UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ANITA HOCHENDONER *et al.*,	)	
	)	
Plaintiffs,	)	CIVIL ACTION NO.
	)	11-10739-DPW
	)	
	)	
GENZYME CORPORATION,	)	
	)	
Defendant,	)	

Consolidated with

PHILIP ADAMO *et al.*,	)	
	)	
Plaintiffs,	)	CIVIL ACTION NO.
	)	13-11336 DPW
v.	)	
	)	
GENZYME CORPORATION	)	
	)	
Defendant.	)	

MEMORANDUM AND ORDER
March 25, 2015

Genzyme Corporation is the manufacturer of Fabrazyme®, the only treatment for Fabry disease approved by the Food and Drug Administration ("FDA") available in the United States. In June 2009, due to various problems at its manufacturing facility, Genzyme was unable to manufacturer sufficient Fabrazyme® to meet the demand for the drug. During this shortage, Genyzme 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. The plaintiffs

in these two cases have sued Genyzme, asserting various state and federal claims alleging that they have been harmed by deprivation of the recommended Fabrazyme® dosage.

I. BACKGROUND

A. Factual Background

Plaintiffs are individuals with Fabry disease and their spouses (who make derivative consortium claims) who reside in the states of Arizona, California, Connecticut, Delaware, Florida, Illinois, Indiana, Iowa, Kentucky, Massachusetts, Michigan, Minnesota, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Pennsylvania, Virginia, and Washington. Hochendoner Compl. ¶¶ 1-23, 34; Adamo Compl. ¶¶ 1-87.[1] Fabry disease is a genetic illness characterized by an inability to synthesize the enzyme alpha-galactosidase A. Hochendoner Compl. ¶ 34; Adamo Compl. ¶ 113. If left untreated, it causes premature death from complications including renal disease, heart attack, and stroke. Hochendoner Compl. ¶¶ 34-35; Adamo Compl. ¶ 114. Currently there is no cure, but the disease is effectively treated with enzyme replacement therapy. Hochendoner Compl. ¶ 37; Adamo Compl. ¶ 116.

Fabrazyme® is the only enzyme replacement therapy with Food and Drug Administration ("FDA") approval. Hochendoner Compl.

[1] Counsel for the Plaintiffs have conceded that the Complaints in the *Hochendoner* and *Adamo* cases are substantively the same.

¶ 45; Adamo Compl. ¶ 124. It was developed by Dr. Robert Desnick, an employee of Defendant Mount Sinai School of Medicine of the City University of New York ("Mt. Sinai") with a grant from the National Institutes of Health ("NIH"). Hochendoner Compl. ¶ 39; Adamo Compl. ¶ 118. Mt. Sinai holds a patent for the production method pursuant to the Bayh-Dole Act, and it has exclusively licensed the patent to Defendant Genzyme Corporation ("Genzyme"), which is the sole supplier of the drug to patients in the United States. Hochendoner Compl. ¶¶ 40-41; Adamo Compl. ¶ 119-120. In April 2003, the FDA approved Fabrazyme® for the treatment of Fabry patients based on a recommended prescribed dose of 1 mg/kg of body weight injected every two weeks as an intravenous infusion. Hochedoner Compl. ¶¶ 42-43; Adamo Compl. ¶¶ 121-122.

From April 2003 until approximately June 2009, Genzyme produced enough Fabrazyme® to treat all currently diagnosed U.S. patients. Hochendoner Compl. ¶ 46; Adamo Compl. ¶ 125. A series of incidents, however, then reduced its availability. Sometime before June 2009, a failure to clean and sterilize bioreactors between production batches led to a viral contamination at a Genzyme plant in Massachusetts where Fabrazyme® is manufactured. Hochendoner Compl. ¶¶ 47-49; Adamo Compl. ¶¶ 126-128. Genzyme accordingly reduced production of Fabrazyme®, which led to a shortage in the U.S. market.

Hochendoner Compl. ¶¶ 47-53; Adamo Compl. ¶¶ 126-137. In November 2009, Genzyme produced Fabrazyme® vials that contained contaminants of particulate steel, glass, and rubber, although it is unclear from the Complaints precisely what impact this had on supply. Hochendoner Compl. ¶ 54; Adamo Compl. ¶ 134. Sometime before March 25, 2011, Genzyme produced and destroyed another lot of defective Fabrazyme®, leading to another shortage. Hochendoner Compl. ¶ 75; Adamo Compl. ¶ 169. A further shortfall of product availability on the U.S. market resulted from Genzyme's reallocation of Fabrazyme® stock to European patients. Hochendoner Compl. ¶ 76; Adamo Compl. ¶ 171.

In response to these production and supply issues, Genzyme instituted a rationing plan for Fabrazyme®. On September 23, 2009, Genzyme organized a meeting of the U.S. Fabrazyme Stakeholders Working Group. Hochendoner Compl. ¶ 63; Adamo Compl. ¶ 146. This group, which included Genzyme employees and institutional representatives from a number of hospitals and medical schools (although not from Mt. Sinai), produced a document entitled "Revised Guidance to the U.S. Fabry Community: Management of Fabrazyme® (agalsidase beta for injection) Supply." Hochendoner Compl. ¶¶ 64-65; Adamo Compl. ¶¶ 147-148. The document announced that there was insufficient Fabrazyme® supply to meet market demand for the remainder of the 2009 calendar year. Hochendoner Compl. Exh. B. It stated that

existing patients would be allocated 30% of the recommended prescribed dose for the remainder of 2009 and that newly diagnosed patients should not yet be prescribed Fabrazyme®. *Id*. In January 2010, the allotted dose for existing patients increased to 50% of the recommended prescribed dose. Hochendoner Compl. ¶ 74. Due to a continued shortage, however, as of June 30, 2011, the date of the filing of the Second Amended Complaint in the *Hochendoner* case, U.S. Fabry patients were still allocated less than the FDA-recommended dose of Fabrazyme®. Hochendoner Compl. ¶ 77. Some Fabry patients diagnosed after June 2009 were receiving the reduced doses at the time of the Hochendoner filing, while others were still denied any access to the drug whatsoever. Hochendoner Compl. ¶¶ 81-82.

In August 2011, Genzyme ceased shipping Fabrazyme® in the United States, but not in Europe, and no U.S. patient received any medication from Genzyme during that month. Adamo Compl. ¶ 179. In November and December 2011, Genzyme allowed some patients in the U.S. to return to full dosage, but subsequently returned all patients to a reduced 50% dose. Adamo Compl. ¶ 182. In August 2010, U.S. Fabry patients had asked the NIH to exercise its "march-in rights" under the Bayh-Dole Act to allow other manufacturers to produce Fabrazyme®. Adamo Compl. ¶ 172. The NIH opened a case in March 2011 but closed it on February

13, 2013, based on Mt. Sinai and Genzyme's representations that it was able to fully supply Fabrazyme® to the U.S. market. Adamo Compl. ¶¶ 174, 241.

The pharmocological effectiveness of Fabrazyme® is diminished or negated by reducing the given dose below the FDA-recommended 1 mg/kg, reducing the dosage frequency to less than the FDA-recommended biweekly schedule, or reducing both below the FDA recommendations in combination. Hochendoner Compl. ¶ 44; Adamo Compl. ¶ 123. On November 16, 2010, the European Medical Agency published a statistical study of the Fabrazyme® supply shortage in Europe, which found that patients had an accelerated course of deterioration on the lower dose. Hochendoner Compl. ¶ 104; Adamo Compl. ¶ 163. Because Genzyme has denied Fabry patients access to the drug in FDA-recommended doses, Fabry patients have suffered a return of the symptoms of their life-threatening disease. Hochendoner Compl. ¶ 125; Adamo Compl. ¶ 208.

B. Procedural History

The *Hochendoner* plaintiffs brought their case against Genzyme and Mt. Sinai in March 2011 in the United States District Court for the Western District of Pennsylvania. Defendants moved to dismiss the case as to Mt. Sinai for lack of personal jurisdiction, to dismiss the case for failure to state a claim upon which relief may be granted, and to transfer any

surviving claims to Massachusetts. The court granted Defendants' Motion to Transfer and directed the Clerk to transfer the case to the District of Massachusetts without ruling on the other aspects of the motion to dismiss.

The *Hochendoner* plaintiffs filed their Second Amended Complaint after the transfer to this court. The *Adamo* plaintiffs filed their Complaint in this court against Genzyme and Mt. Sinai in June 2013, which they thereafter amended. Both Defendants moved to dismiss both Complaints. Genzyme filed motions to dismiss the entirety of each Complaint for failure to meet minimum pleading standards under Fed. R. Civ. P. 8 or, in the alternative, to dismiss multiple counts for failure to state a claim upon which relief may be granted under Fed. R. Civ. P. 12(b)(6). Mt. Sinai filed motions to dismiss joining in the arguments presented in Genzyme's motions, adding a number of arguments contending that particular counts should be dismissed for reasons pertaining solely to Mt. Sinai, and further moving to dismiss the entirety of both cases against Mt. Sinai for lack of personal jurisdiction. In addition, both Defendants moved to dismiss the *Adamo* Complaint as duplicative of the already pending *Hochendoner* case.

On November 20, 2013, the plaintiffs in both the *Hochendoner* and *Adamo* cases filed stipulations of dismissal as

to Mt. Sinai, and I have terminated Mt. Sinai from the cases.[2] I have consolidated the *Hochendoner* and *Adamo* matters. Currently

[2] The dismissal of Mt. Sinai as a defendant relieved me of the need to continue to struggle with the less than seamless transfer protocols created by applicable but impractical Supreme Court case law. The *Hochendoner* case originally came to this court in an awkward posture. It arrived by transfer pursuant to 28 U.S.C. § 1404(a) from the United States District Court for the Western District of Pennsylvania before any determination was made whether that District and/or this District had personal jurisdiction over all Defendants. Having concluded that there is no jurisdiction over all Defendants here, I provisionally determined that under governing law, I was obligated to return the case in a similarly awkward posture to the Western District of Pennsylvania, even though it is uncertain whether there is personal jurisdiction there either. This procedural mandate under 28 U.S.C. § 1404(a) was created by the Supreme Court in *Hoffman* v. *Blaski*, 363 U.S. 335 (1960), which interpreted the statute to require that when, as here, the case could not properly have been brought in the transferee court because that court lacks personal jurisdiction over one of the defendants, it must be returned to the transferor court.

Unfortunately, in none of their initial motion to dismiss submissions filed in the Western District of Pennsylvania or in this Court did the parties reference *Blaski*. Having called *Blaski* to the attention of the parties and considered their further responsive submissions in writing and at a hearing on this matter, I found my options limited to one clumsy way forward. The requirements of § 1404(a) and *Blaski* mandated that I could not hear this case on the merits. The limited language of alternative transfer statutes §§ 1406 and 1631, which I have also considered, did not permit me to transfer the matter to yet a third district – the Southern District of New York - that the parties agree could exercise jurisdiction over all Defendants. Instead, I would have been required to return the case to the Western District of Pennsylvania for that court to determine whether to dismiss, sever, or transfer various elements of the matter, some of which might well be returned to this district.

The course of action I found myself reluctantly forced to contemplate was manifestly inefficient but necessary to satisfy the prescriptive formality that *Blaski* imposes on the statutory schemes. I acknowledge that other courts have adopted imaginative and practical strategems for avoiding the clear holding of *Blaski* and the plain meaning of the relevant

pending before me are the motions to dismiss filed in the two matters by Genzyme.

II. STANDARD OF REVIEW

In order to survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009) (internal citations and quotation marks omitted). All factual allegations in the complaint must be taken as true and all reasonable inferences drawn in the plaintiff's favor. *SEC* v. *Tambone,* 597 F.3d 436, 441 (1st Cir. 2010) (en banc). This "highly deferential" standard of review "does not mean, however, that a court must (or should) accept every allegation made by the complainant, no matter how conclusory or generalized." *United States* v. *AVX Corp.,* 962 F.2d 108, 115 (1st Cir. 1992). Dismissal for failure to state a claim is appropriate when the pleadings fail to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." *Berner* v. *Delahanty,* 129 F.3d 20, 25 (1st Cir. 1997) (internal citations

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statutes. For myself, however, I cannot imagine disregarding a clear, if improvident, Supreme Court holding or a statute's plain meaning in an effort to achieve a more practical but unauthorized result. The most I may properly do is make suggestions for changes in the law to avoid repetition of the inefficiencies the current state of the law generated in these circumstances until the dismissal of Mt. Sinai as a defendant.

omitted). The plaintiff must provide "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the ... claim is and the grounds upon which it rests." *Bell Atl. Corp.* v. *Twombly,* 550 U.S. 544, 555 (2007) (internal citations omitted).

III. DISCUSSION

The eighteen-count Second Amended Complaint in the *Hochendoner* case and the thirty-five count Amended Complaint in the *Adamo* case raise several categories of claims. Both Complaints allege violation of the Bayh-Dole Act (Hochendoner Count V & Adamo Count IV); tort law violations, including negligence (Hochendoner Count I & Adamo Count I), negligence per se (Hochendoner Count II), and strict liability (Hochendoner Count III & Adamo Count II); breach of warranty (Hochendoner Count IV & Adamo Count III); breach of contract duties to third-party beneficiaries under New York Law (Hochendoner Count XVII & Adamo Count XXXIV); and loss of consortium (Hochendoner Count XVIII & Adamo Count XXXV). They also allege violations of numerous state consumer protection and product liability laws. Both Complaints allege violations of the California Business and Professional Code (Hochendoner Count XV & Adamo Count VII), the Michigan Product Liability Act (Hochendoner Count XIV & Adamo Count XVI), the Michigan Deceptive Trade Practice Act

(Hochendoner VIII & Adamo Count XVII), the Nevada Deceptive Trade Practices Act (Hochendoner Count VII & Adamo Count XXI), the North Carolina Unfair and Deceptive Trade Practices Act (Hochendoner Count X & Adamo Count XXIV), the Pennsylvania Unfair Trade Practices and Consumer Protection Law (Hochendoner Count VI & Adamo Count XXVII), the Washington Uniform Deceptive Trade Practices Act (Hochendoner Count XII & Adamo Count XXXII), and the Washington Product Liability Act (Hochendoner Count XIII & Adamo Count XXXIII).

The *Hochendoner* Complaint independently alleges violations of the Delaware Uniform Consumer Fraud Act (Hochendoner Count IX), the Florida Deceptive and Unfair Trade Practices Act (Hochendoner Count XI), and the New Jersey Product Liability Act (Hochendoner Count XVI). For its part, the *Adamo* Complaint alleges violations of the Arizona Consumer Fraud Act (Adamo Count V), the Arizona Products Liability Statute (Adamo Count VI), the Connecticut Product Liability Act (Adamo Count VIII), the Connecticut Unfair Trade Practices Act (Adamo Count IX), the Illinois Uniform Deceptive Trade Practices Act (Adamo Count X), the Indiana Products Liability Act (Adamo Count XI), the Indiana Deceptive Trade Practices Act (Adamo Count XII), the Product Liability Act of Kentucky (Adamo Count XIII), the Kentucky Consumer Protection Act (Adamo Count XIV), the Massachusetts Unfair and Deceptive Trade Practices Act (Adamo Count XV), the

Minnesota Unlawful Trade Practices Act (Adamo Count XVIII), the Nebraska Uniform Deceptive Trade Practices Act (Adamo Count XIX), the Nebraska Product Liability Act (Adamo Count XX), the New Mexico Unfair Trade Practices Act (Adamo Count XXII), the New York Deceptive Trade Practices Act (Adamo Count XXIII), the Ohio Product Liability Act (Adamo Count XXV), the Ohio Deceptive Trade Practices Act (Adamo Count XXVI), the South Carolina Product Liability Act (Adamo Count XXVIII), the South Carolina Unfair Trade Practices Act (Adamo Count XXVIII), the Virginia Consumer Protection Act (Adamo Count XXX), and Virginia's Prohibition on False Advertising (Adamo Count XXXI). I consider first whether the Complaints satisfy the pleading requirements of Fed. R. Civ. P. 8 before addressing each category of substantive claims.

1. Minimum Pleading Standards

Genzyme contends that the entirety of Plaintiffs' Complaints fail to meet minimum pleading standards under Fed. R. Civ. P. 8 because the Complaints do not clearly describe which Plaintiffs suffered from which injury. A liberal reading of the Complaints identifies three possible types of causation leading to three possible types of injury suffered by Plaintiffs.

First, Plaintiffs allege that "[t]he pharmacological effectiveness of Fabrazyme® is diminished or negated by reducing the given dose below the FDA recommended 1 mg/kg, by reducing

the dosage frequency by less that [sic] the FDA recommended every two weeks, or reducing both below FDA recommendations in combination." Hochendoner Compl. ¶ 44; Adamo Compl. ¶¶ 122-123. Plaintiffs allege that this reduced dosage results in a return of symptoms for Fabry patients. Hochendoner Compl. ¶¶ 104, 125; Adamo Compl. ¶ 208.

Second, Plaintiffs allege that Fabry patients had "not only a return of life threatening symptoms but also an accelerated course of deterioration on the lowered dose" (emphasis in Complaint), based on the findings of a study conducted by the European Medical Agency ("EMA"). Hochendoner Compl. ¶ 104; Adamo Compl. ¶¶ 161-163.

Third, Plaintiffs allege that "Genzyme produced Fabrazyme® vials that contained contaminants of particulate steel, glass and rubber." Hochendoner Compl. ¶ 54; Adamo Compl. ¶ 154. Plaintiffs generally allege that:

> As a direct result of the Genzyme Rationing Plan and Genzyme's denial of access to drug, dilution of the dose of drug, change in dosing schedules, and sale of adulterated drug, Fabry patients have had a return of symptoms, accelerated disease development, injury, and otherwise preventable disease progression; or Fabry patients have died from these injuries.

Hochendoner Compl. ¶ 125; Adamo Compl. ¶ 208. Plaintiffs provide no more information about their injuries.[3]

[3] The *Adamo* Complaint adds the facts that "[o]bserved injuries to U.S. patients from the diluted dosage were reported as recently

To satisfy the pleading requirements of Fed. R. Civ. P. 8(a), a complaint must give the defendant fair notice of the plaintiff's claims and the grounds upon which they rest. *Swierkiewicz* v. *Sorema, N.A.,* 534 U.S. 506, 512 (2002); *Conley* v. *Gibson,* 355 U.S. 41, 45–46 (1957). Although the first type of injury is adequately pled for purposes of providing notice, the Complaints do not provide fair notice about what claims are being made regarding the second and third possible types of injury and causation.

a. Diminished Effectiveness of Lower Dosage

Plaintiffs have explained that Fabry disease is a life-threatening illness that, without treatment, leads to complications such as renal disease, heart failure, and strokes. Hochendoner Compl. ¶ 35; Adamo Compl. ¶ 14. Fabrazyme® is the only FDA-approved treatment available for Fabry disease in the United States. Hochendoner Compl. ¶ 45. Genyzme was unable to meet the demand for Fabrazyme® and so adopted a rationing plan under which patients, including Plaintiffs, received a dose below the FDA-approved dosage level. Hochendoner Compl. ¶ 77. Plaintiffs allege that diminished dosing reduces the drug's effectiveness in treating the disease, allowing the disease to

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as February 13, 2013 . . . where Dr. Shagun Chopra . . . discussed the injuries he personally observed in his patients." Adamo Compl. ¶ 210. However, none of the plaintiffs are identified as one of Dr. Chopra's patients.

progress and symptoms to return. Hochendoner Compl. ¶¶ 104, 125. Regarding this claim, Plaintiffs' allegations are clear: *every* U.S. Fabry patient has been prevented from receiving the full FDA-recommended dose of Fabrazyme®.[4] Because this injury is alleged to have occurred to each named Plaintiff, and the Complaints identify the state in which each Plaintiff resides, Genzyme has been given fair notice of which states' laws might apply and what the basis of the claim is (the reduced dosage).

As for Genzyme's concern that it does not know the symptoms of each patient, and the progression of the disease for each, these are details that Genzyme could uncover in discovery. The rule 8 pleading standard requires notice, not details. As the U.S. Supreme Court has explained:

> [The] simplified notice pleading standard relies on liberal discovery rules and summary judgment motions to define disputed facts and issues and to dispose of unmeritorious claims. The provisions for discovery are so flexible and the provisions for pretrial procedure and summary judgment so effective, that attempted surprise in federal practice is aborted very easily, synthetic issues detected, and the gravamen of the dispute brought frankly into the open for the inspection of the court.

[4] The Complaints state that Defendants' actions "prevent certain patients in the United States from obtaining the full United States Food and Drug Administration ('FDA') approved and recommended dose of Fabrazyme® for treatment of Fabry disease" and bans "the remaining U.S. Fabry patients from receiving Fabrazye® treatment" at all. Hochendoner Compl. ¶ 33; Adamo Compl. ¶ 109.

Swierkiewicz, 534 U.S. at 512-13 (internal citations omitted). The allegations in the Complaints therefore provide Genzyme with sufficient notice of Plaintiffs' claims that the symptoms of their disease returned due to lack of sufficient medication.

b. Accelerated Deterioration Due to Lower Dosage

Plaintiffs claim that patients had "not only a return of life threatening symptoms but also an accelerated course of deterioration on the lowered dose," based on a study and press release issued by the EMA. Hochendoner Compl. ¶ 104; Adamo Compl. ¶ 163. For the purposes of a motion to dismiss, I may consider documents such as the EMA Assessment Report that are "incorporated by reference in the [complaint]" and provided as exhibits by the Plaintiffs. *Giragosian* v. *Ryan*, 547 F.3d 59, 65 (1st Cir. 2008) (internal citations omitted). Hochendoner Compl. Exh. J; Adamo Comp. Exh. H. The Assessment Report states that the "pattern of adverse events [on reduced dosages of Fabrazyme®] resembles the natural, but accelerated, course of Fabry's disease." Hochendoner Exh. J at 8. Unlike the Complaints, the Report does not juxtapose the "acceleration" with the "return of life threatening symptoms" and does not indicate that the acceleration was something *more* than the return of the life threatening symptoms that occur when Fabry disease goes untreated. Therefore, it is unclear whether the acceleration is as compared to Fabry disease treated with

Fabrazyme® or to Fabry disease in untreated patients. This ambiguity is crucial, because it means the difference between a claim that the lower dosage is less effective at preventing the harm caused by the disease and a claim that the lower dosage is inherently harmful.

If Plaintiffs' claim is the former, then it is effectively subsumed by the first type of causation and injury alleged. To the extent the Plaintiffs attempt to claim the latter, that claim is inadequately pled in the Complaints. Nowhere do the Assessment Report or the Complaints allege that *all* Fabry patients on reduced dosage suffer from the accelerated progress of their disease. If only some suffer in this way, it is impossible to know which of the Plaintiffs complain about this particular injury. *Cf. Carik* v. *U.S. Dep't of Health & Human Servs.*, 4 F. Supp. 3d 41, 51 (D.D.C. 2013) ("While the plaintiffs have submitted reports from the [EMA] indicating that lower doses of Fabrazyme have been associated with 'a steady increase in the number of reported adverse events' in Fabry patients, the Complaint does not indicate that any of the plaintiffs *in this case* have actually suffered from such adverse events." (emphasis in original)), *appeal dismissed* 564 Fed. App'x 1028 (Fed. Cir. 2014).[5]

[5] The *Carik* case provides a counter-example of a plaintiff who adequately alleged injury-in-fact for purposes of standing by

The Complaints are largely composed of state law claims grounded in the common law and statutes of the separate states in which the Plaintiffs reside. Genzyme cannot know whether accelerated disease progression is being claimed by the Plaintiffs from Washington, Pennsylvania, or any other of the twenty-two states under whose laws Plaintiffs' claims arise. Without identifying the Plaintiffs to whom this type of injury applies or otherwise narrowing the universe of bodies of common law and statutes to be applied to these factual allegations, the Complaints fail to provide "fair notice of what the . . . claim is and the grounds upon which it rests." *Swierkiewicz*, 534 U.S. at 512 (internal citations omitted). To the extent that Plaintiffs are attempting to make a claim of accelerated deterioration attributable to the lower dosage, it will be dismissed.

c. Impact of Particulate Contaminants

Plaintiffs' claim regarding contaminants of particulate steel, glass and rubber also fails, for the same reason. Plaintiffs do not allege that all Fabry patients were directly harmed by the contaminants, nor do they allege that any particular Plaintiff or Plaintiffs were injected with the

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alleging that her eyesight was failing, and that without treatment with Fabrazyme®, her loss of sight would be irreversible. *Carik* v. *U.S. Dep't of Health & Human Servs.*, 4 F. Supp. 3d 41, 51 (D.D.C. 2013), *appeal dismissed* 564 Fed. App'x 1028 (Fed. Cir. 2014).

contents of contaminated vials of Fabrazyme® or were otherwise harmed by those contaminants. Moreover, they do not allege that any direct harm to patients flowed from the contaminants. From all that appears, the only way in which the contaminants were harmful was by further diminishing the already insufficient stock of Fabrazyme® available to Fabry patients. As a result, Plaintiffs have identified neither an injury that resulted from the particulates nor those who allegedly suffered from it. This claim falls short of providing fair notice. To the extent that Plaintiffs are attempting to make a claim of direct harm caused by particulate steel, glass, and rubber, it must be dismissed.

d. Conclusion

In sum, the only adequately pled injury that may form a basis for a claim upon which relief may be granted is the return of symptoms and resumed progression of Fabry disease resulting from the diminished effectiveness of Fabrazyme® when provided in doses lower than recommended by the FDA. All other types of injury and causation will be dismissed for failure to satisfy the minimum pleading requirements of rule 8.

I turn now to whether Plaintiffs have stated a claim for relief for this injury under any of the statutory or common law bases they identify.

2. Violation of the Bayh-Dole Act (Hochendoner Count V & Adamo Count IV)

Plaintiffs claim that Genzyme violated the Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015-28, codified as amended at 35 U.S.C. §§ 200 *et seq.*, which provides protections against nonuse and unreasonable use of publicly funded inventions, by producing insufficient Fabrazyme® to treat U.S. Fabry patients. Although Plaintiffs acknowledge that the statute does not explicitly confer a private right of action, they contend that it does so implicitly through its stated policies and objectives, which include "ensur[ing] that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions." 35 U.S.C. § 200. Neither Plaintiffs nor Genzyme cite any case law (nor am I aware of any) regarding whether the Bayh-Dole Act creates a private right of action for patients and other members of the public who use federally supported inventions.[6] As such, this is a matter of first impression.

[6] The parties cite a number of cases holding that there is no implied right of action for individuals claiming a right to the patent and its proceeds. *See, e.g.*, *Fenner Invs., Ltd.* v. *Hewlett-Packard Co.*, No. 6:08-CV-273, 2010 WL 3275758 at *4 (E.D. Tex. Apr. 15, 2010); *Madey* v. *Duke Univ.*, 413 F. Supp 2d. 601, 613 (M.D.N.C. 2006); *Ciba-Geigy Corp.* v. *Alza Corp.*, 804 F.Supp. 614, 629 (D.N.J. 1992). However, these cases do not

Federal courts infer a private right of action only when there is explicit evidence of a Congressional intent to confer one. "Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress. The judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy. Statutory intent on this latter point is determinative." *Alexander* v. *Sandoval*, 532 U.S. 275, 286 (2001) (internal citations omitted).

The Bayh-Dole Act features many of the characteristics that the *Sandoval* Court identified as indicators that Congress has not created a private right of action. The Act "focus[es] on the person regulated rather than the individuals protected." *Id*. at 289. Instead of creating standards for required availability or otherwise discussing the rights of the public, the Act states the obligations of the organizations and businesses patenting publicly funded inventions. *See* 35 U.S.C. §§ 200 *et seq*. This creates "no implication of an intent to confer rights on a particular class of persons." *Sandoval*, 532 U.S. at 289 (internal quotation marks and citation omitted); *see Gonzaga Univ.* v. *Doe*, 536 U.S. 273, 287 (2002) ("provisions [of statute

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address whether Congress intended to create a private right of action for members of the public challenging the nonuse or unreasonable use of inventions from which they could benefit, and are therefore inapposite.

at issue] lack the sort of 'rights-creating' language critical to showing the requisite congressional intent to create new rights" (citing *Sandoval*, 532 U.S. at 288-89). *Contrast Wilder* v. *Va. Hosp. Ass'n*, 496 U.S. 498, 522-23 (1990) (recognizing private enforcement right for Medicaid reimbursement provision because it explicitly conferred monetary entitlement on individuals).

Moreover, 35 U.S.C. § 200 "is yet a step further removed: It focuses neither on the individuals protected nor even on the funding recipients being regulated, but on the agencies that will do the regulating." *Sandoval*, 532 U.S. at 289. Its purpose is not "to protect the public" or "to prevent nonuse or unreasonable use of inventions," but instead "to ensure that the *Government* obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public. . . ." 35 U.S.C. § 200 (emphasis added). When the focus is on the government, not the potential violator, "there is far less reason to infer a private remedy in favor of individual persons." *Sandoval*, 532 U.S. at 289. *Cf. Suter* v. *Artist M.*, 503 U.S. 347, 363 (1992) (statute requiring state agencies to make "reasonable efforts" to keep children out of foster care not enforceable by private individuals in part because statute's focus was on state agencies rather than beneficiaries).

Additionally, "the methods that [the Bayh-Dole Act] goes on to provide for enforc[ement] . . . manifest [no] intent to create a private remedy; if anything, they suggest the opposite." *Id*. The Bayh-Dole Act provides an express remedy, known as the "march-in" right, through which the government may grant a license to manufacture the invention at issue if the relevant Federal agency determines it necessary to meet requirements for public use as determined by regulations or to alleviate health or safety needs. 35 U.S.C. § 203. "The express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others." *Sandoval*, 532 U.S. at 290. As with other federal statutes the Supreme Court has determined not to confer a private right of action, this identified remedy provides a mechanism for federal review of a potential violation of the statute, rather than leaving individuals aggrieved by such a violation without any form of redress. *See, e.g.*, *Gonzaga Univ.*, 536 U.S. at 289-90.

Congress has thus exhibited no intent to create a private remedy for violation of the Bayh-Dole Act.[7] I am not insensitive

[7] Plaintiffs acknowledge this, noting that it is "likely that Congress simply did not consider whether march-in would be a viable remedy" in this type of situation and therefore failed to provide a private remedy. Plaintiffs argue that nonetheless this court should find that the Bayh-Dole Act creates an implied private right of action. They contend that this interpretation is the only way to avoid a reading whereby the Bayh-Dole Act is rendered unconstitutional, because otherwise the Act allows

to Plaintiffs' policy arguments or unsympathetic to their suffering. However, without statutory intent, "a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Sandoval*, 532 U.S. at 286-87. Accordingly, I will dismiss Count V of the Hochendoner Complaint and Count IV of the Adamo Complaint.

3. Liability to Third-Party Beneficiaries of Contract (Hochendoner Count XVII & Adamo Count XXXIV)

Plaintiffs bring a claim alleging that Genyzme violated the duties that it owes them under New York law as third-party beneficiaries to the License Agreement between Genzyme, Mt. Sinai, and Dr. Desnick.

Under New York law, Plaintiffs bear the burden of proving third-party beneficiary status, and to do so they must "establish (1) the existence of a valid and binding contract

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Genzyme to violate their Fifth Amendment rights. They suggest, then, that the only remedy is to allow a *Bivens* action against Genzyme. However, only a state actor can violate Fifth Amendment rights. *Colorado* v. *Connelly*, 479 U.S. 157, 170 (1986). Similarly, only state actors may be sued through a *Bivens* action. *See generally Bivens* v. *Six Unknown State Agents*, 403 U.S. 388 (1971). Plaintiffs point to no case holding or even seriously addressing the argument that a patentholder is, by virtue of its patent power, a state actor. At least one court has rejected the contention without discussion. *Cranford* v. *Castner*, No. 1:08-cv-00160-MP-AK, 2009 WL 4257835 at *1 (N.D. Fla. 2009). Using a property power granted by the federal government does not mean that Genzyme is a part of the federal government. Because it is not a state actor, Genzyme cannot violate the Fifth Amendment and a *Bivens* action is inappropriate.

between other parties, (2) that the contract was intended for [their] benefit, and (3) that the benefit to [them] is sufficiently immediate, rather than incidental, to indicate the assumption by the contracting parties of a duty to compensate [them] if the benefit is lost." *Burnes Jackson Miller Summit & Spitzer* v. *Linder*, 451 N.E.2d 459, 469 (N.Y. 1983). "[T]he parties' intent to benefit the third party must be apparent from the face of the contract. Absent clear contractual language evincing such intent, New York courts have demonstrated a reluctance to interpret circumstances to construe such an intent." *LaSalle Nat'l Bank* v. *Ernst & Young LLP*, 729 N.Y.S.2d 671, 676 (N.Y. App. Div. 2001) (internal citations omitted).

The only language on the "face of the contract" to which Plaintiffs point is the "whereas" language in the recital clause of the License Agreement.[8] Hochendoner Compl. ¶ 218; Adamo Compl. ¶ 377. However, "[a]lthough a statement in a 'whereas' clause may be useful in interpreting an ambiguous operative clause in a contract, it cannot create any right beyond those

[8] Plaintiffs point in particular to the paragraph of the contract which reads in full:

> WHEREAS, [Mt. Sinai] desires to have recombinant x-galactosidase A developed and made available for general use to patients for the treatment of Fabry Disease, and for these purposes is willing to grant an exclusive license to GENZYME upon the terms and conditions set forth below.

Adamo Compl. Exh. A at 1.

arising from the operative terms of the document." *Grand Manor Health Related Facility, Inc.* v. *Hamilton Equities Inc.*, 885 N.Y.S. 2d 255, 256 (N.Y. App. Div. 2009); *see RSL Commc'ns, PLC* v. *Bildirici*, No. 04 Civ. 5217(RJS), 2010 WL 846551 at *4 (S.D.N.Y. 2010) ("New York law holds that a 'whereas' clause can be used to clarify the meaning of an ambiguous contract, but cannot be used to modify or create substantive rights not found in the contract's operative clauses."); *Burr* v. *Am. Spring Spiral Butt. Co.*, 81 N.Y. 175, 178 (1880) (per curiam) ("Recitals in a contract are not strictly any part of the contract, but they may have a material influence in construing the instrument and determining the intent of the parties.").

Plaintiffs do not point to any operative clause in the License Agreement that the recital clause clarifies regarding its underlying intent to benefit Fabry patients. On the contrary, it is significant that none of the operative clauses mentions Fabry patients, and, even more pertinently, that none of the operative clauses creates any obligation for Genzyme to produce sufficient medicine to meet demand. Plaintiffs simply cannot point to any operative clause that Genzyme breached.[9] If

[9] Notably, Article XV of the License Agreement, entitled "Due Diligence," requires Genzyme to "use its reasonable efforts to develop the product for commercialization," including an obligation to initiate studies on the Product intended for use in clinical trials. Adamo Compl. Exh. A at 8. But no due diligence requirements are imposed on Genzyme to use its

an operative clause had suggested an obligation to third-party beneficiaries, perhaps a recital clause could have clarified that the intent of such a clause was to benefit third parties, namely Fabry patients. Here, however, the recital clause cannot clarify intent when there is no operative clause requiring clarification.

Moreover, the recital clause itself is not as precise as Plaintiffs intimate. Plaintiffs argue that the recital clause reflects the intent of the parties to confer a specific benefit on a specific class of individuals. However, the intent reflected in the recital clause, which simply states that Mt. Sinai desires to have the drug developed and made available for general use to Fabry patients, is quite open-textured. The recital clause is far from the "clear contractual language evincing [the] intent" to bestow third-party beneficiary status that New York law requires. *LaSalle Nat'l Bank*, 729 N.Y.S.2d at 676.

Accordingly, I will dismiss Count XVII of the *Hochendoner* Complaint and Count XXXIV of the *Adamo* Complaint.

4. Tort Law Violations (Hochendoner Counts I-III & Adamo Counts I-II)

Plaintiffs make several claims against Genzyme in tort, including negligence (Hochendoner Count I & Adamo Count I),

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reasonable efforts to market or sell the product, or to manufacture the product to meet the demands of the market.

negligence per se (Hochendoner Count II), and strict liability (Hochendoner Count III & Adamo Count II). Although each tort is treated somewhat differently by the governing laws of each of the relevant states,[10] all subparts of the alleged counts share one important requirement. Liability in tort requires the violation of a duty. *See, e.g.*, *Phx. Prof'l Hockey Club, Inc.* v. *Hirmer*, 502 P.2d 164, 165 (Ariz. 1972) ("[T]he existence of a duty to the plaintiff is a prerequisite to tort liability."); *Laczko* v. *Jules Meyers, Inc.*, 80 Cal. Rptr. 798, 799 (Cal. Ct. App. 1969) ("A tort in essence is the breach of a nonconsensual duty owed another."); *Johnson* v. *Indian River Sch. Dist.*, 723 A.2d 1200, 1202-03 (Del. Super. 1998) ("In order for an action in tort to lie against someone, that person must owe a duty to the injured party."), *aff'd*, 723 A.2d 397 (Del. 1998) (unpublished table decision); *First Nat'l Bank* v. *Filer*, 145 So.

[10] Plaintiffs and Genzyme agree that for each respective Plaintiff the law governing the alleged tort violation is that of the state where the Plaintiff resides and where the injury occurred. I concur. Following a 28 U.S.C. § 1404(a) transfer initiated by a defendant, a transferee court must apply the choice-of-law rules that would govern in the transferor court. *Van Dusen* v. *Barrack,* 376 U.S. 612, 639 (1964); *see Ferens* v. *John Deere Co.*, 494 U.S. 516, 519 (1990). Federal courts deploying Pennsylvania choice of law rules have applied the state law of a plaintiff's residence in cases where plaintiffs allege injury by prescription medication, as the plaintiff's state has a strong interest in ensuring the protection of its residents where the residents received the medication and the injury occurred in the state. *See*, *e.g.*, *Wolfe* v. *McNeil-PPC, Inc.*, 703 F. Supp. 2d 487, 494 (E.D. Pa. 2010); *Bearden* v. *Wyeth*, 482 F. Supp. 2d 614, 622 (E.D. Pa. 2006).

204, 206 (Fla. 1933) (per curiam) ("[T]he general test to determine whether there is a liability in an action of tort, is the question whether the defendant has by act or omission disregarded his duty."); *Jahnke* v. *Inc. City of Des Moines*, 191 N.W.2d 780, 783 (Iowa 1971) ("All definitions of tort include as the starting point the violation of a duty running from the alleged wrongdoer to his victim."); *Beaty* v. *Hertzberg & Golden, PC*, 571 N.W.2d 716, 723 (Mich. 1997) ("It is axiomatic that there can be no tort liability unless defendants owed a duty to plaintiff."); *Cochran* v. *Pub. Serv. Elec. Co.*, 117 A. 620, 621 (N.J. 1922) ("Whether there is a right of action in tort depends on whether there is a duty to the plaintiff which the defendant has violated."), *abrogated on other grounds by Weinberg* v. *Dinger*, 524 A.2d 366, 379-80 (N.J. 1987); *Calloway* v. *City of Reno*, 993 P.2d 1259, 1263 (Nev. 2000) ("A tort . . . is a violation of a duty imposed by law"), *overruled on other grounds by Olson* v. *Richard*, 89 P.3d 31, 33 (Nev. 2004); *Coleman* v. *Cooper*, 366 S.E.2d 2, 5 (N.C. App. 1988) ("In tort, it is axiomatic that there is no liability unless the law imposes a duty."), *partially overruled on other grounds by Meyer* v. *Walls*, 489 S.E.2d 880, 886 (N.C. 1997); *Ebbert* v. *Phila. Elec. Co.*, 198 A. 323, 329 (Pa. 1938) ("The test to determine whether there is liability in an action of tort is in the answer to the question whether the defendant by act or omission injured another

disregarding a duty imposed by law in respect to that other."); *Eastwood* v. *Horse Harbor Found., Inc.*, 241 P.3d 1256, 1262 (Wash. 2010) ("An injury is remediable in tort if it traces back to the breach of a tort duty . . . . and the existence of a duty is a question of law . . . ." (internal citations, quotation marks, and alterations omitted)).

Plaintiffs fail to cite a single case establishing that Genzyme has a duty to manufacture sufficient medication to meet market demand. I can find no such case under the law of any state implicated in these actions. The two previous district cases of which I am aware that have considered the issue both determined that no such duty exists. *See Schubert* v. *Genzyme Corp.*, No. 2:12cv587DAK, 2013 WL 4776286 at *7 (D. Utah Sept. 4, 2013) ("Plaintiff's claim that Genzyme has a duty to meet all market demand for Fabrazyme would assert liability on a theory never before recognized in Utah. The court declines to expand Utah law in such a way."), *reconsideration denied*, 2013 WL 6809143 (D. Utah Dec. 20, 2013); *Lacognata* v. *Hospira Inc.*, No. 8:12-cv-822-T-30TGW, 2012 WL 6962884 at *2 (M.D. Fla. July 2, 2012) ("There is no authority that supports Plaintiff's argument that a drug manufacturer, like Hospira, has a duty to continue supplying a patient with a drug that it knows the patient relies upon for his or her medical health."), *aff'd*, 521 Fed. App'x 866 (11th Cir. 2013), *cert. denied*, 134 S. Ct. 458 (2013); *cf.*

William A. Janssen, *A "Duty" to Continue Selling Medicines*, 40 Am. J.L. & Med. 330, 352-61 (2014) (discussing earlier cases rejecting similar tort claims by experimental drug trial patients).

In addition to citing no cases in which a court has found such a duty, Plaintiffs fail to identify indicia that the highest court of any of the relevant states would expand the state's tort law in such a way as to include the proposed new duty of care. "A federal court sitting in diversity cannot be expected to create new doctrines expanding state law." *Gill* v. *Gulfstream Park Racing Ass'n, Inc.*, 399 F.3d 391, 402 (1st Cir. 2005). It is not appropriate for this court to create the proposed duty as a new component of the common law, especially given that it is such a radical departure from the law as it exists.

Accordingly, I decline to recognize a new common law tort imposing a duty to produce patented medication, and I will dismiss Counts I-III of the *Hochendoner* Complaint and Counts I-II of the *Adamo* Complaint.[11]

[11] Genzyme advances a number of other arguments regarding why particular torts in particular states do not apply to the facts alleged. I have, however, in the interest of judicial efficiency addressed only the duty argument which applies to all of the tort claims in all the relevant states.

5. Violation of Consumer Protection Acts (Hochendoner Counts VI-XII and XV & Adamo Counts V, VII, IX-X, XII, XIV-XV, XVII-XIX, XXI-XXIV, XXVI-XXVII, XXIX, XXX, XXXII-XXXIII)

For much the same reasons, I decline to expand the application of the state consumer protection statutes that form the basis of eight counts in the *Hochendoner* Complaint and nineteen counts in the *Adamo* Complaint alleging violations of the consumer protection laws of twenty-one states: Arizona, California, Delaware, Connecticut, Florida, Illinois, Indiana, Kentucky, Massachusetts, Michigan, Minnesota, Nebraska, Nevada, New Mexico, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Virginia, and Washington.

To the extent that Plaintiffs claim that Genzyme misrepresented that Fabrazyme® would be as efficacious at a lower dose as at the FDA-recommended dosage, and that this misrepresentation violates any of these consumer protection statutes, this claim will be dismissed for the same reasons discussed *infra*, Part II(b)(6), regarding warranty. To the extent that Plaintiffs claim that Genzyme engaged in an unfair or deceptive business practice and violated the consumer protection statutes by failing to provide sufficient medication to meet the needs of U.S. Fabry patients, this fails as well.

Plaintiffs do not cite a single case, and I am aware of none, applying any of the cited consumer protection statutes to

prohibit insufficient medication production by a patentholder as an unfair trade practice. For the same reasons that I decline to create a new duty in tort under the common law of the states in which Plaintiffs reside, *supra* Part II(b)(5), I decline to extend the cited consumer protection statutes to create an entirely new field of unfair business practices. It is inappropriate for a federal court sitting in diversity to create a new doctrine under state law in this manner. *Gill*, 399 F.3d at 402. I therefore will dismiss the counts alleging violations of state consumer protection statutes identified above.[12]

6. Breach of Warranty (Hochendoner Count IV & Adamo Count III)

Plaintiffs claim that Genzyme breached both an express and implied warranty to Fabry patients. Limiting the claims of injury to those that meet the minimum pleading standards (discussed *supra*, Part II(b)(1)), Plaintiffs allege that Genzyme impliedly and expressly warranted that a lower dose of Fabrazyme® was approved by the FDA and efficacious for use in the treatment of Fabry disease. Plaintiffs' claims do not rise to the level of plausibility under *Iqbal*.

[12] As with the state common law tort claims, while recognizing that Genzyme has advanced a number of other arguments as to why several of the consumer protection statutes above do not apply to the facts alleged, in the interests of judicial efficiency, I address only the dispositive arguments which apply to all of the consumer protection statutes raised.

Plaintiffs base their express warranty claims on the first two lines of the FDA package insert for Fabrazyme®, which state:

> INDICATIONS AND USAGE: Fabrazyme® (agalsidase beta) is indicated for use in patients with Fabry disease. Fabrazyme reduces globotriaosylceramide (GL-3) deposition in capillary endothelium of the kidney and certain other cell types.

Hochendoner Compl. Exh. A; Hochendoner Compl. ¶ 265; Adamo Compl. ¶ 253. However, Plaintiffs ignore that immediately following these lines in the package insert are dosing directions, indicating the dosage at which the FDA has approved Fabrazyme® and in the context of which the "Indications and Usage" statement must be read. Hochendoner Compl. Exh. A. 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. The mere existence of the first two lines on the FDA package insert does not create a plausible claim that Genzyme made any express warranty regarding the efficacy of Fabrazyme® at a lower dosage.

Plaintiffs contend that even if Genzyme did not expressly warrant the efficacy of Fabrazyme® at a lower dosage, Genzyme offered an implied warranty by reducing the amount of Fabrazyme® available to each patient and by failing to disclose that the lower dosage might be less effective. However, this claim too

fails to pass the plausibility test. Plaintiffs do not allege that Genzyme ever intimated that the lower dosage would be as efficacious in treating Fabry disease as the recommended one. They do not allege that any Plaintiff *believed* that the lower dose would work as well. Instead, Plaintiffs depend on the mere fact that the amount available was limited and that patients could not access the doses and amounts recommended and approved by the FDA.

Plaintiffs offer no case law in support of the proposition that if a merchant has available only a limited amount of a product, the merchant is impliedly warranting that the limited amount will be as powerful or effective as a greater amount. 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. Plaintiffs have not alleged that Genzyme impliedly warranted that less Fabrazyme® would be as effective as the recommended dose. The alleged facts therefore do not "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). I will accordingly dismiss Count IV of the *Hochendoner* Complaint and Count III of the *Adamo* Complaint.[13]

[13] Count XXXI of the *Adamo* Complaint, alleging violation of the Virginia false advertising law, Va. Code §§ 59.1 *et seq.*, fails for the same reasons. Under Va. Code § 59.1-68.3, a plaintiff may bring a claim for losses resulting from an "untrue,

7. Violation of Product Liability Acts (Hochendoner Counts XIII, XIV, and XVI & Adamo Counts VI, VIII, XI, XIII, XVI, XX, XV, XVIII, XXXIII)

Plaintiffs claim that Genzyme violated the product liability laws of ten states: Arizona, Connecticut, Indiana, Kentucky, Michigan, Nebraska, New Jersey, Ohio, South Carolina, and Washington. They do not claim (in allegations that meet the minimum pleading standards) that the Fabrazyme® product in its design or construction was unsafe; instead, Plaintiffs claim that Genzyme produced an insufficient amount of the product. Hochendoner Compl. ¶ 213.

Several of the Plaintiffs' potential theories for claims under these laws have been addressed and deemed inadequate elsewhere in this Memorandum. To the extent that Plaintiffs' claims are predicated on the allegations that Genzyme misrepresented that Fabrazyme® at a lower dose would be as efficacious as Fabrazyme® at the FDA-recommended dose, or that Genzyme failed to warn that Fabrazyme® would not be as efficacious at a lower dose, Plaintiffs' claims will be dismissed for the reasons discussed *supra*, Part II(B)(6). Similarly, to the extent that Plaintiffs' claims allege that

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deceptive or misleading" "promise, assertion, representation, or statement of fact" in an advertisement. *See* Va. Code § 18.2-216. As discussed above, Plaintiffs have not alleged that Genzyme made any untrue or deceptive statements regarding the efficacy of Fabrazyme® at a lower dosage. Accordingly, I will dismiss this Count as well.

Genzyme did not provide adequate warnings or instructions or that the Fabrazyme® product did not comply with express or implied warranties, Plaintiffs' claims will be dismissed for the reasons discussed *supra*, Part II(B)(6, as well). To the extent that Plaintiffs' claims are predicated on the theory that the lower dose itself caused harm (instead of simply failing to prevent harm caused by the disease) or on the theory that the medication was contaminated with glass, rubber and/or steel particulates, Plaintiffs' claims will be dismissed for the reasons discussed *supra*, Part II(B)(1).

What remains are Plaintiffs' claims that Genzyme violated the state product liability laws by failing to manufacture sufficient Fabrazyme® to meet the U.S. market demand and refusing to fill physicians' prescriptions for the FDA-recommended dosage. These allegations fail to state a claim upon which relief may be granted, because the relevant state statutes do not render such conduct actionable.

Mindful of the exclusions discussed above, I conclude that the only possible basis for liability under the relevant state statutes is for the provision of a defective product — either by design or by manufacture. But, the non-provision of a product does not fit within these prohibitions, and Plaintiffs have offered no case suggesting to the contrary. As illustration, the Washington Product Liability Act creates four categories of

liability for manufacturers: (1) failure to warn, (2) breach of warranty, (3) design defects, and (4) manufacturing defects. Wash. Rev. Code § 7.72.030. None of these categories reaches the failure to provide a product to consumers.

Similarly, the New Jersey Product Liability Act defines "product liability action" to mean "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. 2A:58C-1(b)(3). Plaintiffs allege that Genzyme has not produced sufficient medication to meet the needs of U.S. Fabry patients. The harm is caused by the disease and by the paucity of product available; Plaintiffs do not allege — satisfactorily with the pleading standards — that the harm is caused by the product itself. This allegation therefore does not meet the requirements for stating a claim under the New Jersey product liability law.

The Indiana Products Liability Act is similar, providing for liability for "a person who sells, leases, or otherwise puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer or to the user's or consumer's property." Ind. Code § 34-20-2-1. Plaintiffs' claim is not that the product is unreasonably dangerous, but rather that it was fully efficacious but distributed in

insufficient quantity. Others of the identified product liability laws similarly do not afford relief for such a claim. *See, e.g.,* Ct. Gen. Stat. § 52-572m ("'Product liability claim' shall include, but is not limited to, all actions based on the following theories: Strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation or nondisclosure, whether negligent or innocent."); Ky. Rev. Stat. § 411.300 ("[A] 'product liability action' shall include any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, advertising, packaging or labeling of any product.").

Simply put, the claims asserted here are not for the manufacture and distribution of a defective product, as state product liability laws have developed, but are for a failure to manufacture sufficient quantity of a non-defective product. I am aware of no case in which a court has applied a product liability statute to such a claim. As with many of the other claims raised in these Complaints, it would be inappropriate for a federal court sitting in diversity to render an expansion of state laws in the way Plaintiffs request. *Gill*, 399 F.3d at

402. Accordingly, I will dismiss the counts alleging violations state product liability laws identified above.

8. Loss of Consortium (Hochendoner Count XVIII & Adamo Count XXXV)

Plaintiffs from California, Florida, Michigan, New Jersey Pennsylvania, and Washington are the spouses of Plaintiffs suffering from Fabry disease and allege that they have been and will be deprived of their spouse's aid, comfort, assistance, companionship, and consortium. Hochendoner Compl. ¶¶ 226-227; Adamo Compl. ¶¶ 385-386. Loss of consortium is a derivative claim and cannot survive without the underlying counts to support it. *LeFiell Mfg. Co.* v. *Superior Court*, 122 Cal. Rptr. 3d 841, 849 (Cal. Ct. App. 2011), *aff'd in part and rev'd in part*, 282 P.3d 1242 (Cal. 2012); *Jaffe* v. *Snow*, 610 So. 2d 482, 488 (Fla. Dist. Ct. App. 1992); *Long* v. *Chelsea Cmty. Hosp.*, 557 N.W.2d 157, 162 (Mich. Ct. App. 1996), *abrogated on other grounds by Feyz* v. *Mercy Mem. Hosp.*, 719 N.W.2d 1 (Mich. 2006); *Schroeder* v. *Ear, Nose & Throat Assocs., Inc.*, 557 A.2d 21, 22 (Pa. Super. Ct. 1989); *Francom* v. *Costco Wholesale Corp.*, 991 P.2d 1182, 1195 (Wash. Ct. App. 2000). As the discussions in previous sections of this Memorandum make clear, all underlying Counts will be dismissed. Accordingly, I will dismiss the claims for loss of consortium as well.

IV. CONCLUSION

For the above reasons, I GRANT Genzyme's motions (Dkt. No. 32 in *Hochedoner*, Civ. Action No. 11-10739-DPW; Dkt. No. 12 in *Alamo*, Civ. Action No. 13-11336-DPW) to dismiss the Complaints in their entirety for failure to state a claim upon which relief may be granted.

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