing discussion is not intended to address those questions.

[4] The government takes no position as to whether and in what circumstances § 360k(a) might expressly preempt a claim "with respect to" a *combination* of components that includes a premarket-approved component but was not itself subject to premarket approval. *Cf. Lafountain*, No. 14-1598, 2015 WL 3919796, at *5-6. The resolution of that question would likely depend on fact-specific considerations, such as whether the manufacturer had marketed the components for use in combination with each other. Because the district court found that plaintiffs did not adequately allege that defendants promoted the metal liner for use with the §510(k)-cleared components of the R3 system, JA 68, the court need not reach that question in this case.

B. Assuming the Question Is Properly Before the Court, Any Claims Not Expressly Preempted Are Subject to Normal Implied-Preemption Principles.

The Court has invited the government and the parties to address the potential applicability of implied-preemption principles to any claims in this case that are not expressly preempted. We note at the outset that defendants did not raise implied preemption in their dispositive motions below, nor did they raise it in their original appellate briefing. While this Court may affirm a decision of a district court on grounds other than those relied upon by the lower court, "this rule does not apply to cases in which the party has waived the issue in the district court." *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 335-36 (3d Cir. 2009). This appeal presents in a similar procedural posture to *Holk*, in which a defendant moved to dismiss certain claims on the basis of implied preemption, but did not assert express preemption as a ground for dismissing those claims. 575 F.3d at 335. In light of the defendant's failure to raise the express-preemption issue in district court, this Court declined to consider the issue as an alternative basis for affirmance. *Id.* at 335-36. As in that case, the Court may find it appropriate to leave the subject of implied preemption for another day.[5]

In the event that the Court chooses to reach the issue, the existence of an express-preemption provision such as § 360k(a) does not ordinarily alter the normal operation of implied-preemption principles. Accordingly, state-law medical-device claims that are not expressly preempted remain subject to challenge on implied preemption grounds in certain circumstances. *See Buckman*, 531 U.S. at 352. We note a few general points regarding the application of those principles in this context.

First, the FDCA does not occupy the field of medical-device regulation to the exclusion of state tort law, either in general or with respect to premarket-approved devices in particular. Section 360k(a) itself permits states to subject approved medical devices to tort claims that parallel the requirements of federal law. *See Lohr*, 518 U.S. at 495. And nothing about the terms or structure of the

[5] While *Holk* suggests that defendants' failure to assert implied preemption in their motions to dismiss may preclude them from seeking affirmance on that ground, the federal rules governing the presentation of defenses in civil actions may nevertheless permit defendants to raise this issue in further proceedings before the district court.

FDCA suggests that Congress, having declined to occupy the field expressly, did so *sub silentio*. Thus, there would be no basis for a defendant to challenge state tort claims against approved medical devices on a field-preemption theory, and the defendants here do not make such a challenge in their supplemental brief.[6]

Second, because § 360k(a) expressly preempts state requirements that are "different from, or in addition to," device-specific requirements imposed by federal law, conflict-based implied-preemption analysis will come into play in only two circumstances: when the state requirement embodied in a tort claim is *not* "different" or "additional" (*i.e.*, when it parallels, rather than departs from or adds to, federal requirements), or when the state requirement pertains to generally applicable federal requirements that do not trigger the operation of § 360k(a).

In particular circumstances, parallel state-law tort claims may have features that intrude impermissibly on the operation or enforcement of the FDCA, as where they represent an attempt to enforce the federal scheme, rather than asserting independent state-law requirements. *See Buckman*, 531 U.S. at 352-53.[7] But in the absence of such features, state requirements that parallel device-specific federal requirements are not likely to conflict with those requirements or with the FDCA.

Because federal requirements of general applicability, unlike device-specific federal requirements, generally do not implicate § 360k(a), state requirements that vary from them ordinarily are not expressly preempted. In some cases, divergent state requirements may stand as an obstacle to the operation or objectives of the federal scheme and may be impliedly preempted on that basis. But defenses of conflict preemption involving such claims must be assessed on a case-by-case basis, and defendants have not identified any such claims in this case.

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[6] Defendants have not raised a defense in this case based on principles of field preemption, nor have they suggested that the FDCA occupies the field of medical device regulation to the exclusion of state tort law.

[7] Because the district court found that plaintiffs' state-law tort claim premised on a failure to report adverse events was inadequately pleaded, *see* supra page 5, we do not address whether that claim is impliedly preempted here.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief was prepared using a 14-point proportionately spaced font and contains fewer than 20 pages, consistent with this Court's order of June 20, 2017.

s/ Lindsey Powell
LINDSEY POWELL

CERTIFICATE OF SERVICE

I certify that on September 14, 2017, I electronically filed the foregoing letter brief using the Court's CM/ECF system. Counsel will be served by the CM/ECF system.

s/ Lindsey Powell
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