UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOSEPH M. CARIK, *et al.*

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*

Defendants.

Civil Action No. 12-272 (BAH)

Judge Beryl A. Howell

MEMORANDUM OPINION

The twelve named and thirteen unnamed plaintiffs (collectively, "the plaintiffs") in this action suffer from certain rare diseases and seek declaratory, injunctive, and monetary relief from the defendants, the United States Department of Health and Human Services and its Secretary, the United States Food and Drug Administration and its Commissioner, the United States National Institutes of Health and its Director, (collectively, "the defendants") to ensure an adequate supply of the medications they need.[1] *See* Compl., ECF No. 1, *generally*. The defendants have moved to dismiss this action under Federal Rules of Civil Procedure 12(b)(1) and (b)(6), claiming this Court lacks subject matter jurisdiction over the action and that the plaintiffs have failed to state a claim upon which relief can be granted. *See* Defs.' Mot. to Dismiss ("Defs.' Mot.") at 1, ECF No. 20. For the reasons set forth below, the defendants' motion is granted.

[1] Another defendant, Mount Sinai School of Medicine, was voluntarily dismissed from this action on April 5, 2013. *See* Not. Vol. Dismissal at 1, ECF No. 26. Thus, Defendant Mount Sinai School of Medicine's Motion to Dismiss, ECF No. 17, is denied as moot.

I. BACKGROUND

The plaintiffs' 470-paragraph, 89-page complaint tends to obfuscate the relevant facts of this matter, as it mixes facts, legal arguments, and political and social theory, often in the same paragraph. *See* Compl. *generally*. As the defendants point out "[t]he precise nature of the claims in plaintiffs' . . . complaint is often difficult to discern." Defs.' Mem. Supp. Mot. Dismiss ("Defs.' Mem.") at 27 n.19, ECF No. 20. At base, this suit is about the defendants' response to two drug shortages, which all parties agree were caused by two manufacturers, Genzyme and Hospira. *See* Defs.' Mem. at 20 ("[M]anufacturers, not the government, produce and distribute prescription drugs, [thus] they are the ones who are responsible for the drug shortages"); Compl. ¶ 72 ("Genzyme created a shortage of Fabrazyme"); Compl. ¶ 87 ("Hospira . . . created a drug shortage by switching manufacturing facilities.").

All but one of the plaintiffs suffer from a rare disease known as Fabry disease and hold "state-issued, lawfully obtained prescription[s] for treatment" with a drug known as "Fabrazyme." *See* Compl. ¶¶ 1–24.[2] Plaintiff Jennifer Lacognata suffers from vitamin A deficiency disease and has a "state-issued, lawfully obtained prescription for treatment" with a drug called "Aquasol A." *Id.* ¶ 25. The plaintiffs allege that they were harmed and continue to be harmed by "interstate drug shortages . . . currently caused by FDA licensees and allowed to continue by the willful inaction of the government agencies tasked with protecting the public health and regulating interstate commerce." *Id.* ¶ 69.

Fabrazyme is the only drug available in the United States to treat Fabry disease, a potentially life threatening ailment. *Id.* ¶ 71. A shortage of the drug began in 2009 after the company that makes the drug, Genzyme, which is not a party to this suit, "introduc[ed]

[2] All facts are taken from the Complaint and assumed to be true for the purposes of a motion to dismiss. *See, e.g., Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

adulterated injectable vials [of] Fabrazyme into interstate commerce." *Id.* ¶ 72. This adulteration, caused by a virus entering the production apparatus in the facility where Genzyme manufactured Fabrazyme, eventually led to a consent decree between the United States Department of Justice and Genzyme, pursuant to which the company paid a substantial fine and pledged to fix the problems at its facility. *See* Consent Decree of Permanent Injunction, *United States v. Genzyme Corp. et al.*, No. 10-cv-10865 (D. Mass.), ECF No. 12 ("Consent Decree") *generally*. The Consent Decree also gave the United States some limited oversight over manufacturing at the facility, *see* Consent Decree ¶¶ 4–5, and specifically authorized Genzyme to "manufacture, process, test, pack, label, hold, and distribute (including for export) or cause any of the foregoing at and from the Allston Facility the drugs Cerezyme, Fabrazyme, Myozyme, and Thyrogen," *id.* ¶ 5A. While the Consent Decree contains strict requirements for the production of some drugs, including Thyrogen, Elaprase, and Aldurazyme, *see id.* ¶¶ 5A–B, only a few provisions apply to Fabrazyme, *see id.*

Aquasol A is manufactured by the pharmaceutical company Hospira, which is not a party to this suit, and is the only drug available for the type of vitamin A deficiency with which Plaintiff Lacognata is afflicted. *See id.* ¶¶ 86–87. The plaintiffs allege that Hospira closed the only facility creating Aquasol A, thus creating a shortage of the drug worldwide. *Id.* ¶ 88. The plaintiffs further allege that the defendants continue to issue licenses to Hospira "despite the fact that over thirty-three discrete shortages in the availability of Hospira [manufactured drugs] on the U.S. marketplace have occurred since the FDA first licensed Hospira." *Id.* ¶ 91.

A description of the regulatory scheme administered by the defendants and within which Genzyme and Hospira operate is helpful to understand the context for the plaintiffs' claims.

A. The Regulatory Framework For Pharmaceuticals

1. *"Drug" and "Biological Product" Licensing*

Under the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"), a "drug," is, *inter alia*, an "article[] intended for use in the . . . mitigation, treatment, or prevention of disease" or "intended to affect the structure of any function of the body of man." 21 U.S.C. §§ 321(g)(1)(B–C). All drugs are "new drugs" until their safety and effectiveness is certified under prescribed conditions. *See* 21 U.S.C. § 321(p)(1). Pharmaceutical companies may not market and distribute new drugs in the United States until the FDA approves the company's "new drug application" ("NDA"), demonstrating the safety and effectiveness of the drug. *See* 21 U.S.C.

§ 355(a).

Under the Public Health Service Act ("PHSA"), ch. 373, 58 Stat. 682 (1944) (codified as amended in scattered sections of 42 U.S.C.), a "biological product" is a "virus, therapeutic serum, toxin, antitoxin, vaccine . . . or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i). A biological product is subject to all the provisions of the FDCA, except that a company need not apply for a drug license under the FDCA if the FDA has already approved a "biologics license application" ("BLA") and granted the company a license for the biological product under the PHSA. *See* 42 U.S.C. § 262(j). The FDA may issue licenses for biological products if, *inter alia*, the product is "safe, pure, and potent," and the manufacturing facility for the product meets certain standards. *See id.* §§ 262(a)(2)(C)(i)(I–II).

2. *Enforcement Authority*

The federal government has certain enforcement powers to stop and punish violations of the FDCA: it may, *inter alia*, (1) seek an injunction against the violation, *see* 21 U.S.C. § 332; (2) criminally prosecute the offender, *see* 21 U.S.C. § 333; and/or (3) seize any materials made in violation of the FDCA, *see* 21 U.S.C. § 334. Notably, there is no statutory enforcement authority to force a drug maker to make more of its product or to mandate particular distribution patterns. *See* 21 U.S.C. §§ 300 *et seq. generally*; Defs.' Mem. at 6 ("FDA does not have the authority to force a private entity to manufacture or distribute its products at all, much less distribute them to particular patients.").

In certain circumstances, the FDA is statutorily authorized to revoke approval of a drug manufacturer's NDA or BLA, but such authorization is limited and may only be exercised after certain actions are taken. The FDA "shall" revoke an approved NDA, for example, only after due notice and an opportunity for a hearing, if the drug is not safe, does not have the claimed effects, or the manufacturer fails to file required paperwork. *See* 21 U.S.C. § 355(e). The FDA "may," after notice and an opportunity for a hearing, revoke an approved NDA if the drug manufacturer fails to comply with certain requirements, including for recordkeeping, processing, and labeling. Specifically, an NDA may be revoked when "the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity," or the drug's labeling is false or misleading. *See id.* The circumstances under which the FDA shall or may revoke an approved application do not mention or relate in any way to drug shortages or distribution patterns of the manufacturers. *See id.*

The PHSA requires the FDA to promulgate regulations governing the revocation of an approved BLA, 42 U.S.C. § 262(a)(2)(A), and the associated regulations provide for such a revocation if: (1) FDA staff cannot inspect a manufacturing facility because they cannot access the facility or because the manufacturer has discontinued production "to an extent that a meaningful inspection or evaluation cannot be made"; (2) the manufacturer does not report a change to its application under 21 C.F.R. § 601.12; (3) the manufacturer's facility fails to meet the applicable standards provided for in the license; (4) the manufacturing center or methods have changed to such a degree that a new "showing that the establishment or product meets the requirements established" in the PHSA regulations is required; (5) "[t]he licensed product is not safe and effective"; or (6) the licensed product "is misbranded with respect to any [intended] use." *See* 21 C.F.R. §§ 601.5(b)(1)(i–vi). Similarly to the NDA requirements, due notice and a hearing must be held before a BLA may be revoked. 21 C.F.R. § 601.5(b)(1). Also similarly to the NDA requirements, no federal regulations authorize the FDA to revoke or suspend an approved BLA because the drug manufacturer causes a shortage, exports its drugs, or institutes a rationing program. *See id.*

3. *The Bayh-Dole Act*

Drugs developed, at least in part, with federal funding are subject to what is commonly referred to as the Bayh-Dole Act ("the Act"), 35 U.S.C. §§ 200 *et seq*. The Act is designed "to ensure 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. To effectuate this goal, the Act provides the federal government with "march-in rights," which consist of the right to require a "contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive

license in any field of use to a responsible applicant or applicants" in certain situations. *See* 35 U.S.C. § 203(a). Among those situations is when a "Federal agency determines that such . . . action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees." 35 U.S.C. § 203(a)(2). "To date, the government has never exercised its march-in authority." Defs.' Mem. at 11.

B. The Drug Shortages

The plaintiffs' complaint centers on shortages of the two drugs at issue, Fabrazyme and Aquasol A. The circumstances of each shortage are outlined below.

1. *Fabrazyme Shortage*

In June 2009, "in response to a viral contamination at the plant where Fabrazyme is manufactured," Genzyme "shut down and sanitized" the facility, "causing an interruption in production and a temporary Fabrazyme shortage." Compl. Ex. H ("Revised Guidance to the U.S. Fabry Community: Management of Fabrazyme (agalsidase beta for injection) Supply") at 4, ECF No. 1-8. In response to the shortage, Genzyme convened a "Fabrazyme Stakeholders Working Group" ("FSWG"), consisting of representatives from Genzyme as well as the Fabry Support and Information Group, the National Fabry Disease Foundation, and the Fabry Registry North American Board of Advisors, to recommend action to effectively manage the remaining supply. *See id.* at 1, 4. The FSWG recommended that prescribing physicians provide Fabrazyme doses at "approximately 80% of normal levels, which would be achieved by asking all patients to miss the equivalent of two doses, either by skipping two full infusions or receiving a half-dose for four infusions." *Id.* at 4. When resumption of normal production was delayed, the FSWG recommended reducing dosage levels to thirty percent of normal "to avoid a complete depletion

of the medication." *Id*. at 4–5. These reduced dosage levels persisted until early 2012. *See* Defs.' Mem. Ex. E ("Genzyme Press Release dated March 1, 2012") at 2, ECF No. 20-5.

During the shortage, European patients generally received full doses of Fabrazyme or were prescribed an alternative treatment, due in part to "regulatory authorities recommend[ing] that patients be treated at a full dose or switched to an alternate product." Compl. Ex. G ("Genzyme Fabrazyme (agalsidase beta) Supply Update, Frequently Asked Questions, October 3, 2011") at 1, ECF No. 1-7. The defendants note that a drug called Replagal, which is similar to Fabrazyme but not FDA approved, is available in Europe and was briefly available in the United States during the shortage under an "investigational new drug application . . . which provided U.S. Fabry patients access to the drug while [the drug's manufacturer] pursued market approval."[3] Defs.' Mem. at 15 n.11; *see also* Compl. Ex. M ("European Medicines Agency press release dated October 22, 2010") at 2, ECF No. 1-13 (noting availability in Europe of Replagal). The European Medicines Agency ("EMA") noted that "there has been a steady increase in the number of reported adverse events" in patients since the introduction of the lower Fabrazyme dosages and recommended that only full doses of Fabrazyme or Replagal be administered to patients, with a few exceptions. *Id.* at 1–2. No United States organization, including the FDA, made any similar recommendations for U.S. patients. *See* Compl. *generally*.

2. *Aquasol A Shortage*

Hospira is the sole source of injectable Vitamin A, marketed as Aquasol A, for patients with Vitamin A deficiency. *See* Compl. ¶¶ 376–381. In 2010, Hospira began the process of transferring production of Aquasol A to a different manufacturing facility, resulting in a worldwide shortage of the drug. *Id.* ¶ 384–85. Hospira anticipated returning to shipping the

[3] The manufacturer "submitted a BLA to market Replagal in the United States, but withdrew the BLA in March 2012." Defs.' Mem. at 15 n.11.

medicine by the end of 2012, *id*. ¶ 389, but the FDA's website indicates the shortage is still ongoing. *See* Current Drug Shortages, http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm314743.htm#vitamina.[4]

C. The Plaintiffs' Administrative Efforts

The plaintiffs involved in this litigation made various protests to the defendants prior to filing suit. Those efforts appear to form the basis of their due process claim and are described briefly here.

1. *The Bayh-Dole March-In Petition To The NIH*

In 2010, plaintiff Joseph Carik and other Fabry patients requested through counsel that the "NIH use its march-in authority on U.S. Patent No. 5,356,804," the patent for Fabrazyme. *See* Defs.' Notice of NIH's Decision to Close the March-In Petition ("Defs.' Notice") Ex. A (Letter regarding "2010 Request to HHS to Exercise its Bayh-Dole March-In Authority on U.S. Patent No. 5,356,804") at 1, ECF No. 24-1. The NIH declined to do so, "because any licensing plan that might result from such a proceeding would not, in the judgment of NIH, address the problem [Plaintiff Carik and others] identified," namely, the drug shortage.[5] *Id.* Nevertheless, "[d]ue to the seriousness of Fabry patients' need to obtain their full prescribed dose of Fabrazyme, NIH required [the patent owner, Mount Sinai,] to report on the status of Fabrazyme availability." *Id.* From 2010 through the end of the drug shortage, no third party manufacturer

[4] The Court may take judicial notice of facts that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." FED. R. EVID. 201(b)(2); *see also Cannon v. District of Columbia*, 717 F.3d 200, 205 n.2 (D.C. Cir. 2013) (taking judicial notice of facts available on government website).

[5] Specifically, the NIH found that granting "patent use rights to a third party will not increase the supply of Fabrazyme in the short term because years of clinical studies and regulatory approval would be required before another manufacturer's product could become available to meet patients' needs" and the NIH had "no information that a company is expecting imminent FDA approval of a competing version" of Fabrazyme. Defs.' Mot. Ex. A ("Determination in the Case of Fabrazyme Manufactured by Genzyme Corporation") at 1, ECF No. 20-1. Further, the NIH determined that the patent at issue was "not an obstacle for a company to conduct clinical trials in the United States in furtherance of regulatory approval . . . because such clinical trials are exempt from infringement under the Hatch-Waxman statutory safe harbor provision." *Id.* Finally, the NIH credited Genzyme's expectation that "production of Fabrazyme [would] be back to full supply levels in the first half of 2011," *id.* at 1–2, noting that "Genzyme appears to be working diligently and in good faith to address the Fabrazyme shortage," *id.* at 2.

requested to license the patent from Mount Sinai, Genzyme, or the NIH, and by early 2013, the drug shortage was over. *Id.* Consequently, the NIH closed its march-in case in February, 2013. *Id.* at 2.

2. *The Citizen's Petition To The FDA*

In January, 2011, plaintiff Joseph Carik and Amber Britton, a person who is not party to this litigation, submitted a citizen petition to the FDA "to request that the Commissioner of Food and Drugs allocate full doses of agalsidase beta (Fabrazyme®) to U.S. citizens under its consent decree with Genzyme and/or its patent license under 35 U.S. [sic] § 202." Defs.' Mem. Ex. B ("Citizen Petition") at 2, ECF No. 20-2; *see* Compl. ¶ 342. The petition alleges that the petitioners' constitutional right to due process was violated because Genzyme was rationing Fabrazyme in the United States and that, under the consent decree between the FDA and Genzyme entered into before the shortage began, the FDA could "define the scope of distribution of Fabrazyme." Citizen Petition at 7–8. The petitioners also accused the FDA of "tacitly adopt[ing] the rationing scheme." *Id.* at 8. The FDA indicated to the petitioners that "the issues [in the petition] were 'complex' and required more time to analyze." Compl. ¶ 344. The FDA has not offered any other substantive response to the petition. *Id.* ¶ 345.

D. The Instant Litigation

The plaintiffs filed this action against the federal defendants and Mount Sinai School of Medicine in February, 2012. They allege five causes of action: (1) "Violations of the Doctrine of Separation of Powers"; (2) "Violation of the 10th Amendment of the United States Constitution"; (3) "Violation of the Patent Clause of the US [sic] Constitution"; (4) "Violation of the 5th Amendment"; and (5) "Violation of the Food, Drug and Cosmetics Act." Compl. ¶¶ 417–470. The federal defendants timely moved to dismiss all claims for lack of subject matter

jurisdiction under Federal Rule of Civil Procedure 12(b)(1), alleging that the plaintiffs lack standing, and under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. *See* Defs.' Mot. at 1. Since the plaintiffs do not meet the requisite standing requirements, it is unnecessary to discuss the parties' arguments under Rule 12(b)(6).[6]

II. LEGAL STANDARD

A. Subject Matter Jurisdiction

A federal court has "an affirmative obligation to consider whether the constitutional and statutory authority exist" for it to hear a case. *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1092 (D.C. Cir. 1996) (internal quotation marks omitted). When a purported lack of jurisdiction stems from a lack of standing, however, the court "must assume that [the plaintiff] states a valid legal claim." *Info. Handling Servs., Inc. v. Def. Automated Printing Servs.*, 338 F.3d 1024, 1029 (D.C. Cir. 2003). The proponent of jurisdiction bears the burden of proving that jurisdiction exists. *Khadr v. United States*, 529 F.3d 1112, 1115 (D.C. Cir. 2008). While "the district court may consider materials outside the pleadings," it must "still accept all of the factual allegations in the complaint as true." *Jerome Stevens Pharm., Inc. v. FDA*, 402 F.3d 1249, 1253 (D.C. Cir. 2005) (citations and internal quotation marks omitted). "If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action." FED. R. CIV. P. 12(h)(3).

B. The Requirements for Article III Standing

Article III of the United States Constitution limits the federal judicial power to the resolution of "Cases" and "Controversies." U.S. CONST. art. III, § 2. "In limiting the judicial

[6] Notably, the plaintiffs concede that the "counts [in the Complaint] are not causes of action *per se*, but the bases for which this court may find authority to effect equitable relief." Pls.' Opp'n to Defs.' Mot. Dismiss ("Pls.' Opp'n") at 28, ECF No. 22. Given this apparent acknowledgment of the deficiencies in the assert legal claims, even if the plaintiffs were able to establish standing, which they cannot, dismissal under Rule 12(b)(6) would be likely for the reasons set out in the defendants' thorough briefing. *See* Defs. Mem. at 27–48.

power to 'Cases' and 'Controversies,' Article III of the Constitution restricts it to the traditional role of Anglo-American courts, which is to redress or prevent actual or imminently threatened injury to persons caused by private or official violation of law." *Summers v. Earth Island Inst.*, 555 U.S. 488, 492 (2009). In other words, "[t]he case-or-controversy doctrines state fundamental limits on federal judicial power in our system of government." *Allen v. Wright*, 468 U.S. 737, 750 (1984). "The Art[icle] III doctrine that requires a litigant to have 'standing' to invoke the power of a federal court is perhaps the most important of these doctrines." *Id.* Thus, "standing is a 'threshold jurisdictional question' we must address [] first." *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 943 (D.C. Cir. 2012) (quoting *Byrd v. EPA*, 174 F.3d 239, 243 (D.C. Cir. 1999)).

As the Supreme Court has explained, "the irreducible constitutional minimum of standing contains three elements." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). "First, the plaintiff must have suffered an injury in fact," i.e., "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Id.* (citations and internal quotation marks omitted). Second, "there must be a causal connection between the injury and the conduct complained of," i.e., the injury alleged must be "fairly traceable to the challenged action of the defendant." *Id*. (internal quotation marks omitted). Finally, it must be likely that the injury will be redressed by a favorable decision. *Id.* at 561. Moreover, when a plaintiff seeks prospective declaratory or injunctive relief, allegations of past harms are insufficient. *See, e.g.*, *Dearth v. Holder*, 641 F.3d 499, 501 (D.C. Cir. 2011). Rather, when declaratory or injunctive relief is sought, a plaintiff "must show he is suffering an ongoing injury or faces an immediate threat of [future] injury." *Id.* (citing *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983)).

III. DISCUSSION

The defendants challenge the complaint on the grounds that the plaintiffs' lack standing to bring any of their claims.[7] *See* Defs.' Mem. *generally*. Although the defendants assume for purposes of their argument "that plaintiffs have alleged the requisite injury" as a result of the drug shortages, Defs.' Mem. at 19; Defs.' Reply at 2, and focus instead on the sufficiency of the plaintiffs' showing of causation and redressability, the Court begins with an examination of the alleged injury in fact before turning to the other two prongs of the standing test.

A. Injury in fact

The plaintiffs assert two types of injuries: health-related, physical injuries in connection with the drug shortages and "deprivation of their Constitutionally protected civil rights." *See* Pls.' Opp'n to Defs.' Mot. Dismiss ("Pls.' Opp'n") at 7, ECF No. 22. Each class of injuries is discussed below.

1. *Physical Injuries Related to Drug Shortages*

To plead an injury in fact, the plaintiffs must allege "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan* 504 U.S. at 560 (citations and internal quotation marks omitted). Close scrutiny of the plaintiffs' Complaint reveals that only Plaintiff Lacognata has identified a sufficiently concrete, particularized, and actual or imminent injury as a result of the inability to obtain her medication. *See* Compl. ¶ 394 ("Vitamin A deficiency has already caused Plaintiff Mrs. Lacognata's eyesight to worsen to the extent that she has lost sight in one eye and is losing sight in the other eye."). While the plaintiffs have submitted reports from the European Medicines Agency ("EMA") indicating that lower doses of Fabrazyme have been associated with

[7] As noted, the defendants further argue that even if the plaintiffs could rightfully bring their claims, they fail to state a facially plausible claim for relief, *see* Defs.' Mem *generally*, but it is unnecessary to consider these arguments since the Court finds the plaintiffs lack standing.

"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. *See* Compl. *generally*. Such actual effects are necessary to give rise to standing under the injury in fact prong. *See Public Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1292 (D.C. Cir. 2007) ("*Public Citizen*").

Public Citizen is instructive on this point. In that case, a consumer advocacy organization sued a government agency in an attempt to stop a regulation for automobile tires that would, allegedly, "creat[e] a higher risk of injury than if [the agency] adopted the alternative regulation that [the advocacy organization] advanced." *Id.* at 1291 (internal quotation marks omitted). The court found that, while the harms alleged, namely, car accidents, would be concrete and particularized if they occurred, they were too speculative and remote to support Article III standing. *Id.* at 1294. Since there was no indication that members of the advocacy organization in fact faced the threat of imminent harm in a car accident, the organization was unable to meet the "imminence" prong of the injury in fact analysis. *See id.* at 1293 ("The 'imminence' problem arises because no one can say who those several hundred individuals [who would be involved in car accidents] are out of the 300 million people in the United States, nor can anyone say when such accidents might occur."); *see also Chamber of Commerce v. EPA*, 642 F.3d 192, 202 (D.C. Cir. 2011) ("[B]ecause the petitioners could 'only aver that any significant adverse effects . . . may occur at some point in the future,' they failed to show 'the actual, imminent, or certainly impending injury required to establish standing.'") (alteration in original) (quoting *Ctr. for Biological Diversity v. U.S. Dep't of Interior*, 563 F.3d 466, 478 (D.C. Cir. 2009)); *Electronic Privacy Info. Ctr. v. U.S. Dep't of Educ.*, No. 12-0327, 2013 WL 5377827, at *6 (D.D.C. Sept. 26, 2013) (holding that plaintiffs failed to show imminence of harm where they had "not shown a

substantially increased risk that they will suffer identity fraud" or "that the absolute likelihood of suffering identity fraud is substantial" as a result of a proposed agency rule)

For all of the plaintiffs except Plaintiff Lacognata, the Complaint merely alleges that there is a possibility that adverse effects may result from taking a diluted dose of Fabrazyme. *See* Compl. ¶ 306 ("Ineffective dosing by intravenous infusion is medically dangerous because patients risk a potentially lethal infusion reaction every time they are treated. If patients do not obtain the medical benefit of the infusion, then there is there is [sic] no medical reason to risk injury and death by being infused with the drug."). Although at the motion to dismiss stage of the proceedings, the Court must accept the allegations in the Complaint as true, the Complaint does not allege that any of the plaintiffs *actually suffered* an adverse event as a result of taking the diluted dose of Fabrazyme. *See* Compl. *generally*. Rather, the Complaint alleges that such adverse events are possible, based on a European medical study. *See* Compl. ¶ 314 (discussing the EMA study).

In contrast, Plaintiff Lacognata claims that her eyesight is failing and "[w]ithout treatment soon, Plaintiff Mrs. Lacognata's loss of sight will be irreversible." *Id.* ¶ 395. This is the sort of harm necessary to show the particularized, concrete, imminent injury required for Article III standing. *See Public Citizen, Inc.*, 489 F.3d at 1297 (finding "death, physical injury, and property damage" to be "concrete and particularized injuries" for Article III standing); *id.* at 1293 (contrasting having "actually been in a car accident," which would provide Article III standing, with speculative future car accidents that did not). The plaintiffs suffering from Fabry disease are, instead, asserting the more generalized "increased-risk-of-harm" claims the D.C. Circuit expressly rejected in *Public Citizen*, namely, that there is a risk of adverse effects from taking a diluted dose of Fabrazyme. *See id.* at 1294 ("[W]e have said many times before and

reiterate today: *Allegations of possible future injury do not satisfy the requirements of Art[icle] III*. A threatened injury must be certainly impending to constitute injury in fact.") (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 148 (1990)) (emphasis and alterations in original).

Although the type of risk of harm case presented by the plaintiffs here is generally disfavored in this Circuit, standing based on "probabilistic injuries" is not completely barred. *See Mountain States Legal Found. v. Glickman*, 92 F.3d 1228, 1234 (D.C. Cir. 1996). Indeed, the D.C. Circuit has noted that "[e]nvironmental and health injuries often are purely probabilistic." *Natural Res. Def. Council v. EPA*, 464 F.3d 1, 6 (D.C. Cir. 2006). In such cases, the plaintiffs must "demonstrate a 'substantial probability' that they will be injured." *Id.* In *Public Citizen*, the court elaborated on this requirement, noting that there must be "*both* (i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm with that risk taken into account." *Public Citizen, Inc.*, 489 F.3d at 1295 (emphasis in original).

In the instant case, the 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. *See id*. Furthermore, the plaintiffs have not alleged *any* past physical injury caused by the diluted dosages of Fabrazyme. *See* Compl. *generally*. While in *Public Citizen*, the D.C. Circuit found it appropriate to seek supplemental briefing on the substantiality of the probability of injury, *see Public Citizen* at 1296, such supplemental briefing is unnecessary here. The plaintiffs have failed to allege that any of them suffered physical harm as a result of receiving diluted Fabrazyme doses, or that there is an adequate possibility of future harm, since they have failed to show or plead that any of them are unable now to obtain full doses of Fabrazyme *See* Pls.' Opp'n at 25.

Moreover, to support their claims for declaratory and injunctive relief, the plaintiffs must prove both that they suffered harm and that for "the kind of conduct the suit seeks to enjoin" there is "a real and immediate threat that the harm-producing conduct will recur." *Coalition for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1280 (D.C. Cir. 2012) (citing *City of Los Angeles*, 461 U.S. at 105) (internal quotation marks omitted). Thus, for the Fabrazyme-related claims, the plaintiffs failed to surmount two obstacles: they have not alleged they suffered a physical injury in fact, *see supra*, and their effort to show a continuing threat of a drug shortage falls short. For the latter showing, the plaintiffs offer the conclusory allegation that "not all patients are receiving Fabrazyme," citing as support one of the defendants' exhibits to their Motion to Dismiss. *See* Pls.' Opp'n at 25 (citing Defs.' Mem. Ex. E). Yet, the exhibit the plaintiffs rely upon states the opposite: "[P]atients in the U.S. are now able to return to full dosing in March [2012]. In addition, all new patients in the U.S. are eligible to begin Fabrazyme treatment, at full dosing levels." Defs.' Mem. Ex. E. at 1.

The plaintiffs further argue in support of the immediacy of the threat that "the reasonable inference is that the supply line [for Fabrazyme] is fragile and without spare inventory so there is an imminent threat to Genzyme reinstituting its rationing program." Pls.' Opp'n at 25. In the absence of any supporting documentation or evidence, even at the motion to dismiss stage, such a bald assertion is insufficient to support subject matter jurisdiction, absent an allegation of any actual physical harm caused by the shortage, and the plaintiffs' citation of the defendants' exhibit, which states that the shortage is, in fact, over. *See Whitmore*, 495 U.S. at 158 ("A threatened injury must be *certainly impending* to constitute injury in fact.") (emphasis added). Since the plaintiffs suffering from Fabry disease do not assert either an actual or impending injury or even a substantial probability of such injury, they lack standing under Article III to

bring this suit based on "physical injuries."[8] Plaintiff Lacognata's claims, however, do clear this hurdle.

2. *"Constitutional Injuries" Related To Drug Shortages*

The plaintiffs do not rely on physical injuries alone in their attempt to prove standing. They also allege various "constitutional injuries." Pls.' Opp'n at 8. These injuries include (a) "denial of access to FDA approved medications entirely on the patients' nationality[,]" *id.*; (b) injuries derived from the FDA's alleged failure to inform the court that entered the Consent Decree of the drug shortage, *id.*; (c) deprivation of state police powers under the Tenth Amendment, *id.* at 31; (d) subjective fear of filing for relief with the Courts, *id.* at 14; and (e) various generalized grievances about improper government conduct, *id.* at 1-2, 7, 9-10, 11, 21-22, 29-31, 32, 35.[9] None of these alleged injuries are sufficient to confer Article III standing on any of the plaintiffs. Each alleged injury is discussed individually below.

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[8] The plaintiffs spill considerable ink on the decision in *Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), in which another Judge in this Court found that death row inmates had standing to challenge an FDA determination allowing the importation of a drug used in some states' lethal injection protocols. *Beaty*, 853 F. Supp. 2d at 36–37. *Beaty* is inapposite and not binding here. First, contrary to the plaintiffs' assertion, a decision from another Judge in this District is not "controlling authority on this District," Pls.' Opp'n at 2, making *Beaty*, at best, persuasive authority. *See, e.g.*, *In re Executive Office of the President*, 215 F.3d 20, 24 (D.C. Cir. 2000) ("District Court decisions do not establish the law of the circuit, nor, indeed, do they even establish the law of the district.") (internal citations and quotation marks omitted). Second, *Beaty* was an action brought under the Administrative Procedure Act, 5 U.S.C. §§ 701 *et seq.*, *Beaty*, 853 F. Supp. 2d at 32, a type of action which the plaintiffs are affirmatively not bringing here. *See* Pls.' Opp'n at 3 ("Plaintiffs requested relief is made in equity not under the statutory authority of the APA"). Finally, in *Beaty*, the court found that the plaintiffs had alleged a sufficiently concrete, particularized, and imminent injury in fact since they were "facing lethal injection" in states that planned to use the drug, which could "fail to anesthetize plaintiffs properly during execution, causing conscious suffocation, pain, and cardiac arrest." *Beaty*, 853 F. Supp. 2d at 36. Since the death row inmates were actually scheduled to be executed using the drug, it is unsurprising that the *Beaty* court found the imminence prong of Article III standing satisfied in that case. In the instant case, however, there is no evidence that the plaintiffs will suffer any injury from an inability to obtain Fabrazyme, particularly since the drug shortage is over. *See* Defs.' Mem. Ex. E at 1.

[9] The plaintiffs also state they were deprived of due process and the equal protection of laws. *See* Compl. ¶ 455. The plaintiffs make no colorable allegations in their complaint or their opposition as to what process they were due or how it was violated. *See* Compl.; Pls.' Opp'n *generally*. To the extent the plaintiffs are alleging a lack of equal protection due to national origin discrimination, this alleged injury is addressed in Part III.A.2.a. The Court is unable to make out any colorable allegations of a due process violation, let alone sufficient allegations upon which to predicate Article III standing, in the plaintiffs' Complaint or briefing.

a) National Origin Discrimination

The plaintiffs argue that "Genzyme and the Defendants based the decision (or approval of the decision) for the denial of access to FDA approved medications entirely on the patients' nationality." *Id.* at 8. Assuming, *arguendo*, that such a decision-making process would be a constitutional violation sufficient to give rise to Article III standing, the plaintiffs have not plead such discrimination actually occurred.

The plaintiffs rely upon the alleged availability of full doses of Fabrazyme in Europe, but not in the United States, to support their discrimination claim. *See, e.g.*, Pls.' Opp'n at 8; Compl. ¶ 356. Yet, the plaintiffs' Complaint does not contain any information about the national origin of the plaintiffs except that they are all American citizens. *See* Compl. ¶¶ 1–24. The plaintiffs do not claim that they were prohibited from obtaining Fabrazyme during the drug shortage because of their nationality; rather, they claim they were precluded from obtaining Fabrazyme because of their location. *See, e.g.*, Compl. ¶ 245 ("Genzyme honors overseas prescriptions [for] full doses"); ¶ 259 ("Genzyme has also vetoed all Massachusetts's [sic] doctors' prescriptions for Fabrazyme, in favor of shipping the drug out of the [sic] Massachusetts for patients overseas"); ¶ 273 ("When the EMA banned diluted dosing of Fabrazyme in Europe, Genzyme immediately capitulated by providing full doses overseas . . ."). The plaintiffs do not suggest that Genzyme would provide a German citizen living in the United States with full doses of Fabrazyme, or provide a United States student studying abroad in France with diluted Fabrazyme because of their national origin, as required to plead a colorable discrimination claim.

The Supreme Court has held that "[w]hen the government erects a barrier that makes it more difficult for members of one group to obtain a benefit than it is for members of another group . . . [t]he injury in fact in an equal protection case . . . is the denial of equal treatment

resulting from the imposition of the barrier, not the ultimate inability to obtain the benefit." *N.E. Fla. Chap. Of Assoc. Gen. Contractors of Am. v. City of Jacksonville*, 508 U.S. 656, 666 (1993) ("*Florida Contractors*"). The groups the Court was speaking of in *Florida Contractors* were ethnic groups, specifically various ethnic minorities, *id.* at 658, which are recognized protected classes. *See, e.g.*, *Primas v. District of Columbia*, 719 F.3d 693, 697 (D.C. Cir. 2013) (discussing classes of people based on "race, color, religion, sex, and national origin" as "protected classes" for discrimination claims). Differentiation based on country of current residence, due to the different regulatory regimes present in each location, *see, e.g.*, *id.* ¶¶ 271, 273, is not discrimination based on a suspect class in the same way as discrimination based on race or ethnicity, which was found to confer standing in *Florida Contractors*. *See Florida Contractors*, 508 U.S. at 666.

The plaintiffs have not alleged that any of them were denied access to Fabrazyme because they were United States citizens; rather, the plaintiffs have alleged that they were denied access in the United States. This is a crucial difference, as national origin is a protected class while mere location is not. *See Ayissi-Etoh v. Fannie Mae*, 712 F.3d 572, 576 n.1 (D.C. Cir. 2013) (discussing national origin as one of the classes protected from discrimination under federal law); *accord* 42 U.S.C. § 2000e-2. As such, the plaintiffs have failed to show discrimination on the basis of national origin so as to show an injury in fact for Article III purposes.[10]

[10] Moreover, the plaintiffs' argument has no limiting principle. If standing were conferred on any U.S. citizen based on unequal treatment between the citizen and a person in another country, which operates under a different set of regulations, virtually any citizen could have standing to challenge any U.S. government action. This would eviscerate the injury in fact prong of Article III standing.

b) Informational Injuries

The plaintiffs' next alleged "constitutional injury" is, apparently, that the U.S. District Court for the District of Massachusetts—the court that entered the Consent Decree between the defendants and Genzyme—was not provided by the defendants with information pertaining to the drug shortage. *See* Pls.' Opp'n at 8. Such an injury is insufficient to confer Article III standing because "the 'injury in fact' test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself among the injured." *Lujan*, 504 U.S. at 563 (quoting *Sierra Club v. Morton*, 405 U.S. 727, 734–35 (1972)). Any injury from nondisclosure would flow to the entity denied such information and that entity here is the U.S. District Court for the District of Massachusetts, not the plaintiffs. The plaintiffs do not allege that they are without access to information about Genzyme's practices but, rather, that the District of Massachusetts Court was not informed by the defendants of those practices as they related to the Fabrazyme drug shortage. *See* Pls.' Opp'n at 8. In other words, even if some cognizable injury arose from the plaintiffs' claim about the lack of information,[11] that injury would necessarily not be to the plaintiffs, who consequently could not themselves be "among the injured" within the meaning of *Lujan*. *See Lujan*, 504 U.S. at 563. In short, this alleged informational injury is insufficient to serve as an injury in fact for Article III purposes.

c) Deprivation of States' Traditional Police Powers

In reliance on *Bond v. United States*, 131 S. Ct. 2355 (2011), the plaintiffs assert standing to challenge the defendants' conduct on the grounds that it deprives the states of their traditional police power to protect the health, safety, and welfare of their citizens. *See* Pls.' Opp'n at 31; *see*

[11] The Consent Decree does not require any party to provide to the Massachusetts court information about drug availability. *See* Consent Decree *generally*.

also id. at 13-14, 15, 20, 35-36 (alleging defendants' interference with states' traditional roles). The plaintiffs' reliance on *Bond* is misplaced.

In *Bond*, a criminal defendant was convicted under a federal statute that implemented "provisions of the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, a treaty the United States ratified in 1997." *Bond*, 131 S. Ct. 2360. The defendant challenged her conviction on the grounds that Congress did not have the "constitutional authority to enact" the statute under the Tenth Amendment, since the statute allegedly "exceeded [Congress'] powers . . . in contravention of basic federalism principles." *Id.* The lower courts found the defendant did not have standing to raise a Tenth Amendment claim as an individual, "because a State was not a party to the federal criminal proceeding." *Id.* The Supreme Court reversed. *Id.*

Central to the holding in *Bond* was the finding that the defendant had met all the elements for Article III standing without relying upon the Tenth Amendment claim, and "Article III standing thus had no bearing upon Bond's capacity to assert defenses in the District Court." *Id.* at 2362. The *Bond* defendant was convicted of a crime and sent to prison, thus satisfying "'the case-or-controversy requirement, because the incarceration . . . constitutes a concrete injury, caused by the conviction and redressable by invalidation of the conviction.'" *Id.* (quoting *Spencer v. Kemna*, 523 U.S. 1, 7 (1998)). The Court clarified its holding by noting that "[a]n individual has a direct interest in objecting to laws that upset the constitutional balance between the National Government and the States *when the enforcement of those laws causes injury that is concrete, particular, and redressable*." *Id.* at 2364 (emphasis added). Thus, under *Bond*, the individual alleging a Tenth Amendment claim must independently have Article III standing, which the plaintiffs cannot show here. *See id.*

Additionally, to the extent the plaintiffs are alleging that the states have been deprived of their traditional police powers, they rely on two cases that hold the opposite. In *Wyeth v. Levine*, 555 U.S. 555, 573–74 (2009), the Supreme Court found that the FDCA can and does co-exist with "widely available state rights of action [that] provided appropriate relief" for customers injured by misbranded drugs. The plaintiffs' allegation that the FDA is somehow preventing the States from exercising their power over protecting the health and welfare of their citizens through its interpretation of the FDCA runs directly counter to the Supreme Court's finding in *Wyeth*. The other case cited by the plaintiffs, *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905), predates the FDCA, and "recognized the authority of a state to enact quarantine laws and 'health laws of every description;' indeed, all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other states." *Jacobson*, which dealt with a Massachusetts city ordinance requiring all people in the city to be vaccinated against smallpox, therefore stands only for the unremarkable proposition that was reaffirmed in *Wyeth*: that states have the power to protect the health and welfare of their citizens to a greater degree than provided for by federal law. *See id.* Thus, the plaintiffs' claim that states' rights were violated by the FDA during the drug shortages must fail, considering they have made no allegation that any state sought to take any action regarding the drug shortages at issue or that they were prevented from doing so by the FDA.

In this case, the plaintiffs have not alleged a concrete, particular, and redressable injury. As explained in Part III.B.1, with the exception of Plaintiff Lacognata, the plaintiffs have not

alleged a concrete injury at all.[12] In the absence of an independent basis for Article III standing, the plaintiffs' alleged Tenth Amendment violation is insufficient to allege an injury in fact.

d) Generalized Grievances About Unlawful Government Conduct

The plaintiffs make several nebulous arguments about the defendants' alleged failure to follow federal law, without tying such failure to any specific injury. For example, the plaintiffs complain about (1) the defendants' allegedly unlawful delegation of drug rationing authority to private drug companies separate from the health effects of the rationing itself, *see* Pls.' Opp'n at 1-2, 7, 9-10, 11, 21-22, 29-31, 32, 35; (2) the defendants' alleged failure to enforce the prescription drug regulatory regime, apart from any effects that such a failure caused, *see id.* at 2-3, 9, 12-13, 19, 20; and (3) the grant of an allegedly invalid patent, independent of any harm that the use of the patent caused, *see id.* at 15-18, 32. All of these arguments are unavailing. It is settled law that a "generalized grievance about the conduct of government" is insufficient to constitute a cognizable injury in fact. *Lance v. Coffman*, 549 U.S. 437, 442 (2007); *see Hollingsworth v. Perry*, 133 S. Ct. 2652, 2662 (2013) ("We have repeatedly held that such a 'generalized grievance,' no matter how sincere, is insufficient to confer standing."); *Lance*, 549 U.S. at 439 ("Our refusal to serve as a forum for generalized grievances has a lengthy pedigree."); *United States v. Richardson*, 418 U.S. 166, 175 (1974) (holding litigant could not "employ a federal court as a forum in which to air his generalized grievances about the conduct of government") (quoting *Flast v. Cohen*, 392 U.S. 83, 106 (1968)); *Public Citizen*, 489 F.3d at 1292 ("The Supreme Court also has stated that the asserted injury must be particularized . . . not generalized or undifferentiated."). As the Supreme Court noted unequivocally in *Allen*, "an asserted right to have the Government act in accordance with law is not sufficient, standing

[12] Since Plaintiff Lacognata has not and cannot prove that her physical injuries were actually caused by the defendants, *see* Part III.C, *infra*, her Tenth Amendment claim also fails, because she has no independent grounds for Article III standing to support the alleged Tenth Amendment violation. *See Bond*, 131 S. Ct. at 2364.

alone, to confer jurisdiction on a federal court." 468 U.S. at 754. As these nebulous arguments about the defendants' alleged failure to follow federal law are no more than "an asserted right to have the Government act in accordance with the law," the plaintiffs fail to allege an injury in fact sufficient to grant Article III standing.

e) Subjective Fear of Using the Courts

Finally, the plaintiffs allege that an adverse decision in this case will create a chilling effect on the willingness of future victims of drug shortages to seek judicial review of their grievances. *See* Pls.' Opp'n at 14. Assuming *arguendo* that a chilling effect on seeking relief in the courts is, in fact, an injury in fact sufficient for standing purposes, the plaintiffs cannot assert that they have an injury in fact in this case for substantially the same reasons they have not alleged a physical injury in fact: such a chilling effect has not occurred. The plaintiffs have not alleged that *they* have been chilled in any way from filing suit in federal court; indeed, the filing of this case demonstrates the opposite. *See* Compl. *generally*. Any injury in fact based on an alleged chilling effect is merely speculative and conjectural, which the Supreme Court has consistently held is insufficient to constitute an injury in fact for Article III purposes. *See Clapper v. Amnesty Int'l*, 133 S. Ct. 1138, 1147 (2013); *Lujan*, 504 U.S. at 564; *City of Los Angeles*, 461 U.S. at 108.

In sum, the only plaintiff to raise a cognizable injury in fact is Plaintiff Lacognata, who has alleged a physical injury in her deteriorating eye sight and, potentially, a Tenth Amendment claim. *See* Parts III.B.1 and III.B.2.c, *supra*. Nevertheless, Plaintiff Lacognata does not adequately plead the second portion of the standing inquiry, namely, that there is "a causal connection between the injury and the conduct complained of." *Lujan*, 504 U.S. at 560.

Notably, even if the other plaintiffs were able to allege a sufficient injury in fact, their claims would fail on this second prong as well.

B. Causation

The defendants aver that the two pharmaceutical manufacturers, Genzyme and Hospira, caused the shortages of Fabrazyme and Aquasol A, respectively, *see* Defs.' Mem. at 20; Defs.' Reply at 3, and the plaintiffs agree, *see* Pls.' Opp'n at 9 ("Everyone agrees that the manufacturers caused the shortages."); *see also* Compl. ¶¶ 72, 87. The plaintiffs argue that "the ongoing injuries from these shortages are [exacerbated] by government action and inaction." Pls.' Opp'n at 9. The plaintiffs, however, do not show that any action or inaction by the defendants has a sufficient causal link to their alleged injuries. Instead, all of the alleged injuries were caused by "the independent action of some third party[,]" here, the pharmaceutical companies, "not before the court." *Lujan*, 550 U.S. at 560 (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41–42 (1976)).

The plaintiffs attempt to show causation through two theories, neither of which is persuasive. First, they argue that the defendants had a duty to act to alleviate the effects of the drug shortages. *See* Pls.' Opp'n at 9 ("[I]t is during a shortage that vulnerable patients most rely on the prudence and expertise of the Government and FDA to protect them from further injuries from these manufacturers."); *id.* at 12 (arguing the defendants had a duty to withdraw the licenses authorizing marketing of Fabrazyme and Aquasol A from the manufacturers through "the Separation of Powers doctrine and Non-Delegation doctrine."). Second, the plaintiffs argue that "the Defendants have through its [sic] policies and actions placed at least apparent authority to exercise traditional State police powers in the hands of private individuals and with the expectation of FDA consent." *Id.* at 9. Each theory is discussed, and rejected, below.

1. *The Defendants' Alleged Duty to Act*

Without citing any authority, the plaintiffs allege that the defendants have a duty, whether based in statute, *see* Pls.' Opp'n at 9, or in the Constitution, *see id.* at 12, to revoke the manufacturers' drug and biological product licenses as a result of the drug shortages, and that the failure to revoke these licenses exacerbated the plaintiffs' injuries. *See* Pls.' Opp'n at 9–10. The defendants correctly point out, however, that the defendants have no such statutory duty. *See* Defs.' Mem. at 20–21; Defs.' Reply at 4–5. The FDCA and the regulations promulgated pursuant to the PHSA authorize the defendants to revoke licenses only in certain, narrow circumstances, none of which include a licensee causing a drug shortage. *See* 21 U.S.C. § 355(e); 42 U.S.C. § 262(a)(2)(A); 21 C.F.R. § 601.5(b)(1). Most notably, even if the plaintiffs could show that the defendants had a duty to revoke the licenses under the statutes, it could only do so after notice and hearing, which have not occurred. *See* 21 U.S.C. § 355(e); 21 C.F.R. § 601.5(b)(1). There is, quite simply, no statutory basis for the defendants to have taken the action plaintiffs allege they should have taken, let alone a duty to do so.

As for the plaintiffs' constitutional arguments, *see* Pls.' Opp'n at 12, the plaintiffs cite no provision of the Constitution nor any other authority to suggest that the Constitution itself requires the defendants to revoke a drug or biological product license when a pharmaceutical company causes a drug shortage. The plaintiffs' argument appears to be based on the idea that the defendants delegated the power to ration pharmaceuticals to the manufacturers when the drug shortages occurred, yet the plaintiffs have not provided any authority that the defendants were responsible for rationing drugs in the first place. *See* Pls.' Opp'n *generally*. Instead, the plaintiffs make the conclusory statement that "nationwide rationing of necessary medicines during a national emergency has always been a governmental power as well as being an

absolutely necessary function of the government on behalf of the people." Pls.' Opp'n at 35. Even if such a function is historically a governmental function, authority for such action must be grounded in statute or the Constitution and the plaintiffs have simply failed to plead any affirmative basis authorizing the defendants to take the actions that the plaintiffs allege they should have taken. The plaintiffs' effort to show that the defendants caused the drug shortages based on the Non-Delegation and Separation of Powers doctrines is, consequently, unavailing.

Moreover, as the defendants point out, the "plaintiffs' causation theory does not make sense." Defs.' Mem. at 21. The plaintiffs appear to be alleging that the federal government, through the FDA, should have revoked the drug manufacturers' licenses, an action which would have resulted in no drugs being available for distribution. *See id.* This argument also conflicts with the plaintiffs' Tenth Amendment argument, which appears to allege that the states were the only entities with the appropriate police power to ration the drugs. *See* Pls. Mem. at 35–36. In short, this argument verges on the nonsensical.

Without a showing that the defendants had a duty to take action, "[t]he links in the chain of causation between the challenged Government conduct and the asserted injury are far too weak for the chain as a whole to sustain [the plaintiffs'] standing." *Wright*, 468 U.S. at 759. The plaintiffs have completely failed to show how the defendants had a duty, or even the ability, to act to stop Hospira from shifting production of Aquasol A to another plant without first securing adequate stockpiles of the drug. As such, the only plaintiff who was able to plead an injury in fact for Article III purposes, Plaintiff Lacognata, has failed to plead causation under this theory.[13]

[13] Since the remaining plaintiffs have failed to show an injury in fact, there was no injury to cause, making the causation prong of the analysis irrelevant. Assuming, *arguendo*, that the Fabrazyme plaintiffs had shown an injury in fact, the same rationale applies: those plaintiffs have not shown how government action or inaction affected the Fabrazyme shortage at all, nor what the defendants were authorized to do to alleviate the effects of the shortage.

2. *Attributing the Pharmaceutical Companies' Actions to the Defendants*

Without citing any authority, the plaintiffs suggest that the defendants tacitly approved the drug rationing scheme for Fabrazyme, Pls.' Opp'n at 9, since they had direct oversight of Genzyme as a result of the Consent Decree in *United States v. Genzyme Corp*, and because the defendants were aware of, and took no action to stop, the pharmaceutical companies' drug rationing plans. *See* Pls.' Opp'n at 9–10, 35–36. As the defendants rightfully point out, the actions of private pharmaceutical companies are not fairly attributable to the defendants because "[e]ven extensive regulation by the government does not transform the actions of the regulated entity into those of the government," *S.F. Arts & Athletics, Inc. v. U.S. Olympic Comm.*, 483 U.S. 522, 544 (1987), and because "[m]ere approval of or acquiescence in the initiatives of a private party is not sufficient to justify holding the [government] responsible for those initiatives," *Blum v. Yaretsky*, 457 U.S. 991, 1004–05 (1982).[14] *See* Defs.' Reply at 3–4.

The Supreme Court in *San Francisco Arts and Athletics, Inc.* noted specifically that "[t]he Government may subsidize private entities without assuming constitutional responsibility for their actions," 483 U.S. at 544, and that "a government 'normally can be held responsible for a private decision only when it has exercised coercive power or has provided such significant

[14] The plaintiffs rely upon *Lugar v. Edmondson Oil Co., Inc.*, 457 U.S. 922 (1982), for the proposition that the actions of the pharmaceutical manufacturers at issue here are fairly attributable to the defendants, because the government actions here meet the four part test set out in *Lugar*. *See* Pls.' Opp'n at 35 (citing *Lugar*, 457 U.S. at 937). This Circuit has noted that "*Lugar* explicitly limits its analysis to 'the particular context of prejudgment attachment' and cautions that 'we do not hold today that a private party's mere invocation of state legal procedures constitutes joint participation or conspiracy with state officials satisfying the § 1983 requirement of action under color of law." *Hoai v. Vo*, 935 F.2d 308, 313 (D.C. Cir. 1991) (quoting *Lugar*, 457 U.S. at 939 n.21). Thus, not only is *Lugar* inapposite on its facts since it applies to prejudgment attachment under state laws, but that case also cuts against the plaintiffs. *Lugar* squarely rejects the plaintiffs' broad contention that the actions of private parties can be fairly attributed to the government merely because the private parties invoke state legal procedures or, by analogy, that the reliance of the pharmaceutical manufacturers on the federal regulatory scheme to distribute Fabrazyme and Aquasol A somehow creates liability for the federal government defendants for drug shortages. *See Lugar*, 457 U.S. at 939 n.21. Additionally, the plaintiffs offer nothing more than a conclusory statement that the FDA compelled "private entities to make drug rationing decisions" despite the FDA having no control over the drug distribution decisions of private entities. *See* Defs.' Mem. at 20.

encouragement, either overt or covert, that the choice must in law be deemed to be that of the [government,]'" *id*. at 546 (quoting *Blum*, 457 U.S. at 1004). The plaintiffs have failed to make an adequate showing that the mere awareness by the defendants of the rationing scheme for Fabrazyme and the facility transfer for Aquasol A can, in any way, cause the drug shortages to be attributed to the defendants. The plaintiffs have failed to plead any encouragement by the defendants to the drug companies involved in the shortages, let alone "such significant encouragement . . . that the choice must in law be deemed to be that of the [government]." *Id.* Thus, the plaintiffs have failed to show that there is even a colorable claim that the defendants caused any cognizable injury to Plaintiff Lacognata, who has alleged an injury in fact, or the remaining plaintiffs, who have not alleged an injury in fact.

* * *

Since only one of the plaintiffs has shown an injury in fact, and none of the plaintiffs have shown the injuries alleged were caused by the defendants, it is unnecessary to turn to the third prong of the Article III standing analysis, redressability. *See Lujan*, 504 U.S. at 560. In any event, since the defendants did not cause any injury to the plaintiffs, any action the plaintiffs request the Court take involving the defendants could not redress the plaintiffs' injuries.

IV. CONCLUSION

The Court joins in the defendants' "utmost sympathy for patients suffering from Fabry disease and vitamin A deficiency" and likewise does "not question the legitimacy of plaintiffs' desire for access to Fabrazyme and Aquasol A." Defs.' Mem. at 4. Nevertheless, the plaintiffs have, with the exception of Plaintiff Lacognata, failed to show that they suffered an injury in fact for the purposes of showing standing under Article III, and all of the plaintiffs, including Plaintiff Lacognata, have failed to show that the defendants' actions or inactions caused any

injury. Accordingly, for the aforementioned reasons, the defendants' Motion to Dismiss under Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction, ECF No. 20, is GRANTED. Defendant Mount Sinai School of Medicine's Motion to Dismiss, ECF No. 17, is DENIED as moot as that defendant has already been voluntarily dismissed from this action. *See* Not. of Voluntary Dismissal at 1, ECF No. 26.

An appropriate Order accompanies this Memorandum Opinion.

Date: November 27, 2013

Digitally signed by Beryl A. Howell
DN: cn=Beryl A. Howell, o=District Court for the District of Columbia, ou=District Court Judge, email=howell_chambers@dcd.uscourts.gov, c=US
Date: 2013.11.27 18:15:34 -05'00'

BERYL A. HOWELL
United States District Judge