

United States Court of Appeals For the First Circuit

No. 22-1782

TRINA WILKINS; JAMES BISHOP; LISA BISHOP; AMBER BRITTON; TONI CORDOVA; JOHN CORTINA; JILL CORTINA; GEORGE DEMKO; DOVAN HELTON; MARY HELTON; NATE BROOKS; SYDNEY JOHNSON; D.J.; DAMON LAFORCE; ERIN MASULA; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; DARLENE COOKINGHAM; THOMAS STANZIANO; WENDY STANZIANO; EDDIE VIERS, individually as surviving spouse of Teresa Viers, deceased, and as personal representative of the Estate of Teresa Viers; WILLIAM MCNEW; JAMES WALLACE; JEANNE WALLACE, individually as surviving spouse of Joseph Wallace, deceased, and as personal representative of the Estate of Joseph Wallace; SAMUEL WALLACE,

Plaintiffs, Appellants,

v.

GENZYME CORPORATION,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Douglas P. Woodlock, U.S. District Judge]

Before

Kayatta, Lynch, and Montecalvo,
Circuit Judges.

Jonathan M. Gesk and C. Allen Black, Jr., with whom Law Office of C. Allen Black, Jr. and Gesk Moritz, LLC were on brief, for appellants.

Robert G. Jones, with whom Renee T. Whyte, Ezra D. Geggler, and Ropes & Gray LLP were on brief, for appellees.

February 15, 2024

KAYATTA, Circuit Judge. Filed in February of 2020, this lawsuit seeks monetary recovery on behalf of more than two dozen individuals for injuries allegedly caused by drug manufacturer Genzyme Corporation's ("Genzyme") mishandling of a prescription drug shortage between 2009 and 2012. Given that eight to eleven years have passed between the events giving rise to this lawsuit and its commencement, the applicable statutory limitations periods would normally have rendered plaintiffs' claims fatally stale. Plaintiffs argue, however, that two prior putative class actions, a so-called savings statute, and a tolling agreement between the parties all align to bridge any gap that would otherwise have prevented this lawsuit from proceeding.

The district court agreed, at least in part, and rejected Genzyme's contention that the delay in filing this lawsuit required its dismissal under Rule 12(b)(6) of the Federal Rules of Civil Procedure. See Wilkins v. Genzyme Corp., No. 21-10023, 2022 WL 4237528, at *18 (D. Mass. Sept. 14, 2022). At the same time, the district court dismissed without prejudice the claims of all but four plaintiffs for lack of standing, and it dismissed with prejudice all remaining claims of those four plaintiffs on the merits. Id. at *19-31. All plaintiffs then timely appealed. For the reasons that follow, we vacate the district court's judgment in part and remand for further proceedings consistent with this opinion.

I.

Given the number of parties, claims, and issues in this lawsuit, a roadmap of our decision may prove helpful. The opinion commences with two threshold questions of justiciability -- Article III standing and subject matter jurisdiction. We conclude that all plaintiffs have standing and that this court has jurisdiction to proceed with this case, at least with respect to plaintiffs' individual claims.

We then turn to the district court's rejection of Genzyme's statute-of-limitations defense. Because Genzyme has not appealed that rejection, we can consider Genzyme's reliance on that defense on this appeal only to the extent it might serve as an alternative basis to affirm the judgment with respect to four plaintiffs whose claims were dismissed with prejudice. After unspooling plaintiffs' tolling-related arguments, we conclude that all four plaintiffs waited far too long before filing this lawsuit. In so concluding, we make a series of subsidiary findings that will guide the district court's treatment of the claims advanced by the remaining twenty-two plaintiffs.

As to the claims advanced by those plaintiffs, we conclude that the district court incorrectly dismissed those plaintiffs' claims for lack of standing. For that reason, we vacate the judgment dismissing those claims and remand the case to the district court. The district court can then decide, in

whatever order it thinks prudent: (1) whether the claims withstand Genzyme's limitations defense as explicated in this opinion, and (2) whether the claims survive Genzyme's challenge to their merits under Rule 12(b)(6).

With this roadmap in hand, we start with the facts.

II.

We previously detailed the allegations that underpin this litigation in Hochendoner v. Genzyme Corp., 823 F.3d 724 (1st Cir. 2016) ("Hochendoner II"), so we provide only an abbreviated version here. Because of the preliminary procedural posture of this case, we summarize the facts as alleged by plaintiffs, rather than as they might otherwise be shown to be. See Germanowski v. Harris, 854 F.3d 68, 69 (1st Cir. 2017) ("Because this appeal follows a dismissal pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, we accept as true all well-pleaded facts in [the] complaint and draw all reasonable inferences in [plaintiffs'] favor.").

Genzyme makes what was at relevant times the only drug approved in the United States for treating Fabry disease, a progressive affliction that leads to destructive inflammation, organ failure, and premature death. Hochendoner II, 823 F.3d at 728. Genzyme's drug, called Fabrazyme, slows the progression of Fabry disease when administered at the proper dosage every two

weeks. Id. During the relevant time period, Fabrazyme was the only FDA-approved treatment for Fabry disease in the United States.

From 2003 until 2009, Genzyme steadily provided the FDA-approved dosage of Fabrazyme to U.S. patients. Id. Then, in June 2009, upon discovering viral contamination in one of its facility's bioreactors, Genzyme suspended bulk production of Fabrazyme, leading to shortages. Id. at 728-29. Genzyme initiated a rationing plan, providing U.S. patients with reduced doses in order to prolong the drug's available supply. Id. In November 2009, Genzyme discovered particulate contamination in another batch of Fabrazyme, exacerbating the shortage. Id. at 728. In 2011, Genzyme worsened the shortage in the United States by diverting some Fabrazyme to the European market. Id. Plaintiffs aver that Genzyme did so to ward off competition from an alternative Fabry disease treatment approved only in Europe, while Genzyme's monopoly over the domestic market enabled the company to continue peddling reduced doses to U.S. Fabry patients without fear of losing market share.

It was not until after March 2012 that Genzyme succeeded in restoring full supplies of Fabrazyme to U.S. patients. In the meantime, U.S. patients had received reduced doses or, for a period in August 2011, no doses at all. Id. at 728-29. Plaintiffs variously allege that they experienced injuries as a result, including worsening symptoms and acceleration of the disease's

progression, sensitization to the drug upon returning to a full dose, shortened life expectancies, and/or financial harm. They allege that Genzyme knew that low-dose Fabrazyme would not effectively treat Fabry disease and yet continued to sell the reduced doses to patients. They also allege that Genzyme knowingly misrepresented both the effectiveness of its low-dose regimen and the expected duration of the shortage.

The Fabrazyme shortage provoked several lawsuits against Genzyme that form the predicate for this case. In March 2011, a group of plaintiffs, on behalf of a putative class of all U.S. Fabry patients, brought suit in the U.S. District Court for the Western District of Pennsylvania, which transferred the case to the District of Massachusetts ("the Hochendoner lawsuit"). In June 2013, another group of plaintiffs, on behalf of a similar putative class, brought suit directly in the District of Massachusetts ("the Adamo lawsuit"). Both lawsuits alleged an array of common law and statutory claims against Genzyme. The district court consolidated the two lawsuits before dismissing both on the pleadings in March 2015. See Hochendoner v. Genzyme Corp., 95 F. Supp. 3d 15, 21, 35 (D. Mass. 2015).

On appeal, we concluded that the complaint failed to sufficiently allege a cognizable injury to any individual plaintiff to establish Article III standing, save for what the parties called a "sensitization" theory of injury as alleged by

one of the Adamo plaintiffs named James Mooney (and his wife, Laura Kurtz-Mooney). Hochendoner II, 823 F.3d at 734-35. As to all plaintiffs but the Mooneys, "[u]tterly absent . . . [was] any allegation linking the . . . injuries to any specific plaintiff." Id. at 732. We therefore remanded the case so that the district court could adjudicate the Mooneys' sensitization-based claims, while dismissing without prejudice due to a lack of standing all other claims presented for review on that appeal. Id. at 735-37.

Thereafter, the parties engaged in settlement discussions. As part of that effort, the plaintiffs and Genzyme agreed, effective May 17, 2017, to toll "[a]ny applicable statutes of limitations pertaining to any matters asserted" during the Hochendoner and Adamo lawsuits ("Tolling Agreement"). While it seems that Genzyme ultimately reached agreement with some of the Hochendoner and Adamo plaintiffs -- including the Mooneys -- others remained unable to settle their claims. As a result, Genzyme terminated the Tolling Agreement effective February 29, 2020, the same day on which those plaintiffs filed the current lawsuit.

The twenty-six plaintiffs, almost all of whom were plaintiffs in the Hochendoner/Adamo lawsuits, filed the present action in the U.S. District Court for the Southern District of Indiana.¹ The case was transferred back to the District of

¹ The only new plaintiffs are relatives of the Adamo plaintiffs: William McNew (surviving son of Teresa Viers), James

Massachusetts. The new complaint asserts twenty-four counts of common law and statutory claims on behalf of the named plaintiffs and "all others similarly situated." Plaintiffs allege federal subject matter jurisdiction under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d), and supplemental jurisdiction over related claims under 28 U.S.C. § 1367. As we will discuss, this time each plaintiff has alleged the specific injuries that they claim to have suffered.

In response to the new complaint, Genzyme raised threshold challenges to the court's subject matter jurisdiction and plaintiffs' standing. As to the court's subject matter jurisdiction, Genzyme contended that all of the claims upon which class certification was sought were untimely and that, once those claims were dismissed, the court could no longer maintain subject matter jurisdiction under CAFA. The district court rejected this argument because it found that many of the plaintiffs' claims were timely refiled. Wilkins, 2022 WL 4237528, at *18.

As to standing, however, Genzyme's arguments fared better. The district court held that only four of the twenty-six plaintiffs -- those bringing claims based on the same "sensitization" theory of injury that we recognized in Hochendoner II -- could establish Article III standing. See

and Samuel Wallace (surviving sons of Joseph Wallace), and Nate Brooks (spouse of Mary Helton).

Wilkins, 2022 WL 4237528, at *18-21. It rejected plaintiffs' other proffered theories of standing and dismissed all claims of the other twenty-two plaintiffs on those grounds. Id. Then, the court dismissed the four plaintiffs' outstanding sensitization-based claims on the merits under Rule 12(b)(6) for failure to state a claim upon which relief could be granted. Id. at *31.

Plaintiffs now appeal the district court's dismissal of their claims for lack of standing and for failure to state a claim.

III.

In considering plaintiffs' appeal, we first turn to two threshold questions of justiciability -- Article III standing and subject matter jurisdiction.

A.

Plaintiffs seeking to invoke federal jurisdiction must first establish that they have constitutional standing to sue in federal court. See Dantzler, Inc. v. Empresas Berríos Inventory & Operations, Inc., 958 F.3d 38, 46 (1st Cir. 2020). Because the existence of standing for pleading purposes is a legal question, we review it de novo on appeal. See In re Evenflo Co., Mktg., Sales Pracs. & Prods. Liab. Litig., 54 F.4th 28, 34 (1st Cir. 2022). "To satisfy th[e] standing requirement, a plaintiff must sufficiently plead three elements: injury in fact, traceability, and redressability." Id. (alteration in original) (quoting Kerin v. Titeflex Corp., 770 F.3d 978, 981 (1st Cir. 2014)). When, as

here, no class has been certified below, "our review is limited to whether [the named plaintiffs have] standing." Id. (alteration in original) (quoting Kerin, 770 F.3d at 981). Further, "standing is not dispensed in gross." Town of Chester v. Laroe Ests., Inc., 581 U.S. 433, 439 (2017) (quoting Davis v. Fed. Election Comm'n, 554 U.S. 724, 734 (2008)). Instead, "a plaintiff must demonstrate standing for each claim he seeks to press and for each form of relief that is sought." Id. (quoting Davis, 554 U.S. at 734).

We previously addressed similar questions of standing in Hochendoner II. We found that standing in that case "hinge[d] on the presence or absence of a plausibly pleaded injury in fact." 823 F.3d at 731. While plaintiffs had alleged three possible theories of harm -- acceleration, contamination, and sensitization -- we found that the complaint only alleged that one of the identified plaintiffs, James Mooney, had suffered one of those harms, sensitization. Id. at 734-35. Key to our holding was the complaint's failure to provide "specific information . . . regarding the harm, if any, that ha[d] befallen each individual plaintiff" (with one exception). Id. at 732. We therefore ordered that the complaint be dismissed without prejudice, except as to Mooney and his spouse. Id. at 737. Following remand, after plaintiffs filed an amended complaint in Adamo, the parties ultimately settled the Mooneys' outstanding claims.

On this appeal from the dismissal of plaintiffs' most recent lawsuit, Genzyme contends that plaintiffs have made the same mistake in failing to specify which alleged defect caused which individual plaintiff to suffer which, if any, specific harm. We disagree. The complaint that commenced this new lawsuit, unlike the prior complaints in the Hochendoner and Adamo lawsuits, makes specific allegations about the particular injuries suffered by each individual plaintiff.

In support of their "acceleration" theory of injury, plaintiffs allege that the low and/or contaminated Fabrazyme doses caused their Fabry disease symptoms to worsen more quickly than they would have had plaintiffs received full doses.² Plaintiffs allege that "[a]s a result of being subjected to multiple defects, all of which cause and/or increase inflammation, all surviving [p]laintiffs now have a worse clinical outcome than if they had been given no drug at all because of the merger of the inflammatory disease process created by the triply-inflammatory adulterated Fabrazyme cocktail." (Emphasis added.)

² Plaintiffs also allege that the defective Fabrazyme doses shortened their life expectancies. On appeal, plaintiffs devote one conclusory sentence to this claim and offer no explanation as to how their "reduced-life-expectancy" theory of injury differs meaningfully from their acceleration theory for purposes of Article III standing. We therefore find that plaintiffs have waived the issue on appeal. See United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990) ("[I]ssues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.").

The complaint then adds further detail for each Fabry-patient plaintiff. Typical of such individual allegations is the claim that "[p]laintiff [Trina Wilkins's] clinical status has deteriorated as the Fabry disease has accelerated due to the defective Fabrazyme treatment as evidenced by the occurrence, progression, and exacerbation of [various] physical injuries . . . [including] anaphylactic infusion reactions, venous collapse, vascular thrombosis" and so on.

The district court found these allegations insufficient to show that "the symptoms experienced were the result of 'defective' dosing" as opposed to the typical progression of Fabry disease without any treatment. Wilkins, 2022 WL 4237528, at *20. As the foregoing allegations make clear, however, plaintiffs' complaint includes multiple specific allegations precisely to that effect. And despite Genzyme's argument to the contrary, at the present stage of litigation we accept as true plaintiffs' "say-so" that they suffered the physical injuries in question. See Germanowski, 854 F.3d at 69. Whether a defective drug treatment actually caused the decline in each plaintiff's health as alleged goes to the merits of the claim itself, not to standing to seek recovery for the harm.

In support of their "contamination" theory of harm -- which the district court labeled the "Vesivirus theory" -- twenty-one plaintiffs allege that they (or their spouses) suffered

physical injuries as a result of receiving Fabrazyme doses contaminated with Vesivirus and particulate matter. Plaintiffs' complaint alleges that Genzyme contaminated Fabrazyme, then sold contaminated lots to plaintiffs, which caused the injuries. Plaintiffs allege that, for example, "[t]he Fabrazyme lots [plaintiff Trina Wilkins] was injected with contained Vesivirus 2117 which injured her by inducing Vesivirus-induced vesiculating chronic non-anaphylactic rashes that are not treatable with steroids." As another example, plaintiffs allege that "[i]n 2013 and 2015, [plaintiff Michael Masula] was . . . delivered and injected with defective Fabrazyme containing Vesivirus . . . which injured him by inducing [injuries similar to those alleged by Trina Wilkins]." Thirteen other Fabry-patient plaintiffs and six spousal plaintiffs make similar specific claims of harm from the alleged contamination. And contrary to Genzyme's arguments on appeal, these allegations assert a direct causal connection between the contaminated Fabrazyme and the injuries suffered by plaintiffs and are therefore sufficient to confer standing as to the relevant claims.

Plaintiffs finally allege a "financial" theory of harm: that they were injured by paying for ineffective and medically worthless doses of Fabrazyme. Economic injury is sufficient to confer standing, so much so that, as one court noted, "where a plaintiff alleges financial harm, standing 'is often assumed

without discussion.'" Cottrell v. Alcon Lab'ys, 874 F.3d 154, 163 (3d Cir. 2017) (quoting Danvers Motor Co. v. Ford Motor Co., 432 F.3d 286, 293 (3d Cir. 2005)). Other courts considering similar claims of economic injury from payment for defective medication have found such allegations sufficient for standing purposes. See Harris v. Pfizer Inc., 586 F. Supp. 3d 231, 239 (S.D.N.Y. 2022); In re Zantac (Ranitidine) Prods. Liab. Litig., No. 21-10335, 2022 WL 16729170, at *3 (11th Cir. Nov. 7, 2022). We readily agree. While Genzyme argues that plaintiffs effectively got "what they paid for" because they knew they were purchasing a reduced dose that had not been clinically tested, such an argument goes to the merits of the claim, not to standing.

Taken as a whole, plaintiffs' newly pleaded, individual claims closely resemble the types of claims routinely and successfully asserted in classic product liability lawsuits. See, e.g., Garside v. Osco Drug, Inc., 976 F.2d 77, 78 (1st Cir. 1992). Genzyme is alleged to have supplied a product (reduced/contaminated Fabrazyme doses without accurate warnings) that injured each plaintiff by, in some instances, accelerating the progression of their disease, causing them to experience a rash and other symptoms of contamination, triggering a harmful sensitization to a drug they needed to take, and making them pay for harmful medication. These claims are at least plausible, and an assessment of standing provides no occasion to venture further

in adjudicating the merits of the claims. As we said in Hochendoner II, "[a]n individual's plausible allegations of a personal injury will generally suffice to plead an injury in fact, even if the claim is ultimately lacking on the merits." 823 F.3d at 734. All of which is to say that, for purposes of establishing Article III standing, plaintiffs' allegations pass muster.

B.

Standing, though, cannot by itself sustain a lawsuit if the court in which the suit resides otherwise lacks subject matter jurisdiction. Genzyme argues that plaintiffs' complaint does not establish federal jurisdiction because there is no complete diversity of citizenship, nor is there "CAFA-based diversity jurisdiction." But plaintiffs bring this case as a putative class action, with respect to some, if not all, claims. On its face, the action as pleaded fits the broad definition of a "class action" as defined in CAFA.³ See 28 U.S.C. § 1332(d)(1)(B). It also meets CAFA's jurisdictional requirements as a putative class action in which the amount in controversy is over \$5 million and one plaintiff class member is a citizen of a different state than one defendant. See id. §§ 1332(d)(2)(A), (6); see also id. § 1332(d)(8) (noting that CAFA applies "to any class action

³ This is not to say, however, that plaintiffs' action necessarily qualifies for certification under Rule 23 of the Federal Rules of Civil Procedure.

before or after the entry of a class certification order"). And there is no suggestion that this action fits within any exception listed at 28 U.S.C. § 1332(d)(4) or (5). Accordingly, the district court certainly had subject matter jurisdiction over the case at the time of filing.⁴

Still, Genzyme argues that the "CAFA claim" is doomed to fail, and that once it fails there will remain no basis upon which to assert subject matter jurisdiction. But Genzyme puts the cart before the horse. Suppose that A sues B (who is arguably a citizen of A's state) on two counts, one a federal claim and the other a state claim, and the federal claim is vulnerable to an affirmative defense based on the statute of limitations. No one would reasonably say that the court lacks jurisdiction to decide the case. At most, if the court exercised that jurisdiction to decide the statute-of-limitations defense, and subsequently dismissed the federal claim, then only at that point would the court be called upon to consider whether it should decide to continue exercising jurisdiction over the supplemental state claim. See 28 U.S.C. § 1367(c)(3).

⁴ We thus need not decide whether the alternative ground on which the district court accepted jurisdiction was proper. See Wilkins, 2022 WL 4237528, at *20 n.18 (expressing doubts about whether the lawsuit could proceed as a class action but proceeding to analyze plaintiffs' remaining claims individually).

Moreover, federal jurisdiction may persist under CAFA even if a traditional analysis under section 1367(a)(3) would otherwise militate against continuing to exercise jurisdiction at that point. Many courts have held that federal CAFA jurisdiction survives denial of class certification, such that a federal court retains subject matter jurisdiction over the residual individual action even where jurisdiction is premised solely on CAFA. See, e.g., *Coba v. Ford Motor Co.*, 932 F.3d 114, 119 (3d Cir. 2019); *Louisiana v. Am. Nat'l Prop. & Cas. Co.*, 746 F.3d 633, 639 (5th Cir. 2014). But see *Coll. of Dental Surgeons of P.R. v. Conn. Gen. Life Ins. Co.*, 585 F.3d 33, 42 (1st Cir. 2009) (expressing "no opinion" on the issue). After all, CAFA was enacted in part because some state courts were seen as exercising too little rigor in certifying class actions under state practices. See *Amoche v. Guarantee Tr. Life Ins. Co.*, 556 F.3d 41, 49 (1st Cir. 2009) ("In CAFA, Congress expressly expanded federal jurisdiction largely for the benefit of defendants against a background of what it considered to be abusive class action practices in state courts."). If a federal court decision finding that a class should not be certified meant that the case would be relegated to state court, where it might then be reconsidered for certification under state procedures, one of CAFA's key purposes would be frustrated. So, for present purposes, Genzyme's CAFA-based jurisdictional argument is, at the very least, premature.

IV.

A.

As an adjunct to its jurisdictional argument, Genzyme also presses on appeal its affirmative defense that the action is untimely. The district court considered that defense and ruled against Genzyme, but Genzyme did not appeal (or, technically, cross-appeal). Genzyme suggests that it need not have cross-appealed the district court's ruling rejecting its limitations defense because we can rely on any argument apparent in the record to affirm a judgment. See Mass. Mut. Life Ins. v. Ludwig, 426 U.S. 479, 481 (1976); Olsen v. Correiro, 189 F.3d 52, 58 n.3 (1st Cir. 1999). As to the four plaintiffs whose sensitization-based claims were dismissed for failure to state a claim, Genzyme is correct. It is entitled to press its timeliness defense as an alternative basis for affirming the district court's judgment dismissing the claims of those four plaintiffs with prejudice. Cf. Delgado-Caraballo v. Hosp. Pavia Hato Rey, Inc., 889 F.3d 30, 39 n.15 (1st Cir. 2018).

However, as to the remaining twenty-two plaintiffs whose claims were dismissed without prejudice on standing grounds, accepting Genzyme's statute-of-limitations defense on the merits would transform the judgment against those plaintiffs from a dismissal without prejudice into a dismissal with prejudice. Such a change would leave them worse off. As a result, because Genzyme

failed to cross-appeal, Genzyme is prohibited from now asserting on appeal its statute-of-limitations defense against the claims of those twenty-two plaintiffs. See id.

B.

Against this admittedly reticulated background, we now turn to the merits of Genzyme's argument that the dismissal with prejudice of four plaintiffs' claims can be affirmed on the alternative grounds that the claims are untimely. Those plaintiffs are Trina Wilkins and Damon LaForce (both plaintiffs previously in the Adamo lawsuit) and Thomas Stanziano and Wendy Stanziano (both plaintiffs previously in the Hochendoner lawsuit).⁵

Plaintiffs argue that their claims in this lawsuit have survived the passage of time because: (1) Some of them previously commenced a class action lawsuit arising out of Genzyme's alleged defalcations; (2) Indiana law granted them a three-year tolling period from the end of those timely lawsuits within which to reassert their claims; and, in any event, (3) the Tolling Agreement preserved their claims. We consider each of these assertions in turn.

1.

The parties do not dispute on appeal the district court's finding that the limitations period on all claims save for

⁵ Ms. Stanziano brings a derivative loss-of-consortium claim tracking her spouse's sensitization claims.

sensitization and fraud claims would have expired by no later than the end of 2011, in the absence of any tolling.⁶ See Wilkins, 2022 WL 4237528, at *10-13. Nor do the parties dispute on appeal the district court's finding that the limitations period on the fraud claims expired but for possible tolling by March of 2013,⁷ or that the limitations period on the sensitization claims expired but for possible tolling by the end of 2014. Id. at *13.

The Stanzianos filed suit as named plaintiffs in Hochendoner in March of 2011. So there is no dispute that their claims were then timely asserted. Wilkins and LaForce, however, did not sue until June of 2013. Had they asserted sensitization claims at that time, those claims would have been timely. However, Wilkins and LaForce never made any sensitization allegations in Adamo. So, for Wilkins and LaForce, all of their claims when first asserted were untimely, absent the benefit of some tolling effect.

⁶ The district court grouped plaintiffs' claims into three categories based on the type of harm alleged for purposes of ascertaining their accrual and expiration dates: low dosing/contamination, sensitization, and fraud. The parties on appeal do not dispute this aspect of the district court's method.

⁷ Plaintiffs do argue that the statute of limitations has not run on their breach-of-fiduciary-duty claims on the grounds that plaintiffs' fiduciary relationship with Genzyme is ongoing. However, the claim would have accrued, just like the rest of their claims, when plaintiffs knew or could have reasonably discovered their injury. See City of E. Chi. v. E. Chi. Second Century, Inc., 908 N.E.2d 611, 618 (Ind. 2009).

To obtain such a benefit, Wilkins and LaForce rely on the rule of American Pipe & Const. Co. v. Utah, which they claim applies because Hochendoner was a putative class action. See 414 U.S. 538, 553 (1974); Crown, Cork & Seal Co. v. Parker, 462 U.S. 345, 350 (1983) (holding that the timely filing of a purported class action suit tolls the statute of limitations for putative class members who seek to either intervene in the suit or file their own individual lawsuits after class action certification has been denied). American Pipe, however, involved the saving of a federal cause of action by application of a federally recognized tolling rule. See 414 U.S. at 541. And plaintiffs concede -- indeed argue -- that in this action involving claims arising purely under state law, we must look to Indiana law to determine whether the claims of the Adamo plaintiffs are somehow saved notwithstanding the passage of more than two years from their accrual. See Casey v. Merck & Co., Inc., 653 F.3d 95, 100 (2d Cir. 2011) ("[A] federal court evaluating the timeliness of state law claims must look to the law of the relevant state to determine whether, and to what extent, the statute of limitations should be tolled by the filing of a putative class action in another jurisdiction."); see also In re Urethane Antitrust Litig., 663 F. Supp. 2d 1067, 1081-82 (D. Kan. 2009) (declining to apply American Pipe tolling when sitting in diversity because of the established

principle that "state law alone must govern the application of a tolling principle to a state's statute of limitations").

The district court proceeded accordingly, and found that Indiana courts would not apply American Pipe-style tolling to save a claim where neither the putative class action nor the subsequent individual claim was filed in an Indiana court. See Wilkins, 2022 WL 4237528, at *14 (collecting cases). Plaintiffs' briefs on appeal offer no challenge to that conclusion. Hence, plaintiffs lack any basis for claiming that the Hochendoner complaint tolled the running of the limitations period for members of the putative class who waited until after the limitations period expired to sue in Adamo.

To summarize, we conclude that neither American Pipe itself nor any analogue in Indiana law of American Pipe can play any role in rendering any of plaintiffs' claims timely. And that means that the claims of Wilkins and LaForce were untimely when first filed in 2013. We turn next to the second part of plaintiffs' tolling troika: the Indiana Journey's Account Statute.

2.

As we have found, all claims raised by the Stanzianos in the Hochendoner lawsuit were timely when originally filed. Their prior lawsuit, however, was itself dismissed without prejudice in March 2015, as affirmed in May 2016. Hochendoner II, 823 F.3d at 737. So to reassert their claims in this new lawsuit, filed well

after the two-year limitations period on their claims ran, the Stanzianos need to rely on one or more tolling doctrines that will bridge the gap between the passing of the limitations period and the filing of this new lawsuit in 2020.

Toward that end, the Stanzianos invoke an Indiana savings statute that, they argue, extended for three years their ability to refile any otherwise timely Hochendoner claims following this court's affirmance of their dismissal in 2016. See Hochendoner II, 823 F.3d at 728 (dismissing consolidated Hochendoner and Adamo actions). The statute in question, Indiana's "Journey's Account Statute," provides that a party may refile an action that was dismissed on any grounds apart from the party's own negligence no later than three years after its dismissal, even if the statute of limitations has run. Ind. Code § 34-11-8-1.⁸

⁸ The statute provides in relevant part:

(a) This section applies if a plaintiff commences an action and:

(1) the plaintiff fails in the action from any cause except negligence in the prosecution of the action; . . .

(b) If subsection (a) applies, a new action may be brought not later than the later of:

(1) three (3) years after the date of the determination under subsection (a); or

(2) the last date an action could have been commenced under the statute of limitations governing the original action;

Indeed, "when it applies, the [Journey's Account] Statute serves to resuscitate actions that have otherwise expired under a statute of limitations." Al-Challah v. Barger Packaging, 820 N.E.2d 670, 674 (Ind. Ct. App. 2005) (alteration in original) (quoting Cox v. Am. Aggregates Corp., 684 N.E.2d 193, 195 (Ind. 1997)). However, "[t]he Journey's Account Statute is not an exception to the statute of limitations; it merely allows the continuation of a previous suit filed within the statute of limitations." Vesolowski v. Repay, 520 N.E.2d 433, 435 (Ind. 1988).

The Stanzianos argue that their 2020 complaint falls squarely under the protection of the Journey's Account Statute because this court's 2016 affirmance of the dismissal of the consolidated Hochendoner/Adamo action was not due to their own negligence, and the 2020 complaint was but a "continuation" of that action that cured the standing deficiencies highlighted by the district court and this court.

This attempted reliance on the Journey's Account Statute fails. The Stanzianos' lawsuit in this case is not a continuation of their prior Hochendoner lawsuit within the meaning of the Journey's Account Statute, because all the claims that the Stanzianos now assert pivot on highly material allegations of

and be considered a continuation of the original action commenced by the plaintiff.

Ind. Code § 34-11-8-1 (2005).

individual injuries and causation that they did not allege in Hochendoner. "Generally, for an action to be considered a continuation of the former [for purposes of the Indiana Journey's Account Statute], the parties, the facts, and the causes of action must be the same." Land v. Int'l Bus. Machs. Corp., 108 F. Supp. 3d 632, 637 (S.D. Ind. 2015); cf. Eads v. Cmty. Hosp., 932 N.E.2d 1239, 1246 (Ind. 2010) (holding that where the "new complaint changed no parties, facts or elements, and altered only the procedural requirements to assert the claim," the second action was preserved under the Journey's Account Statute as a continuation of the first); Kindred Nursing Ctrs. v. Est. of McGoffney, 15 N.E.3d 641, 646, 646 n.1 (Ind. Ct. App. 2014) (noting that the second suit was a continuation of the first because it was "essentially identical to the one previously filed" and "add[ed] no new allegations or parties").

The Stanzianos' new 2020 complaint alleges for the first time that the "'[l]ow dose' . . . caused antibody sensitization to Fabrazyme making it impossible for [Mr. Stanziano] to resume full dose treatment with Fabrazyme without steroids as he had before the 'low dosing' began." It also newly alleges that "[i]n 2013 and 2015, [Mr. Stanziano] was . . . injected with defective Fabrazyme containing Vesivirus[,] " that Mr. Stanziano's "Fabry disease has accelerated due to the defective Fabrazyme treatment as evidenced by" an enumerated list of Mr. Stanziano's physical

injuries, and that Mr. Stanziano "was also damaged by paying over \$200,000 for medically worthless Fabrazyme." But for the addition of these new facts particular to Mr. Stanziano, the Stanzianos would have no standing to sue, much less successfully so. See Hochendoner II, 823 F.3d at 732 (dismissing plaintiffs' predecessor claims for lack of standing because "no specific information [was] provided regarding the harm, if any, that has befallen each individual plaintiff"). Accordingly, we agree with the district court that the Indiana tolling statute has no application to the Stanzianos' claims.

3.

We turn, finally, to the Tolling Agreement. The district court read the Tolling Agreement as both pausing the clock and as reviving otherwise expired claims. Certainly the agreement paused any further running of the limitations clock. But we think it is equally clear that the agreement did not revive claims for which the limitations period had expired before the parties signed the Tolling Agreement.

The Tolling Agreement provided that "[a]ny applicable statutes of limitations pertaining to any matters asserted in the [Hochendoner and Adamo lawsuits] shall be tolled during the term of this Agreement." (Emphasis added.) Adding belt to suspenders, the Tolling Agreement also stated that "notwithstanding the foregoing," Genzyme still has "the right to assert any [timeliness]

defense based upon passage of time prior to the [effective date of the agreement]." In rejecting the clear meaning of this language, the district court cited language stating that "[t]he parties desire to provide for additional time to allow them to complete the process of finalizing documentation giving effect to that agreement in principle[,]" and that the agreement is in part "to facilitate orderly settlement and resolution of the Plaintiffs' claims." Wilkins, 2022 WL 4237528, at *15. The court suggested that such language would have had no meaning unless the Tolling Agreement revived stale claims. Id. at *16.

We disagree. The language cited by the district court simply explained why the parties decided to pause the running of the clock. Nothing in that language suggests that it was somehow intended to supersede the express statement preserving Genzyme's right to press its defense based on the passage of time prior to the effective date of the Tolling Agreement. Consequently, as to Wilkins, LaForce, and the Stanzianos, because the time within which they needed to file suit expired long before the Tolling Agreement was signed, none of their claims in this case survive Genzyme's statute-of-limitations defense.

v.

We take stock of where we are. First, we have subject matter jurisdiction over this action under 28 U.S.C. §§ 1332(d) and 1367, at least with respect to plaintiffs' individual claims.

Second, all plaintiffs have Article III standing to pursue their claims. Third, we have only considered Genzyme's statutes-of-limitations defense as an alternative basis to affirm the judgment as to the four plaintiffs whose claims were dismissed with prejudice. Fourth, as to those plaintiffs, the limitations periods on all their claims expired well before this lawsuit was filed. More specifically, their claims are time-barred because they were either untimely when first filed or rely on material new facts rendering the Journey's Account Statute inapplicable, and because the Tolling Agreement did not revive any otherwise expired claims.

We have not addressed the merits of Genzyme's Rule 12(b)(6) challenge to the complaint. Nor have we directly addressed Genzyme's limitations defense to the claims of the remaining twenty-two plaintiffs. With the guidance provided by this opinion, we leave it to the district court to decide in the first instance which of these issues to address first and how to do so.

VI.

For the foregoing reasons, we affirm the district court's dismissal of all claims by plaintiffs Wilkins, LaForce, and the Stanzianos. But we otherwise reverse the district court's judgment dismissing the claims of the other plaintiffs for lack of standing, leave it to the district court in the first instance to

consider the merits of those claims or their defenses, and remand the case for further proceedings consistent with this opinion. No costs are awarded.