No. 24-

IN THE

Supreme Court of the United States

TRINA WILKINS, DAMON LAFORCE, THOMAS STANZIANO, AND WENDY STANZIANO, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED,

Petitioners,

v.

GENZYME CORPORATION,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

I. Whether the Class Action Fairness Act creates a combination of both Federal Question jurisdiction and Diversity jurisdiction, termed minimal diversity jurisdiction for an interstate case of "national importance."

II. Whether State or Federal equitable tolling and relation back doctrines apply to re-filed and "tag-along" CAFA cases.

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

Petitioners are Trina Wilkins, Damon LaForce, Thomas Stanziano, and Wendy Stanziano on behalf of themselves and all other similarly situated. They were the plaintiffs in the District Courts of Massachusetts and Indiana, and appellants in the First Circuit Court of Appeals.

Respondent is Genzyme Corporation, a wholly owned subsidiary of Sanofi, a French Corporation. Genzyme was the defendant in the District Courts of Massachusetts and Indiana, and appellees in the First Circuit Court of Appeals.

RELATED PROCEEDINGS

United States Court of Appeals for the First Circuit:

- *Wilkins v. Genzyme Corp.*, 93 F.4th 33 (1st Cir. 2024).

- *Hochendoner v. Genzyme Corp.*, 823 F.3d 724 (1st Cir. 2016).

United States District Court for the District of Massachusetts:

- *Wilkins v. Genzyme Corp.*, No. CV 21-10023-DPW, 2022 WL 4237528 (D. Mass. Sept. 14, 2022), aff'd in part, rev'd in part and remanded, 93 F.4th 33 (1st Cir. 2024)

- *Hochendoner v. Genzyme Corp.* 95 F. Supp. 3d 15 (D. Mass. 2015), aff'd in part, vacated in part, remanded, 823 F.3d 724 (1st Cir. 2016). (consolidated, with *Adamo v. Genzyme*).

United States District Court for the District of Indiana:

- *Wilkins v. Genzyme Corp.* (transferred to the District Court of Massachusetts. No. CV 21-10023-DPW (pending).

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The opinion of the First Circuit Court of Appeals is reported at 93 F.4th 33, and it is reprinted in the Appendix to the Petition "Pet. App." at 1a. *Wilkins v. Genzyme Corp.*, 93 F.4th 33 (1st Cir. 2024).

Judgment filed on February 15, 2024, in the United States Court of Appeals for the First Circuit affirming the order of dismissal of Petitioners' complaint against Genzyme Corporation entered by the United States District Court for the Massachusetts is published as 93 F.4th 33 in the Federal Reporter. It is reprinted in the Appendix to the Petition "Pet. App." at 1a. *Wilkins v. Genzyme Corp.*, 93 F.4th 33 (1st Cir. 2024).

Petitioners' timely petition for panel and *en banc* rehearing was denied on May 15, 2024. It is reprinted at in the Appendix to the Petition at Pet. App. 110a.

The opinion of the District Court for the District of Massachusetts is not reported and is reprinted at Pet. App. 32a. *Wilkins v. Genzyme Corp.*, No. CV 21-10023-DPW, 2022 WL 4237528 (D. Mass. Sept. 14, 2022), aff'd in part, rev'd in part and remanded, 93 F.4th 33 (1st Cir. 2024).

JURISDICTION

The First Circuit Court of Appeals issued its opinion on February 15, 2024. Petitioner's timely hearing petition for panel rehearing and *en banc* rehearing was denied on May 15, 2024. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The Class Action Fairness Act (2005) provides.

(d)(1) In this subsection--

> (A) the term "class" means all of the class members in a class action;
>
> (B) the term "class action" means any civil action filed under rule 23 of the Federal Rules of Civil Procedure or similar State statute or rule of judicial procedure authorizing an action to be brought by 1 or more representative persons as a class action;
>
> (C) the term "class certification order" means an order issued by a court approving the treatment of some or all aspects of a civil action as a class action; and
>
> (D) the term "class members" means the persons (named or unnamed) who fall within the definition of the proposed or certified class in a class action.

(d)(2) The district courts shall have original jurisdiction of any civil action in which the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and is a class action in which--

> (A) any member of a class of plaintiffs is a citizen of a State different from any defendant; …

28 U.S.C.A. § 1332 (d)

28 U.S.C.A. § 1367 provides.

> (a) Except as provided in subsections (b) and (c) or as expressly provided otherwise by Federal statute, in any civil action of which the district courts have original jurisdiction, the district courts shall have supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution. Such supplemental jurisdiction shall include claims that involve the joinder or intervention of additional parties.
>
> (b) In any civil action of which the district courts have original jurisdiction founded solely on section 1332 of this title, the district courts shall not have supplemental jurisdiction under subsection (a) over claims by plaintiffs against persons made parties under Rule 14, 19, 20, or 24 of the Federal Rules of Civil Procedure, or over claims by persons proposed to be joined as plaintiffs under Rule 19 of such rules, or seeking to intervene as plaintiffs under Rule 24 of such rules, when exercising supplemental jurisdiction over such claims would be inconsistent with the jurisdictional requirements of section 1332.

(c) The district courts may decline to exercise supplemental jurisdiction over a claim under subsection (a) if--

(1) the claim raises a novel or complex issue of State law,

(2) the claim substantially predominates over the claim or claims over which the district court has original jurisdiction,

(3) the district court has dismissed all claims over which it has original jurisdiction, or

(4) in exceptional circumstances, there are other compelling reasons for declining jurisdiction.

(d) The period of limitations for any claim asserted under subsection (a), and for any other claim in the same action that is voluntarily dismissed at the same time as or after the dismissal of the claim under subsection (a), shall be tolled while the claim is pending and for a period of 30 days after it is dismissed unless State law provides for a longer tolling period.

INTRODUCTION

During a national drug shortage, the FDA suspends enforcement of the U.S. Food, Drug and Cosmetic Act "FDCA" to allow untested, adulterated, and unapproved

drugs into interstate commerce to alleviate the shortage. However, the 50 States do not suspend their laws to accommodate the FDA's decree, nor has Congress amended the FDCA to allow such prohibited products into commerce. The receipt of these untested, adulterated, and unapproved drugs during a national drug shortage is still presumptively injurious. As such, all 50 State laws still ban them. State residents can and should sue for injuries arising from receipt of these otherwise illegal drug products in commerce. However, the States take different approaches to tolling the statute of limitations while a class action case is in Federal Court, and the Federal Circuits are split as to which approach is correct.

Petitioners have received untested, adulterated, and unapproved drug (termed "low dose" Fabrazyme) through interstate commerce and pled injuries, such as failure to warn, lack of informed consent and adverse events. Other plaintiffs have died. Genzyme admittedly did not disclose warnings to users that "low dose" would be dangerous and ineffective for treating Fabry disease according to their internal documents. It warned Australians not to take it, but not Americans. It entered a felony guilty plea with the Department of Justice to distributing adulterated and misbranded drug throughout the States. It kept doing it for two and one half years (but only to Americans), billing hundreds of millions of dollars for the useless and dangerous drug.

Federal preemption did not apply, since the FDA never approved the dose and purity that it was sent through interstate commerce. State prescribing physicians had not changed their recommendation for full and pure doses either, so the learned intermediary doctrine did not

apply. The Plaintiffs who received the substitution drug collectively sued in federal court under state substantive laws and invoked Class Action Fairness Act (2005) "CAFA" 28 U.S.C. § 1332(d) under "minimal diversity" with an invocation to a Rule 23 class certification hearing. The class action was dismissed, except for one Plaintiff (Mr. Mooney) that had a "sensitization" reaction to the drug. He has since settled. At no point did Petitioners Wilkins, LaForce and Stanziano file in State courts.

Petitioner Stanziano timely filed in 2011. Petitioners Wilkins and LaForce timely filed in 2013. The District Court dismissed all their cases with prejudice for failure to state a claim under Rule 12(b)6 in 2015. In 2016, the appeal's panel found the lower court had committed error and converted their dismissals from "with prejudice" into ones "without prejudice" under Rule 12(b)1. However, as the subsequent appeal panel has ruled, in the time it took for the District Court to erroneously dismiss the case in 2015, the relevant statutes of limitations had run out in 2014. In other words, the original appellate decision dismissing "without prejudice" in 2016 automatically had converted back into one "with prejudice" but under a different legal theory. In the time it took the district court to reach the wrong decision, the court had exhausted the Petitioners statute of limitations, despite originally being timely to court.

Petitioners believed that they had been dismissed without prejudice and that the pendency of the original class action in federal court had tolled the statute of limitations under CAFA. Thus, they re-filed their original class action again in Indiana Federal Court claiming the "sensitization" type of adverse event that original First

Circuit panel found showed a "plausible" medical injury. Sensitization is not the most common adverse event among the class. The First Circuit rejected the application of federal tolling doctrines in CAFA cases. Instead, it applied state law tolling doctrine and found that Indiana's laws could not save the CAFA case.

If federal tolling doctrines such as *American Pipe*, had been applied, then this class action would have been preserved. "A federal class action is no longer 'an invitation to joinder' but a truly representative suit designed to avoid, rather than encourage, unnecessary filing of repetitious papers and motions." *Am. Pipe & Const. Co. v. Utah*, 414 U.S. 538, 550 (1974). On the other hand, some federal courts still look to state tolling doctrines for class actions. The States themselves have taken opposite sides on whether class actions are valuable. Some States embrace cross-jurisdictional tolling under the policies of Federal Rule 23. Other states reject it for fear of becoming magnet states for class actions. Most states have never promulgated a rule. In such situations, disagreement among the district courts has led to numerous Circuits certifying the question to determine if a State would permit them to adjudicate the CAFA case. *Casey v. Merck & Co.*, 678 F.3d 134, 137. ("[t]he Supreme Court of Virginia held [that it] "does not toll the statute of limitations for unnamed putative class members due to the pendency of a putative class action in another jurisdiction." (2d Cir. 2012) *but compare* ("New York courts have ... long embraced the principles of *American Pipe* [federal cross jurisdictional tolling]."). *Chavez v. Occidental Chem. Corp.*, 933 F.3d 186, 196 (2d Cir. 2019).

Petitioner Wilkins is a resident of Indiana. The Supreme Court of Indiana has never adopted or declined to apply "cross-jurisdictional" tolling. The Eastern District of District of Pennsylvania "conclude[d] that the Supreme Court of Indiana would adopt cross-jurisdictional class action tolling." *In re Linerboard Antitrust Litig.*, 223 F.R.D. 335, 349 (E.D. Pa. 2004) (emphasis added). The E.D of Louisiana took the opposite view ("Absent clear guidance, however, the Court will not expand Indiana's class action tolling doctrine [to cross-jurisdictional class actions]. *In re Vioxx Prod. Liab. Litig.*, No. MDL NO. 1657, 2007 WL 3334339, at *6 (E.D. La. Nov. 8, 2007) (emphasis added). The First Circuit chose the view of the Eastern District of Louisiana. Ironically, Indiana's lower State court agrees with the Eastern District of Pennsylvania, "Since the instant suit was filed as a class action and was duly certified as such, this case should be treated as if it were a certified class action from the day the amended complaint was filed [applying *American Pipe* tolling.]." *Arnold v. Dirrim*, 398 N.E.2d 426, 440 (Ind. Ct. App. 1979).

The First Circuit's and other federal courts' interpretation of CAFA and interpolation of state-law equitable tolling doctrines cannot be reconciled with the purpose of CAFA. If the federal courts have initial jurisdiction of "cases of national importance under diversity jurisdiction," state equitable tolling doctrines should be irrelevant or preempted. *See Shady Grove* "[t]he Court… holds that Federal Rule of Civil Procedure 23, which prescribes procedures for the conduct of class actions in federal courts, preempts the application of [New York's ban for class actions] in [federal] diversity suits. *Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins.*

Co., 559 U.S. 393, 437, (2010). However, for CAFA cases, the States (not Congress) are still deciding whether to allow class actions to proceed in federal court. CAFA jurisdiction should not depend on state law doctrines for class action filing (or re-filing), since Congress' substantive intent was to change how the diversity statute operated under CAFA.

While Congress did not explicitly say which equitable doctrines would apply to its creation of CAFA jurisdiction, the Senate report accompanying CAFA cites federal "*American Pipe*" tolling as applying in pure diversity cases. The label "diversity" or "federal question" jurisdiction should not be relevant, but many of the federal courts have still operated under the assumption that CAFA did not change anything.

The problem is further exacerbated by the critical need to enforce all 50 States' substantive pure food and drug laws in federal court under CAFA. Traditionally, pure food and drug class actions were enforceable only by state courts since they only had state-law claims *Merrell Dow Pharms. Inc. v. Thompson,* 478 U.S. 804, 809–10 (1986). In *Dow*, this Court concluded that enforcement of these pure state law claims is solely limited to state class action jurisdiction. In 2015, Congress changed this approach when it "federalized" defective drug suits under CAFA. Congress cited its overreaching interest in interstate commerce to provide federal courts with jurisdiction in such diversity suits.

The result is that the federal courts are now working at cross-purposes to Congress and the States. All sovereigns agree that deterrence of the sale of untested, adulterated,

and unapproved medical drugs is necessary to protect the health and safety of States, the Nation, and its citizens. The States' only disagreement is whether class actions are valuable judicial mechanisms in their own state courts.

CAFA class actions asserting injury from the same acts of felony distribution of untested, adulterated, and unapproved drugs into interstate commerce (and its sale within a State) will find that they cannot realistically enforce the State laws at the federal level because States do not agree with each other on the utility of class actions. Strangely, *American Pipe* concerned only financial injuries from construction pipes that had been price-fixed and distributed through interstate commerce. Here the product is a defective drug that has injured and killed Americans throughout the nation. According to the First Circuit, the federal courts would need Congress to create a federal cause of action so it could adjudicate the CAFA class under federal tolling doctrines. This is despite Genzyme pleading guilty to committing acts of felony introduction of adulterated and misbranded drug into interstate commerce in a consent decree with the Department of Justice, just like the defendant did in *American Pipe* but for a far less dangerous product.

Congress could not have foreseen or desired the federal courts to work at cross purposes in the enforcement of Congress' and the 50 States' substantive laws. If CAFA cases are to proceed promptly, then the Federal Courts must apply federal tolling doctrines. Essential uniform rules of equity are what Congress intended the federal courts to apply.

This is a well-recognized and entrenched conflict. The question presented are important and recur frequently, and the clarity and operation of CAFA has been frustrated. Congress' and the 50 States' ban of unapproved and untested medical drugs is an overriding federal and State interest. Finally, the First Circuit's decision is wrong. It adopts procedural rules that defeat the operation of the principles of equity. It should have adopted an "enabling approach" to CAFA under the diversity statute.

For all these reasons and those presented below, Petitioners respectfully ask this Court to grant the petition.

STATEMENT OF THE CASE

A. FABRY DISEASE AND FABRAZYME TREATMENT

Genzyme makes what was at relevant times the only drug approved in the United States for treating Fabry disease, a progressive disease that leads to destructive inflammation, organ failure, and premature death." Pet. App. 4a. "Genzyme's drug, called Fabrazyme, slows the progression of Fabry disease when administered at the proper dosage [(1mg/kg)] every two weeks. *Id.* at 5a. "During the relevant times, Fabrazyme was the only FDA-approved treatment for Fabry disease in the United States." *Id.* Individual treatment with Fabrazyme costs approximately $600,000 per year per patient. *Wilkins* Complaint ¶ 41. 1:21-cv-10023-DPW Document 67 Filed 10/05/20, ("hereinafter, "Compl."). Approximately 2,500 Americans have been diagnosed with Fabry disease, which is a rare disease similar to Tay-Sachs disease.

From 2003 until 2009, Genzyme steadily provided the FDA-approved dosage of Fabrazyme to U.S. patients [1mg/kg every two weeks]." *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.* "Genzyme initiated a rationing plan, providing U.S. patients with reduced doses in order to prolong the drug's available supply. In November 2009, Genzyme discovered particulate contamination in another batch of Fabrazyme, exacerbating the shortage." *Id.* The drug also entered commerce with glass, rubber, and steel particles in the vials. Compl. ¶ 122. "In 2011, Genzyme worsened the shortage in the United States by diverting [] Fabrazyme [away from America] to the European market." *Id.* "[]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." *Wilkins v. Genzyme Corp.*, 93 F.4th 33, 38 (1st Cir. 2024).

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 from a period in August 2009-2012, or no doses at all." Pet. App. 5a. "Plaintiffs variously allege that they experienced [physical] 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 without warnings. Pet. App. 5a-6a. "They also allege that Genzyme knowingly misrepresented both the effectiveness of its low-dose regimen, the expected duration of the shortage to American Fabry patients" and the types and frequencies of adverse events from the low dose as well the contaminations." Pet. App. 6a and *e.g.*, Compl. ¶ 88.

At all relevant times, the U.S. government held property rights in Fabrazyme since the invention was funded under a tax-payer grant from the National Institutes of Health. Compl. ¶ 27. It also billed third party payors including Medicare, Medicaid, and the VA for the unapproved drug. Compl. ¶ 328.

In 2010, Genzyme pled guilty to felony introduction of improperly labeled "low dose" and contaminated Fabrazyme into interstate commerce under a consent decree with the Department of Justice. *United States v. Genzyme Corp.*, No. 1:10-cv-10865-MLW, ECF No. 12 (entered May 24, 2010). "[T]he drugs [Fabrazyme, Cerezyme, and Myozyme] were adulterated due to variances in strength, purity or quality [from the FDA approved label]." 19 No. 5 *FDA Enforcement Manual Newsl.* 8 (Jul. 2010).

Genzyme continued the "low dose" substitutions for full doses until 2012. Compl. ¶ 236. Europe banned low dosing in 2010 as being both dangerous and ineffective less than one year into the shortage. *Hochendoner et al. v. Genzyme*, Case 1:11-cv-10739-DPW Exhibit 1 filed 03/09/2011. European regulatory authorities "noted that since the introduction of a lowered dose Fabrazyme, a steady increase in [the] number of reported adverse event matching the increase in the number of patients on

the lowered dose. At first, most of the events were pain-related, soon followed by reports of events affecting the heart, the central nervous system, and the kidneys.[] It reported that a decrease in number of reported adverse events has been observed, which reflects the fact that more patients have either been switched to Replagal [not available in the U.S.] of have started receiving a full dose of Fabrazyme again." *Id.* No U.S. treating physician had prescribed "low dose" for the treatment of Fabry disease. Compl. ¶ 236. Genzyme only sent "low doses" to Americans after Europe had banned the practice. Compl. ¶ 209.

B. PROCEDURAL HISTORY

In March 2011, a group of plaintiffs, on behalf of a putative class of all U.S. Fabry patients, sued Genzyme in the U.S. District Court for the Western District of Pennsylvania, which transferred the case to the District of Massachusetts ('the *Hochendoner* lawsuit')." Pet. App. 6a. Petitioner Stanziano and his wife, Wendy in a derivative action, were members of the *Hochendoner* lawsuit. *Hochendoner et al. v. Genzyme*, Case 1:11-cv-10739-DPW filed 03/09/2011. "In June 2013, another group of plaintiffs, on behalf of a similar putative class, sued Genzyme directly in the District of Massachusetts ('the *Adamo* lawsuit')." *Id.* Petitioners Wilkins and LaForce were members of the *Adamo* lawsuit. *Adamo et al. v. Genzyme*, 1:13-cv-11336-DPW filed 6/03/2013. "Both lawsuits alleged an array of common law and statutory claims against Genzyme" arising from the same conduct, transactions and occurrences which was the distribution of adulterated "low dose" Fabrazyme instead of the pure and approved "full dose." *Id.* Genzyme's "low dosing" of Petitioner Stanziano was continuing while his case was pending in the *Hochendoner* lawsuit. "The district court

consolidated the two lawsuits before dismissing both on the pleadings in March 2015, for failure to state a claim. *See Hochendoner v. Genzyme Corp.*, 95 F. Supp. 3d 15, 21, 35 (D. Mass. 2015)." *Id.*

On appeal, the various types of physical injuries were furcated into the kinds of adverse events to analyze standing and "plausibility" of physical injury under *Twombly/Iqbal*. *Id.* The first panel concluded that the complaint failed to sufficiently allege a plausible physical injury from low dose Fabrazyme sufficient "to confer Article III standing, save what the district court called a 'sensitization' theory of injury as alleged by one of the *Adamo* plaintiffs named James Mooney (and his wife, Laura Kurtz-Mooney)." Pet. App. 7a. It remanded his case "so that the district court could adjudicate Mr. Mooney's' sensitization-based claims." *Id.* It dismissed without prejudice due to a lack of standing all other Plaintiffs' claims for paying for the defective medication and experiencing "non-sensitization" based physical injuries. *Id.*

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 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." Pet. App. 7a.

The twenty-six plaintiffs, almost all of whom were plaintiffs in the *Hochendoner/Adamo* lawsuits, [re-filed] the present action in the U.S. District Court for the Southern District of Indiana." *Id.* The case was transferred under venue provisions "back to the District of Massachusetts." *Id.* "The new complaint assert[ed] twenty-four counts of common law and statutory claims on behalf of the named plaintiffs and 'all others similarly situated.'" *Id.* Plaintiffs again alleged 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." Pet. App. 8a. "[T]his time each plaintiff had alleged the specific" physical injuries that they had suffered from "low dose" Fabrazyme. *Id.*

When this case again came before the new First Circuit panel, it concluded that the refiled case was too late. Pet. App. 26a. "Neither *American Pipe* itself nor any analogue in Indiana law of *American Pipe* could play any role in rendering any of the *Adamo* plaintiffs' claims timely for non-sensitization physical injuries." Pet. App. 21a. However, because Genzyme had not presented the Statute of limitations on cross-appeal, the First Circuit bifurcated the case into "sensitization injuries" and dismissed with prejudice Petitioners Wilkins, LaForce and Stanziano. Pet. App. 17a. It found that the remaining plaintiffs had been improperly dismissed as to standing and remanded these "non-sensitization" plaintiffs' claims back to the district court, where Genzyme could raise the statute of limitations defense. *Id.*

For Petitioners Stanziano, Wilkins, and LaForce, the panel determined that they had all made a proper

claim at least for "sensitization injuries" under Rule 12(b)(1) standing doctrine and Rule 12(b)6. The First Circuit ruled that the District Court had erred in dismissing their cases under Rule 12(b)6 on the merits for failure to attach third party medical testimony to the Complaint attesting to each individual's injury causation. Pet. App. 80a. Conversely, the new *Wilkins* panel found that in the time the federal court had taken to adjudicate the original class actions under *Hochendoner* and *Adamo*, the Petitioners' statute of limitations had been exhausted prior to the original panel's dismissal without prejudice. Therefore, the original dismissal without prejudice for standing still operated with prejudice on the merits under Rule 12(b)6 as to the statute of limitations. Pet. App. 26a

The *Wilkins* panel found that the Stanzianos' lawsuit in the refiled case is not a continuation of the prior *Hochendoner* lawsuit "within the meaning of the [Indiana] Journey's Account [savings] Statute, because all the [physical injury] claims that the Stanzianos' now assert pivot on highly material allegations of individual [physical] injuries and [medical] 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)." Pet. App. 23a.[1]

1. The First Circuit adopts a nomenclature that the Petitioners have not used. The District Court and First Circuit cite to *Hochendoner* I, II, III (and presumably IV and V) to reference each prior proceeding. However, all these cases originate from

REASONS TO GRANT THE PETITION

In the present case, the opposite of what Congress had intended under CAFA has happened. A class action of true "national importance" has stalled for over a decade without substantive adjudication. Petitioner Stanziano was the first to file any of the Fabrazyme cases in the nation. He pled CAFA class action jurisdiction then and pled it again. His case has been pending at the pleadings stage since at least 2011. The Fabrazyme cases in various forms have been pending in one federal court or another since this time.[2]

Conversely, in the only Fabrazyme case that was not pled as a class ("*Schubert*"), the Utah federal court moved to discovery in three years, even though it had been filed after Petitioner Stanzianos' class action. The District Court of Utah found that "to the extent that Plaintiff claims that the lowered dosage of the medication was more harmful than receiving no medication, there is a distinction between the [failure to supply the market versus selling defective drug] cases and Plaintiff's claim survives at the pleading stage. Plaintiff alleges that Genzyme knew a reduced dosage of the medication would be more harmful than no medication. Whether there is support for this allegation will need to be proven or

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either *Hochendoner* (Stanziano Petitioner) or *Adamo* (Wilkins and LaForce Petitioners). To prevent confusion, the Petitioners will refer to the source of the original suits, not these cases' later procedural positions.

2. The exception is the time Plaintiffs and Defendant were negotiating settlement under a mutual tolling agreement. *See*, Pet. App. 7a.

rebutted through discovery and/or trial." *Schubert v. Genzyme Corp.*, No. 2:12CV587DAK, 2013 WL 4776286, at *6 (D. Utah Sept. 4, 2013).

Sadly, Dr. Schubert died before he could receive pure and full doses of Fabrazyme. The discovery information revealed that Genzyme knew "low doses" would be dangerous. It also warned Australians, but not Americans, against taking it. Specifically, Australian regulatory authorities wanted to save costs, so it asked Genzyme if "low dosing" was safe and effective. Genzyme's response… was that that reducing the dose "to 0.2 mg/kg . . . across the board would have **significant clinical consequences** for patients, with the expectation that **many would suffer irreversible harm** as a result of insufficient dosing," and that "treatment at a higher dose is **necessary and may be life-saving**." In the same communication, Genzyme stated that the suggestion to "reduce the dose of Fabrazyme® to 0.2 mg/kg in all patients **ignores the cumulative evidence** in the extant literature" and that to believe such a reduction could occur "with little or no loss of efficacy is conjectural." GENZYME013854; GENZYME013847 (*Schubert v. Genzyme*, case 2:12-cv-00587-HCN-DAO, ECF Doc. 173 unsealed 5/21/20). *Wilkins* Complaint. 1:21-cv-10023-DPW Document 67 Filed 10/05/20, ¶ 308. In a related email, Genzyme senior management stated that such a "**blanket dose adjustment would be insane.**" GENZYME013840 (*Schubert*). *Id.* at ¶ 192.

The warnings that Genzyme gave Australians would have protected Americans. Similarly, if Genzyme had reported these effects to the FDA, the agency would have likely rescinded its non-enforcement policy for "low

dosing" during the Fabrazyme shortage. If discovery for the Petitioners had occurred at the pace in Utah, American's citizens' lives could probably have been saved between 2009 and 2012.

Mr. Mooney was the only plaintiff to meet the First Circuit's pleading standard set out in the original First Circuit Court appeal under the *Hochendoner* and *Adamo* lawsuits. Unlike Dr. Schubert, Mr. Mooney had a different adverse event. In *Schubert*, the patient deteriorated rapidly on low doses and died before he could obtain full doses. This type of adverse event is termed "treatment failure" in the medical nomenclature. Mr. Mooney's injuries followed a different medical-causation path. Although he too suffered treatment failure, he also suffered a sensitization/anaphylaxis that only occurs after prior serial low dosing followed by re-introduction to full doses. These anaphylactic events were not as common as Dr. Schubert's "treatment failure." Sensitization has occurred in perhaps 3-4% of patients given low doses.[3]

Petitioners Wilkins, Stanziano and LaForce had experienced this Mooney-type adverse "sensitization" event but had not pled it with the specificity of Mooney. Since the statute of limitations had passed and their individual causes of actions had been dismissed as to standing without prejudice under Rule 12(b)1, the subsequent First Circuit panel deemed the original non-prejudicial dismissal to have operated as one with prejudice under Rule 12(b)6. This is despite the court

3. This statistical observation is anecdotal. The sensitization reactions are collected from the total number of Plaintiffs in *Schubert* and *Adamo*. No medical study has ever been done.

court still having original jurisdiction under 28 U.S.C. § 1367(a). According to the most recent First Circuit panel, it was now too late for Petitioners to amend or refile alleging either a *Schubert*-based physical injury "treatment failure" or the *Mooney* type adverse event (sensitization). Plaintiffs have identified other adverse events, including acceleration of disease (noted by the European regulatory authorities), blistering rashes, risk of spontaneous abortions, and a risk for hematological cancer.

Even though defective Fabrazyme cases were co-pending in various federal courts in Pennsylvania (Stanziano,) Utah (Schubert), and Massachusetts (Wilkins and LaForce), no federal court has still ever heard a Fabrazyme case on the merits.

At least for defective drug cases, either Congress made a mistake in passing CAFA, or the federal courts have made a mistake in administering CAFA. Guidance from this Court is sorely needed. The decision below is at odds with the proper functioning CAFA, enforcement of the States' substantive laws, and the prior precedent of this Court.

I. Congress' purpose under CAFA has been frustrated by excluding federal equitable doctrines from minimal diversity cases of "national importance."

A. Congress expects and requires federal courts to apply federal (not state) equitable doctrines to CAFA interstate cases of "national importance."

28 U.S.C.A. § 1332 (d)(2) provides "The district courts shall have original jurisdiction" over cases that are minimally diverse, and the aggregate claims exceed $5 million. The Congress refers to these cases in CAFA as "cases of interstate cases of national importance under diversity jurisdiction" CLASS ACTION FAIRNESS ACT OF 2005, PL 109–2, February 18, 2005, 119 Stat 4, sec. 2 (b)(2). They have two jurisdictional elements—minimal diversity and an aggregate value greater that $5 million. Congress did not create a doctrinal definition of "national importance." However, the Senate report accompanying CAFA discusses cases where federal jurisdiction is permissive (unlike here). Congress cites defective drug cases as being "nationally important." "If a case presents issues of national or interstate significance, that argues in favor of the matter being handled in federal court. For example, if a nationally distributed pharmaceutical product is alleged to have caused injurious side-effects and class actions on the subject are filed, those cases presumably should be heard in federal court because of the nationwide ramifications of the dispute and the probable interface with federal drug laws (even if claims are not directly filed under such laws)…. If such issues are identified, that point favors the exercise of federal jurisdiction." S. REP. 109-14, 36, 2005 U.S.C.C.A.N. 3,

35. This Court agrees that CAFA's primary objective [is] ensuring "Federal court consideration of interstate cases of national importance." § 2(b)(2), 119 Stat. 5. *Standard Fire Ins. Co. v. Knowles*, 568 U.S. 588, 595, (2013). Indeed, this Court has found that CAFA's "provisions should be read broadly, with a strong preference that interstate class actions should be heard in a federal court..." *Dart Cherokee Basin Operating Co., LLC v. Owens*, 574 U.S. 81, 89 (2014).

The promise of CAFA to "(1) assure fair and prompt recoveries for class members with legitimate claims" is why the Petitioners sought federal court adjudication instead of filing state suits and going through the remand process. CLASS ACTION FAIRNESS ACT OF 2005, PL 109–2, February 18, 2005, 119 Stat 4, sec. 2 (b)(1). Congress stated that "[a]ssuming that a case is a meritorious class action asserting meritorious claims, there is no reason to believe such a case heard by a federal court would have an outcome different from a state court case, particularly given that the federal court normally would apply the same state substantive law as a state court considering the same case. S. REP. 109-14, 55, 2005 U.S.C.C.A.N. 3, 52.

CAFA does not expressly incorporate state equitable tolling laws. Only one section refers to the operation of state law doctrines. Section 11(D) requires that federal courts toll the statute of limitations while they consider whether to send the case back to state court. "The limitations periods on any claims asserted in a mass action that is removed to Federal court pursuant to this subsection shall be deemed tolled during the period that the action is pending in Federal court. 28 U.S.C.A. § 1332 11(D)." Presumably, Congress' intent was to preserve the

ability of Plaintiffs to proceed to a merits determination in at least one jurisdiction.

If § 1332 11(D) is read disjunctively, then only a removed class would obtain federal tolling of the statute of limitation. If read conjunctively, then federal equitable doctrines would always apply whether the case is originally filed in federal court or removed there. Federal jurisdiction, once established under CAFA would appear to be absolute and continuing until an adjudication on the merits. Therefore, state tolling doctrines should be either irrelevant or preempted.

Some members of Congress worried that Federal Courts would not be timely or effective in adjudicating pharmaceutical cases under state laws. The opposition to CAFA argued that pharmaceutical cases should be excluded: "Critics' Contention No. 13: S. 5 [CAFA] will make it harder for consumers to bring class action lawsuits against pharmaceutical manufacturers and should be amended to exclude drug cases.— [Reply]. S. 5 poses no barrier for consumers seeking to bring suits against pharmaceutical manufacturers. All the bill does is move certain class actions to federal court." S. REP. 109-14, 75, 2005 U.S.C.C.A.N. 3, 70. See also id. at 39: "The Committee also wishes to stress that the inquiry under this criterion should not be whether identical (or nearly identical) class actions have been filed. The inquiry is whether similar factual allegations have been made against the defendant in multiple class actions, regardless of whether the same causes of actions were asserted or whether the purported plaintiff classes were the same (or even overlapped in significant respects)."

The First Circuit does not dispute that the Plaintiffs have legitimate claims. Nor would anyone dispute that a class action would be judicially economical. Genzyme pled guilty to committing the acts, and the Plaintiffs properly alleged that they purchased the defective drug during these times, although adverse events have varied among them. It would seem straightforward to allow the class to proceed.

The error in the First Circuit's approach is to divide cases into classical "diversity" and "federal question" subject matter jurisdiction. This bifurcation is a relic of pre-CAFA cases. If a case was a "diversity" case under 28 U.S.C. § 1331, then the court applied state equitable doctrine. However, if the case was a "federal question" case under 28 U.S.C. § 1332 then court applied federal equitable doctrines. CAFA merged the two, stating that the Framers did not intend cases of national and interstate importance to be able to escape federal adjudication on the merits based over what Congress saw as a substantively meaningless distinction between a "federal question case" and a "diversity case." It termed this distinction "false federalism." (i.e., applying a single state's law to all asserted [class] claims). S. REP. 109-14, 63, 2005 U.S.C.C.A.N. 3, 59.

Additional factors favoring federal adjudication are present here. The U.S. Government owned rights in the Fabrazyme patent during the shortage. Plaintiffs had petitioned the National Institutes Health ("NIH") to end Genzyme's exclusive license in 2010. "2010 Request to HHS to Exercise its Bayh-Dole March-In Authority on U.S. Patent No. 5,356,804. "DETERMINATION IN THE CASE OF FABRAZYME" (denied Dec. 1, 2010), available

at https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf. They re-petitioned the NIH when they discovered that the drug was being shipped overseas to Europeans who had an alternative equivalent treatment. *Id.* (denied as moot, Feb. 13, 2013 (unpublished)). They also petitioned the FDA to allocate full doses to Americans in 2012, as it had only been approved at the full dose under the U.S. Food Drug and Cosmetic Act. Citizens Petition "#FDA-2011-P-0055-0001/CP requesting full dose Fabrazyme" (FDA Docket No. FDA-2011-P-0055-0001/CP denied as moot, Aug. 14, 2014, unpublished). When there was no response from the FDA, they sued in D.C. Federal District Court to require the FDA to enforce the U.S. Food, Drug and Cosmetic Act. *Carik v. United States Dep't of Health & Hum. Servs.*, 4 F. Supp. 3d 41 (D.D.C. 2013).

Ultimately, NIH refused to open the taxpayer funded patent to competition, and then declared the issue mooted by the end of the shortage. The FDA delayed its decision until 2014 until after the shortage and also declared it moot. The District Court for the District of Columbia stated that the Plaintiffs did not have Art. III standing under the Constitution because they could not produce evidence of a quantifiable risk from "low doses." ("[T]he plaintiffs have not attempted to quantify the increased risk of physical injury from diluted dosages of Fabrazyme, which would be necessary for the plaintiffs to show they are entitled to the requested injunctive relief.") *Id.* 53. Petitioner Stanziano was one of the members of the Carik lawsuit, but he had not experienced the anaphylactic reaction since full doses had not been reinitiated. It was impossible for him to quantify an unknown risk, so access to the courts was impossible too.

Genzyme also continuously defrauded Medicare and the V.A. from 2009 to 2012 by billing the cost of the "low dose" drug which was at a dose and purity that had never been approved by the FDA or registered in the National Formulary. Genzyme never obtained consent from state or federal public health authorities for a "national emergency" waiver to substitute "low dose" Fabrazyme for the lawful state law prescriptions.

It would seem impossible for the federal courts to have "lost" jurisdiction of such a nationally important case through an unseen trapdoor mechanism in CAFA. However, if the First Circuit had properly applied federal tolling doctrines, this case would have been preserved the interest of Congress in interstate cases of "national importance."

B. This Court has already settled the issue of whether Federal equitable policies and doctrines apply to CAFA—Federal doctrines always preempt state doctrines.

In *Shady Grove*, this Court was faced with a similarly conflicting view of CAFA class actions. New York law banned class actions seeking statutory damages, but CAFA would let them proceed. In a plurality opinion, this Court ruled that a state law prohibiting class actions for statutory damages was in substantive conflict with the desire of Congress to enable class adjudications under Rule 23. *Shady Grove*, 559 U.S. at 399. This Court held that the "[l]line between eligibility and certifiability is entirely artificial. Both are preconditions for maintaining a class action." *Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.,* 559 U.S. 393, 399 (2010). Therefore,

federal doctrine preserving a CAFA class action preempts any conflicting state law.

In another CAFA case, this Court stated that "administrative simplicity is a major virtue in a jurisdictional statute. (SCALIA, J., concurring in judgment, eschewing 'the sort of vague boundary that is to be avoided in the area of subject-matter jurisdiction wherever possible'). 'Complex jurisdictional tests complicate a case, eating up time and money as the parties litigate, not the merits of their claims, but which court is the right court to decide those claims. Complex tests produce appeals and reversals, encourage gamesmanship, and, again, diminish the likelihood that results and settlements will reflect a claim's legal and factual merits. Judicial resources too are at stake. Courts have an independent obligation to determine whether subject-matter jurisdiction exists, even when no party challenges it. So courts benefit from straightforward rules under which they can readily assure themselves of their power to hear a case.'" *Hertz Corp. v. Friend*, 559 U.S. 77, 94 (2010) (internal citations omitted.). *See also, Standard Fire*, "[w]hen judges must decide jurisdictional matters, simplicity is a virtue." *Standard Fire Ins. Co. v. Knowles*, 568 U.S. 588, 595 (2013). Whether a single claimant is dismissed for a pleading technicality should have no effect on the viability of a CAFA case, and it should be curable.

The operation of state equitable tolling doctrines has had the same effect of quashing a CAFA case before it can reach certification as was the case in *Shady Grove*. Had *American Pipe* tolling been applied instead of state "cross-jurisdictional" tolling, Petitioners Wilkins and LaForce would have been timely to plead for their "tag

along" case for all their various species of adverse events. Plaintiff Stanziano, who had already filed in 2011 would still have been able to proceed, and the remaining litigants would not have been bifurcated for more adjudications as to their "non-sensitization" adverse events. Indeed, the entire point of filing the *Adamo* lawsuit in Massachusetts was to pool resources with the *Hochendoner* Plaintiffs who were already there. The same court would also have all of the parties before it at the same time, allowing efficient adjudication.

In *Artis*, this Court also confronted a similar issue over the expiration of state law claims while a case was pending in federal court. *Artis v. D.C.*, 583 U.S. 71 (2018). "If a district court declines to exercise jurisdiction over a claim asserted under § 1367(a) and the plaintiff wishes to continue pursuing it, she must refile the claim in state court. If the state court would hold the claim time barred, however, then, absent a curative provision, the district court's dismissal of the state-law claim without prejudice would be tantamount to a dismissal with prejudice. ([U]nder the doctrine of pendent jurisdiction, if the statute of limitations on state-law claims expires before the federal court 'relinquish[es] jurisdiction[,] ... a dismissal will foreclose the plaintiff from litigating his claims'). To prevent that result, § 1367(d) supplies "a tolling rule that must be applied by state courts.' Section 1367(d) provides: 'The period of limitations for any claim asserted under subsection (a), and for any other claim in the same action that is voluntarily dismissed at the same time as or after the dismissal of the claim under subsection (a), shall be tolled while the claim is pending and for a period of 30 days after it is dismissed unless State law provides for a longer tolling period.'" *Artis*, 583 U.S. at 76 (internal

citations omitted). The *Artis* Court ruled that Section 1367(d) operates as a stop-the-clock rule, not a grace period. Thus, the Plaintiff could successfully refile her state law claim.

The House Report accompanying creation of supplemental jurisdiction 1337(d) also explains that Congress appreciated that "[s]upplemental jurisdiction has enabled federal courts and litigants to ... deal economically—in single rather than multiple litigation—with related matters." H.R. Rep. No. 101–734, p. 28 (1990). This Court has found that "With tolling available, a plaintiff disinclined to litigate simultaneously in two forums is no longer impelled to choose between forgoing either her federal claims or her state claims." *Artis v. D.C.*, 583 U.S. 71, 90 (2018).

Here, if federal doctrinal laws are applied, then the CAFA case can proceed efficiently for all parties.

As these cases illustrate, if there is a conflicting state law or doctrine that disables a litigants timely filed suits, the federal courts will apply their federal equitable doctrines to preserve it under either CAFA or 1337(d). This case presents the Court with the ideal vehicle to resolve a conflict among the federal courts on how to preserve the Congress' interest in creating minimal diversity jurisdiction for federal courts cases "of national importance." The Court should grant certiorari to harmonize the divergent approaches that the federal courts have taken to administering CAFA class actions.

II. The Question Presented is Important.

Interpolating state rules into a defective drug CAFA case defeats the State and Federal substantive laws outlawing such drugs. The 50 States' substantive laws are not in conflict with Congress' power to regulate interstate commerce. Indeed, all sovereigns would agree that their governmental interest in the safety and effectiveness of pharmaceutical drugs is critical to public health at the state and federal level. The States' only disagreement with Congress is whether they would recognize class actions filed in other jurisdictions.

While FDA's "enforcement discretion" approach to the U.S. Food, Drugs and Cosmetic Act has been termed a "derogation of duty" by the federal courts, the position does not help the victims being sold otherwise banned drugs arriving through interstate commerce. ("The FDCA imposes mandatory duties upon the agency charged with its enforcement. The FDA acted in derogation of those duties by permitting the importation of thiopental, a concededly misbranded and unapproved new drug…), *Cook v. Food & Drug Admin.,* 733 F.3d 1, 12 (D.C. Cir. 2013). 21 U.S.C. §§ 301-399. Nevertheless, Americans who receive these universally banned drugs during a shortage must still make a terrible choice. If they don't take the unapproved drug then they may die of their disease; if they do take it, then it may be ineffective, dangerous, or both. Treating physicians cannot offer any guidance because no medical data exists in the effects of such untested drugs. The only protections for citizens are found in the common laws of the 50 States requiring disclosure of risks and ineffectiveness, whether or not the FDA enters a period of "enforcement discretion."

State law class actions have always been critical to enforcement of the now substantially uniform 50 States' pure food and drug laws. This Court observed that "through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." A drug manufacturer "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." Thus, when the risks of a particular drug become apparent, the manufacturer has "a duty to provide a warning that adequately describe[s] that risk." *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 312 (2019) (internal citations omitted). As this Court also held in *Wyeth*: "State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Wyeth v. Levine*, 555 U.S. 555, 579 (2009).

If the federal courts do not choose an "enabling approach" to defective drug CAFA suits, they are unlikely to filed and even when they are the adjudications will not be prompt. This is especially true now that CAFA has essentially "federalized" most defective drug suits. Such an outcome would effectively disable the operation of the substantive police powers reserved to the States under the Tenth Amendment.

III. The First Circuit Court of Appeals' Decision is Wrong.

The original First Circuit's assessment of its own power to adjudicate the *Hochendoner/Adamo* lawsuits was the predicate error that has only been compounded by the subsequent error in the *Wilkins* lawsuit. The original panel looked to Constitutional doctrines instead of Congress to determine its jurisdiction. Since there was at least minimal diversity and an aggregate amount over $5 million in the original class, a dismissal as to standing was not warranted. Genzyme was also properly on notice as to what the claims against it were in the first filed *Hochendoner* lawsuit. "[T]he defendants [had] the essential information necessary to determine both the subject matter and size of the prospective litigation...." *Am. Pipe & Const. Co. v. Utah*, 414 U.S. 538, 554 (1974).

The original First Circuit panel unnecessarily complicated the analysis for the claims. 28 U.S.C. 1367(a) states that "in any civil action of which the district courts have original jurisdiction [as here], the district courts shall have supplemental jurisdiction over all other claims that are so related to claims in the action." Presumably, the various species of physical injuries would apply to original as well as supplemental jurisdiction for standing purposes since Mr. Mooney's claim had made survived the original dismissal.

Of course since the data on low dose was never released, the Plaintiffs have never been able to plead with adverse event causality that the original panel desired. The legal presumption that a misbranded drug is always injurious was never granted to Petitioners. However, this

Court stated in *Exxon* that "[a]lthough the district courts may not exercise jurisdiction absent a statutory basis, it is well established—in certain classes of cases—that, once a court has original jurisdiction over some claims in the action, it may exercise supplemental jurisdiction over additional claims that are part of the same case or controversy. *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 552 (2005).

The subsequent First Circuit panel has thus compounded the error of the previous panel. If the originally filed cases cannot be used to relate the injuries back to the first complaint, then the Statute of limitations prevents refiling, even though the original complaint alleged harm from the same conduct, transactions and occurrence original set out in the pleading. Pet. App. 23a. The Petitioners also tried to make out a claim for treatment failure; however, the First Circuit found this species of injury to have been waived. ("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.) Pet. App. 11a FN4. This injury was not waived because it still remains functionally impossible to classify all the medical causation injuries when no discovery has been made available

Of note is that the First Circuit also cites and aligns itself with the Second Circuit's flawed approach

to embracing an issue that Congress termed "false federalism" when it enacted CAFA. The Second Circuit found that the "[t]he rule of *American Pipe*—which allows tolling within the federal court system in federal question class actions—does not mandate cross-jurisdictional tolling as a matter of state procedure." *Casey v. Merck & Co.,* 653 F.3d 95, 100 (2d Cir. 2011), *certified question answered*, 283 Va. 411, 722 S.E.2d 842 (2012). However, the Second Circuit failed to analyze Congress' intent when it enacted CAFA. The First Circuit's citation to an antitrust litigation is similarly flawed. The State of Tennessee has "no interest in furthering the efficiency and economy of the class-action procedures of another jurisdiction." *In re Urethane Antitrust Litig.*, 663 F. Supp. 2d 1067, 1081 (D. Kan. 2009). Even though, Tennessee may not have an interest in furthering interstate class actions, Congress does.

The First Circuit also rejects the "Continuing Tort" approach to drug substitution cases. However, federal courts have recognized at least under federal common law, that intentional prolongation of medical suffering equitably estops a Defendant from raising a statute of limitations defense until the tortious conduct has ceased. *See*, *Heard v. Sheahan*, 253 F.3d 316, 318 (7th Cir. 2001). "(Every day that they [breached their duty and] prolonged his agony by not treating his painful condition marked a fresh infliction of punishment.)." Under modern jurisprudence each time a person is exposed to a defective drug, a new legal injury occurs for a "failure to obtain fully informed consent." Additional physical injuries can be created, made worse, extended, or even change during the time informed consent was not obtained. As explained by Benjamin Cardozo, "[T]he wrong complained of (lack of

informed consent) is not merely negligence. It is trespass. Every human being of adult years and sound mind has a right to determine what shall be done with his own body." *Schloendorff v. Soc'y of New York Hosp.*, 211 N.Y. 125, 129, 105 N.E. 92, 93 (1914). Presumably, it should make no difference when the "low dose" practice started, only when it stopped. The plaintiffs' bodies were being serially violated. *See, for example Nat'l R.R. Passenger Corp. v. Morgan*, 536 U.S. 101, 106 (2002), (discussing continuing violation for workplace discrimination claim). Indeed, a "continuing trespass" (whether to a person's land or her body) is the archetypal continuing tort. All the Plaintiffs share a common root of harm from their lack of fully informed consent to "low dosing."

The First Circuit's only argument that the plaintiffs should not be allowed back into federal court is to protect the defendant against stale claims. However, Genzyme was first put on notice in 2011 that the drug was defective by Petitioner Stanziano. Moreover, it has a duty to preserve evidence from 2011 forward.

The First Circuit also fails to weigh to the countervailing maxims of equity. Equity will not suffer a wrong to be without a remedy. Equity aids the vigilant, and Equity will take jurisdiction to avoid a multiplicity of suits. Moreover, it is impossible to blame the Plaintiffs for taking "low-dose" Fabrazyme given the limited information that they had when Genzyme reduced their doses. If they had been told what the Australians knew, they would not have used it to treat their Fabry disease. The Petitioners hands are clean, and they were diligent in filing suit.

In any event, discovery is still necessary for the Petitioners to find out what happened to their own bodies. No data has ever been collected or disclosed on the effects years of "low dose" Fabrazyme treatment that Genzyme released into interstate commerce between 2009 and 2012. The First Circuit's dismissal serves no rational purpose and defeats the common interest of citizens, the States, and Congress in creating federal jurisdiction over interstate cases of "national importance."

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

TABLE OF APPENDICES

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT, FILED FEBRUARY 15, 2024

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.

Appendix A

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.

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 U.S. Dist. LEXIS 165678, 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. 2022 U.S. Dist. LEXIS 165678, [WL] 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 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

1. The only new plaintiffs are relatives of the *Adamo* plaintiffs: William McNew (surviving son of Teresa Viers), James and Samuel Wallace (surviving sons of Joseph Wallace), and Nate Brooks (spouse of Mary Helton).

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 U.S. Dist. LEXIS 165678, 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 Wilkins*, 2022 U.S. Dist. LEXIS 165678, 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. 2022 U.S. Dist. LEXIS 165678, [WL] 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 Berrios 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, 137 S. Ct. 1645, 198 L. Ed. 2d 64 (2017) (quoting *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734, 128 S. Ct. 2759, 171 L. Ed. 2d 737 (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.)

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

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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.").

of 'defective' dosing" as opposed to the typical progression of Fabry disease without any treatment. *Wilkins*, 2022 U.S. Dist. LEXIS 165678, 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 U.S. App. LEXIS 30823, 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

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

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 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).

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4. We thus need not decide whether the alternative ground on which the district court accepted jurisdiction was proper. *See Wilkins*, 2022 U.S. Dist. LEXIS 165678, 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, 96 S. Ct. 2158, 48 L. Ed. 2d 784 (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. Pavía 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 sensitization and fraud claims would have expired by

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

no later than the end of 2011, in the absence of any tolling.[6] *See Wilkins*, 2022 U.S. Dist. LEXIS 165678, 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. 2022 U.S. Dist. LEXIS 165678, [WL] 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.

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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, 94 S. Ct. 756, 38 L. Ed. 2d 713 (1974); *Crown, Cork & Seal Co. v. Parker*, 462 U.S. 345, 350, 103 S. Ct. 2392, 76 L. Ed. 2d 628 (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 U.S. Dist. LEXIS 165678, 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] Indeed, "when it applies, the [Journey's Account] Statute serves to resuscitate actions that have otherwise expired under a statute of limitations."

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

Ind. Code § 34-11-8-1 (2005).

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 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 U.S. Dist. LEXIS 165678, 2022 WL 4237528, at *15. The court suggested that such language would have had no meaning unless the Tolling Agreement revived stale claims. 2022 U.S. Dist. LEXIS 165678, [WL] 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.

APPENDIX B — JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT, FILED FEBRUARY 15, 2024

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.

Appendix B

JUDGMENT

Entered: February 15, 2024

This cause came on to be heard on appeal from the United States District Court for the District of Massachusetts and was argued by counsel.

Upon consideration whereof, it is now here ordered, adjudged and decreed as follows: The judgment of the district court is affirmed in part and reversed in part, and the matter is remanded to the district court for further proceedings consistent with the opinion issued this day.

By the Court:

Maria R. Hamilton, Clerk

APPENDIX C — CASE MANAGEMENT ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT, FILED FEBRUARY 15, 2024

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.

Appendix C

ORDER OF COURT

Entered: February 15, 2024

The court refers this case to the court's Civil Appeals Management Program pursuant to 1st Cir. R. 33.0.

By the Court:

Maria R. Hamilton, Clerk

APPENDIX D — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS, FILED SEPTEMBER 14, 2022

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 21-10023-DPW

TRINA WILKINS, ET AL.,

Plaintiffs,

v.

GENZYME CORPORATION,

Defendant.

September 14, 2022

MEMORANDUM AND ORDER

[TABLE OF CONTENTS OMITTED]

Fabrazyme is a drug prescribed to treat a rare genetic disorder, Fabry disease. A shortage of the drug several years ago led numerous Fabry patients—among them Plaintiffs in this case—to sue Genzyme, Fabrazyme's manufacturer. The First Circuit rejected Plaintiffs' claims in that litigation for lack of standing. I now consider new litigation begun thereafter by Plaintiffs—in another federal district court outside the First Circuit—that seeks

to improve on the pleadings the First Circuit rejected. Most Plaintiffs now before me as a result of transfer of the litigation to this district again fail to establish standing. But there are four who manage to do so on a basis recognized in the prior litigation. Nevertheless, those Plaintiffs otherwise plead their claims inadequately as to the merits. Accordingly, in the end I have determined to dismiss this action in its entirety with respect to all Plaintiffs.

I. BACKGROUND

A. The Parties

Plaintiffs are twenty-six named individuals who either suffer from Fabry disease and have taken Fabrazyme or are relatives of such individuals according to the now-operative complaint. Second Amended Complaint ("SAC") at ¶¶1-26, ECF No. 67. Among named Plaintiffs are citizens of California, Florida, Indiana, Massachusetts, Michigan, Nevada, New York, North Carolina, Pennsylvania, Washington, Tennessee, and Virginia.

Defendant Genzyme Corporation ("Genzyme") is a Massachusetts corporation with a principal place of business in Cambridge, Massachusetts; the company markets and sells Fabrazyme throughout the United States. *Id.* at ¶27.

Appendix D

B. Fabry Disease, Fabrazyme, and the 2009 Shortage

Fabry disease arises in roughly 1 in 3,000 births. SAC at ¶31. The condition results from a missing or mutated gene for the enzyme alpha-galactosidase, which is needed to metabolize the fat globotriaosylceramide ("GL-3"). *Id.* at ¶32. Without the enzyme, GL-3 builds up in cells, blood vessels, and organs, causing inflammation and death, typically from strokes, kidney failure, or heart enlargement. *Id.*

Fabrazyme is a synthetic version of alpha-galactosidase. *Id.* at ¶33-34. It cannot undo prior harm from Fabry disease but it mitigates the condition. *Id.* at ¶35. Because Fabrazyme metabolizes quickly, the standard regimen is to receive injections every two weeks. *Id.* at ¶36. Although at all relevant times Fabrazyme was the only medication for Fabry patients available in the United States; a competitor drug called Replagal® was sold in other countries. *Id.* at ¶140.

A Fabrazyme shortage arose in June 2009 when Genzyme's production stalled due to various problems at its manufacturing facility. *Hochendoner* v. *Genzyme Corp.*, 95 F. Supp. 3d 15, 18 (D. Mass. 2015) ("*Hochendoner I*"), *aff'd in part, vacated in part, remanded*, 823 F.3d 724 (1st Cir. 2016) ("*Hochendoner II*"). These problems included a contamination of Genzyme's bioreactors with vesivirus. SAC at ¶¶42-87. "During this shortage, Genzyme adopted a rationing plan under which United States Fabry sufferers would be allocated less than the

recommended dose, and newly diagnosed Fabry patients would not be prescribed the drug." *Hochendoner I*, 95 F. Supp. 3d at 18.

C. Prior Litigation

Following the shortage, patients filed lawsuits against Genzyme in the Western District of Pennsylvania ("the *Hochendoner* action")[1] and in this Court ("the *Adamo* action"); I sometimes refer in this Memorandum to these actions collectively as the *Hochendoner/Adamo* actions.[2] *See Hochendoner I*, 95 F. Supp. 3d at 20-21; *see also*

1. Certain of the plaintiffs now again before me—Amber Britton, George Demko, Michael Masula, Erin Masula, Thomas Olszewski, Darlene Cookingham, Thomas Stanziano, and Wendy Stanziano—were plaintiffs in the *Hochendoner* action originally filed in the United States District Court for the Western District of Pennsylvania on March 9, 2011. *See Hochendoner* v. *Genzyme Corp.*, No. 2:11-cv-00313-CB (filed Mar. 9, 2011, W.D. Pa.), ECF No. 1; No. 1:11-cv-10739-DPW (filed June 30, 2011, D. Mass.), ECF No. 29.

2. The following plaintiffs now again before me—Trina Wilkins, James Bishop, Lisa Bishop, Toni Cordova, John Cortina, Jill Cortina, Mary Helton, Donovan Helton, D.J., Sydney Johnson, Damon LaForce, James Matthews, Eddie Viers, and Jeanne Wallace—were plaintiffs in the *Adamo* action originally filed in this Court on June 3, 2013. S*ee Adamo* v. *Genzyme Corp.*, 1:13-cv-11336-DPW (filed June 3, 2013, D. Mass.), ECF No. 1. Additionally, several new Plaintiffs now before me are relatives of *Adamo* plaintiffs. They include William McNew (surviving son of Teresa Viers), SAC ¶23, James and Samuel Wallace (surviving sons of Joseph Wallace), *id.* ¶¶25-26, and Nate Brooks (spouse of Mary Helton), *id.* ¶10.

Schubert v. *Genzyme Corp.*, No. 2:12CV587DAK, 2013 WL 4776286, at *1 (D. Utah Sept. 4, 2013).[3] Upon transfer by the Western District of Pennsylvania to this Court in *Hochendoner I*, I consolidated the two actions and ruled on motions to dismiss in both matters. 95 F. Supp. 3d at 21. I granted the motions to dismiss, finding that the complaint failed under Rules 8 and 12(b)(6) of the Federal Rules of Civil Procedure. *Id.* The First Circuit affirmed—"with one small exception," discussed below—based on standing, an issue not raised until appeal. *Hochendoner II*, 823 F.3d at 728, 730 (1st Cir. 2016).

1. *Hochendoner I:* Consolidation in the District of Massachusetts

I found the *Hochendoner/Adamo* complaints broadly described "three possible types of causation leading to three possible types of injury suffered by [p]laintiffs." *Hochendoner I*, 95 F. Supp. 3d at 23. The first causal chain posited that lower doses of Fabrazyme reduced the drug's effectiveness, leading to "a return of symptoms in Fabry patients." *Id.* The second causal chain posited that lower doses of Fabrazyme accelerated the course of the

3. An individual plaintiff, separate from the Plaintiffs here, sued Genzyme in *Schubert.* Throughout their Second Amended Complaint, Plaintiffs cite extensively to the Proposed Fourth Amended Complaint in *Schubert*, which described internal communications at Genzyme concerning the Fabrazyme shortage. *Schubert* ended in June 2015 with a stipulated motion to dismiss with prejudice all claims and causes of action against Genzyme. *Schubert* v. *Genzyme Corp.*, 2:12-cv-00587-DAK (D. Utah dismissed June 24, 2015), ECF No. 195.

disease. *Id.* The third causal chain posited that Genzyme's Fabrazyme vials were contaminated with particulate steel, glass, and rubber. *Id.*

For the latter two alleged causal chains—acceleration and contaminants—I found the pleading insufficient to provide fair notice as required by Fed. R. Civ. P.8 as to which of the plaintiffs suffered injury under those theories. *Id.* at 24. For the first causal chain—effectiveness reduction—I dismissed the counts for failure to state a claim under Fed. R. Civ. P.12(b)(6). As a result, numerous state common law claims of negligence, negligence per se, strict liability, breach of warranty, loss of consortium, and claims under state consumer protection acts and state product liability acts were dismissed. *Id.* at 29-35.

2. *Hochendoner II:* In the Court of Appeals for the First Circuit

On appeal, the *Hochendoner I* plaintiffs only pursued the acceleration and contaminant theories. The First Circuit found these claims failed the Article III standing requirement. Standing, the First Circuit explained on appeal, requires a "plaintiff-by-plaintiff and claim-by-claim analysis" that "demands allegations *linking* each plaintiff to each of [the alleged] injuries." *Hochendoner II*, 823 F.3d at 733 (emphasis added). The Court of Appeals observed that the complaints' allegations did not show a particularized injury because no specific information was referenced regarding the harm experienced by each individual plaintiff. *Id.* The Court of Appeals determined that the *Hochendoner I* plaintiffs made "no assertion at

any point in the complaints that any specific plaintiff took or received a dose contaminated with particulate matter"; they simply alleged broadly that Genzyme produced contaminated Fabrazyme. *Id.* at 732.

However, the First Circuit reversed my order with respect to a somewhat different causation theory—the "increased risk" theory—which it found successfully alleged as to one plaintiff, James Mooney (not a plaintiff here). That theory, a variant of the "reduced effectiveness" theory, posited that, by forcing patients to forego Fabrazyme doses, Genzyme caused an "increased risk and severity of acute adverse reactions due to inconsistent infusion schedules," the complaint adequately alleged that Mr. Mooney suffered "an allergic reaction attributable to his exposure to a reduced dose of Fabrazyme." *Id.* at 733-35. The First Circuit further found the Mooney claims on that theory might satisfy Fed. R. Civ. P. 12(b)(6) and thus vacated the dismissal of those claims and remanded to evaluate the pleading further to see whether the pleading was adequate. *Id.* at 735.

Because it chose to affirm dismissal of plaintiffs' claims for lack of standing—that is, a dismissal for lack of subject matter jurisdiction, which "normally operates without prejudice"—the First Circuit directed on remand clarification that "the judgment is to operate without prejudice as to claims based on the acceleration and contaminant injuries." *Id.* at 736.

Appendix D

D. The Instant Litigation

1. *Hochendoner III*—Before Transfer: In the Southern District of Indiana

Plaintiffs now before me were unsuccessful in settling their claims in the wake of remand. Nearly four years later, on February 29, 2020, they filed the present action in the United States District Court for the Southern District of Indiana. *Wilkins* v. *Genzyme Corp.*, 20-cv-00051-TWP-DML (S.D. Ind. filed Feb. 29, 2020) ("*Hochendoner III*").[4] On May 6, 2020, they filed a First Amended Complaint changing identification of the entity or entities alleged to be the defendant. First Amended Complaint ("FAC"), *id.* (S.D. Ind. May 6, 2020), ECF No. 10. On October 5, 2020, Plaintiffs filed the now-operative Second Amended Complaint, naming Genzyme as the sole defendant. SAC, *id.* (S.D. Ind. Oct. 5, 2020), ECF No. 67.

2. *Hochendoner IV*: After Transfer in the District of Massachusetts

In the wake of remand, the plaintiffs entered into settlement negotiations with Genzyme. During these negotiations, the plaintiffs and Genzyme struck an agreement on May 17, 2017 that tolled "[a]ny applicable

4. Although the first named plaintiff in *Hochendoner I* and *Hochendoner II* is not a plaintiff in the litigation transferred to my docket from the Southern District of Indiana, I will continue to refer to the case—before transfer as *Hochendoner III* and after transfer as *Hochendoner IV*—to emphasize its status as a descendant in the *Hochendoner* family of litigation.

statutes of limitations pertaining to any matters asserted" during the *Hochendoner I* and *Adamo* lawsuits. [ECF No. 105-1 at ¶1] Plaintiffs now before me were unsuccessful in settling their claims. I came to preside over this matter, now *Hochendoner IV*, following transfer pursuant to 28 U.S.C. § 1404(a). Transfer Order, *id.* (S.D. Ind. Dec. 30, 2020), ECF No. 78. Meanwhile, in response to the pending motion to dismiss the Second Amended Complaint in this litigation again in this Court, Plaintiffs moved, ECF No. 105, to file a Third Amended Complaint, ECF No. 105-2.

a. Operative Second Amended Complaint

The operative Second Amended Complaint makes class allegations as to payments for defective and/or ineffective Fabrazyme, in addition to twenty-four individual counts.[5] The class allegations are under Fed. R. Civ. P. 23 on behalf of five representative plaintiffs,[6] the other plaintiffs named in the complaint, and "all others similarly situated," defined to include "any and all individuals residing in the United States of America and who have been diagnosed with Fabry disease, received Fabrazyme at any time from July 1, 2009 through March 2012 in a reduced dose amount, and who paid for the reduced dose Fabrazyme, either directly or through an insurance plan and the spouses of

5. Although these counts are labeled "individual" counts, they are still apparently pled in support of the class claims and each includes reference to "all others similarly situated."

6. These five co-representative plaintiffs are Trina Wilkins, George Demko, Michael Masula, Thomas Olszewski, and Tom Stanziano. SAC at ¶342.

any such person." ECF No. 67 at ¶342. Plaintiffs say that I have subject matter jurisdiction under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d). The individual claims include nine counts under common law (Counts 1-4, 20-24) and several under state statutes concerned with deceptive and unfair trade practices (Counts 5, 9, 11-14, and 18), product liability (Counts 6-7, 10, and 19), consumer protection (Counts 8 and 15), false advertising (Count 16), and wrongful death/survival (Count 17).

The individual claims, stated in the order presented in the Second Amended Complaint, are as follows:

1. Negligence
2. Negligence per se
3. Strict Liability
4. Breach of Warranty
5. Florida Deceptive and Unfair Trade Practices Act Violation
6. Indiana Products Liability Action Violation
7. Product Liability Act of Kentucky Violation
8. Kentucky Consumer Protection Act Violation
9. Massachusetts Unfair and Deceptive Trade Practices Act Violation
10. Michigan State Product Liability Act Violation
11. Michigan State Law Deceptive Trade Practice Violation

12. Nevada State Law Deceptive Trade Practice Violation
13. North Carolina Unfair and Deceptive Trade Practices Act Violation
14. Pennsylvania Unfair Trade Practices Consumer Protection Law Violation
15. Virginia Consumer Protection Act Violation
16. Virginia Prohibition of False Advertising Violation
17. Virginia Wrongful Death or in the alternative Survival Action Claims
18. Washington Uniform Deceptive Trade Practices Act
19. Washington Product Liability Act Violation
20. Fraud
21. Fraudulent Concealment
22. Breach of Fiduciary Duty
23. Unjust Enrichment
24. Loss of Consortium

It is worth noting that Plaintiffs flag three ways in which the current lawsuit seeks to fix problems identified with their claims in *Hochendoner I* and *Hochendoner II*. First, they say their injuries "are discussed individually and not in the aggregate." Opposition to MTD at 6, ECF No. 108. Second, they say Plaintiffs "who received 'low doses' plead 'acceleration' of their disease," an allegation

they contend "is vetted pleading language as a cause of action" under the First Circuit's decision in *Hochendoner II*. *Id.* Third, they say they "plead anaphylactic reactions to 'low dose' Fabrazyme," which they contend is also vetted language under *Hochendoner II*. *Id.* I observe also that Plaintiffs newly allege in the Second Amended Complaint extensive contamination of Fabrazyme dosages with vesivirus, the pathogen found in Genzyme's bioreactors that led to the Fabrazyme shortage. *See* SAC at ¶¶42-87.

b. Proposed Third Amended Complaint

Although the Second Amended Complaint remains the operative pleading before me, Plaintiffs seek to file a Third Amended Complaint, ("TAC") ECF No. 105, which they say is appropriate in response to Genzyme's Motion to Dismiss (described below). The Third Amended Complaint would bring four small changes. First, it would attach a tolling agreement the parties entered into after the decision in *Hochendoner II*. *Id.* ¶18. Second, it would add allegations based on a draft of a letter that Genzyme included with its Motion to Dismiss. *Id.* ¶20. Third, it would drop causes of action under the Massachusetts Deceptive Trade Practices Act, Washington Uniform Deceptive Trade Practices Act, and Washington Product Liability Act.[7] *Id.* ¶24. Fourth, it would drop claims related to 2013 and 2015 contaminations at the Framingham Plant. *Id.* ¶25.

7. Plaintiffs only directly reference dropping the Massachusetts claim, but the Washington claims are apparently withdrawn as well, since they do not appear in the proposed Third Amended Complaint.

E. Genzyme's Asserted Grounds for Dismissal

Defendant presents four grounds for dismissal of this case. First, Genzyme says the litigation should be dismissed pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction, because all putative class claims that support federal jurisdiction are untimely and complete diversity is lacking between the parties. In any event, Genzyme contends I should decline to exercise supplemental jurisdiction over any remaining state law claims. Second, Genzyme contends each Plaintiff lacks standing as another reason to dismiss under Fed. R. Civ. P.12(b)(1). Third, Genzyme contends Plaintiffs' claims all essentially sound in fraud and fail to meet the Fed. R. Civ. P.9(b) particularity standard. Fourth, Genzyme contends Plaintiffs have failed to state a claim under Fed. R. Civ. P.8 and Fed. R. Civ. P.12(b)(6).

As to the proposed Third Amended Complaint, Genzyme says I should deny this request outright, because presenting another complaint at this point in the litigation would be prejudicial and is futile, since the proposed Third Amended Complaint will not overcome the inadequacies of the Second Amended Complaint that provide the basis for dismissal.

II. THRESHOLD CONSIDERATIONS

I must identify at the outset two basic threshold considerations—choice of law and whether and how to treat a proposed amended complaint—that shape my approach to consideration of Genzyme's motion to dismiss contentions.

Appendix D

A. Choosing the Law

As alleged, this is a diversity case upon transfer from the United States District Court for the Southern District of Indiana, albeit said to have been raised under the Federal Class Action Fairness Act. In these circumstances, "a federal court sitting in diversity or exercising supplemental jurisdiction over state law claims must apply state substantive law, but a federal court applies federal rules of procedure to its proceedings." *Hoyos* v. *Telecorp Commc'ns, Inc.*, 488 F.3d 1, 5 (1st Cir. 2007) (citing *Gasperini* v. *Ctr. For Humanities, Inc.*, 518 U.S. 415, 427 (1996)). For questions of state law, I follow Indiana choice-of-law rules, as would an Indiana federal court sitting in diversity. *See AER Advisors, Inc.* v. *Fidelity Brokerage Servs., LLC*, 921 F.3d 282, 289 (1st Cir. 2019) ("[T]he transferee court applies the *state law* that the transferor court would have applied to any questions of *state law*."); *Gre-Ter Enter., Inc.* v. *Mgmt. Recruiters Int'l, Inc.*, 329 F. Supp. 3d 667, 675 (S.D. Ind. 2018) (citing *Klaxon Co.* v. *Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941)). For questions of federal law, I apply federal law as interpreted by the First Circuit. *AER Advisors*, 921 F.3d at 289-91.

B. Amending the Complaint

Fed. R. Civ. P.15(a)(2) provides that "a party may amend its pleading only with the opposing party's written consent or the court's leave," and that the court "should freely give leave when justice so requires." Fed. R. Civ. P.15(a)(2). That said, "amendments may be denied for

several reasons, including 'undue delay, bad faith, dilatory motive of the requesting party, repeated failure to cure deficiencies, and futility of amendment.'" *Hagerty ex rel. United States* v. *Cyberonics, Inc.*, 844 F.3d 26, 34 (1st Cir. 2016) (quoting *United States ex rel. Rost* v. *Pfizer, Inc.*, 507 F.3d 720, 733-34 (1st Cir. 2007), *overruled on other grounds by Allison Engine* v. *United States ex rel. Sanders*, 553 U.S. 662 (2008)). In this posture, "'[f]utility' means that the complaint, as amended, would fail to state a claim upon which relief could be granted." *Glassman* v. *Computervision Corp.*, 90 F.3d 617, 623 (1st Cir. 1996). In canvassing Genzyme's contentions in support of the operative Second Amended Complaint, I am alert to the implications for allowing a proposed Third Amended Complaint to become the operative pleading in the litigation.

III. MOTION TO DISMISS

I address first the standard for a Rule 12(b)(6) motion, the standard integral to other issues before me. I "assume that well-pleaded facts are true and ask whether such facts and inferences reasonably drawn from those facts plausibly state a claim." *Doe* v. *Pawtucket Sch. Dep't*, 969 F.3d 1, 7 (1st Cir. 2020) (citing *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009)). However, I do not accept "legal conclusions clothed as factual allegations." *Thompson* v. *JPMorgan Chase Bank, N.A.*, 982 F.3d 809, 811 (1st Cir. 2020) (citing *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544, 555-56 (2007)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft*, 556 U.S. at 678. The

well-pleaded facts must permit me to "infer more than the mere possibility of misconduct." *Id.* at 679. Plaintiffs must "nudge[ ] their claims across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570.

I employ this Rule 12(b)(6) standard as well for Rule 12(b)(1) motions. "Rule 12(b)(1) motions challenging subject-matter jurisdiction are divided into two categories: facial challenges and factual challenges." *Cebollero-Bertran* v. *Puerto Rico*, 4 F.4th 63, 69 (1st Cir. 2021). In the posture of Genzyme's motion to dismiss, with its "facial challenges [Genzyme] raises a question of law without contesting the facts." *Id.* Accordingly, "[t]he analysis is essentially the same as a Rule 12(b)(6) analysis: [I] accept the well-pleaded facts alleged in the complaint as true and ask whether the plaintiff has stated a plausible claim that the court has subject matter jurisdiction." *Id.*

Similarly, the standing analysis under Rule 12(b)(1) mirrors Rule 12(b)(6) analysis. "[A]t the pleading stage, the plaintiff bears the burden of establishing sufficient factual matter to plausibly demonstrate his standing to bring the action. Neither conclusory assertions nor unfounded speculation can supply the necessary heft." *Hochendoner II*, 823 F.3d at 731.

With recognition that Genzyme suggests the proposed Third Amended Complaint is futile, I turn first to Genzyme's Motion to Dismiss as applied to the currently operative Second Amended Complaint. *See supra* Section II.B. But I reference points that would be added by the proposed Third Amended Complaint, when

relevant.[8] In addressing the Motion to Dismiss, I start with the arguments about subject matter jurisdiction. This is because "federal courts are required to determine whether Article III jurisdiction exists prior to proceeding to the merits of the case." *See United Seniors Ass'n, Inc.* v. *Philip Morris USA*, 500 F.3d 19, 23 (1st Cir. 2007).

A. Subject Matter Jurisdiction

Genzyme contends I lack subject matter jurisdiction because the claims underlying the CAFA class claims—the only aspect of this litigation that could support federal jurisdiction in the first place—are all time-barred. For their part, Plaintiffs say tolling under *American Pipe & Const. Co.* v. *Utah*, 414 U.S. 538 (1974), Indiana's Journey Account Statute,[9]

8. For purposes of this analysis, I ignore the 2013 and 2015 claims concerning the Framingham plant and the Massachusetts and Washington claims, all of which the plaintiffs have abandoned in the Third Amended Complaint. *See supra* note 7 and accompanying text.

9. Plaintiffs also reference the Massachusetts Savings Statute, but Massachusetts law does not apply in this circumstance, because I am directed by Massachusetts law to apply Indiana law. *See Hemric* v. *Reed & Price Mfg. Co.*, 739 F.2d 1, 3 (1st Cir. 1984) ("[W]e are aware of no case suggesting that Massachusetts would abandon the traditional rule that local law of the forum determines whether an action is barred by a statute of limitations.").

and a May 2017 tolling agreement[10] between the parties' work to preserve their claims.

I begin my analysis by identifying the relevant statutes of limitations and when Plaintiffs' claims accrued, in order to assess if and when any of the claims have expired. I then address *American Pipe* tolling, the tolling agreement, and Indiana's Journey's Account Statute.

1. Expiration of Claims

Because statutes of limitations are substantive law under federal direction, *see Guaranty Trust Co. of New York* v. *York*, 326 U.S. 99, 110-12 (1945), I rely on Indiana choice-of-law principles. Under those principles, statutes of limitations are treated as procedural, so Indiana's statutes of limitations apply. *Autocephalous Greek-Orthodox Church of Cyprus* v. *Goldberg & Feldman Fine Arts Inc.*, 717 F. Supp. 1374, 1385 (S.D. Ind. 1989), *aff'd*, 917 F.2d 278 (7th Cir. 1990). But there is an exception. For statutory claims arising under the law of another

10. A copy of this agreement is attached to the Third Amended Complaint and undisputed by the parties. Although I have yet to rule on allowing the Third Amended Complaint, I consider its contents here. "While, ordinarily, a district court's review under Rule 12(b)(6) is limited to consideration of the facts set forth in the complaint and the documents attached thereto, an exception exists for 'documents the authenticity of which are not disputed by the parties. . . ." *Town of Acton* v. *W.R. Grace & Co. Conn. Techs.*, Inc., No. 13-12376-DPW, 2014 WL 7721850, at *5 (D. Mass. Sep. 22, 2014) (quoting *Watterson* v. *Page*, 987 F.2d 1, 3 (1st Cir. 1993)).

state, that state's relevant statute of limitations applies. *Shearer* v. *Thor Motor Coach, Inc.*, 470 F. Supp. 3d 874, 879 (N.D. Ind. 2020). And there is an exception to this exception: If the statutory claim originated at common law, then Indiana's statutes of limitations still apply. *Id.* at 879-880; *see also Big Rivers Elec. Corp.* v. *Gen. Elec. Co.*, 820 F. Supp. 1123, 1125-26 (S.D. Ind. 1992).

a. Claims Related to Product Liability Under Indiana Law

Indiana's statutes of limitations apply for all the common law claims here—as well as the claim under the Indiana Product Liability Act. The common law claims are for negligence, negligence per se, strict liability, breach of warranty, fraud, fraudulent concealment, breach of fiduciary duty, unjust enrichment, and loss of consortium.

A two-year statute of limitations applies for the common law claims. A two-year statute of limitations for claims related to products liability, as alleged here, negligence, negligence per se, and strict liability, arises from the Indiana Products Liability Act. *See* Ind. Code § 34-20-3-1. Likewise, the statute of limitations is set at two years for breach of fiduciary duty under Indiana law. *See* Ind. Code § 34-11-2-4; *Shriner* v. *Sheehan*, 773 N.E. 2d 833, 846 (Ind. Ct. App. 2002).

b. Claims Subsumed by Products Liability Under Indiana Law

In Count Four, Plaintiffs allege various breaches of express and implied warranties under common law. [Dkt.

No. 67 ¶¶ 361-64.] These claims are subsumed under the Indiana Product Liability Act for two reasons, and accordingly a two-year statute of limitations applies. First, where a breach of warranty claim is "tort-based," "several federal district courts and other panels of the [Indiana] Court of Appeals" have found the claim "subsumed into the [Indiana Product Liability Act]." *Kovach* v. *Caligor Midwest*, 913 N.E.2d 193, 197 (Ind. 2009); *see Cavender* v. *Medtronic, Inc.*, No. 3:16-CV-232, 2017 WL 1365354, at *7 (N.D. Ind. Apr. 14, 2017) ("[I]f it walks like a duck and quacks like a duck, it's a tort—not a breach of warranty claim—and it is subsumed by the [Indiana Product Liability Act]."). Although Plaintiffs pleaded that low-dose Fabrazyme "is not fit for the ordinary purpose for which it is customarily or foreseeably used" [Dkt. No. 67 ¶362(d)]—language framing Plaintiffs' claim in warranty—Plaintiffs did not provide additional facts that set the claim outside of tort. [*See generally* Dkt. No. 67 ¶¶362-64.] *See Lyons* v. *Leatt Corp.*, No. 4:15-CV-17-TLS, 2015 WL 7016469, at *3 (N.D. Ind. Nov. 10, 2015) (using language that framed plaintiff 's claim as a breach of warranty did not shield it from being subsumed under the Indiana Product Liability Act where it sounded in tort). Second, Plaintiffs did not bring their claim for breach of warranty under the Indiana adoption of the Uniform Commercial Code, which is "independent" from the Indiana Products Liability Act and provides for different damages. *Atkinson* v. *P & G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1024-25 (N.D. Ind. 2011).

Similarly, the claims sounding in fraud and in unjust enrichment are subject to the two-year statute

of limitations, since this litigation continues to present a products liability case and the fraud and unjust enrichment claims arise out of that framework. In Indiana, it is "the nature or substance of the cause of action, rather than the form of the action, which determines the applicability of the statute of limitations." *Shideler* v. *Dwyer*, 417 N.E.2d 281, 285 (Ind. 1981) (quoting *Koehring Co.* v. *Nat'l Automatic Tool Co.*, 257 F. Supp. 282, 292 (S. D. Ind. 1966), *aff'd*, 385 F.2d 414 (7th Cir. 1967) (per curiam)).[11] "Where an unjust enrichment claim arises out of a tort-based products liability claim as occurred here, Indiana would apply a two-year limitations period." *Juday* v. *Merck & Co.*, No. CV 16-1547, 2017 WL 1374527, at *3 (E.D. Pa. Apr. 17, 2017) (citing *Knutson* v. *UGS*, 2007 WL 2122192 at *5 (S.D. Ind. July 19, 2007) and *Schwindt* v. *Hologic, Inc.*, 2011 WL 3806511 at *7 (S.D. Ind. Aug. 26, 2011)), *aff'd, Juday* v. *Merck & Co Inc*, 730 F. App'x 107 (3d Cir. 2018). The same is true for the fraud claims. *See In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2007 WL 3334339, at *6 (E.D. La. Nov. 8, 2007) (finding under Indiana law that two-year statute of limitations applied to fraud claims in product liability suit).

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11. I recognize there is some debate about how far the Indiana Supreme Court will ultimately take this doctrine in claims as presented to be subsumed by other statutes of limitations based on "form." *See Lewis* v. *Methodist Hosp., Inc.*, 326 F.3d 851, 854-56 (7th Cir. 2003). The crux of this debate is that there are provisions in the Indiana code providing state statutes of limitations—including for fraud—and that such provisions may become meaningless if every claim is always read to be subsumed by another relevant statute of limitations. Here, the framing of the litigation has firmly and consistently been in essence as a product liability case. *Cf. In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2007 WL 3334339, at *6 (E.D. La. Nov. 8, 2007).

c. Loss of Consortium Claims Under Indiana Law

Loss of consortium is a derivative claim, and thus tied to the relevant statute of limitations for the loved one's claim; consequently, it does not have a set statute of limitations but will rely upon that of the claim from which it is derived. *See Palmer v. Gorecki*, 844 N.E.2d 149, 157 (Ind. Ct. App. 2006).

d. Other State Statutes

All other claims brought are under statutes of other states. I find it unnecessary to scrutinize whether Indiana courts would identify these claims as originating separately at common law, because the claims in all events have expired for purposes of Indiana law or the law of the other states, as I will explain momentarily. To frame that explanation, I observe that the various state statutes of limitations are as follows:

- Three years for the Florida Deceptive and Unfair Trade Practices Act. Fla. Stat. § 95.11(3)(f); *Koski* v. *Carrier Corp.*, 347 F. Supp. 3d 1185, 1192 (S.D. Fla. 2017).

- One year for the Kentucky Products Liability Act. Ky. Rev. Stat. Ann. § 413.140(1)(a). *Bosch* v. *Bayer Healthcare Pharms., Inc.*, 13 F. Supp. 3d 730, 737 (W.D. Ky. 2014).

- Two years for the Kentucky Consumer Protection Act. Ky. Rev. Stat. Ann. § 367.220(5). *Arnold* v.

Liberty Mut. Ins. Co., 392 F. Supp. 3d 747, 766-67 (E.D. Ky. 2019).

- Three years for the Michigan Product Liability Act. Mich. Comp. Laws § 600.5805(12); *McMan* v. *C.S. Bard, Inc.*, No. 19-12670, 2021 WL 3079894, at *3 (E.D. Mich. July 21, 2021).

- Six years for the Michigan Consumer Protection Act.[12] Mich. Comp. Laws § 445.911(9).

- Four years for the Nevada Deceptive Trade Practices Act. Nev. Rev. Stat. § 11.190(2)(d).

- Four years for the North Carolina Deceptive Trade Practices Act. N.C. Gen. Stat. § 75-16.2; *Dreamstreet Invs., Inc. v. MidCountry Bank.*, 842 F.3d 825, 830 (4th Cir. 2016).

- Six years for the Pennsylvania Consumer Protection Act. 42 Pa. Cons. Stat. § 5527(b); *Rodgers* v. *Lincoln Benefit Life Co.*, No. 19-cv-350, 2019 WL 4750193, at *2 (W.D. Pa. Sept. 30, 2019).

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12. In Count 11, Plaintiffs allege a violation of the "Michigan State Law Deceptive Trade Practice" and cite to Mich. Comp. Laws § 445.903 *et seq.* Plaintiffs' citation is actually to the Michigan Consumer Protection Act, and finding no "Michigan State Law Deceptive Trade Practice" Act, I have applied the Michigan Consumer Protection Act statute of limitations.

- Two years for the Virginia Consumer Protection Act. Va. Code Ann. § 59.1-204.1.

- Two years for the Virginia False Advertising Act. *Parker-Smith* v. *Sto Corp.*, 551 S.E.2d 615, 619 (Va. 2001).

- Two years for Virginia Wrongful Death/Survival Actions. Va. Code Ann. § 8.01-244.

2. Accrual of Claims

With the expiration framework in place, I turn to the issue of when Plaintiffs' claims accrued. "The determination of when a cause of action accrues is generally a question of law." *Cooper Indus., LLC* v. *City of S. Bend*, 899 N.E.2d 1274, 1280 (Ind. 2009). I note that Indiana courts are inclined to construe limitation provisions as "enacted upon the presumption that one having a well-founded claim will not delay enforcing it." *Shideler*, 417 N.E.2d at 283. "They are practical and pragmatic devices to spare the courts from litigation of stale claims, and the citizen from being put to his defense after memories have faded, witnesses have died or disappeared, and evidence has been lost." *Havens* v. *Ritchey*, 582 N.E.2d 792, 794 (Ind. 1991) (quoting *Rohrabaugh* v. *Wagoner*, 413 N.E.2d 891, 893 (Ind. 1980)).

Under Indiana's discovery rule, a cause of action accrues "when a party knows, or in the exercise of ordinary diligence could discover, that . . . an injury had been sustained as a result of the tortious act of another."

Strauser v. *Westfield Ins. Co.*, 827 N.E.2d 1181, 1185 (Ind. Ct. App. 2005). The rule "does not mandate that plaintiffs know with precision the legal injury that has been suffered, but merely anticipates that a plaintiff be possessed of sufficient information to cause him to inquire further in order to determine whether a legal wrong has occurred." *Perryman* v. *Motorist Mut. Ins. Co.*, 846 N.E.2d 683, 689 (Ind. Ct. App. 2006). The question is whether "the acts and circumstances of an injury would put a person of common knowledge and experience on notice that some right of his has been invaded or that some claim against another party might exist." *Id.* (quoting *Mitchell* v. *Holler*, 429 S.E.2d 793, 795 (S.C. 1993)). "Stated more succinctly, the law does not require a smoking gun in order for the statute of limitations to commence." *Id.*

To be sure, the doctrine of fraudulent concealment may toll the statute of limitations in certain circumstances. But "the affirmative acts of concealment must be calculated to mislead and hinder a plaintiff from obtaining information by the use of ordinary diligence, or to prevent inquiry or elude investigation." *Study* v. *State*, 24 N.E.3d 947, 956 (Ind. 2015) (quoting *Olcott Int'l. & Co., Inc.*, v. *Micro Data Base Sys., Inc.*, 793 N.E.2d 1063, 1072 (Ind. Ct. App. 2003)).

Examining the operative Second Amended Complaint, I can identify three types of harm alleged for purposes of accrual of claims. I consider at what point in time claims would have accrued in Indiana, using Indiana standards. Of course, statutes from Florida, Kentucky, Michigan, Nevada, North Carolina, Pennsylvania, and Virginia are

still theoretically in play, since I have left to the side the question of whether any of these statutes cover claims originating at common law. However, none of these states would apply a discovery rule substantially more plaintiff-friendly than Indiana's.[13]

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13. Florida law is at most no more generous to Plaintiffs than Indiana law. The Florida Supreme Court has said the delayed discovery doctrine "generally provides that a cause of action does not accrue until the plaintiff either knows or reasonably should know of the tortious act giving rise to the cause of action." *R.R. v. New Life Cmty. Church of CMA, Inc.*, 303 So. 3d 916, 921 (Fla. 2020) (citation omitted). The Florida discovery rule only has a statutory basis for claims of fraud, products liability, professional and medical malpractice, and intentional torts based on abuse. *Id.*

Kentucky's discovery rule mirrors Indiana's. *Fluke Corp.* v. *LeMaster*, 306 S.W.3d 55, 60 (Ky. 2010) ("[A] cause of action will not accrue until the plaintiff discovers (or in the exercise of reasonable diligence should have discovered) not only that he has been injured, but also that this injury may have been caused by the defendant's conduct.")

The Michigan Consumer Protection Act is no more generous than Indiana in terms of discovery; it provides that an action "must not be brought more than 6 years after the occurrence of the method, act, or practice that is the subject of the action or more than 1 year after the last payment in a transaction involving the method, act, or practice that is the subject of the action, whichever period of time ends at a later date." Mich. Comp. Laws § 445.911(9).

The Nevada Deceptive Trade Practices Act mirrors Indiana's discovery rule by providing that "the cause of action shall be deemed to accrue when the aggrieved party discovers, or by the exercise of due diligence should have discovered, the facts constituting the deceptive trade practice." Nev. Rev. Stat. § 11.190(2)(d).

Appendix D

a. Harm Caused by Law Dosing and Contamination

The first type of harm is said to be caused by some combination of low dosing and contamination. Both low

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The North Carolina Deceptive Trade Practices Act provides simply that claims must be brought within four years of accrual. N.C. Gen. Stat. § 75-16.2. In general, "this statute commences when the violations actually occur." *Wood* v. *S. Carolina Bank & Trust Co. of the Piedmont, N.A.*, No. 3:11-CV-00300, 2012 WL 395318, at *2 (W.D.N.C. Feb. 7, 2012). "However, when the violation of the statute arises out of fraud, the statute of limitations does not accrue until the unfair or deceptive act is discovered or should have been discovered," which mirrors the Indiana discovery rule. *Id.*

Pennsylvania's discovery rule is comparable to Indiana's. The limitations period may not begin "until the discovery of the injury is reasonably possible." *Miller* v. *Ginsberg*, 874 A.2d 93, 97 (Pa. 2005) (quoting *Dalrymple* v. *Brown*, 701 A.2d 164, 167 (Pa. 1997)).

The Virginia Consumer Protection Act is no more generous than Indiana law; it provides that "the right of action shall be deemed to accrue and the prescribed limitation period shall begin to run from the date the injury is sustained in the case of injury to the person or damage to property." Va. Code Ann. § 8.01-230; *see* Va. Code Ann. § 59.1-204.1. However, "claims for violation of the Consumer Protection Act that are based upon any misrepresentation, deception, or fraud shall be deemed to accrue when such fraud is discovered or by the exercise of due diligence reasonably should have been discovered." *Skibinski* v. *Lunger*, No. 06-152, 2006 WL 1571820, at *3 (Va. Cir. Ct. June 7, 2006); *see* Va. Code. Ann. § 8.01-249. Wrongful death/survival actions must come within two years after death of the injured person. Va. Code Ann. § 8.01-244(B). The limitations period for false advertising is based on the "catch-all" provision and does not specify a discovery rule. *See Parker-Smith* v. *Sto Corp.*, 551 S.E.2d 615, 619 (Va. 2001); Va. Code Ann. § 8.01-248.

dosing and contaminated doses are alleged to have begun in 2009. *See* SAC at ¶¶1, 2, 6, 8, 9, 11-15, 17, 18, 20, 22, 24. The allegations describe news coverage in 2009 about the viral contamination, SAC at ¶55, Genzyme's public communications about the shortage, *id.* at ¶207, ¶239, ¶273, and communications about non-viral contaminants, *id.* at ¶171. Thus, Plaintiffs' claims accrued by the end of 2009. This is well before the filing of the *Hochendoner* case in the Western District of Pennsylvania on March 9, 2011, when a subset of plaintiffs asserted claims based on low dosing and contamination.

b. Harm Caused by Sensitization

The second type of harm is that identified by the Court of Appeals in *Hochendoner II*, 823 F.3d at 733-35; the sensitization harm asserted by Mr. Mooney. That harm is alleged to have arisen for some plaintiffs upon return to a full dose. It applies for three named Plaintiffs: Trina Wilkins, Tom Stanziano, and Damon LaForce (and also Mr. Stanziano's wife, who brings a derivative action for loss of consortium). *Id.* at ¶¶1, 14, 20, 118-19. Their return to full dosage was in 2012, so accrual would have been by no later than the end of that year.

c. Harm Caused by Fraud

The third type of harm concerns fraud. These allegations derived from the 2009 contamination. SAC at ¶128-340, 441-71. Thus, there is a fair argument that plaintiffs should have been aware of this injury by the

end of 2009.[14] I acknowledge that, with fraud as alleged, Plaintiffs may have had a more difficult time recognizing the harm. Nevertheless, even allowing Plaintiffs the benefit of a generous reading of the doctrine of fraudulent concealment, their claims would have accrued by the time the *Hochendoner* complaint was filed in the Western District of Pennsylvania on March 9, 2011. In that complaint it was alleged that Genzyme "expressly or impliedly misrepresent[ed] that the reduced dose of Fabrazyme® was in accordance with statutory mandates

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14. I note here that plaintiffs include in their complaint internal communications from Genzyme that are quite damning and show efforts to conceal information. *See*, *e.g.*, SAC ¶220, ¶229 (showing Genzyme executive wrote to employee "Did we lie to the [Fabry Stakeholders Working Group?]," a group of physicians and patient advocates from which Genzyme sought endorsement). The information being actively concealed, however, was not about contaminants or vesivirus—or even the limited effectiveness of low-dose Fabrazyme. Rather, the information being actively concealed was the likelihood of an extended delay before full doses would be available. The studies discussed in the complaint were publicly available, and it would have been obvious that a lower dose was sub-optimal. Plaintiffs make only passing mention of harm coming from this concealment. They say in the body of their complaint that "[h]ad the true information about the supply situation been provided to [them] and their doctors, they would have acted with great urgency in September, 2009 to seek alternative treatment, such as Replagal®, through a compassionate use exemption or additional Fabrazyme through private arrangements with other patients and doctors." SAC ¶299. But they do not otherwise substantiate this point beyond that conclusory allegation. They do not describe advice from their doctors or any efforts to obtain a compassionate use exemption that were reconsidered because of Genzyme's statements.

and efficacious for use," and "instructed and/or through knowledge and consent reduced the dose of Fabrazyme® to dangerous, sub-efficacious and unapproved levels." Compl. ¶¶ 71(f), 83(k), *Hochendoner* v. *Genzyme Corp.*, No. 2:11-cv-00313 (W.D. Pa. Mar. 9, 2011), ECF No. 1.

d. Summary

To synthesize these conclusions, for purposes of Indiana law, the low-dose/contaminant-based claims and fraud-based claims likely expired by the end of 2011 and certainly by March 2013. The sensitization claims appear to have expired by the end of 2014. The fraud claims conceivably expired by the end of 2011 and certainly by March 2013.

Turning to consider statutes of other states, any low-dose/contaminant-based claims or fraud-based claims under:

- The Florida Deceptive and Unfair Trade Practices Act likely expired by the end of 2013 and certainly by March 2015.

- The Kentucky Products Liability Act likely expired by the end of 2012 and certainly by March 2013.

- The Kentucky Consumer Protection Act likely expired by the end of 2011 and certainly by March 2013.

- The Michigan Product Liability Act likely expired by the end of 2012 and certainly by March 2014.

- The Michigan Consumer Protection Act likely expired by the end of 2015 and certainly by March 2017.

- The Nevada Deceptive Trade Practices Act likely expired by the end of 2013 and certainly by March 2015.

- The Pennsylvania Consumer Protection Act likely expired by the end of 2015 and certainly by the end of March 2017.

- The Virginia Consumer Protection Act likely expired by the end of 2011 and certainly by the end of March 2013.

- The Virginia False Advertising Act likely expired by the end of 2011 and certainly by the end of March 2013.

As for sensitization, I observe Ms. Wilkins is alleged to be a resident of both Kentucky as well as Indiana. Her Kentucky Product Liability claim expired by the end of 2013. And her Kentucky Consumer Protection claim expired by the end of 2014. The other relevant individuals are Mr. LaForce, who was a Virginia resident during low-dose treatment, and Mr. Stanziano and his wife, who are both Florida residents. SAC at ¶¶ 14, 20, 21. Mr. LaForce's claims under the Virginia Consumer Protection Act and

the Virginia False Advertising Act would have expired by the end of 2014. Mr. Stanziano's claim under the Florida Deceptive and Unfair Trade Practices Act would have expired by the end of 2016. And any derivative claim for loss of consortium by his wife, Wendy Stanziano, would have expired by the end of 2016 as well.

Lastly, the Virginia Wrongful Death/Survival actions raised by Eddie Viers and Jeanne Wallace do not fit neatly into the paradigm just employed for the other claims. *See* SAC at ¶¶ 22, 24. As noted, these claims must be raised within two years of the deceased's death. The complaint specifies that Mr. Viers lost his wife Teresa Viers in September 2019. There is no information about when Ms. Wallace's husband Joseph Wallace died. Based on this information, the complaint is insufficient as to Ms. Wallace's claim. However, Mr. Viers' claim would have accrued in September 2019 and he would have until September 2021 to bring a claim—a deadline he met, since this lawsuit was filed in February 2020. Thus, Mr. Viers has the only claim for Wrongful Death Survival not barred under a statute of limitation enforced by Indiana.

3. *American Pipe* Tolling

On a different front, Plaintiffs and Genzyme debate the applicability of the Supreme Court's *American Pipe* tolling doctrine, which preserves the claims of putative class members when a class action is filed in court. *See generally American Pipe & Const. Co.* v. *Utah*, 414 U.S. 538 (1974). Although this debate is interesting, the parties overlook an important consideration. *American Pipe* does

not by its terms apply where a court sits in diversity, presiding over state law claims, as I do now. *See Casey* v. *Merck & Co.*, 653 F.3d 95, 100 (2d Cir. 2011), *certified question answered*, 283 Va. 411, 722 S.E.2d 842 (2012). Accordingly, to determine the applicability of *American Pipe* tolling, I must consider whether the relevant state courts have adopted this doctrine, in addition to whether the doctrine itself fits with the facts. Moreover, I must consider whether the relevant states would be likely to adopt cross-jurisdictional tolling—that is, whether they would recognize any relevant tolling for a class action filed outside of the state's courts. *Id.*

At the outset, I am of the view that *American Pipe* tolling is a poor fit for the facts of this case, even assuming the doctrine applies. The doctrine has continued to introduce questions as different issues arise in class action litigation. The First Circuit has acknowledged relatively recent Supreme Court clarification that "[w]hile a putative class member may join an existing suit or file an individual action upon denial of class certification, a putative class member may not commence a class action anew beyond the time allowed by the untolled statute of limitations." *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 16 (1st Cir. 2019) (citing *China Agritech, Inc.* v. *Resh*, 138 S. Ct. 1800, 1807 (2018)). The First Circuit has even more recently extended this reasoning, holding that the Supreme Court in *China Agritech* "effectively ruled that the tolling effect of a motion to certify a class applies only to individual claims, no matter how the motion is ultimately resolved." *Id.* at 17. At least one district court outside the First Circuit has found this reasoning

compelling. *See Torres* v. *Wells Fargo Bank, N.A.*, No. CV 17-9305 DMG (RAOx), 2019 WL 7169790, at *8 (C.D. Cal. Sept. 27, 2019).

In this case, Plaintiffs argue the class claims have been tolled. But that is directly at odds with *In re Celexa.* I am, of course, not directly bound by the First Circuit on this issue, but I have no reason to believe Indiana's courts would employ *American Pipe* tolling here.

The state law component to this equation gives all the more reason to doubt that Plaintiffs can rely on *American Pipe.* It appears that "[m]ost states, following the Supreme Court's reasoning in *American Pipe*, have adopted a rule allowing tolling during the pendency of a class action filed in their own courts." *In re Fosamax Prod. Liab. Litig.*, 694 F. Supp. 2d 253, 258 (S.D.N.Y. 2010), *aff'd sub nom. Casey* v. *Merck & Co.*, 678 F.3d 134 (2d Cir. 2012). But "[o]nly a small fraction of states have addressed the cross-jurisdictional tolling issue . . . and there is no clear consensus among them." *Id.* "Recognizing the lack of consensus on the issue and the frequently articulated concern of forum shopping, federal courts generally have been disinclined to import cross-jurisdictional tolling into the law of a state that has not ruled on the issue." *Id.*

Although the lower Indiana appellate court has adopted *American Pipe*-style tolling as a matter of state law, *Ling* v. *Webb*, 834 N.E.2d 1137, 1141-42 (Ind. Ct. App. 2005), Indiana courts have not explicitly adopted cross-jurisdictional tolling, *see In re Vioxx Prod. Liab. Litig.*, 2007 WL 3334339, at *6. For that reason, federal courts

have been wary of assuming Indiana would recognize such tolling. *See id.; see also Shea* v. *Gen. Motors LLC*, 567 F. Supp. 3d 1011, 1022 (N.D. Ind. 2021); *In re Urethane Antitrust Litig.*, 663 F. Supp. 2d 1067, 1082 (D. Kan. 2009). *But see In re Linerboard Antitrust Litig.*, 223 F.R.D. 335, 349 (E.D. Pa. 2004) (holding Indiana courts likely would observe cross-jurisdictional tolling for an antitrust claim).

Given this context and the fact that the doctrine seems inappropriate in this circumstance, in any event, I find *American Pipe* tolling unavailable for plaintiffs.

4. Tolling Agreement

Plaintiffs also contend their claims are preserved by a tolling agreement. The parties entered into an agreement on May 17, 2017[15] that provides:

> [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 beginning on [May 17, 2017], and Genzyme agrees it will not assert any defense of statute of limitations, laches or any similar defense based upon the passage of time during the term of this Agreement against the Plaintiffs or members of the putative class alleged in the Lawsuits.

15. Notably, this date falls after the expiration of all the claims as found above, except for a wrongful death claim.

Tolling Agreement, Mot. for Third Amended Compl., ECF No. 105-1, Ex. A.

Plaintiffs say this language saves them, but Genzyme points to the next sentence, which says that "[n]otwithstanding the foregoing, Genzyme does not waive and expressly reserves the right to assert any such defense based upon the passage of time *prior to* the effective date of this Agreement or the passage of time *after* the termination of this Agreement." *Id.* (emphasis supplied).

This contention presents me with a question of contract interpretation, as to which I turn to Indiana choice-of-law principles. In Indiana, "[t]he court will consider all acts of the parties touching the transaction in relation to the several states involved and will apply as the law governing the transaction the law of that state with which the facts are in *most intimate contact.*" *Nat'l Union Fire Ins. Co. of Pittsburgh, PA* v. *Standard Fusee Corp.*, 940 N.E.2d 810, 814 (Ind. 2010) (emphasis in original) (quoting *W.H. Barber Co.* v. *Hughes*, 63 N.E.2d 417, 423 (Ind. 1945)). There are five types of contact Indiana courts consider: "(1) the place of contracting; (2) the place of negotiation of the contract; (3) the place of performance; (4) the location of the subject matter of the contract; and (5) the domicile, residence, nationality, place of incorporation and place of business of the parties." *Id.* Because none of these contacts applies here, and indeed there is no apparent state with the "most intimate contact"—this dispute being one that involves plaintiffs from many different states—I apply Indiana law.

Appendix D

Under Indiana law, "[c]onstruction of the terms of a written contract is a pure question of law for the court." *Peoples Bank & Tr. Co.* v. *Price*, 714 N.E.2d 712, 716 (Ind. Ct. App. 1999). "If the language of the instrument is unambiguous, the intent of the parties is determined from the four corners of that instrument," but if "a contract is ambiguous or uncertain, its meaning is to be determined by extrinsic evidence and its construction is a matter for the fact finder." *Id.* In general, "it is . . . appropriate to construe an ambiguous agreement against its drafter." *Trinity Homes, LLC* v. *Fang*, 848 N.E.2d 1065, 1068 (Ind. 2006). Further, I "should attempt to determine the intent of the parties at the time the contract was made as discovered by the language used to express their rights and duties." *Price*, 714 N.E.2d at 717. "The contract is to be read as a whole when trying to ascertain the intent of the parties." *Id.* I "must accept an interpretation of the contract which harmonizes its provisions as opposed to one which causes the provisions to be conflicting." *Id.*

I find as an initial matter the tolling agreement unambiguously preserves the claims that Plaintiffs made in the *Hochendoner I* litigation. The contract plainly says 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." On its face I take this language to preserve Plaintiff 's claims.

True, the next sentence says that "notwithstanding the foregoing" Genzyme still has "the right to assert any [timeliness] defense based upon passage of time prior to the [May 17, 2017]."

But I must read the contract as a whole. The agreement also says 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 the agreement recites that the parties' agreement is in part "to facilitate the orderly settlement and resolution of the Plaintiffs' claims." *Id.*

For these provisions to exist in harmony, it would make no sense for the sentence that Genzyme highlights to drain the prior sentence of all meaning. Genzyme's emphasized sentence makes sense as a clarification that the agreement does not save any claims not already made. But by the same token the sentence reads naturally as a preservation of the claims that Plaintiffs already made in litigation, since that meaning is the one that would facilitate negotiations between the parties.

Accordingly, I find the tolling agreement preserves Plaintiffs' claims. It is then an open question the exact extent of what is preserved and what Plaintiffs are allowed to argue in a new action reliant on this tolling agreement. I address this issue *infra* in subsection IV.B.6.

5. Indiana Journey's Account Statute

I turn meanwhile to Indiana's Journey's Account statute, which Plaintiffs say is of further help in saving their claims. This statute preserves claims after a lawsuit is dismissed in certain circumstances. The lawsuit cannot have been dismissed for "negligence in the prosecution of the action," Ind. Code § 34-11-8-1(a)(1), and the new

lawsuit must be filed within three years after the prior action failed, *id.* § 34-11-8-1(b)(1). "It is well settled that in order for the saving power of the [Journey's Account Statute] to apply, the decision ending the previous suit must not have been a decision on the merits." *Allen* v. *State*, 30 N.E.3d 1280, 1283 (Ind. Ct. App. 2015). Overall, "[t]he Journey's Account Statute is designed to ensure that the diligent suitor retains the right to a hearing in court until he receives a judgment on the merits. Its broad and liberal purpose is not to be frittered away by narrow construction." *Vesolowski* v. *Repay*, 520 N.E.2d 433, 434 (Ind. 1988).

Genzyme argues that statute cannot apply because *American Pipe* tolling doctrine makes clear that the right to file a new class action cannot be tolled. But *American Pipe* tolling is irrelevant to the current question. Indiana's statute is its own independent method by which claims might be preserved. Indeed, the statute has been used by a federal court in Indiana to preserve class claims. *Leathermon* v. *Grandview Mem'l Gardens, Inc.*, No. 4:07-CV-137-SEB-WGH, 2011 WL 2445980, at *10 (S.D. Ind. June 15, 2011).

Thus, I move forward and inquire whether Plaintiffs' suit would satisfy these requirements. Plaintiffs do not seem to argue that the statute operated independently to allow for them to file this suit; they acknowledge that they "had three years to file a new action" and that the tolling agreement was signed not long before the statute would have lapsed. [*See* Opposition to Motion to Dismiss at 9, ECF No. 108] Specifically, the *Hochendoner/Adamo*

suit was dismissed with respect to the current Plaintiffs on May 23, 2016, when the First Circuit released its ruling in *Hochendoner II*. *See* 823 F.3d at 724. The tolling agreement was signed on May 17, 2017. The window for the Journey's Account Statute to operate on its own closed on May 23, 2019. And the lawsuit now before me was filed on February 29, 2020.

The exact role then of the Journey's Account Statute in Plaintiffs' argument is unclear. Plaintiffs argue that Genzyme seeks for me to deprive them of "the protection of Indiana's savings statute and the parties' tolling agreement." Their best theory is seemingly that the statute helped to keep their claims alive after the dismissal and the tolling agreement locked them in. I see no Indiana caselaw on the interaction between tolling agreements and this statute, so I am reluctant to wade into uncharted, state-patrolled legal waters. I note that Indiana courts have said the 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." *Hayes* v. *Westminster Village N., Inc.*, 953 N.E.2d 114, 118 (Ind. Ct. App. 2011). This characterization makes the statute seem less like a broad tolling device and more like a specific mechanism to allow claims to move forward when a suit has been filed.

Even so, to evaluate Plaintiffs' arguments thoroughly, I now will consider how the new complaint maps onto the prior action and whether it would seem like a permissible extension, timing aside. First, I address the requirement that there be no negligence in the prosecution of the action.

"Examples of conduct which would likely be deemed negligence in prosecuting a case presumably include dismissal for failure to prosecute, dismissal for failure to comply with the discovery rules, failure to pay filing fees, and naming the wrong party." *Dempsey* v. *Belanger*, 959 N.E.2d 861, 866 (Ind. Ct. App. 2011). "The Journey's Account Statute's typical use is to save an action filed in the wrong court by allowing the plaintiff enough time to refile the same claim in the correct forum." *Al-Challah* v. *Barger Packaging*, 820 N.E.2d 670, 672 (Ind. Ct. App. 2005).

Next, I consider the nexus needed between the prior claim and the new one. The Indiana Supreme Court has emphasized that "[a] plaintiff invoking the benefit of the [Journey's Account Statute] is not required to prove the second complaint is a 'continuation' of the first." *Eads* v. *Cmty. Hosp.*, 932 N.E.2d 1239, 1245 (Ind. 2010). "The two *must assert fundamentally the same claim*, but whether one suit is a 'continuation' of another is the result of meeting the test of subsections, (a) and (b), not the cause."[16] *Id.* (emphasis added).

In *Eads*, the plaintiff sought to bring a medical malpractice claim after previously bringing a general negligence claim. *Id.* In finding the two were "fundamentally the same claim," the court noted that

16. As I have earlier observed in this memorandum, part (a) of the statute establishes the requirement that the plaintiff was unsuccessful in the earlier action on the basis of a cause other than negligence in the prosecution. Ind. Code § 34-11-8-1. Part (b) establishes when the new action may be brought.

"[b]oth complaints allege[d] identical historical facts and assert[ed]" the same basis for a claim, specifically the hospital's failure to ensure the plaintiff had "a safe means of egress." *Id.* The court also observed that "the source of a medical malpractice claim" was also "basic tort law" and "[t]here [were] no more legal elements to [the malpractice claim] than there [were] to other negligence torts." *Id.* at 1246 (quoting *Burke* v. *Capello*, 520 N.E.2d 439, 441 (Ind. 1988), *overruled in part by Vergara* v. *Doan*, 593 N.E.2d 185 (Ind. 1992)); *see also Land* v. *Int'l Bus. Machs. Corp.*, 108 F. Supp. 3d 632, 648-49 (S.D. Ind. 2015) (finding continuation permissible where complaint was "altered" only to name state entities as defendants, a procedural requirement).

The scenario in *Eads* may be contrasted with another case in which the parties changed and elements of the different claims—a 42 U.S.C. § 1983 claim versus gross negligence—were demonstrably distinct. *Eads*, 932 N.E.2d at 1246 (citing *McGill* v. *Ling*, 801 N.E.2d 678 (Ind. Ct. App. 2004)); *see also Sutton* v. *Scott*, 732 F. App'x 482, 483 (7th Cir. 2018) (Mem.) (finding "suit against the United States [that] sought to rescind [a] forfeiture" was "not remotely the 'same claim'" as "a tort action against one's lawyers," who were being sued for their representation earlier concerning the forfeiture).

I find that the operative Second Amended Complaint before me is close to satisfying the requirements of the Journey's Account Statute (except for the timing component), but I also find that it differs from that statute's customary function. On the one hand, most of the

claims are the same and use the same elements. But on the other hand, entirely new causes of action have been added (wrongful death/survival; fraud; fraudulent concealment; breach of fiduciary duty; unjust enrichment), and the facts have been substantially enhanced.

6. What Is Preserved

As a general proposition, I have found preserved by the Tolling Agreement Plaintiffs' claims from the *Hochendoner I* litigation—with a possible assist from Indiana's Journey's Account Statute. Thus the question becomes what claims were actually preserved. Unfortunately, this issue was not addressed in the briefing.

The key phrase is in the tolling agreement: "[a]ny applicable statutes of limitations pertaining to any matters asserted in" the prior lawsuits. The narrowest reading of this phrase is that precisely the same claims can be brought as were asserted in the prior action. A slightly more expansive interpretation—one consonant, to my mind, with the type of continuation envisioned by Indiana's Journey's Account Statute—is that the same fundamental claims can be brought, with modifications that address flaws in the earlier action. A more liberal reading than these initial two interpretations may be possible, also. The phrase reads "any *matters* asserted" in the prior lawsuit. "Matters" could refer not simply to specific claims but more broadly to the conduct discussed. This interpretation could open the door to new causes of action that still focus on the same issues as in the earlier suit.

Given this array of possible meanings, I draw again on Indiana's principles for contract interpretation and find that the meaning on this point is ambiguous. Thus, I am to consider extrinsic evidence that would shed light on the parties' agreement, but the current pleadings do not provide any extrinsic evidence. I conclude then that the meaning of this part of the tolling agreement would be a factual issue in dispute, to be resolved at a later stage in this litigation, with implications for the claims that may be ultimately successful. *See Banknorth, N.A.* v. *BJ's Wholesale Club, Inc.*, 394 F. Supp. 2d 283, 285-86 (D. Me. 2005) (explaining that although the defendant may raise meritorious arguments, "they require factual determinations more appropriately made at summary judgment or trial" and not on a motion to dismiss).

B. Standing

As the First Circuit advised in an earlier stage of this litigation, "[t]he heartland of constitutional standing is composed of the familiar amalgam of injury in fact, causation, and redressability." *Hochendoner II*, 823 F.3d at 731. For this case, injury and causation are most pertinent.

The injury must be "concrete and particularized and actual or imminent, not conjectural or hypothetical." *Susan B. Anthony List* v. *Driehaus*, 513 U.S. 149, 158 (2014) (citations and quotations omitted). As the First Circuit explained in addressing Plaintiffs' prior action, "concrete" means the injury "actually exist[s]" and "particularized" means a plaintiff has experienced harm

"in a personal and individual way." *Hochendoner II*, 823 F.3d at 731 (quoting *Spokeo, Inc.* v. *Robins*, 578 U.S. 330, 339 (2016)). Where, as here, plaintiffs allege a variety of injuries and "causal chains," the standing doctrine requires specific allegations "linking each plaintiff to each of these injuries." *Id.* at 733. Although all alleged injuries may flow from the same set of facts, "a plaintiff who has been subject to injurious conduct of one kind" does not "by virtue of that injury" hold "the necessary stake in litigating conduct of another kind, although similar, to which he has not been subject." *Blum* v. *Yaretsky*, 457 U.S. 991, 999 (1982).

For causation, a plaintiff must show that her injury is "fairly traceable to the challenged conduct of the defendant." *Sopkeo*, 578 U.S. at 338. This "requires the plaintiff to show a sufficiently direct causal connection between the challenged action and the identified harm." *Katz* v. *Pershing, LLC*, 672 F.3d 64, 71 (1st Cir. 2012). The connection "cannot be overly attenuated." *Donahue* v. *City of Boston*, 304 F.3d 110, 115 (1st Cir. 2002). "Because the opposing party must be the source of the harm, causation is absent if the injury stems from the independent action of a third party." *Katz*, 672 F.3d at 71-72.

Although Plaintiffs embellish their pleadings from their initial suit in an attempt to establish standing, they are unsuccessful, with the exception of four Plaintiffs. Overall, Plaintiffs improve on showing particularized harm compared with *Hochendoner/Adamo*, but none of the harm they successfully show is fairly traceable to misconduct by Genzyme (again with the exception of four

Plaintiffs). And other harm they allege fails because it is speculative or insufficiently alleged.

1. Theories of Harm

I can discern five theories of injury in the Second Amended Complaint:

a. Acceleration Theory

The first is an acceleration theory. This theory posits that patients received defective Fabrazyme that caused Plaintiffs' Fabry symptoms to worsen at a faster pace than would have occurred with proper Fabrazyme. This theory is analogous to the acceleration theory in the *Hochendoner/Adamo* action. This harm is alleged for almost every Plaintiff. For each of these Plaintiffs, the complaint says the Plaintiff'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 at least the following physical injuries, symptoms, and diagnostic criteria." *See*, *e.g.*, SAC at ¶¶1-2. What follows then is a laundry list of ailments. These allegations do not specify what is meant by "defective Fabrazyme." The surrounding sentences refer both to low dosing and vesivirus-contaminated Fabrazyme.

b. Sensitization Theory

The second is a sensitization theory. This theory posits that some Plaintiffs (Ms. Wilkins, Mr. LaForce,

and Mr. Stanziano) became sensitized from low doses of Fabrazyme and consequently experienced dangerous reactions upon returning to full doses. *See id.* at ¶¶1, 14, 20. This theory is analogous to the theory found successful for Mr. Mooney in the *Hochendoner/Adamo* action. *See Hochendoner II*, 823 F.3d at 734-36.

c. Vesivirus Theory

The third is a vesivirus theory. This theory posits that the presence of vesivirus in the Fabrazyme doses given to Plaintiffs caused "vesivirus-induced vesiculating non-anaphylactic rashes," as well as an increased "risk of developing fulminating vesivirus infection, and vesivirus induced hematological cancer." *See*, *e.g.*, SAC at ¶1-2. This theory is applied to almost every Plaintiff. Plaintiffs allege generally that Genzyme contaminated its bioreactors—containers similar to fermentation tanks that are used to produce Fabrazyme—with vesivirus at some point before July 2009. *Id.* at ¶42. Genzyme named the particular strain of vesivirus "2117 (Allston)" for the manufacturing facility where it was detected (Allston, Massachusetts). *Id.* at ¶47.

d. Life Expectancy Theory

The fourth is a life expectancy theory. This theory posits that low doses of Fabrazyme decreased Plaintiffs' life expectancy. *See*, *e.g.*, *id.* at ¶¶1-2. This theory is also applied to almost every Plaintiff.

e. Financial Theory

The fifth is a financial theory. This theory posits that Plaintiffs spent money on medically worthless medication, worthless "because it was ineffective for treating Fabry disease and unsafe to administer at the dosage and purity which it was sold." *See*, *e.g.*, *id.* at ¶¶1-2. This theory is also applied to almost every plaintiff.

2. Success of the Five Theories of Harm

I now address whether any of the five theories of harm satisfy the requirements of constitutional standing. Like the Court of Appeals in *Hochendoner II*, I find that only the sensitization theory succeeds.

The acceleration theory fails for insufficiently showing causation. Plaintiffs' allegations repeatedly refer to "defective" Fabrazyme without specifying whether the problem was dosage or contaminants, a failure which undermines Plaintiffs' claims. Plaintiffs' open-ended pleading fails to make meaningful allegations of causal ties.

Moreover, there is no information to corroborate that any Plaintiff received a dose contaminated with vesivirus; the link to be drawn is apparently that Genzyme reported vesivirus at its plant and Plaintiffs experienced symptoms they claim—with no particularized allegation—resulted from contamination. Although the Second Amended Complaint describes distressing ailments suffered by numerous patients and attempts to connect them to

"defective" doses of Fabrazyme, it does not for any Plaintiff provide information to show that the symptoms experienced were the result of "defective" dosing and not simply the progression of Fabry disease as would have occurred without the drug and perhaps even at a faster pace. There is no information from a physician about symptoms or a comparison with symptom progression before "defective" doses.

The Second Amended Complaint does reference research from Europe showing that acceleration can occur and that "Europe banned 'low-dosing' entirely and required Genzyme Corporation to change the label to warn patients of possible acceleration of Fabry-disease process." SAC ¶98-99. And the Second Amended Complaint states for various Plaintiffs that they have experienced an acceleration of symptoms due to "defective" doses. But a study showing that acceleration *can* occur says nothing of whether Plaintiffs themselves suffered acceleration. As the First Circuit made clear in the prior iteration of this suit, "[n]either conclusory assertions nor unfounded speculation can supply the necessary heft" to establish standing. *Hochendoner II*, 823 F.3d at 731. As pleaded, Plaintiffs only speculate regarding the cause of their injuries.

The vesisvirus theory fails as well for insufficiently showing causation. I have explained the weak basis plaintiffs provide for vesivirus being in a dose they received. Additionally, the specific symptom they describe for this injury theory—vesivirus-induced vesiculating non-anaphylactic rashes—is consistent with known side effects of Fabrazyme. Plaintiffs simply provide their say-so that

these rashes are from vesivirus. No plaintiff provides any particularized allegation of a vesivirus diagnosis or of the virus being detected in their body.

The vesivirus theory also fails for being too speculative, and the life expectancy theory fails for this reason, too. With the vesivirus theory, the complaint states baldly that vesivirus exposure has increased the risk of certain health problems for Plaintiffs. And with the life expectancy theory, the complaint states simply that low doses have resulted in a lower life expectancy. But Article III standing requires showing harm that is "actual or imminent, not conjectural or hypothetical." *Susan B. Anthony List*, 573 U.S. at 158 (quoting *Lujan* v. *Defens. of Wildlife*, 504 U.S. 555, 560 (1992)). These vague prognostications in the operative complaint now before me also are insufficient.

Finally, the financial theory also fails because it is insufficiently pled to show injury. Plaintiffs spent money on a medication that they knew would come in a lesser quantity than what they usually purchased. Their only arguments to show the medication was worthless are based on conclusory statements that the doses harmed them in some way. *See*, *e.g.*, SAC ¶1. But again, Plaintiffs do not offer any particularized allegation to show that low doses or a highly speculative contamination of vesivirus caused them harm. The harm they describe is consistent with the progression of Fabry disease.

Nevertheless, the sensitization theory of standing succeeds, as it did before the First Circuit in *Hochendoner II*. Plaintiffs plausibly allege that "'[l]ow dosing' a protein like Fabrazyme increases the likelihood that Fabrazyme

will induce an immune response against Fabrazyme itself because the immune system is more likely to interpret low-dose protein as a pathogen and become hypersensitive to subsequent injections." SAC ¶104. As a result, Mr. LaForce, Mr. Stanziano,[17] and Ms. Wilkins all say they experienced anaphylactic response upon returning to a full dose. *Id.* at ¶¶1, 14, 20. The allegations here mirror the allegations in the prior suit but with some specificity. And Genzyme does not dispute the success of this theory for the four remaining plaintiffs in their motion to dismiss.

IV. CLASS ACTION STATUS

To this point, I have found that the May 2017 tolling agreement between the parties preserved Plaintiffs' claims—at least in some form—but that only four Plaintiffs succeed in establishing standing, and then on a narrow, idiosyncratic basis (with one of these Plaintiffs doing so with a derivative loss-of-consortium claim). To maintain this action as a class action under Rule 23 requires that the class be "so numerous that joinder of all members is impracticable." Fed. R. Civ. P.23(a)(1). Genzyme has not challenged whether Plaintiffs satisfy the numerosity requirements. But with only four Plaintiffs who experienced a very specific type of injury, I have doubts about whether this suit may proceed on a class action basis.[18]

17. Mr. Stanziano's wife, Ms. Stanziano, also sues through a derivative loss-of-consortium claim on a surviving sensitization claim by Mr. Stanziano.

18. In *Rovinelli* v. *Trans World Entertainment Corporation* I had occasion to address a similar, though not identical, issue:

At this point, I will evaluate the claims of these plaintiffs only on an individual basis.

How and whether to proceed as to state law claims where "the pleaded matters [were not] properly dealt with through a class action in federal court." *See* No. 19-11304-DPW, 2021 WL 752822, at *1 (D. Mass. Feb. 2, 2021). There I found that the plaintiffs' allegations did not provide facts demonstrating "commonality and predominance that are required to adjudicate claims as a class action under Fed. R. Civ. [P.] 23." *Id.* I explained that the plaintiffs *never* had proper jurisdiction in federal court pursuant to the CAFA, and I struck the class allegations. *Id.* at *13. I then considered whether I had subject matter jurisdiction to proceed with respect to plaintiffs remaining claims, all brought under state law. *Id.* I concluded that I would not exercise supplemental jurisdiction over the state law claims because the "jurisdictional hook" of the CAFA was improper, and the amount in controversy was insufficient for the "ordinary diversity of citizenship analysis." *Id.* at *16.

The current matter presents different circumstances. Genzyme is a citizen of Massachusetts, whereas the four remaining Plaintiffs are variously citizens of Indiana, Kentucky, Florida, and Virginia. In most Counts, Plaintiffs "demand[ed] judgment against [Genzyme] in an amount in excess of $75,000.00," and pleaded both "*individually* and on behalf of all others similarly situated." SAC ¶457 (emphasis added). Although most of Plaintiffs' allegations containing injuries have been dismissed for standing, the remaining allegations, if proven, would likely have damages that could exceed $75,000.00. Plainly, I cannot say to a legal certainty that the claim is for less. *See Stewart* v. *Tupperware Corp.*, 356 F.3d 335, 338 (1st Cir. 2004) (explaining that a plaintiff 's allegation of damages "controls" if it is "made in good faith," since "[i]t must appear to a legal certainty that the claim is really for less . . . to justify dismissal" when challenged (quoting *St. Paul Mercury Indem. Co.* v. *Red Cab Co.*, 303 U.S. 283, 288-89 (1938))).

V. MERITS

I now must address the claims made by Ms. Wilkins, as a resident of Indiana and Kentucky, Mr. and Ms. Stanziano, as Florida residents, and Mr. LaForce, as a Virginia resident. Notably, several of these claims—for fraud, fraudulent concealment, breach of fiduciary duty, and unjust enrichment—were not brought in the *Hochedoner I & II* litigation. I nevertheless address them here. As I explained above, however, whether these claims can be brought is a matter of factual dispute involving the meaning of the tolling agreement.

I address first whether the heightened pleading standards of Fed. R. Civ. P. 9(b) should apply and then examine each claim through the lens fashioned in that manner. The standing theory I have found viable—the sensitization theory—is the one standing theory accepted in *Hochendoner II*.

A. Rule 9(b) Heightened Pleading Standards

Genzyme contends that all claims in the Second Amended Complaint "are grounded in allegations of fraudulent, misleading, or deceptive conduct," and so they must satisfy Rule 9(b)'s heightened pleading standards.

Genzyme also contends that Plaintiffs' "fraud claims are grounded in the same core theory as the rest of their product liability claims," and so the fraud claims should be subject to the two-year statute of applications relevant for product liability in Indiana.

Plaintiffs apparently agree with Genzyme's Rule 9(b) contention and point to the First Circuit's instruction that "Rule 9(b)'s heightened pleading requirements apply not only to claims of fraud simpliciter but also to related claims as long as the central allegations of those claims 'effectively charge fraud.'" *Foisie* v. *Worcester Polytechnic Inst.*, 967 F.3d 27, 49 (1st Cir. 2020) (quoting *Mulder* v. *Kohl's Dep't Stores, Inc.*, 865 F.3d 17, 21-22 (1st Cir. 2017)).

Considering the theory of harm before me and how it interacts with the causes of action, I find Rule 9(b)'s pleading standards applicable to the denominated fraud claim. At bottom, though Plaintiffs make many allegations of Genzyme concealing information in their other claims, those claims are fundamentally about product liability and Rule 9(b) does not apply. I will return to a discussion of the fraud denominated claims in Section V.K. *infra.*

B. Negligence

The negligence claims asserted by Mr. LaForce and Mr. Stanziano (and derivatively Ms. Stanziano) fail. *See* SAC at ¶¶350-352. The negligence claims are brought under theories of products liability. *See*, *e.g.*, *West* v. *Caterpillar Tractor Co., Inc.*, 336 So. 2d 80, 84 (Fla. 1976) ("Products liability deals with recourse for personal injury . . . resulting from the use of a product and, in the past, has covered actions for negligence. . . ."). Florida and Virginia both recognize three theories of negligence for products liability cases: negligent design,

negligent manufacture, and negligent failure to warn.[19] *Powell* v. *Diehl Woodworking Mach., Inc.*, 198 F. Supp. 3d 628, 633 (E.D. Va. 2016) ("Virginia law only recognizes three products liability claims: negligent assembly or manufacture, negligent design, and failure to warn."); *Ugaz* v. *Am. Airlines, Inc.*, 576 F. Supp. 2d 1354, 1374-75 (S.D. Fla. 2008) ("In Florida, a product may be defective by virtue of a design defect, a manufacturing defect, or an inadequate warning.").

"To prove any products liability claim sounding in negligence, whether negligent design, negligent

19. Plaintiffs seem to allege that Genzyme acted negligently by "fail[ing] to test or require the testing of the effects of reducing the dosage of Fabrazyme to unapproved levels." SAC ¶ 351(j.). Florida and Virginia law do not recognize an independent negligence theory for failure to test a product. *See Horton* v. *Hoosier Racing Tire Corp.*, No. 8:15-cv-1453-T-17TGW, 2015 WL 12859316, at *4 (M.D. Fla. Dec. 15, 2015) ("Florida courts have refused to recognize an independent claim for negligent failure to test."); *Powell* v. *Diehl Woodworking Mach., Inc.*, 198 F. Supp. 3d 628, 633-34 (E.D. Va. 2016) (explaining the same). Rather, failure to test allegations must "fit [ ] into one of the traditional theories, or [be] dismiss[ed] [ ] altogether." *Powell*, 198 F. Supp. 3d at 634. Plaintiffs do not plead this claim as a part of a recognized negligence claim. Moreover, Plaintiffs do not show that they received a defective product or that Genzyme did not test the Fabrazyme they received. Accordingly, this claim fails.

Additionally, Plaintiffs seem to allege negligence on the basis of "negligent[ ] monitor[ing]" and "negligent[ ] marketing." SAC ¶ 351(l.);(o.). Setting aside whether Florida and Virginia law would recognize these theories of liability in a negligence products liability claim, Plaintiffs have not stated a claim based on these allegations because Plaintiffs fail to show causation.

manufacture, or the negligent failure to provide adequate warnings or instructions, a plaintiff must establish (1) that the defendant owed a duty of care toward the plaintiff, (2) that the defendant breached that duty, (3) that the breach was the proximate cause of the plaintiff 's injury, and (4) that the product was defective or unreasonably dangerous." *Cooper* v. *Old Williamsburg Candle Corp.*, 653 F. Supp. 2d 1220, 1226 (M.D. Fla. 2009). Plaintiffs cannot meet this burden.

1. Negligent Design Theory

A claim for negligent design requires showing a defect in the product caused Plaintiffs' injuries. *Wolicki-Gables* v. *Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1287 (M.D. Fla. 2009); *see Dodson* v. *C.R. Bard, Inc.*, No. 3:20cv596 (DJN), 2020 WL 7647631, at *5 (E.D. Va. Dec. 23, 2020) ("At minimum, [p]laintiff must provide some allegation that a design defect existed and that such a defect proximately caused [p]laintiff 's injuries."). Plaintiffs have not clearly alleged a defect. As I have explained, Plaintiffs seem to allege that the Fabrazyme was defective due to contaminants or low dosage, *supra* Section III.B.1.a.; [SAC ¶¶ 2, 8, 351], but the pleadings are unclear and such "[a] bare allegation of a 'defect' is no more than a legal conclusion" that is insufficient to state a claim. *Ball* v. *Takeda Pharms. Am., Inc.*, 963 F. Supp. 2d 497, 505 (E.D. Va. 2013), *aff 'd* 587 F. App'x 78 (4th Cir. 2014) (per curiam) (Mem.). Plaintiffs also fail to plead causation. Plaintiffs do not demonstrate that they ever took "defective Fabrazyme," and, as a result, cannot show that "defective Fabrazyme" caused their alleged injuries.

2. Negligent Manufacture Theory

The negligent manufacture theory fails along the same lines as the negligent design theory—Plaintiffs do not show a causal connection between the manufacturing defects they allege (contamination) and their relevant injuries (sensitization). *Cooper*, 653 F. Supp. 2d at 1226; Va. Prac. Tort and Personal Injury Law § 15:15 ("[A] plaintiff may not recover for damages in a product liability action absent a legally sufficient causal link between the alleged wrong and the plaintiff 's resulting damages.").

3. Failure to Warn Theory

In general, "a manufacturer has a duty to warn its customers of risks posed by its products." *Higgins* v. *Forest Lab'ys*, 48 F. Supp. 3d 878, 884 (W.D. Va. 2014). The failure-to-warn theory, however, fails in the face of the learned intermediary doctrine, which instructs that a drug manufacturer's duty to warn extends to a patient's physician, but not to the patient, based on the proposition that a physician has the expertise to read warning labels and advise patients. *See id.* (describing this doctrine in Virginia courts); *Small* v. *Amgen, Inc.*, 723 F. App'x 722, 724-25 (11th Cir. 2018) (per curiam) (explaining the same under Florida law). Accordingly, a "[p]laintiff must show [it is] more likely than not the warning to the physician was inadequate and the warning did not sufficiently inform the prescribing physician about the risks involved in prescribing the drug." *Chase* v. *Novartis Pharm. Corp.*, 740 F. Supp. 2d 1295, 1297 (M.D. Fla. 2006) (internal quotations omitted) (applying Florida law); *see also*

Higgins, 48 F. Supp. 3d at 884-87 (describing doctrine in similar terms for Virginia).

If a physician is independently aware of a risk associated with a medication, then the patient has no claim against the manufacturer, regardless of any warnings provided. *See Higgins*, 48 F. Supp. 3d at 893 (granting summary judgment on failure-to-warn claim on these grounds); *see also Tillman* v. *C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1335 (M.D. Fla. 2015) ("[T]he failure of the manufacturer to provide the physician with an adequate warning is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that an adequate warning should have communicated.").

Plaintiffs' allegations in this matter are thus insufficient to support a failure-to-warn claim. Although Plaintiffs allege that Genzyme "failed to provide adequate warnings, cautions, and directions concerning the dangers and limitations of the 'low dose' of Fabrazyme" and "expressly and impliedly misrepresent[ed] that injection with Vesivirus-containing Fabrazyme is harmless," SAC ¶¶351(k.), they have not provided any allegation about what their doctors knew or what they advised, let alone the warnings that Genzyme provided.

C. Negligence Per Se

Mr. LaForce and Mr. Stanziano (and derivatively Ms. Stanziano) also make claims for negligence per se. Mr. LaForce's claim fails because the relevant provision

of Virginia law he cites, Va. Code Ann. § 54.1-3461 et seq., applies to adulterated products, while the viable standing theory identified in *Hochendoner II* is not based on adulteration. *See* 823 F.3d at 732-33. The Stanzianos' claims fail because they do not identify what portions, if any, of Florida law Genzyme violated. *See* SAC at ¶352 n.10. In Plaintiffs' narrative Opposition to Genzyme's Motion to Dismiss, Mr. Stanziano says his claim is "based on the violations of the Florida Pure Food and Drug Acts," but he does so without specifying what provision of the Florida law Genzyme violated. Accordingly, the Stanzianos fail to state a claim because they do not specify that there was a "violation of a statute which establishes a duty upon a party to take precautions to protect a particular class of persons from a particular injury or type of injury." *Hesterly* v. *Royal Caribbean Cruises, Ltd.*, 515 F. Supp. 2d 1278, 1287 n.6 (S.D. Fla. 2007).

D. Strict Liability

Mr. LaForce's claim for strict liability stumbles at the threshold because, as he admits, Virginia does not permit strict product liability claims. *See Harris* v. *T.I. Inc.*, 413 S.E. 2d 605, 609-10 (Va. 1992).

The Stanzianos' strict liability claims fail more particularly because any claim based on failure to warn cannot avoid the learned intermediary doctrine, as described above, and they do not demonstrate a causal connection between any alleged defect in the Fabrazyme Mr. Stanziano actually received and his injury. In Florida, to make a claim against a manufacturer "on the

theory of strict liability tort, the user must establish the manufacturer's relationship to the product in question, the defect and unreasonably dangerous condition of the product, and the existence of a *proximate causal connection* between such condition and the user's injuries or damage." *Siemens Energy & Automation, Inc.* v. *Medina*, 719 So.2d 312, 315 (Fla. Dist. Ct. App. 1998) (emphasis added) (quoting *West* v. *Caterpillar Tractor Co.*, 336 So.2d 80, 87 (Fla. 1976)).

E. Breach of Warranty

1. Claims for Breach of Implied Warranties

Mr. LaForce and the Stanzianos bring claims for breach of implied warranties of merchantability or fitness. SAC ¶362. The claims for breach of implied warranty of merchantability fail because Mr. LaForce and the Stanzianos show no defect in the Fabrazyme actually received. *See* Fla. Stat. § 672.314 (defining in relevant part that merchantable good is "fit for the ordinary purposes for which such goods are used"); Va. Code Ann. § 8.2-314 (same); *see also Egbebike* v. *Wal-Mart Stores E., LP*, No. 3:13-cv-865-J-34MCR, 2014 WL 3053184, at *6 (M.D. Fla. July 7, 2014) (requiring plaintiff to prove that there is a defect in the product to sustain a claim for breach of implied warranty of merchantability for defective product under Florida law).

The Stanzianos' claims for breach of implied warranty of merchantability and fitness also fail because they do not adequately allege how Mr. Stanziano was in privity

with Genzyme. *See Cruz* v. *Mylan, Inc.*, No. 8:09-CV-1106T17-EAJ, 2010 WL 598688, at *2 (M.D. Fla. Feb. 17, 2010). Although the complaint states Mr. Stanziano "was in privity with Genzyme throughout his treatment with his Genzyme case coordinator as well as being registered in the Genzyme sponsored Fabry Registry," the complaint does not allege that he and Genzyme had a buyer-seller relationship. *See id.* ("A plaintiff who purchases a product, but does not buy it directly from the defendant, is not in privity with that defendant" (quoting *T.W.M.* v. *Am. Med. Sys., Inc.*, 886 F. Supp. 842, 844 (N.D. Fla. 1995).); *cf. id.* (recognizing exceptions to this rule for express warranties, but not implied warranties, where a buyer has an extensive relationship with a manufacturer).

Mr. LaForce's claim for breach of implied warranty of fitness also fails. First, Virginia's statute refers specifically to a "buyer" and a "seller," but Genzyme did not sell directly to Mr. LaForce. I do recognize that it is not completely clear from Virginia caselaw if these facts on their own bar Mr. LaForce from bringing this claim. *See Bayliner Marine Corp.* v. *Crow*, 509 S.E.2d 499, 503 (Va. 1999) (seemingly not barring on this ground a claim brought by a buyer against a manufacturer, where purchase was made through an exclusive dealer). But second, if the claim is not barred for lack of direct sales relation, it still would fail because Plaintiffs must prove that Genzyme "at the time of contracting [had] reason to know" a "particular purpose for which the goods [were] required and that [the plaintiffs] [ ] rel[ied] on [Genzyme's] skill or judgment to select or furnish" the Fabrazyme. *See* Va. Code Ann. § 8.2-315. Neither Mr. LaForce nor the

Stanzianos have pled this sufficiently because they do not explain how Genzyme would have perceived their reliance when Genzyme would necessarily have understood that Fabrazyme patients made decisions under the care of a physician.

2. Claims for Breach of Expressed Warranty

The claims for breach of express warranty fail because neither Mr. LaForce nor the Stanzianos trace their injuries to any specified breaches of an express warranty. The complaint alleges:

> [1] [Genzyme] expressly warranted in the Fabrazyme product insert that Fabrazyme reduces globotriaosylceramide deposition in capillary endothelium of the kidney and certain other cell types, despite never having tested whether the product at these doses was efficacious and having observed that such dosing does not reduce such deposition; . . .
>
> [2] [Genzyme] expressly warranted in the Fabrazyme product insert that Fabrazyme is indicated for use to treat Fabry disease, despite never having obtained FDA approval for using 'low dose' for such an indication; . . .
>
> [3] in affirmatively representing that the drug given at full dosage would be sold to citizens at various dates, but breached such promises repeatedly since June 2009; . . .

> [4] in expressly and impliedly warranting that a "low dose" of Fabrazyme was approved for use by the FDA and efficacious for use in the treatment of Fabry disease; . . .
>
> [5] in expressly and impliedly misrepresenting that injection with vesivirus-contaminated Fabrazyme is harmless, non-immunogenic, without impact on the efficacious treatment of Fabry disease with Fabrazyme, even though no medical testing had ever been undertaken to establish the objective truth of such material medical claims and further concealing previously published medical literature rendering such statements regarding medical safety of vesivirus injection as false.

SAC at ¶¶362(a), 362(b), 362(m), 362(n), 362(q).

Causation is an essential element for a breach of warranty claim. *See* 77A C.J.S. Sales § 484. But the plaintiffs do not show how the breach of any such warranties led to their anaphylactic reactions upon returning to a full dose.

Additionally, with the exception of the third and fifth enumerated items, Plaintiffs do not sufficiently establish that Genzyme made these warranties. I addressed similar allegations in *Hochendoner I* and noted that the language that Plaintiffs cited from the package insert contained "dosing directions, indicating the dosage at which the FDA [had] approved Fabrazyme® and in the context

of which the 'Indications and Usage' statement must be read." *Hochendoner I*, 95 F. Supp. 3d at 32. "Nowhere does the package insert state that a lower dosage would be as efficacious for use in the treatment of Fabry disease as the dose recommended on the packaging and by the FDA. Nowhere does the package insert state that a lower dosage is FDA-approved." *Id.*

F. Florida Deceptive and Unfair Trade Practices

Despite Mr. Stanziano claiming financial injury in addition to personal injury, I have only found viable his standing theory based on personal injury. Thus, the Stanzianos' claims under the Florida Deceptive and Unfair Trade Practices Act fails because the law "expressly states that it 'does not apply to . . . [a] claim for personal injury." *Echols v. RJ Reynolds Tobacco Co.*, No. 13-cv-14215, 2014 WL 5305633, at *5 (S.D. Fla. Oct. 15, 2014) (quoting Fla. Stat. § 501.212(3)) (dismissing claim because damages sought for personal injury).

G. Indiana Product Liability Act and Kentucky Product Liability Act

Ms. Wilkins' claims under the Indiana Product Liability Act and the Kentucky Product Liability Act fail for reasons similar to those that render the negligence product liability claims of the Stanzianos and Mr. LaForce inadequate.

Like Florida and Virginia, Indiana and Kentucky recognize product liability claims based on manufacturing

defects, design defects, and failures to warn. *See Brewer* v. *PACCAR, Inc.*, 124 N.E.3d 616, 621 (Ind. 2019); *Clark* v. *Hauck Mfg. Co.*, 910 S.W.2d 247, 251 (Ky. 1995) (Barker, J.), *overruled on other grounds by Martin* v. *Ohio Cnty. Hosp. Corp.*, 295 S.W.3d 104 (Ky. 2009).

A manufacturing defect claim will fail for lack of causation. *Jarrett* v. *Wright Med. Tech., Inc.*, No. 1:12-cv-00064-SEB-DML, 2021 WL 4307026, at *8 (S.D. Ind. Sept. 22, 2021); *Red Hed Oil, Inc.* v. *H.T. Hackney Co.*, 292 F. Supp. 3d 764, 773 (E.D. Ky. 2017) ("Regardless of the theory a plaintiff pursues, he must show causation in a products liability case.").

As for a design defect claim, like Mr. LaForce and the Stanzianos, Ms. Wilkins does not specify in the Second Amended Complaint a theory of design defect under either Indiana law or Kentucky law. Under Indiana law, plaintiffs bringing a products liability claim based on an alleged design defect "must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances of *designing the product*." *TRW Vehicle Safety Sys., Inc.* v. *Moore*, 936 N.E.2d 201, 209 (Ind. 2010) (emphasis added) (quoting Ind. Code § 34-20-2-2). Kentucky law requires "establish[ing] existence of an alternative, safer design that is practical under the relevant circumstances." *Primal Vantage Co., Inc.* v. *O'Bryan*, ___ S.W.3d ___, 2022 WL 3641122, at *12 (Ky. Aug. 18, 2022) (Minton, C.J.). *But see Kaiser* v. *Johnson & Johnson*, 947 F.3d 996, 1014 (7th Cir. 2020) (explaining that Indiana law does not require proof of an alternative design, though it "can be relevant to design-defect liability").

In her narrative opposition to Genzyme's motion to dismiss her Kentucky claim, Ms. Wilkins does say that she shows a design defect "in that Fabrazyme is a pharmaceutical and therefore Genzyme is strictly liable for the effects of vesivirus and particulates on [her] vesivirus infection and her inflammation and her accelerated disease process." And she says further "[t]he product was defectively designed in that it was administered at 'low' dose which makes it impossible to treat Fabry disease." These allegations do not state a claim under either Indiana or Kentucky law. The first point she makes is off the mark because what she really alleges is a manufacturing defect, and in any event that claim fails for causation. The second point fails as well because although low-dose Fabrazyme may be less effective than full dose—as was certainly known to patients and their doctors—the complaint does not show that low-dose Fabrazyme "makes it impossible to treat Fabry disease."

The failure-to-warn claims fail because of the learned intermediary doctrine in both Kentucky and Indiana, in the same way the claims brought by Mr. LaForce and Mr. Stanziano fail under Florida and Virginia law. *See Larkin* v. *Pfizer, Inc.*, 153 S.W.3d 758, 762-770 (Ky. 2004) (describing and adopting the doctrine); *Ortho Pharm. Corp.* v. *Chapman*, 388 N.E.2d 541, 548 (Ind. Ct. App. 1979) ("[A] manufacturers [sic] duty to warn extends only to the medical profession, and not the ultimate users.").

H. Kentucky Consumer Protection Act

The Kentucky Consumer Protection Act prohibits "[u]nfair, false, misleading, or deceptive acts or practices

in the conduct of any trade or commerce." Ky. Rev. Stat. Ann. § 367.170. To prove a violation of the Act, a plaintiff must show that they "(1) purchase[d] or lease[d] goods or services (2) for personal, family or household purposes and (3) [was] injured as a result of a seller's prohibited practice or act." *Simpson* v. *Champion Petfoods USA, Inc.*, 397 F. Supp. 3d 952, 961 (E.D. Ky. 2019) (Bertelsman, J.).

Genzyme says that Ms. Wilkins's claim under the Kentucky Consumer Protection Act "fails as a matter of law because [she] has not sufficiently alleged that she purchased Fabrazyme directly from Genzyme such that she was in privity with Genzyme." Genzyme also says that, even if she did show she was in privity, her claim would fail because it is inadequately alleged.

As to the first argument, the Second Amended Complaint says that Ms. Wilkins "was in privity with Genzyme throughout her treatment with her Genzyme case care coordinator as well as being registered in the Genzyme sponsored Fabry Registry." SAC at ¶1. While the complaint does not show explicitly a buyer-seller relationship, Kentucky allows an exception where "'express warranties were clearly intended for the product's consumers,' even if the warranties did not 'expressly state that they run directly to the intended consumers.'" *Yonts* v. *Easton Tech. Prods., Inc.*, 676 F. App'x 413, 420 (6th Cir. 2017) (quoting *Naiser* v. *Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 739-40 (W.D. Ky. 2013)). However, this exception does not extend to implied warranties. *See Naiser*, 975 F. Supp. 2d at 739 (observing, in deciding to recognize exception to privity rule involving

an express warranty, that the most recent Kentucky Supreme Court decision not to find an exception involved an implied warranty).

Thus, to the extent this exception applies, Ms. Wilkins might be able to make an argument based on express warranties. But this argument fails based on causation, for the same reasons identified in discussing the warranty claims brought by Mr. LaForce and the Stanzianos. "The breach of the express warranty must have caused the injury," Ky. Prod. Liab. L. § 6:2, which Ms. Wilkins does not demonstrate.

I. Virginia Consumer Protection Act

Mr. LaForce may not bring a claim under the Virginia Consumer Protection Act, because sales of Fabrazyme are regulated by the U.S. Food and Drug Administration. The Act does not apply to "[a]ny aspect of a consumer transaction which aspect is authorized under laws or regulations of this Commonwealth or the United States, or the formal advisory opinions of any regulatory body or official of this Commonwealth or the United States." Va. Code Ann. § 59.1-199(A). Thus, for example, a federal court has found that plaintiffs could not sue a company for representations made "in advertisements and other marketing materials concerning the safety and effectiveness" of a medical device, because regulations about the device were "authorized and regulated by the FDA under federal law." *Ali* v. *Allergan USA, Inc.*, No. 12-cv-115, 2012 WL 3692396, at *19 (E.D. Va. Aug. 23, 2012).

Appendix D

J. Virginia False Advertising Act

Mr. LaForce's claim under the Virginia False Advertising Act fails for the same reason I found inadequate a claim under the Act in *Hochendoner I*. As I explained there, "[u]nder Va. Code § 59.1-68.3, a plaintiff may bring a claim for losses resulting from an 'untrue, deceptive or misleading' 'promise, assertion, representation, or statement of fact' in an advertisement." *Hochendoner I*, 95 F. Supp. 3d at 33 n.13 (quoting Va. Code Ann. § 18.2-216). But Mr. LaForce has not sufficiently "alleged that Genzyme made any untrue or deceptive statements regarding the efficacy of Fabrazyme® at a lower dosage." *See id.*

K. Fraud and Fraudulent Concealment

The fraud claims asserted by Mr. LaForce and the Stanzianos fail because they cannot trace the harm they experienced to information that Genzyme is alleged to have withheld intentionally. I note that here Rule 9(b)'s heightened pleading requirements apply in full force. *See supra* Section V.A.

The elements of fraud in Florida are: "(1) a false statement concerning a material fact; (2) the representor's knowledge that the representation is false; (3) an intention that the representation induce another to act on it; and (4) *consequent injury by the party acting in reliance* on the representation." *Butler* v. *Yusem*, 44 So. 3d 102, 105 (Fla. 2010) (per curiam) (emphasis added) (quoting *Johnson* v.

Davis, 480 So.2d 625, 627 (Fla. 1985)). The elements in Florida for fraudulent concealment are similar.[20]

In Virginia, a plaintiff bringing a fraud action "bears the burden of proving by clear and convincing evidence" these elements: "(1) a false representation, (2) of a material fact, (3) made intentionally and knowingly, (4) with intent to mislead, (5) reliance by the party misled, and (6) *resulting damage to the party misled.*" *Richmond Metro. Auth.* v. *McDevitt St. Bovis, Inc.*, 507 S.E.2d 344, 346 (Va. 1998) (emphasis added) (quoting *Evaluation Rsch. Corp.* v. *Alequin*, 439 S.E.2d 387, 390 (Va. 1994)). Virginia does not have a separate cause of action for fraudulent concealment, though "[c]oncealment of a material fact by one who knows that the other party is acting upon the assumption that the fact does not exist constitutes actionable fraud." *Bank of Montreal* v. *Signet Bank*, 193 F.3d 818,827 (4th Cir. 1999) (quoting *Allen Realty Corp.* v. *Holbert*, 318 S.E.3d 592, 597 (Va. 1984)). "In all cases of fraud [under Virginia law] the plaintiff must prove that it acted to its detriment in actual and justifiable reliance on the defendant's misrepresentation (or on the assumption that the concealed fact does not exist)." *Id.*

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20. A claim for fraudulent concealment in Florida must show (1) the defendant "concealed or failed to disclose a material fact"; (2) the defendant "knew or should have known the material fact should be disclosed"; (3) the defendant "knew [its] concealment of or failure to disclose the material fact would induce the plaintiffs to act"; (4) the defendant "had a duty to disclose the material fact"; and (5) "the *plaintiffs detrimentally relied on the misinformation.*" *Hess* v. *Philip Morris USA, Inc.*, 175 So. 3d 687, 691 (Fla. 2015) (emphasis added) (quoting *R.J. Reynolds Tobacco Co.* v. *Martin*, 53 So.3d 1060, 1068 (Fla. Dist. Ct. App. 2010)).

Thus, Plaintiffs must allege some form of injury that resulted from them relying on Genzyme's alleged false statements or concealment. They do not do so. The only information that Plaintiffs can plausibly show Genzyme concealed was that the Fabrazyme shortage would last longer than initially forecast. As I observed earlier at footnote 14 in this Memorandum, Plaintiffs say at paragraph 299 of the complaint that "[h]ad the true information about the supply situation been provided to [them] and their doctors, they would have acted with great urgency in September, 2009 to seek alternative treatment, such as Replagal®, through a compassionate use exemption or additional Fabrazyme through private arrangements with other patients and doctors." SAC ¶299. But Plaintiffs do not plead with any particularity how they relied on Genzyme's statements in deciding not to pursue alternative treatment, arrangements, or a compassionate use exemption. They do not allege, for example, any communications involving their medical providers that they actually reconsidered due to Genzyme's statements.

L. Breach of Fiduciary Duty

The claims brought by Mr. LaForce and the Stanzianos for breach of fiduciary duty fail because they do not establish a fiduciary duty between Genzyme and customers taking Fabrazyme.

In Florida, "[c]ourts have found a fiduciary relation implied in law when 'confidence is reposed by one party and a trust accepted by the other.'" *Cap. Bank v. MVB, Inc.*, 644 So. 2d 515, 518 (Fla. Dist. Ct. App. 1994) (quoting

Dale v. *Jennings*, 107 So. 175, 179 (Fla. 1925)). "A fiduciary relationship must be established by competent evidence, and the burden of proving such a relationship is on the party asserting it." *Orlinsky* v. *Patraka*, 971 So.2d 796, 800 (Fla. Dist. Ct. App. 2007). "[A] party must allege some degree of dependency on one side and some degree of undertaking on the other side to advise, counsel, and protect the weaker party." *Orlinsky*, 971 So. at 800 (Fla. Dist. Ct. App. 2007) (quoting *Watkins* v. *NCNB Nat'l Bank of Fla., N.A.*, 622 So.2d 1063, 1065 (Fla. Dist. Ct. App. 1993)).

In Virginia, "there is a fiduciary relationship 'when special confidence has been reposed in one who in equity and good conscience is bound to act in good faith and with due regard for the interests of the one reposing the confidence.'" *Allen Realty Corp.* v. *Holbert*, 318 S.E.2d 592, 595 (Va. 1984) (quoting *H-B P'ship* v. *Wimmer*, 257 S.E.2d 770, 773 (Va. 1979)). "[T]o establish breach of a fiduciary duty, a plaintiff must show that (1) the defendant owed a fiduciary duty (2) the defendant breached that duty and (3) damages resulted from the breach." *Tech Sys., Inc.* v. *Pyles*, 630 F. App'x 184, 187 (4th Cir. 2015) (per curiam).

Plaintiffs mention a few features of their relationship with Genzyme to show the company owed them a fiduciary duty. First, they say Genzyme "maintained and still maintains a close personal relationship with Plaintiffs, including monitoring their health both through individual case managers and through the Fabry registry clinical trial." SAC at ¶474. Second, "[w]hen a shortage of Fabrazyme was imminent, Genzyme undertook to create

a body of experts for reviewing the effectiveness and safety of 'low-dose' Fabrazyme which included doctors and employees of Genzyme." *Id.* at ¶475. Third, Genzyme "created further fiduciary duties by affirmatively undertaking to 'protect the most vulnerable patients' who were the American Fabry patients and then telling each individual plaintiff that it would protect them even though Genzyme knew that Americans did not have free-market access to Replagal." *Id.* at ¶477.

The relationship between Genzyme and Fabry patients may appear closer than a standard relationship between a manufacturer and a consumer, but I do not find that Florida or Virginia would recognize this to be a fiduciary relationship. The complaint does not say where the statements attributed to Genzyme about protecting vulnerable patients come from. More importantly, patients still saw their own doctors and would necessarily have known they were dealing with a private company. As discussed above, Florida and Virginia both follow the doctrine of the learned intermediary. The assumption in these states appears to be that a patient relies on her doctor when making medical decisions, not the manufacturer.

M. Unjust Enrichment

The unjust enrichment claims that Mr. LaForce and the Stanzianos bring against Genzyme also fail.

In Florida, the elements for an unjust enrichment action are: "(1) plaintiff has conferred a benefit on the

defendant, who has knowledge thereof; (2) defendant voluntarily accepts and retains the benefit conferred; and (3) the circumstances are such that it would be inequitable for the defendant to retain the benefit without first paying the value thereof to the plaintiff." *Agritrade, LP* v. *Quercia*, 253 So.3d 28, 33 (Fla. Dist. Ct. App. 2017) (quoting *Peoples Nat'l Bank of Com.* v. *First Union Nat'l Bank of Fla.*, 667 So.2d 876, 879 (Fla. Dist. Ct. App. 1996)). "Equitable" is meant to reference the idea of fairness "and does not mandate that unjust enrichment be construed as seeking only an equitable, as opposed to a legal, remedy." *Duty Free World, Inc.* v. *Miami Perfume Junction, Inc.*, 253 So.3d 689, 694 (Fla. Dist. Ct. App. 2018).

In Virginia, the elements of an unjust enrichment claim are: "(1) [the plaintiff] conferred a benefit on [the defendant]; (2) [the defendant] knew of the benefit and should reasonably have expected to repay [the plaintiff]; and (3) [the defendant] accepted or retained the benefit without paying for its value." *Schmidt* v. *Household Fin. Corp., II*, 661 S.E.2d 834, 838 (Va. 2008). The doctrine "effects a 'contract implied in law' requiring one who accepts and receives goods, services, or money from another to make reasonable compensation for those services." *James G. Davis Constr. Corp.* v. *FTJ, Inc.*, 841 S.E.2d 642, 647 (Va. 2020). "Typical examples of unjust enrichment involve a payment or overpayment under a mistake of fact . . . or the acceptance of services without a contract for those services." *Id.* (internal citation omitted).

Mr. LaForce and the Stanzianos say this doctrine applies because "it would be unjust to allow Genzyme to

retain the monies it charged" for low-dose Fabrazyme, when it knew the low doses sold were "ineffective and dangerous." SAC at ¶484. They say "[t]he scale and level of deception is so unconscionable that restitution to the individual Plaintiffs and disgorgement of the entire monies derived from the sale of 'low-dose' and [v]esivirus contaminated Fabrazyme is required in equity." *Id.* at ¶485.

This argument is unpersuasive. As I discussed in relation to the financial standing issue, Plaintiffs have not shown that what they received from Genzyme was something of lesser value than what they intended to purchase or that they were operating "under a mistake of fact" as to what they would receive. *Cf. Hochendoner I*, 95 F. Supp. 3d at 32 (observing, in discussing an argument on warranties, "[a] shop owner does not warrant that one cup of sugar (the only cup in stock) will make as sweet a cake as the two cups of sugar for which the recipe calls"). Under the sensitization theory, Plaintiffs may have been harmed by the product, but that is an issue for tort law.

N. Loss of Consortium

Ms. Stanziano's loss of consortium claim fails because it is derivative of Mr. Stanziano's claims, which as indicated in this general discussion I will dismiss. *See Gates* v. *Foley*, 247 So.2d 40, 45 (Fla. 1971) (explaining that loss of consortium "is a derivative right and [wife] may recover only if her husband has a cause of action against the same defendant").

Appendix D

VI. THIRD AMENDED COMPLAINT

Having found Plaintiffs' Second Amended Complaint inadequate, even incorporating the new information asserted in the proposed Third Amended Complaint, I will deny the request to file a Third Amended Complaint because doing so would be futile in light of the shortcomings identified for dismissing the Second Amended Complaint.

VII. CONCLUSION

For the reasons set forth above, Genzyme's Motion [ECF No. 102] to Dismiss is GRANTED with respect to all claims made by Plaintiffs. All claims are dismissed without prejudice, except for the claims I address on the merits, which are claims asserted by Mr. LaForce, Mr. Stanziano, Ms. Stanziano, and Ms. Wilkins concerning harm they experienced due to sensitization to Fabrazyme. I DENY as futile the Motion [ECF No. 105] to file a Third Amended Complaint.

/s/ Douglas P. Woodlock
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE

APPENDIX E — ORDER OF DISMISSAL OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS, DATED SEPTEMBER 14, 2022

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO.
21-10023-DPW

TRINA WILKINS, JAMES BISHOP; LISA BISHOP; AMBER BRITTON; TONI CORDOVA; JOHN CORTINA; JILL CORTINA; GEORGE DEMKO; DOVAN HELTON; MARY HELTON; NATE BROOKS; SYDNEY JOHNSON; PLAINTIFF D.J.; DAMON LAFORCE; MICHAEL MASULA; ERIN 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; JEANNE WALLACE INDIVIDUALLY AS SURVIVING SPOUSE OF JOSEPH WALLACE, DECEASED, AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF JOSEPH WALLACE; JAMES WALLACE; AND SAMUEL WALLACE,

Plaintiffs,

v.

GENZYME CORPORATION,

Defendant.

Appendix E

ORDER OF DISMISSAL

WOODLOCK, D.J.

In accordance with this Court's Memorandum and Order [ECF #117] issued on September 14, 2022, granting the Defendant's Motion to Dismiss the Second Amended Complaint, it is hereby ORDERED the above-entitled action be, and hereby is, DISMISSED in its entirety.

BY THE COURT,

/s/ Barbara I. Beatty
Deputy Clerk

DATED: September 14, 2022

APPENDIX F — DENIAL OF REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT, FILED MAY 15, 2024

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,

SANOFI-AVENTIS, SA;
SANOFI-AVENTIS U.S., LLC,

Defendants.

Appendix F

Before

Kayatta, Lynch, Gelpí,
Montecalvo and Rikelman,
Circuit Judges.

ORDER OF COURT

Entered: May 15, 2024

The petition for rehearing having been denied by the panel of judges who decided the case, and the petition for rehearing en banc having been submitted to the active judges of this court and a majority of the judges not having voted that the case be heard en banc, it is ordered that the petition for rehearing and petition for rehearing en banc be denied.

By the Court:

Maria R. Hamilton, Clerk