

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 25-2920

HAROLD R. BERK,
Appellant

v.

TERUMO MEDICAL CORPORATION; TERUMO AMERICAS HOLDING, INC.;
TERUMO PUERTO RICO, LLC; TERUMO LATIN AMERICA CORPORATION

On Appeal from the United States District Court
for the District of Delaware
(D.C. Civil Action No. 1:23-cv-00010)
District Judge: Honorable Jennifer L. Hall

Submitted Pursuant to Third Circuit LAR 34.1(a)
October 1, 2026

Before: MATEY, MONTGOMERY-REEVES, and NYGAARD, *Circuit Judges**

(Opinion filed: October 2, 2026)

OPINION*

PER CURIAM

* This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

Harold Berk, proceeding pro se, appeals from the District Court's order dismissing his products liability and negligence claims against medical device producer Terumo and associated affiliates ("Terumo"). We will affirm in part, vacate in part, and remand for further proceedings.

I.

Berk filed a products liability and negligence complaint in the District Court based on diversity jurisdiction against Terumo, alleging that Terumo had manufactured a defective medical device called an Angio-Seal, which failed to properly implant in Berk's artery wall, leading to significant internal bleeding, a severely harmful hematoma, five surgical interventions and over one million dollars in medical expenses. After a series of motions, Berk filed his second amended complaint, and proceeded to file various discovery-related motions, including a request for a protective order to facilitate his receipt of unredacted reports from the FDA. The District Court dismissed his second amended complaint, reasoning that Berk's claims were preempted, and that he had not sufficiently pleaded that Terumo had violated FDA requirements in the production of its Angio-Seal. Berk's discovery-related motions were denied in light of the Court's dismissal of his complaint, though he was granted leave to refile his complaint and any related discovery motions.

Berk then filed his operative third-amended complaint ("TAC"), which contained the same essential facts as his original complaint, but specifically alleged four causes of action: 1) products liability based on a manufacturing defect; 2) negligence based on Terumo's insufficient quality control measures at its factory; 3) failure to warn and 4)

violations of the New Jersey Products Liability Act (NJPLA) for manufacturing defects and inadequate warnings. In his TAC, Berk alleged that his failed Angio-Seal lacked sufficient tensile strength and included a 2022 Food and Drug Administration (“FDA”) inspection report of the Puerto Rican factory that produced the device to support his claims.

Defendants filed a motion to dismiss the TAC, arguing that the Federal Food, Drug, and Cosmetics Act of 1938 (“FDCA”) preempted Berk’s claims and that he failed to state a claim pursuant to Rule 12(b)(6). Berk then filed a supplemental memorandum, seeking to add a July 2024 report that was an update to the FDA’s earlier 2022 factory inspection that Berk had included with his TAC. The District Court granted Berk’s motion to include the updated 2024 factory report, and then dismissed Berk’s complaint, concluding that he had not cured the deficiencies identified in his second-amended complaint. Berk appeals. Defendant-appellees have also filed a motion to take judicial notice of two articles that purport to show that a patient’s pre-existing medical condition can cause the Angio-Seal to fail or otherwise malfunction.

II.

We have jurisdiction under 28 U.S.C. § 1291. We review questions of preemption *de novo*. *See Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 708 (3d Cir. 2018). We review questions that pertain to the scope or opportunity for discovery under an abuse of discretion standard. *See Brumfield v. Sanders*, 232 F.3d 376, 380 (3d Cir. 2000).

III.

Before addressing the merits of Berk’s claims, we conclude that the District Court did not abuse its discretion in denying Berk’s motion for a protective order. Berk cannot show that the denial “made it impossible to obtain crucial evidence,” *Massachusetts Sch. of L. at Andover, Inc. v. Am. Bar Ass’n*, 107 F.3d 1026, 1032 (3d Cir. 1997) (quotation marks and citation omitted), where the District Court specifically granted him the opportunity to refile his discovery motions once he submitted a complaint that sufficiently stated a claim for relief. We turn now to the issue of preemption.

Terumo’s Angio-Seal is a Class III medical device, meaning that, pursuant to the Medical Device Amendments (MDA) of the FDCA, it is subject to the FDA’s premarket approval (PMA) procedures. *See* 21 U.S.C. § 360c(a)(1)(C); *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 928 (5th Cir. 2006). Courts have explained that the PMA process is “rigorous” and involves a thorough review of the device’s safety and efficacy, its ingredients and manufacturing process, and its labeling. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-18 (2008). “Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.” *Id.* at 319; *see* 21 U.S.C. § 360e(d)(5)(A)(i).

The MDA also includes an express preemption clause, which prevents a state from imposing on any requirements on covered medical devices that are “different from, or in addition to” any requirements already imposed by the FDA, and any requirement that “relates to the safety or effectiveness of the device.” 21 U.S.C. § 360k(a)(1), (2).

Therefore, courts have routinely held that this clause preempts common law causes of action for negligence and strict products liability relating to a medical device, because those causes of action would impose requirements different than, or in addition to, those already imposed by the FDA’s premarket approval process. *See Riegel*, 552 U.S. at 323-25; *Horn v. Thoratec Corp.*, 376 F.3d 163, 176 (3d Cir. 2004); *Gomez*, 442 F.3d at 929-30. Not all state claims are preempted, however, because “[e]ven for Class III devices, the [MDA’s] 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.” *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 768 (3d Cir. 2018) (citation omitted). So, a claim that alleged a medical device failed to conform with FDA requirements prescribed by its PMA, or violated other FDA requirements, would not be preempted. *See Horn*, 376 F.3d at 179.

The District Court properly concluded that Berk’s failure-to-warn claims are expressly preempted. Berk alleges, *inter alia*, that Terumo’s brochure with safety information used too small a font to be easily legible, and that Terumo had a duty to warn him about the severe adverse side effects that might ensue as a result of using the Angio-Seal. The PMA process includes review of the device’s proposed labeling, *see* 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A), and Berk does not allege that Terumo’s warning label or informational brochure deviated from the Angio-Seal’s PMA requirements, or violated any other FDA requirements. Because Berk seeks to impose different or additional requirements on the Angio-Seal labeling—larger font size, more detailed information

about adverse events—his failure-to-warn claims are necessarily preempted. *See, e.g., Horn*, 376 F.3d at 177 (holding that Plaintiff’s failure-to-warn claim imposed a duty that was either in addition to or different from the FDA requirements, and therefore were “necessarily preempted by federally imposed PMA requirements under § 360k(a)”); *Riegel*, 552 U.S. at 329 (“Surely this means that the MDA would pre-empt a jury determination that the FDA-approved labeling for a [medical device] violated a state common-law requirement for additional warnings.”). Berk’s arguments to the contrary fail because he relies exclusively on cases that address failure-to-warn claims in the context of prescription drugs, which have different statutory regulation than medical devices do. *See, e.g., Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (“And when Congress enacted an express pre-emption provision for medical devices in 1976 . . . it declined to enact such a provision for prescription drugs.”)

Unlike his failure-to-warn claims, Berk’s products’ liability and negligence claims all allege that the failed Angio-Seal did not conform to its FDA requirements because Terumo defectively manufactured it. In his TAC, Berk argued that the tensile strength of the Angio-Seal was insufficient, and that Terumo was violating FDA requirements by failing to maintain proper quality assurance procedures at the Puerto Rican factory where Terumo’s Angio-Seals are produced. Berk relied heavily on a 2022 FDA inspection report of the factory, which identified two “non-conforming” procedures being employed at the factory for quality control of the products, but the report nevertheless stated that “[n]o significant objectionable observations resulted from [the] review.” ECF Doc. 101-8 at 42. However, the District Court had also allowed the filing of a 2024 follow-up

inspection report of the same factory, which contained information that could plausibly support an inference that Terumo had violated FDA requirements, as Berk alleges.

In contrast to the relatively mild concerns articulated in the 2022 inspection report, the 2024 report points to several inadequacies in the factory operational procedures. *See* ECF Doc. 111-1 at 6-10. The report indicates that the factory “has not established adequate receiving, in-process and finished device acceptance activities for these components that are critical for the devices intended use” and proceeds to list three component ingredients for which the factory has inadequate procedures. *See* ECF Doc. 111-1 at 6-7. The document identifies “Suture” as one of the problematic components, and seemingly notes that the material has a quality assurance requirement that “unconditioned straight tensile break strength shall be 10 lbs minimum, individual test” whereas the report notes that “there is no in process acceptance activities for the tensile strength of the suture which is the functional requirement.” *Id.* at 7. Tensile strength was the specific default that Berk alleged in his TAC, and further, the 2024 inspection report notes that the factory had received “at least nine (9) documented complaints dating from February 2022 that state in their narrative that the suture has been broken.” *Id.* This is especially significant given that Berk alleges that his Angio-Seal failed due to issues with its tensile strength in December 2021, a mere two months from the date of other tensile-related issues identified in the report. In total, the 2024 report contains four observations that record ways in which the factory failed to establish adequate procedures, including ones related to “corrective and preventative action,” ensuring “sampling methods are

adequate for intended use,” and ensuring “received product and services conform to specified requirements.” ECF Doc. 111-1 at 8, 9.

At a motion to dismiss stage, Berk is entitled to reasonable inferences in his favor, *see In re Stone & Webster, Inc., Sec. Litig.*, 414 F.3d 187, 200 (1st Cir. 2005), and the 2024 inspection report he presented supports a plausible inference that the Angio-Seal was not produced pursuant to the rigorous PMA requirements imposed on Terumo by the FDA, as he alleged. Accordingly, his manufacturing defect claims in count one and count four and his negligence claim (count two) are not preempted by the MDA.¹

We acknowledge that Terumo also argues, variously, that the claims brought under the NJPLA fail even if they are not preempted, because New Jersey law does not apply, and that Berk’s other claims fail under Florida law. However, the parties contest which state’s law should apply to this case, and the District Court did not reach the choice-of-law issues in this case. We will leave those issues and the other arguments for the District Court to resolve in the first instance. *See Singleton v. Wulff*, 428 U.S. 106, 120 (1976) (“It is the general rule, of course, that a federal appellate court does not consider an issue not passed upon below.”); *see also Harper v. Amazon.com Servs., Inc.*, 12 F.4th 287, 295 (3d Cir. 2021) (stating that determining which law controls is a “question[] best considered by the District Court”).

¹ We deny Appellees’ motion for judicial notice.

In sum, we will vacate the District Court’s judgment to the extent that it dismissed Berk’s manufacturing defect claims (in counts one and four) and his negligence claim (in count two). We will affirm the District Court’s judgment as to Berk’s failure to warn claims (in counts three and four). This matter is remanded for further proceedings consistent with this opinion.²

² Berk argues that the judge who dismissed his TAC was biased against him and requests that his case be returned to a different judge. We deny his request. His objections stem from the adverse rulings against him, which “do[] not form an adequate basis for recusal.” *Securacomm Consulting, Inc. v. Securacom Inc.*, 224 F.3d 273, 278 (3d Cir. 2000). Aside from ruling against him without an explanation that he deems sufficient, Berk has not identified any reason that the Judge’s “impartiality might reasonably be questioned,” or pointed to an indication of “personal bias or prejudice,” 28 U.S.C. § 455(a), (b)(1), and we do not discern any.

*Judge Matey sees no error in the District Court’s decision and would affirm the Court’s Judgment.