**PRECEDENTIAL**

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 16-3785

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WALTER SHUKER; VIVIAN SHUKER,
Appellants

v.

SMITH & NEPHEW, PLC; SMITH & NEPHEW, INC.

_____

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(E.D. Pa. No. 5-13-cv-06158)
Honorable Juan R. Sánchez

_____

Argued: June 16, 2017

Before: JORDAN, GREENAWAY, JR., and KRAUSE,
*Circuit Judges*

(Opinion Filed: March 1, 2018)

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OPINION OF THE COURT

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KRAUSE, *Circuit Judge*.

With the Medical Device Amendments of 1976, Congress added comprehensive medical device approval processes to the Federal Food, Drug, and Cosmetic Act, prescribing tiers of federal requirements for certain devices corresponding to the device's inherent risk level. In exchange for compliance with the strictest federal mandates, Congress afforded manufacturers express preemption from state laws imposing different or additional "safety or effectiveness" requirements for those devices. 21 U.S.C. § 360k(a)(2). This case presents an issue of first impression among the Courts of Appeals: how courts should apply that express preemption provision to state law tort claims challenging the design and manufacture of a medical device comprised of multiple components, some of which are from "Class III" medical devices subject to federal requirements, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322-23 (2008), and some of which are from medical devices that carry a different class designation

and are not subject to those requirements, *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-78, 494-95 (1996).

Because the plaintiffs' negligence, strict liability, and breach of implied warranty claims in their Second Amended Complaint are expressly preempted, we will affirm the District Court's ruling in that respect. But because the plaintiffs adequately pleaded other, non-preempted claims, and because jurisdictional discovery is warranted with respect to personal jurisdiction over one of the defendants, we will reverse the District Court's dismissal of some of the plaintiffs' claims in their Third Amended Complaint, vacate the District Court's personal jurisdiction ruling, and remand for proceedings consistent with this opinion.

## I. Background

After Walter Shuker underwent a hip replacement surgery that resulted in unexpected complications, he and his wife, Vivian Shuker, brought tort claims against Smith & Nephew, Inc. ("Smith & Nephew"), the manufacturer of his hip replacement system, and Smith & Nephew, PLC ("PLC"), the manufacturer's parent company. Before turning to the details of Mr. and Mrs. Shuker's dispute with Smith & Nephew and with PLC, we review the relevant statutory and regulatory scheme for context.

### A. Statutory and Regulatory Context

For purposes of federal statutes governing medical devices, the term "device" is a broad one, encompassing instruments, machines, implants, and "other similar or related" articles, and "including any component, part, or

accessory" of those articles. 21 U.S.C. § 321(h). "Device" refers not just to "replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators," but also to "such devices as elastic bandages and examination gloves," as well as to the constituent parts of those items. *Riegel*, 552 U.S. at 316-17.

The Federal Food, Drug, and Cosmetic Act did not originally authorize federal regulation in connection with the introduction of new medical devices, but, over time, consumers and the U.S. Food and Drug Administration ("FDA") began voicing "mounting . . . concern" about the unexamined health risks of devices being introduced to the public. *Lohr*, 518 U.S. at 475-76. Several states responded to those concerns by adopting regulatory measures, but Congress "stepped in" by enacting the Medical Device Amendments of 1976, "which swept back some state obligations and imposed a regime of detailed federal oversight." *Riegel*, 552 U.S. at 315-16. As explained in more detail below, Congress's approach here, as in other regulatory contexts,[1] was twofold: first, it established a system of federal regulation over the introduction of new devices, instituting tiered federal requirements calibrated to each device's risk level, and, second, it enacted a provision stating that federal

[1] *See, e.g.*, Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, sec. 2, §§ 3-13, 24, 86 Stat. 973, 979-92, 997 (codified as amended at 7 U.S.C. §§ 136a-136k, 136v); Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, §§ 4-5, 79 Stat. 282, 283 (1965) (codified as amended at 15 U.S.C. §§ 1333-1334).

medical device requirements supersede any different or additional state safety or effectiveness requirements. *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, sec. 2, §§ 513-516, 521, 90 Stat. 539, 540-60, 562 (codified as amended at 21 U.S.C. §§ 360c-360f, 360k).

### 1. Medical Device Approval Procedures

Approval procedures for new medical devices under the Medical Device Amendments vary depending on a device's class designation. The statute divides devices into three classes "based on the risk that they pose to the public" and applies more rigorous prerequisites to devices that pose greater risks. *Lohr*, 518 U.S. at 476-77; *see* 21 U.S.C. §§ 360c(a)(1), 360d, 360e. Because Class I devices pose the least risks, Class II devices are "more harmful," and Class III devices pose the greatest risks, *Lohr*, 518 U.S. at 477; *see* 21 U.S.C. § 360c(a)(1), Class III devices receive "the most federal oversight," and Class I and II devices receive much less, *Riegel*, 552 U.S. at 316-17. We describe the FDA's comprehensive approval procedures for Class III devices before summarizing the more lenient approval procedures for Class I and Class II devices.

#### a. Class III Devices: Premarket Approval

Before becoming available to the public, a Class III device must receive "premarket approval" through a process by which the device's manufacturer "provide[s] reasonable assurance of [the device's] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C). The premarket approval process "is a rigorous one," requiring manufacturers to "submit detailed information regarding the safety and efficacy of their devices,

which the FDA then reviews, spending an average of 1,200 hours on each submission." *Lohr*, 518 U.S. at 477.

Submissions are typically "multivolume application[s]," and thus the time devoted by the FDA to reviewing manufacturers' premarket approval submissions is, unsurprisingly, substantial. *Riegel*, 552 U.S. at 317-18. Pursuant to the Medical Device Amendments, premarket approval applications must include, among other things, "a full statement of the device's components, ingredients, and properties," *id.* at 318 (internal quotation marks omitted); *see* 21 U.S.C. § 360e(c)(1)(B), which the FDA may choose to subject to "performance standards," 21 U.S.C. § 360d(a)(1), (a)(2)(B)(i). And they likewise must provide "a specimen of the proposed labeling," which shall specify "conditions of use" under which the FDA will evaluate the device's safety and effectiveness. *Riegel*, 552 U.S. at 318; *see* 21 U.S.C. § 360e(c)(1)(F). The FDA must also determine that the labeling is not false or misleading before granting premarket approval to the device. *Riegel*, 552 U.S. at 318; *see* 21 U.S.C. § 360e(d)(1)(A).

After reviewing an application, the FDA grants premarket approval only if, based on a weighing of "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," it finds "there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. §§ 360c(a)(2)(C), 360e(d)). Once approved, the device may be manufactured, advertised, and distributed to the public, but those marketing activities may not be done in a manner "inconsistent with . . . the [premarket] approval order for the device." 21 C.F.R. § 814.80. To that end, a manufacturer

wishing to make "incremental change[s]" that affect the device's safety and effectiveness must submit a supplemental premarket approval application. 21 U.S.C. § 360e(d)(5); *accord Riegel*, 552 U.S. at 319.

Notwithstanding the strictures imposed on manufacturers, the Act allows more leeway to health care providers. Even after the FDA grants premarket approval to a medical device or to any supplements, it does not "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient . . . ." 21 U.S.C. § 396. And physicians' ability to prescribe legally marketed devices as they see fit means that "'off-label' usage," or use "for some other purpose than that for which [a device] has been approved by the FDA," is "an accepted and necessary corollary of the FDA's mission to regulate . . . without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Although the statute thus expressly contemplates the possibility that physicians may use a Class III device for unapproved purposes, a manufacturer may not vary the design or manufacture of the pre-approved device, even in anticipation of such uses. *See* 21 U.S.C. § 396.

**b. Class I and Class II Devices: § 510(k) Approval**

In contrast to the rigorous premarket approval process for Class III devices, Class I and Class II devices are subject to "a limited form of review" set forth at 21 U.S.C. § 360(k) and known as the "§ 510(k) process" (reflecting the number of the relevant section in the Federal Food, Drug, and Cosmetic Act). *Lohr*, 518 U.S. at 478. Compared to a

premarket approval application, compliance with the § 510(k) process requires a far less exhaustive submission. *See* 21 U.S.C. § 360(k); 21 C.F.R. § 807.87. In many cases, § 510(k) approval rests not on proof of the device's safety, but merely on a finding that a device is "substantially equivalent" to a preexisting approved medical device. *Lohr*, 518 U.S. at 478. A § 510(k) approval thus provides comparatively "little protection to the public." *Id.* at 493.

**2. Express Preemption Provision**

The Medical Device Amendments' comprehensive and tiered approval procedures for medical devices leave only limited room for additional state regulation, especially considering the statute contains a broad express preemption provision. This provision proclaims that "no State . . . may establish or continue in effect with respect to a device . . . any requirement" that "is different from, or in addition to," any federal requirement and that relates either "to the safety or effectiveness of the device" or "to any other matter" included in a federal requirement applicable to the device. 21 U.S.C. § 360k(a).[2] The statute thus preempts any state requirement that has "the effect of establishing a substantive requirement for [the] specific device" in question that relates to safety,

[2] The express preemption provision includes an exception for state requirements that the Secretary of Health and Human Services has exempted from preemption by regulation, *see* 21 U.S.C. § 360k(b), but because the Shukers' common law tort claims are not included within the Secretary's regulatory exemptions, *see* 21 C.F.R. §§ 808.53 to .101, that exception is not pertinent here.

effectiveness, or "any other matter" that forms a federal requirement, so long as the state requirement is "different from, or in addition to," the federal mandate. *Lohr*, 518 U.S. at 499-500 (quoting 21 U.S.C. § 360k(a); 21 C.F.R. § 808.1(d)(6)(ii)). The "overarching concern" behind this provision is "that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* at 500.

Application of the express preemption provision tracks the Medical Device Amendments' tiered statutory scheme for medical device approvals. Because manufacturers of Class I and Class II devices receive only § 510(k) approval and emerge from the approval process with no safety review specific to those devices, manufacturers do not receive the benefit of express preemption, *see Lohr*, 518 U.S. at 492-94. In contrast, because a manufacturer of a Class III device must receive premarket approval, clear "federal safety review" that "is specific to [the] individual device[]," and thereby satisfy federal requirements applicable to the device, the manufacturer of that Class III device receives express preemption protections from state requirements that are "different from, or in addition to," the federal requirements imposed on the device through the premarket approval process. *Riegel*, 552 U.S. at 322-23 (quoting 21 U.S.C. § 360k(a)(1)). This protection inures to manufacturers regardless of how a device is used by third parties. *See* 21 U.S.C. § 396 (contemplating off-label uses of devices by physicians); *see also Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1343-45 (10th Cir. 2015) (holding that the fact that a claim alleges off-label use does not "insulate" it from express preemption).

But state laws are not shut out entirely. Even for Class III devices, the Medical Device Amendments' express preemption provision does not reach "parallel" claims, i.e., claims premised on state requirements that merely incorporate applicable federal requirements and therefore are not "different from, or in addition to," federal requirements. *Lohr*, 518 U.S. at 494-95 (citing 21 U.S.C. § 360k(a)(1)); *accord Riegel*, 552 U.S. at 330.

The question of first impression we confront today[3] arises at the intersection of these different classes of devices with their different approval schemes: How do we apply the Medical Device Amendments' express preemption provision to a "hybrid system," i.e., a system that is itself a "device" but that is comprised of Class II components in addition to one or more Class III components?[4] We recount the facts of the parties' dispute before turning to our answer.

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[3] *Cf. Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1323, 1327-33 (11th Cir. 2017) (addressing preemption as applied to a device comprised of only Class III components, not as applied to a device comprised of a Class III component and Class II components); *Spellman v. Smith & Nephew, Inc.*, No. 16-8080, 2016 WL 5364206, at *1, *3-4 (D. Ariz. Sept. 26, 2016) (same), *appeal docketed*, No. 17-15351 (9th Cir. Feb. 28, 2017).

[4] Here, and when not quoting another source, we use the term "component" to mean, collectively, "component, part, or accessory," 21 U.S.C. § 321(h), to the extent there are any differences between the three. By "system" we mean, in Mr. Shuker's case, the entire hip replacement "device"

### B. Factual and Procedural History[5]

Mr. Shuker underwent total hip replacement surgery in 2009. The hip replacement system "implant[ed]" was regulated as a "device" under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h), but was comprised of multiple components, all manufactured by Smith & Nephew. Some components replaced the top of Mr. Shuker's thighbone (or femur) with a metal head, metal sleeve, and a stem connecting the metal head to the thighbone, while another component rested on his hip socket (or acetabulum). These components were all Class II devices approved through the relatively lenient § 510(k) process. A final component, the "R3 metal liner," mediated the connection between his hip socket and his thighbone and was seated atop the hip socket component, App. 42; unlike the other components, the liner underwent the rigorous premarket approval process as a supplemental component for a separate Smith & Nephew

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implanted in his hip, including all of its constituent components. *Id.*

[5] The factual summary below draws from record evidence that we consider in reviewing the District Court's summary judgment ruling regarding preemption, and its dismissal of PLC for lack of personal jurisdiction. But we consider only the complaint, its exhibits, "undisputedly authentic document[s]" upon which the plaintiffs' claims are based, and the public record in reviewing the District Court's dismissal of the Shukers' Third Amended Complaint for failure to state a claim. *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

Class III device, the Birmingham Hip Resurfacing System. *Shuker v. Smith & Nephew PLC*, No. 13-6158, 2015 WL 1475368, at *2-3 (E.D. Pa. Mar. 31, 2015). Together with the metal head and metal head sleeve replacing the top of Mr. Shuker's thighbone, the metal liner created a "metal-on-metal articulation" at Mr. Shuker's hip socket. *Id.* at *3.

As is customary, the FDA's premarket approval requirements for the liner extended to the liner's accompanying labeling, which was required to state that "the R3 metal liner [was] intended for use as part of the [Birmingham Hip Resurfacing System] only" and that "the R3 metal liner must be replaced with an R3 poly[ethylene] liner" if the Birmingham Hip Resurfacing System were abandoned or later revised in favor of a total hip replacement system. *Id.* at *2. Thus, as the parties agree, *see* Appellant's Br. 6-7; Appellee Smith & Nephew's Br. 6, because the R3 metal liner's labeling reflected that the FDA had not approved the liner for use outside of the Birmingham Hip Resurfacing System or in a total hip replacement system, Smith & Nephew's promotional materials marketing the R3 metal liner as an "option for its R3 Acetabular System," a separate hip system, App. 14, constituted "off-label promotion," *Shuker*, 2015 WL 1475368, at *13, and the liner's use in Mr. Shuker's total hip replacement system constituted an "off-label" use, *Buckman Co.*, 531 U.S. at 350.

About twenty-one months after his hip replacement surgery, Mr. Shuker "began developing increasing pain and discomfort in his buttocks, groin, and thigh, limiting his daily activities." *Shuker*, 2015 WL 1475368, at *3. His surgeon performed an aspiration procedure that revealed "metallic debris" within Mr. Shuker's body, indicating that

"Mr. Shuker's pain was caused by metal sensitivity due to the degeneration of the metal-on-metal articulation," which needed to be replaced to relieve his pain. *Id*. Mr. Shuker then underwent revision surgery to replace the R3 metal liner, followed by additional surgeries to remove and replace his entire hip replacement system when the first revision surgery did not relieve his pain.

Seeking to hold Smith & Nephew and its parent company PLC liable for Mr. Shuker's hip replacement complications and for Mrs. Shuker's loss of consortium, the Shukers filed suit, bringing various common law claims, and later adding claims based on violations of federal law.[6] PLC moved for dismissal from the case for lack of personal jurisdiction, and Smith & Nephew moved for summary judgment on some of the Shukers' claims, asserting that the Medical Device Amendments expressly preempted those claims.

Without an opinion but with a lengthy explanatory footnote accompanying its order, the District Court granted PLC's motion to dismiss. In a separate order and opinion, the District Court granted summary judgment in favor of Smith & Nephew, holding as relevant to this appeal that the negligence, strict liability, and breach of implied warranty claims in the Shukers' Second Amended Complaint were

[6] The Shukers originally filed suit in Pennsylvania state court, but Smith & Nephew and PLC removed the case to federal court. The District Court had subject-matter jurisdiction pursuant to 28 U.S.C. § 1332(a).

preempted because "the heart of each of [the Shukers'] claims" challenged the safety and effectiveness of the R3 metal liner, which had received premarket approval, was therefore subject to federal requirements, and, hence, gave Smith & Nephew the benefit of express preemption. *Shuker*, 2015 WL 1475368, at *6-11, *17. The District Court also granted the Shukers the opportunity to amend their complaint against Smith & Nephew as to their non-preempted claims alleging off-label promotion in violation of federal law, and the Shukers proceeded to file a Third Amended Complaint. Ultimately, however, the District Court dismissed that complaint for failure to state a claim. *See Shuker v. Smith & Nephew PLC*, 211 F. Supp. 3d 695, 700-05 (E.D. Pa. 2016).

This appeal followed.[7]

## II. Discussion

We resolve the questions presented by this case in three parts. First, we consider whether the negligence, strict liability, and breach of implied warranty claims in the Shukers' Second Amended Complaint are expressly preempted. *See* Section II.A, *infra*. Second, we review the District Court's decision to dismiss the claims in the Shukers' Third Amended Complaint with prejudice. *See* Section II.B, *infra*. Finally, we consider personal jurisdiction as to PLC and whether jurisdictional discovery is warranted. *See* Section II.C, *infra*.

[7] We have jurisdiction pursuant to 28 U.S.C. § 1291.

### A. Preemption

The District Court granted summary judgment to Smith & Nephew on express preemption grounds with respect to the negligence, strict liability, and breach of implied warranty claims in the Shukers' Second Amended Complaint. We review that grant de novo, *Steele v. Cicchi*, 855 F.3d 494, 500 (3d Cir. 2017), and will affirm if Smith & Nephew has established that "there is no genuine dispute as to any material fact" and, viewing the facts in the light most favorable to plaintiffs, Smith & Nephew "is entitled to judgment as a matter of law," Fed. R. Civ. P. 56(a); *see also Steele*, 855 F.3d at 500.

Here, that decision turns on whether the Medical Device Amendments expressly preempt the Shukers' negligence, strict liability, and breach of implied warranty claims in their Second Amended Complaint—the primary issue addressed in the parties' original briefing, as well as their supplemental briefing and an amicus brief filed by the FDA at the request of the Court.[8] We undertake this analysis

[8] While the supplemental briefing and the FDA's submission address implied preemption as well as express preemption, we confine our analysis to express preemption today. The Medical Device Amendments can preempt state common law claims against medical device manufacturers both expressly and impliedly, *see Buckman Co.*, 531 U.S. at 348 & n.2, and the existence of an express preemption provision like § 360k(a), as the FDA points out, "does not ordinarily alter the normal operation of implied-preemption

by (1) reviewing the two-step framework for determining whether a claim concerning a "device" is preempted under the Amendments' express preemption provision, (2) determining what constitutes the "device" when a system is comprised of components with mixed-class designations, and (3) applying the framework applicable to that "device" to the facts of this case.

### 1. Principles Governing Express Preemption Under the Medical Device Amendments

In products liability actions like this one, the Supreme Court has specified that "the historic primacy of state regulation of matters of health and safety" requires us to apply the "presumption against the pre-emption of state

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principles." FDA Amicus Br. 13. However, because Smith & Nephew raised only express preemption arguments before the District Court, we conclude implied preemption arguments are not properly before us on appeal, *see Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 335-36 (3d Cir. 2009). Even if they were, because, e.g., Smith & Nephew preserved its preemption defense and did not "explicitly disclaim[] the applicability of [implied] preemption," *Holk*, 575 F.3d at 336, we would still begin with (and here, would end with) express preemption, for the statute's plain wording "necessarily contains the best evidence of Congress' preemptive intent," *Chamber of Commerce of the U.S. v. Whiting*, 563 U.S. 582, 594 (2011) (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)).

police power regulations."[9] *Lohr*, 518 U.S. at 485 (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518 (1992)); *accord Wyeth v. Levine*, 555 U.S. 555, 565 & n.3 (2009). We therefore begin with the principle that "the historic police powers of the States," such as their power to regulate "matters of health and safety," are "not to be superseded" unless preemption "was the clear and manifest purpose of Congress." *Lohr*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Congress's intent is our "ultimate touchstone," and "we look to the language, structure, and purpose of the relevant statutory and regulatory scheme to develop a reasoned understanding of the way in which Congress intended the statute and its surrounding

[9] We disagree with Smith & Nephew's assertion that "[a]ny presumption against express preemption no longer exists." Appellee Smith & Nephew's Br. 21. Smith & Nephew relies on a Supreme Court case that addressed whether the federal Bankruptcy Code's express preemption provision preempts a Puerto Rico statute, *see Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 136 S. Ct. 1938, 1945-46 (2016) (discussing 11 U.S.C. § 903(1)), but that case did not address preemption of claims invoking "historic . . . state regulation of matters of health and safety," such as the products liability claims at issue here, *Lohr*, 518 U.S. at 485. As that case does not "directly control[]" here, we "leav[e] to [the Supreme Court] the prerogative of overruling its own decisions," *Agostini v. Felton*, 521 U.S. 203, 237 (1997), and continue to apply the presumption against preemption to claims, like those in this case, that invoke "the historic police powers of the States," *Lohr*, 518 U.S. at 485.

regulatory scheme to affect business, consumers, and the law." *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 687 (3d Cir. 2016) (internal quotation marks omitted) (quoting *Wyeth*, 555 U.S. at 565; *Lohr*, 518 U.S. at 486).

The express preemption provision of the Medical Device Amendments states that "no State or political subdivision of a State may establish or continue in effect with respect to a device. . . any requirement" that "is different from, or in addition to, any requirement applicable under [the Federal Food, Drug, and Cosmetic Act]" and that relates either "to the safety or effectiveness of the device" or "to any other matter included in a requirement applicable to the device under [the Act]." 21 U.S.C. § 360k(a). Based on this statutory language, the Supreme Court, in *Riegel v. Medtronic, Inc.*, prescribed a two-step framework for determining whether a state law cause of action is preempted. 552 U.S. at 321-22. *First,* we ask "whether the Federal Government has established requirements applicable" to the specific "device" at issue. *Id.* at 321. If it has, then, *second*, we ask "whether the [plaintiffs'] claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.* at 321-22 (quoting 21 U.S.C. § 360k(a)). If we answer both questions in the affirmative, then the plaintiffs' claims are expressly preempted. *See id.* at 321-30. If, instead, the answer to the second question is no, then the "state duties in such a case 'parallel,' rather than add to, federal requirements," and the claims are not preempted. *Id.* at 330 (quoting *Lohr*, 518 U.S. at 495).

The first step of *Riegel*'s two-step framework, however, presumes agreement as to the "device" to which it

applies. 21 U.S.C. § 360k(a). Therefore, before a court can apply the test, it must address a threshold question: What device is the subject of the "federal requirements"? *Riegel*, 552 U.S. at 321. This question, while ancillary when each component of a system receives the same review by the FDA, is central when evaluating hybrid systems, like the one implanted in Mr. Shuker's hip that contain both Class II and Class III components. In that situation, neither the statute nor the relevant guidance from the Supreme Court, *see Riegel*, 552 U.S. at 321, specifies how we should apply the *Riegel* test. Do we analyze express preemption at the level of the system or the component? That is the problem we confront today.

**2. Determining the Device at Issue**

The Shukers urge on appeal that the "device" at issue is the entire hybrid system itself. Any other determination, they argue, would produce unfairness and incongruity by according preemption even when a component is used off-label in a manner "that was never studied or approved by the FDA," Appellant's Br. 23 (capitalization omitted), merely because that component part was pre-approved for use with another system. Appellees, seconded by the FDA, counter that analysis at the component level is the only way to harmonize various provisions of the statute. We agree with Appellees for three reasons.

*First*, analysis at the component level finds support in the text of the statute and regulations. The Federal Food, Drug, and Cosmetic Act defines "device" to mean not simply a finished "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or

related article," but also "any component, part, or accessory" of that article. 21 U.S.C. § 321(h). Codified in 1938 with the original Act, this definition has always provided that the term "device" includes "components, parts, and accessories," mirroring the definition for "drug" immediately preceding it, which was and is defined to include "articles intended for use as a component" of a drug. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 201(g), (h), 52 Stat. 1040, 1041 (1938) (codified as amended at 21 U.S.C. § 321(g), (h)). The implementing regulations, at least for quality control purposes, also describe "[c]omponent" to include "any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device." 21 C.F.R. § 820.3(c).[10]

[10] We note that neither the definition of "device," nor the express preemption provision, makes any exception for instances where components that received premarket approval are used with components that did not receive such approval. *See* 21 U.S.C. §§ 321(h), 360k(a). That is, no exception applies where components that confer express preemption protections (by virtue of being subject to federal requirements imposed through the premarket approval process) are used with components that do not. And we cannot ourselves imply such an exception, for "[w]here Congress explicitly enumerates certain exceptions to a general prohibition," *United States v. Smith*, 499 U.S. 160, 167 (1991), as it has done here in the statutory section containing the Medical Device Amendments' express preemption provision, *see* 21 U.S.C. § 360k(b); note 2, *supra*, then "additional exceptions

*Second*, the Act's provision for off-label use supports a component-level analysis. While the premarket approval process requires strict manufacturer compliance with respect to a device's labeling and advertising, *see* 21 U.S.C. §§ 352(q)-(r), 360e(d)(1)(A), the statutory scheme contemplates that physicians will prescribe or administer components outside of a system with which the FDA approved their use. As noted, off-label uses of devices (and components) are "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co.*, 531 U.S. at 350. Put differently, the regulatory landscape contemplates that devices may be broken down into component parts and individual components used separately by third parties. Even then, however, premarket approval requirements "apply equally" to the components, as manufacturers "generally may not deviate from the requirements imposed through premarket approval regardless of how [a component] is used." FDA Amicus Br. 8; *see also* 21 U.S.C. § 396. Congress thereby has evinced an intent not to "discourage[]" device manufacturers "from seeking . . . approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer . . . to unpredictable civil liability," *Buckman Co.*, 531 U.S. at 350, and instead to "protect[] manufacturers that have complied

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are not to be implied, in the absence of evidence of a contrary legislative intent," *Smith*, 499 U.S. at 167.

with detailed federal requirements from being subject[] to liability under state law for doing what federal law required." FDA Amicus Br. 9. It is not surprising, then, that several courts have held that when a single component of a Class III device is used on its own, rather than in the premarket-approved system, express preemption adheres to the individual premarket-approved component. *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. 2014); *Houston v. Medtronic, Inc.*, No. 13-1679, 2014 WL 1364455, at *4 (C.D. Cal. Apr. 2, 2014).

*Third*, the FDA, "the federal agency to which Congress has delegated its authority to implement provisions of the Act," *Lohr*, 518 U.S. at 496, also takes the position that because "the definition of 'device' encompasses . . . premarket-approved . . . system[s], and each of the 'component[s], part[s], [and] accessor[ies]' of these devices," the relevant device for preemption purposes must be evaluated at the component level. FDA Amicus Br. 7 (all but first alteration in original) (quoting 21 U.S.C. § 321(h)).[11]

[11] We "do not defer to an agency's view" concerning preemption, but such views as presented in an amicus brief are "'entitled to respect' . . . to the extent [they] ha[ve] the 'power to persuade.'" *Sikkelee*, 822 F.3d at 693-94 (alterations in original) (quoting *Gonzalez v. Oregon*, 546 U.S. 243, 255-56 (2006)). *See also Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

And, contrary to the Shukers' argument that "[t]he FDA reviews . . . *systems*, not individual . . . *components*," Appellant's Br. 17, the Medical Device Amendments direct the FDA, "where necessary to provide reasonable assurance of . . . safe and effective performance," to establish performance standards for device components, 21 U.S.C. § 360d(a)(2)(B)(i), while the FDA's regulations require manufacturers of finished devices, if "deviations from device specifications could occur as a result of the manufacturing process," to monitor and control "component . . . characteristics during production." 21 C.F.R. § 820.70(a)(2). What's more, just like manufacturers of finished devices, manufacturers of "components or accessories" are subject to device registration and reporting requirements. *Id.* §§ 803.3(*l*)(3), 806.2(h)(3), 807.20(a)(6); *see id.* §§ 803.50, 806.10. *See generally* 21 U.S.C. §§ 360(b), (j), 360i(a)(1), (g)(1).

Taken together, the statutory definition of "device," the treatment of off-label uses, and the guidance of the FDA all counsel in favor of scrutinizing hybrid systems at the component-level. In that circumstance, § 360k(a) preempts any state law "with respect to" a Class III component that is "different from, or in addition to" a federal requirement and that relates either "to the safety or effectiveness of the device" or "to any other matter included in a requirement applicable to the device under [the Act]." 21 U.S.C. § 360k(a). And the *Riegel* test is properly framed at Step One as "whether the Federal Government has established requirements applicable" to a component of the hybrid system, and at Step Two, "whether the [plaintiffs'] claims are based upon [state] requirements with respect to [that component] that are 'different from, or in addition to,' the federal ones, and that

relate to safety and effectiveness." *Riegel*, 552 U.S. at 321-22 (quoting 21 U.S.C. § 360k(a)). This formulation of *Riegel*'s test for hybrid systems comports with the "'most basic' interpretive rule that a statute is to be construed so that effect is given to *all* its provisions." *Doe v. Mercy Catholic Med. Ctr.*, 850 F.3d 545, 555 (3d Cir. 2017) (quoting *Corley v. United States*, 556 U.S. 303, 314 (2009)).[12]

### 3. Application to the Shukers' Claims

We turn next to the application of this test to the Shukers' claims and conclude that both prongs of *Riegel* are satisfied. At Step One, the R3 metal liner is a Class III component that received premarket approval as part of the Birmingham Hip Resurfacing System; and that premarket approval "imposed requirements on the liner with respect to its composition, dimensions, and labeling, among other specifications." FDA Amicus Br. 7. *See also* App. 470-473; *Shuker*, 2015 WL 1475368, at *2-3.

[12] Our decision accords with those of the district courts that have grappled with the Act's definition of "device" while addressing how the Medical Device Amendments' express preemption provision should apply to devices with components of mixed-class designations. *See, e.g.*, *Nagel v. Smith & Nephew, Inc.*, No. 15-0927, 2016 WL 4098715, at *4-5 (D. Conn. July 28, 2016); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 858 (W.D. Tenn. 2015); *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 255 (E.D.N.Y. 2014); *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 405-406 (S.D.N.Y. 2013).

*Riegel* Step Two is also met, given the different requirements that would follow from imposing liability for the tort claims at issue; that is, the negligence, strict liability, and breach of implied warranty claims of the Second Amended Complaint.[13] The express preemption provision forecloses claims based on "violations of common-law duties" to the extent that they impose more than "parallel federal requirements," *Lohr*, 518 U.S. at 495. The Shukers' claims, however, would impose requirements "with respect to" the R3 metal liner that are "different from, or in addition to," federal ones, 21 U.S.C. § 360k(a)), because, as the District Court correctly observed, "the heart of each of [the Shukers'] claims" challenged the safety and effectiveness of the R3 metal liner, *Shuker*, 2015 WL 1475368, at *11.

Neither in the District Court nor on appeal have the Shukers identified any freestanding defect with the Class II device or the R3 Acetabular System *per se*. To the contrary, despite conclusory allegations that the R3 System was defective with and without the R3 metal liner that would foreseeably be used with it, the Shukers' negligence, strict liability and breach of implied warranty claims rest on the

[13] Although the Shukers separately asserted ostensibly parallel claims based on violations of federal law in their Second Amended Complaint, they do not attempt to revive those claims on appeal, resting instead on the amended claims alleging off-label promotion and asserted in their Third Amended Complaint, which we address later in this opinion, *see infra* Part II.B.

premise that the R3 System was defective only because it was used with the R3 metal liner. *See* Tr. of Oral Arg. 79:13-18 (identifying that the defects arose when "all of the components" are used "in tandem"); *id.* at 7:19-22 (explaining "[y]ou can't have the debris coming out without the conjunction of the Class 2 and Class 3 components coming together. It's that friction that causes it. So it would be irresponsible to say . . . [that] only the liner caused the metal debris or only the cup caused the metal debris.").[14]

[14] Some district courts, in evaluating complaints that allege "injuries stemming from the combination of [premarket and non-premarket] component parts," have declined to apply express preemption to claims arising from the *interaction* of these mixed class components because "the combination of component[s]" itself was not subject to premarket approval. *Lafountain v. Smith & Nephew*, No. 14-1598, 2016 WL 3919796, at *5-6 (D. Conn. 2015); *see also Huskey v. Ethicon*, 29 F. Supp. 3d 736, 751 (S.D. W. Va. 2014). These courts "decline[d] to separate the device into its component parts to create express preemption." *Lafountain*, 2016 WL 3919796 at *6. But for the reasons we have explained, *see* Section II.A.2, *supra*, we think the better reading of the statute is to separate a device into its component parts. *See* 21 U.S.C. § 321(h). Express preemption therefore applies to a so-called "combination" claim, like any other, so long as the claims are based on state requirements "with respect to" a device that are "different from, or in addition to" federal requirements. 21 U.S.C. § 360k(a).

Even the failure-to-warn allegations embedded in the Shukers' negligence claim would impose different requirements on the R3 metal liner, as the Shukers seek to impose liability because defendants did not accompany their product with proper warnings regarding the risks associated with a premarket-approved device, the R3 metal liner. But the FDA already imposed device-specific labeling requirements on the liner, and thus, as the FDA itself points out in its amicus submission, "a state warning requirement that applie[s] specifically to the use of the R3 system's components with the R3 metal liner in particular" is preempted. FDA Amicus Br. 11 n. 3.[15]

In sum, the negligence, strict liability, and breach of implied warranty claims asserted in the Second Amended

[15] This is not to say that all failure-to-warn allegations as to hybrid systems would be preempted. On the contrary, as the FDA notes, a claim premised on a state requirement that the R3 System carry a warning against "use with metal liners," or that it only be used with polyethylene liners, for example, "would not implicate § 360k(a)" because "the FDA did not impose device-specific labeling requirements on the R3 system components." FDA Amicus Br. 11. But such a claim is not before us, and to the extent the Shukers take issue with the off-label use of the R3 liner as opposed to the promotion of that use, their recourse is in a malpractice claim against the physician that prescribed the off-label use, not in a products liability claim against the Appellees. *See generally, e.g.*, Pa. R. Civ. P. 1042.1 (discussing professional liability actions in Pennsylvania); *Thierfelder v. Wolfert*, 52 A.3d 1251, 1253-54, 1261, 1264 (Pa. 2012) (same).

Complaint, would impose non-parallel state law requirements and are therefore expressly preempted. We will affirm the District Court's order in that respect.

**B. Claims in the Third Amended Complaint**

We turn next to the Shukers' contention that the District Court erred in holding that their off-label promotion claims in the Third Amended Complaint failed to state a claim. We exercise plenary review over the District Court's dismissal of those claims, *see Santiago v. Warminster Twp.*, 629 F.3d 121, 128 (3d Cir. 2010), and thus we will affirm only if the Shukers did not plead "factual content that allows the court to draw the reasonable inference that [Smith & Nephew] is liable for the misconduct alleged," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

The Shukers' Third Amended Complaint included three state law tort claims based on Smith & Nephew's alleged off-label promotion in violation of federal law: negligence, loss of consortium, and fraud. We assess each claim in turn, first acknowledging "the elements [the Shukers] must plead to state a claim," then accepting "all of the complaint's well-pleaded facts as true" while disregarding "any legal conclusions," and finally determining whether the well-pleaded factual allegations "plausibly give rise to an entitlement to relief." *Santiago*, 629 F.3d at 129-31 (brackets and internal quotation marks omitted). We view the factual allegations in the light most favorable to the Shukers and construe all reasonable inferences in their favor. *See United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 257 (3d Cir. 2016); *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 790, 793 (3d Cir. 2016). If the Shukers have specified "the means through which" Smith &

Nephew acted unlawfully, included "details" confirming those means, and alleged facts connecting those means to their own injuries, then we must conclude that they have plausibly stated a claim for relief. *Schuchardt v. President of the U.S.*, 839 F.3d 336, 349-50 (3d Cir. 2016).

Applying these principles, we hold that the Shukers have met their pleading burden with respect to their negligence and loss of consortium claims. Although they did not adequately plead their fraud claim, which they were required to plead with particularity, *see* Fed. R. Civ. P. 9(b), we will nonetheless vacate the District Court's dismissal of that claim to the extent that it was with prejudice. We discuss each of the Shukers' three claims from their Third Amended Complaint below.

**1. Negligence Based on Off-Label Promotion**

The elements of negligence under Pennsylvania law are: (1) "a legally recognized duty or obligation of the defendant," (2) "the breach thereof," and (3) a "causal connection" between the breach and the plaintiffs' damages. *Green v. Pa. Hosp.*, 123 A.3d 310, 315-16 (Pa. 2015).[16] We

[16] We assume that Pennsylvania law applies without undertaking a choice of law analysis, because both Smith & Nephew and the District Court assumed that Pennsylvania law applied to the claims in the Third Amended Complaint, and because the Shukers have waived any objection to that choice of law by failing to make it, *see Williams v. BASF Catalysts LLC*, 765 F.3d 306, 316 (3d Cir. 2014) ("[P]arties may waive choice-of-law issues.").

modify these elements somewhat because, for the negligence claim alleged here to escape express preemption as a parallel claim, the "duty" element must arise from federal requirements applicable to a medical device. *Id.* at 316; *see Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 495. To state a parallel negligence claim, then, the Shukers were required to plead (1) a duty arising from federal requirements applicable to a medical device, (2) a breach of that duty, and (3) a causal connection between the breach and the Shukers' injuries.

Construing all reasonable inferences in the Shukers' favor, *see Victaulic Co.*, 839 F.3d at 257, the Shukers' Third Amended Complaint plausibly alleges each of these three required elements. First, as to duty, the complaint alleges that the R3 metal liner received premarket approval as part of the Birmingham Hip Resurfacing System and was approved "only . . for use with [that] . . . [s]ystem," App. 473, leading to the reasonable inference that the R3 metal liner was a "restricted device" under the Medical Device Amendments, 21 U.S.C. § 360j(e), and that federal law therefore imposed a duty on Smith & Nephew to refrain from publishing "false or misleading" advertising with respect to the R3 metal liner, 21 U.S.C. §§ 331(b), 352(q), even if such advertising was for the purpose of marketing a separate device, 21 C.F.R. § 801.6.

Second, as to breach, the complaint asserts that, even though the FDA did not approve the R3 metal liner for use with any hip system other than the Birmingham Hip Resurfacing System, Smith & Nephew "actively marketed the [R3] metal liner as 'optional' for the [separate] R3 Acetabular System," App. 479. The complaint also cites to Smith & Nephew's February 2009 press release, which explicitly

announces "the introduction of a metal liner option for [Smith & Nephew's] R3 Acetabular System." App. 14.[17] These factual allegations give rise to the reasonable inference that Smith & Nephew's marketing was "misleading" regarding the FDA-approved uses of the R3 metal liner, 21 U.S.C. § 352(q), and that Smith & Nephew breached its duty under federal law not to advertise its medical device in that misleading manner.[18]

Finally, as to causation, the Shukers' Third Amended Complaint alleges that Mr. Shuker's surgeon "either read" or "was aware" of the information in Smith & Nephew's press release, that the surgeon proceeded to find the R3 metal liner "appropriate" for Mr. Shuker, "given his body habitus and his

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[17] Because we may consider a "document integral to or explicitly relied upon in the complaint" in considering a Rule 12(b)(6) motion to dismiss, *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d 280, 292 (3d Cir. 1999), our analysis relies on the text of the entire Smith & Nephew press release from February 2009, which is reproduced only in part in the Shukers' Third Amended Complaint but is part of the District Court record.

[18] To the extent Smith & Nephew contends that a dispute of fact exists as to whether Smith & Nephew's promotional materials were false or misleading, the Shukers are entitled to discovery to explore this issue for, if discovery produces "conflicting evidence," a factual dispute like this one can ripen into a question for a jury to decide. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 290 (3d Cir. 2017).

activity level," and that Mr. Shuker endured pain "caused by metal sensitivity due to the degeneration of the metal on metal articulation" in his hip replacement system. App. 480, 483. Together these factual allegations lead to the reasonable inference that Smith & Nephew's marketing materials caused Mr. Shuker's surgeon to recommend the R3 metal liner and to install it within Mr. Shuker's hip replacement system, a course of action which in turn caused Mr. Shuker's subsequent injuries.

Because the factual allegations in the Shukers' Third Amended Complaint allow us reasonably to infer each of the three legal elements of the Shukers' parallel negligence claim, the complaint contains sufficient facts to "nudg[e]" that claim "across the line from conceivable to plausible," *Iqbal*, 556 U.S. at 683, and hence the District Court's dismissal of that claim was in error.

**2. Loss of Consortium**

Loss of consortium is an injury referring to "the impact of one spouse's physical injuries upon the other spouse's marital privileges and amenities," and, while remaining "a . . . distinct cause of action" for "loss of services, society, and conjugal affection of one's spouse," is a claim "derivative" of a spouse's separate claim of injury. *Darr Constr. Co. v. Workmen's Comp. Appeal Bd.*, 715 A.2d 1075, 1079-80 (Pa. 1998). Because we hold the Shukers have adequately pleaded a negligence claim premised on Mr. Shuker's injuries, they have also adequately pleaded the derivative claim of loss of consortium.

The Third Amended Complaint alleges that, after Mr. Shuker's hip replacement surgery and "due to the degeneration of the metal on metal articulation," he experienced "buttocks, groin and thigh discomfort" that "caused him pain and extremely limited his daily activities." App. 483. Thus, we can reasonably infer that, because of Smith & Nephew's misleading marketing in violation of federal law, the R3 metal liner's subsequent use in Mr. Shuker's hip replacement surgery, and Mr. Shuker's ensuing "physical injuries," Mrs. Shuker suffered a loss of her husband's "services, society, and conjugal affection." *Darr Constr.*, 715 A.2d at 1080. The Shukers' loss of consortium claim therefore states a facially plausible entitlement to relief arising from state requirements that are "parallel" to federal ones, *Lohr*, 518 U.S. at 495; *see Iqbal*, 556 U.S. at 678, and the District Court erred in dismissing it.

**3. Fraud**

In contrast to the Shukers' pleading of their other claims, the Shukers' pleading of their fraud claim is not adequate because it does not satisfy Rule 9(b)'s requirement that, though "intent . . . and other conditions of a person's mind may be alleged generally," plaintiffs "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

To plead fraud under Pennsylvania law, a plaintiff must allege (1) "a representation" which is (2) "material to the transaction at hand," (3) "made falsely, with knowledge of its falsity or recklessness as to whether it is true or false," and (4) made "with the intent of misleading another into relying on it"; (5) "justifiable reliance on the misrepresentation"; and

(6) that "the resulting injury was proximately caused by the reliance." *Gibbs v. Ernst*, 647 A.2d 882, 889 (Pa. 1994). But in addition, a plaintiff in federal court, to comply with Rule 9(b), must allege "the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation" and must state "the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the precise misconduct with which it is charged." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (brackets and internal quotation marks omitted).

Here, the Shukers' Third Amended Complaint pleads many of the elements of a fraud claim: (1) it alleges that Smith & Nephew made "representation[s]" by including and incorporating representations Smith & Nephew made regarding the R3 metal liner; (2) it alleges "material[ity]" by describing those representations' importance in influencing surgeons, such as Mr. Shuker's surgeon, to use the R3 metal liner off-label; (3) it alleges "falsity" by stating that, contrary to Smith & Nephew's representations, the company received FDA approval regarding the R3 metal liner's use within the Birmingham Hip Resurfacing system only; and (4) it alleges "intent" by contending that Smith & Nephew represented that the R3 metal liner was available for use within other hip systems, even though the company had never sought FDA approval for use within those systems. *Gibbs*, 647 A.2d at 889.

Their complaint comes up short, however, because it does not plead the element of "justifiable reliance" on Smith & Nephew's misrepresentation with the particularly required for Rule 9(b). *Id.* Specifically, because "[i]t is not enough

simply to assert that a statement was 'fraudulent' and that reliance upon it induced some action," *Blumenstock v. Gibson*, 811 A.2d 1029, 1038 (Pa. Super. Ct. 2002), the complaint had to contain details about "the relationship of the parties involved and the nature of the transaction," *Drelles v. Mfrs. Life Ins. Co.*, 881 A.2d 822, 841 (Pa. Super. Ct. 2005). Such details are necessary for a reviewing court to determine, for example, whether a representation's "obvious" falsity precludes a finding of justifiable reliance, *id.* at 840, or, if the representations at issue were not obviously false, whether the representation actually provoked reliance by "induc[ing] or influenc[ing] the plaintiff's [or his agent's] course of conduct," *Commonwealth v. TAP Pharm. Prods., Inc.*, 36 A.3d 1112, 1144 (Pa. Commw. Ct. 2011), *vacated on other grounds*, 94 A.3d 364 (Pa. 2014) (mem.) (per curiam).

The complaint does not meet this standard. In asserting that Mr. Shuker's surgeon "read" or "was aware" of Smith & Nephew's press release about the R3 metal liner, App. 480, the complaint does not provide any details about how the press release "induced or influenced" the surgeon's course of conduct, *TAP Pharm Prods.*, 36 A.3d at 1144. The bald assertion that "[the press release's] claims (or those of equal substance) influenced [the surgeon]" does not suffice, App. 480, because, at least for Rule 9(b) purposes, that statement is merely a "naked assertion[] devoid of further factual enhancement," amounting to "nothing more than a formulaic recitation of the element[] of a cause of action," *Iqbal*, 556 U.S. at 678. As the Shukers have not stated "the circumstances of the alleged [influence on Mr. Shuker's surgeon] with sufficient particularity to place [Smith & Nephew] on notice of the precise misconduct with which it is charged," *Frederico*, 507 F.3d at 200 (brackets and internal

quotation marks omitted), we conclude that the Shukers' fraud claim was insufficiently pleaded under Rule 9(b), and we will therefore affirm the District Court's dismissal.

We hold, however, that the District Court erred in dismissing the Shukers' fraud claim with prejudice. In most instances where plaintiffs fail to plead fraud with particularity—and especially in cases where plaintiffs may be able to supplement their complaints with additional factual content after discovery—district courts should dismiss the fraud claim "with leave to amend the deficient pleading." 5A Charles Alan Wright et al., *Federal Practice & Procedure* § 1300 (3d ed. 2017); *accord Warden v. McLelland*, 288 F.3d 105, 115 (3d Cir. 2002). Accordingly, given that we will reverse the District Court's dismissal of the negligence and loss of consortium claims and allow those claims to proceed to discovery, we will vacate the dismissal of the fraud claim to the extent that it was with prejudice and without leave to amend.[19]

### C. Personal Jurisdiction

Because two of the Shukers' claims will proceed to discovery, we turn now to the Shukers' challenge to the

[19] As we are allowing some of the claims in the Third Amended Complaint to proceed to discovery, we need not address the Shukers' contention that, if we hold they failed to state a claim in their Third Amended Complaint, then they were entitled to additional discovery before that complaint was filed.

District Court's denial of jurisdictional discovery as to Smith & Nephew's parent company, PLC, and to the District Court's dismissal of PLC for lack of personal jurisdiction. We review the District Court's decision to deny jurisdictional discovery for abuse of discretion, *see Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 455 (3d Cir. 2003), and we exercise plenary review over the District Court's ultimate personal jurisdiction determination, *see D'Jamoos ex rel. Estate of Weingeroff v. Pilatus Aircraft Ltd.*, 566 F.3d 94, 101 (3d Cir. 2009). As the District Court did not hold an evidentiary hearing on personal jurisdiction in this case, we take the Shukers' allegations as true, resolve all factual disputes in the Shukers' favor, and require them merely to "establish a prima facie case of personal jurisdiction . . . ." *O'Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 316 (3d Cir. 2007) (quoting *Miller Yacht Sales, Inc. v. Smith*, 384 F.3d 93, 97 (3d Cir. 2004)). We separately consider the Shukers' two theories of personal jurisdiction: specific personal jurisdiction premised on a "stream-of-commerce" theory, and general personal jurisdiction premised on an "alter ego" theory. Appellant's Br. 14.

We perceive no merit in the Shukers' stream-of-commerce theory of personal jurisdiction. That theory sounds in specific personal jurisdiction, which exists when alleged injuries "arise out of or relate to" activities '"purposefully directed" by a defendant toward residents of the forum state. *Metcalfe v. Renaissance Marine, Inc.*, 566 F.3d 324, 334 (3d Cir. 2009). The stream-of-commerce theory contends, essentially, that specific personal jurisdiction exists over a non-resident defendant when that defendant "has injected its goods into the forum state indirectly via the so-called stream of commerce," rendering it foreseeable that one of the

defendant's goods could cause injury in the forum state. *D'Jamoos*, 566 F.3d at 104-05.

A plurality of Supreme Court Justices has twice rejected the stream-of-commerce theory, *see J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 877-85 (2011) (plurality opinion); *Asahi Metal Indus. Co. v. Superior Court*, 480 U.S. 102, 108-13 (1987) (plurality opinion), stating, in a manner consistent with our own case law, that plaintiffs must instead rely on "some act by which the defendant purposefully avails itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws," *Asahi*, 480 U.S. at 109; *see D'Jamoos*, 566 F.3d at 102-03. Indeed, the Supreme Court has recently held that "[t]he bare fact that [a non-resident defendant] contracted with a [resident] distributor is not enough to establish personal jurisdiction in the State." *Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773, 1783 (2017). We thus have no cause to revisit our Court's precedent on this issue, and we decline to adopt the Shukers' stream-of-commerce theory of specific personal jurisdiction. *See D'Jamoos*, 566 F.3d at 102-06.

To the extent the Shukers seek to establish specific personal jurisdiction over PLC without reference to the stream-of-commerce theory, their allegations do not meet our Circuit's requirement of purposeful availment: "what is necessary is a deliberate targeting of the forum," *O'Connor*, 496 F.3d at 317, so efforts "to exploit a national market" that "necessarily included Pennsylvania" are insufficient, *D'Jamoos*, 566 F.3d at 104. Yet, nationally directed efforts are all that the Shukers alleged here, for their factual allegations state only that PLC sold its products through

Smith & Nephew in Pennsylvania as part of its efforts to sell products in the United States generally—not in Pennsylvania specifically. We therefore agree with the District Court's decision to reject the Shukers' arguments regarding specific personal jurisdiction over PLC.

We hold, however, that the Shukers are entitled to limited jurisdictional discovery to explore their alter ego theory of general personal jurisdiction, i.e., jurisdiction arising from a defendant's "'continuous and systematic' contacts with the forum, whether or not those contacts are related to the [plaintiffs'] cause of action." *Metcalfe*, 566 F.3d at 334 (quoting *Helicopteros Nacionales de Colom., S.A. v. Hall*, 466 U.S. 408, 416 (1984)). Unlike the Shukers' stream-of-commerce theory, the alter ego theory finds support in our case law, which instructs that, if a subsidiary is merely the agent of a parent corporation, *see D'Jamoos*, 566 F.3d at 108-09; *Lucas v. Gulf & W. Indus., Inc.*, 666 F.2d 800, 805-06 (3d Cir. 1981), *abrogated in part on other grounds by EF Operating Corp. v. Am. Bldgs.*, 993 F.2d 1046 (3d Cir. 1993), or if the parent corporation otherwise "controls" the subsidiary, *Kehm Oil Co. v. Texaco, Inc.*, 537 F.3d 290, 300 (3d Cir. 2008), then personal jurisdiction exists over the parent whenever personal jurisdiction (whether general or specific) exists over the subsidiary.

Under the alter ego theory, the Shukers' factual allegations regarding PLC, if viewed in isolation, suffice to make a prima facie showing of personal jurisdiction, which is all they must do at this juncture. *See D'Jamoos*, 566 F.3d at 102. Their allegations paint a plausible picture of control by PLC over Smith & Nephew: the two companies' decisionmaking is integrated, PLC has authority over Smith

& Nephew's strategic business decisions, PLC pays for the development of Smith & Nephew's products, and executives from both companies work together to make decisions regarding Smith & Nephew's hip systems, as shown in a 2012 Smith & Nephew press release that directed investor and media inquiries not to Smith & Nephew employees, but to PLC executives. Given that no party disputes that personal jurisdiction exists over Smith & Nephew as PLC's subsidiary in Pennsylvania, the Shukers' allegations, taken as true and in isolation, would suffice to show that PLC controlled Smith & Nephew, that Smith & Nephew was PLC's agent, and that personal jurisdiction must exist over both Smith & Nephew and PLC in Pennsylvania. *See Kehm Oil*, 537 F.3d at 300-01.

Our record, though, is not limited to the Shukers' allegations about personal jurisdiction over PLC; it includes declarations from PLC and Smith & Nephew executives that contradict many of the Shukers' assertions. For instance, the executives assert that PLC had "no involvement" in the design, manufacture, or distribution of Smith & Nephew's R3 Acetabular System for hip replacements in the United States and, moreover, that PLC had never approved any business decision regarding that system. App. 320. Because the executives' declarations create a factual dispute regarding the basis for personal jurisdiction over PLC, it is appropriate here to allow the parties and the District Court to "revisit[]" the factual issues by means of limited jurisdictional discovery, which we "ordinarily allow" when a plaintiff's claim to personal jurisdiction "is not clearly frivolous."[20] *Metcalfe*,

[20] We note that such jurisdictional discovery "is not a license for the parties to engage in a fishing expedition" and

566 F.3d at 331, 336. Accordingly, the District Court abused its discretion in denying jurisdictional discovery, and we will therefore vacate the dismissal of PLC for lack of personal jurisdiction and remand for the District Court to grant the Shukers the opportunity to conduct jurisdictional discovery.[21]

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that "the District Court should take care to circumscribe the scope of discovery . . . to only the factual questions necessary to determine its jurisdiction." *Schuchardt*, 839 F.3d at 353-54. This principle is all the more true after the 2015 amendments to the Federal Rules of Civil Procedure, which added a discussion of proportionality to Rule 26(b)(1). *Victaulic Co.*, 839 F.3d at 258-59. Applying that rule here, the Shukers may obtain only jurisdictional discovery "regarding . . . nonprivileged matter that is relevant to [personal jurisdiction over PLC] and proportional to the needs of the case," taking into account "the importance of the issue[] at stake . . . , the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issue[], and whether the burden or expense of the proposed discovery outweighs its likely benefit." *Id.* at 259 (quoting Fed. R. Civ. P. 26(b)(1)).

[21] If evidence adduced from such discovery supports the conclusion that personal jurisdiction is proper as to PLC, then the Shukers may to seek leave under Federal Rule of Civil Procedure 15(a)(2) to amend their Third Amended Complaint to join PLC as a co-defendant.

## III. Conclusion

For the foregoing reasons, we will affirm in part, reverse in part, and remand to the District Court for proceedings consistent with this opinion.