UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE, Plaintiff, *v.* FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants, and SAREPTA THERAPEUTICS, Intervenor-Defendant.	Case No. 1:17-cv-3960 August 30, 2018

PLAINTIFF'S COMBINED REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF (1) PLAINTIFF'S CROSS MOTION FOR SUMMARY JUDGMENT AND (2) PLAINTIFF'S MOTION TO STRIKE

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INTRODUCTION

Defendants' opposition only further confirms that Seife's cross-motion for summary judgment should be granted. Defendants strain mightily to establish that Exemption 4 does not permit a court to balance the public interest in disclosure against competitive harm that will result, but defendants strain in vain. FOIA's text, structure, legislative history, and prior application by the courts all refute defendants' claim that the public interest may not even be considered in applying Exemption 4. And defendants do not deny the overwhelming public interest in disclosure of the withheld CSR data, which is essential to evaluating the credible claims of possible scientific misconduct and FDA impropriety in the approval of Exondys 51, and which will also inform the treatment decisions of doctors, patients, and their families.

The undisputed public interest alone would warrant disclosure of the withheld CSR data even if the defendants had established substantial competitive harm, but they have not. The generalized and conclusory claims of harm repeated in defendants' opposition fall woefully short of meeting their burden to establish through admissible evidence that substantial and imminent competitive harm is reasonably foreseeable, as the 2016 FOIA amendments require. Nor do defendants ever come to terms with the core significance of the information already made public by operation of law, voluntary disclosures, and FDA proceedings—that so much detail about the drug and its development is public that release of additional granular details could cause no substantial harm.

As Seife has shown, even incremental harm is not established here for multiple reasons: Without demographic information that Seife is not seeking, the data could not be used to create a historical control set. If Sarepta engaged in scientific misconduct as some suspect, the questionable data cannot be used by competitors in any meaningful way. And even if no scientific misconduct occurred, the data at issue could not support a competitor's new drug approval application, which

defendants' own authority considers the key competitive harm consideration in this context. *See Webb v. HHS*, 696 F.2d 101, 103 (D.C. Cir. 1982). Defendants' opposition has no answer to any of this.

Finally, the supplemental submission by Ian Estepan fails to remedy the legal insufficiency of his declaration. Seife's motion to strike the Estepan testimony is properly before the Court, defendants have not cured its fundamental flaws, and Estepan's submissions should be stricken from the record.

ARGUMENT

I. DEFENDANTS FAIL TO ESTABLISH ANY PROPER BASIS FOR WITHHOLDING INFORMATION IMPORTANT BOTH TO FDA OVERSIGHT AND TO PUBLIC HEALTH

A. The Public Interest In the Withheld Information Should Be Considered And Compels Disclosure

Seife has demonstrated that this Court can and should weigh the capacity of the withheld clinical study information to shed light on the FDA's performance of its statutory duties under Exemption 4, particularly given the substantial concerns that exist of possible scientific misconduct and agency malfeasance.[1] *See* Seife Br. at 14-15, 36-42, ECF No. 86; Seife Decl. ¶¶ 93-149. The Court may also properly consider the "collateral" value of disclosure for physicians, patients, and researchers, particularly given the FDA's mission to protect public health. Seife Br. at 15-16. Desperate to foreclose either inquiry, defendants argue that Exemption 4 precludes any public interest balance

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[1] The FDA attempts to brush aside evidence of potential misconduct as "suppositions and innuendos." FDA Opp. Br. at 1, ECF No. 99. The misconduct concerns of FDA reviewers are fully documented, *e.g.*, Kenney Decl., ECF No. 90, Exs. D-M, and as Sarepta has put it, the exhibits documenting the concerns of misconduct "speak for [them]se[lves]." Sarepta Rule 56 Counter Statement ¶¶ 102-110, 112-117, 119-120, ECF No. 103.

The FDA also attacks Seife's declaration as argumentative and lacking personal knowledge. FDA Opp. Br. 18, n.13. Seife is an experienced math and science journalist who authored a book on statistics and has previously used FOIA requests to document instances of research misconduct detected by FDA staff that were never acted upon. *See* Seife C., Research Misconduct Identified by the US Food and Drug Administration Out of Sight, Out of Mind, Out of the Peer-Reviewed Literature. *JAMA Intern Med.* 2015; 175(4):567–577. Seife is drawing on this background in reviewing the documentary evidence the FDA disclosed and in reaching his conclusions, Seife Decl. ¶¶ 4-7, 85, ECF No. 87, that the withheld information in the CSRs would shed light on the agency's performance of its statutory duties, *id.* ¶¶ 108-149.

whatsoever and automatically requires information to be withheld if likely substantial competitive harm is shown. *See, e.g.,* Sarepta Opp. Br. at 23-27, ECF No. 101; FDA Opp. Br. at 1, 14-18. That argument fails.

First, nearly all of FOIA's exemptions—including Exemption 4—are discretionary, not mandatory, and inherently require a balancing of interests. Multiple sources confirm Congress intended balancing under Exemption 4. Congress understood that agencies applying Exemption 4 "must balance the competitive interest of a business against the public's right to know vital health, safety, economic, and legal information," 95th Cong., 2d Sess., pt. 1, at 2-3 (1980), and expected courts applying Exemption 4 to "invalidate any agency regulation that prevent [sic] the release of information vital to the public interest," H.R. Rep. No. 95-1382, at 45-46 (1978).

Second, the Supreme Court has similarly noted that "the language, logic, [and] history of [FOIA]" require a case-by-case balance to be struck between "open government . . . [and] preserving workable confidentiality in governmental decisionmaking." *Chrysler Corp. v. Brown*, 441 U.S. 281, 290-92 (1979). As the Court explained, "[s]uccess lies in providing a workable formula which encompasses, balances, and protects all interests, yet places emphasis on the fullest responsible disclosure." *Id.* at 292, n.12 (quoting S. Rep. No. 813, 89th Cong., 1st Sess., at 3 (1965)). The Court made clear that this balancing applies fully to Exemption 4, noting that restrictions of the Trade Secrets Act, 18 U.S.C. § 1905, are simply a factor to be considered in deciding if "disclosure is in the public interest." *Id.* at 301, n.29 (quoting H.R. Rep. No. 94-880, pt. 1, at 23 (1976)).[2]

[2] The Second Circuit has not addressed the Trade Secrets Act's relevance to Exemption 4. Seife Br. 12, n.3. While other Circuits have disagreed, the appropriate approach is that expressed by Judge Posner for the Seventh Circuit that the Trade Secrets Act does not apply to all confidential commercial information (CCI) within Exemption 4 and that there are significant policy differences between CCI and trade secrets that make it inapplicable here. *Gen. Elec. Co. v. U.S. Nuclear Regulatory Comm'n*, 750 F.2d 1394, 1401-02 (7th Cir. 1984) (Posner, J.); *see also Charles River Park "A", Inc. v. HUD,* 519 F.2d 935, 943 (D.C. Cir. 1975) ("[T]he court must bear in mind that section 1905 is a criminal statute and should be narrowly construed."); *United States v. Wiltberger*, 18 U.S. 76, 95-96 (1820) (Marshall, C.J.) (any crime not enumerated in the language of the statute cannot be

Third, Second Circuit precedent does not foreclose public interest balancing under Exemption 4. *See* Seife Br. 12, n.3, 14, n.4. In *Continental Stock Transfer & Transportation Co. v. Securities & Exchange Commission*, 566 F.2d 373 (2d Cir. 1977), this Circuit adopted the D.C. Circuit's *National Parks* test for determining the scope of Exemption 4. In so doing, it cited with approval *Charles River Park*, 519 F.2d at 943, a D.C. Circuit decision making clear that a "public interest consideration" can be properly weighed in applying Exemption 4. *See Continental Stock,* 566 F.2d at 375 (also noting *Charles River Park* was authored by a Second Circuit judge sitting by designation).

Sarepta nonetheless claims that *Nadler v. FDIC*, 92 F.3d 93 (2d Cir. 1996), precludes any public interest consideration under Exemption 4 because it describes only a two-part test. Sarepta Opp. Br. at 25. But no public interest argument was made in *Nadler*. *See* Brief for Plaintiffs-Appellants Jerrold Nadler et al., 1996 WL 33661985 (2d Cir. 1996). Sarepta's argument turns on the assumption that the *Nadler* court considered *sua sponte* an argument not presented, and then rejected it without comment, all because it cited a case *embracing* the public interest test without discussing that portion of the opinion. *See Nadler*, 92 F.3d at 95 (citing *GC Micro Corp. v. Def. Logistics Agency*, 33 F.3d 1109 (9th Cir. 1994)). But that suggestion is nonsensical, given the absence of a public interest argument in *Nadler* and the positive citation to *GC Micro* expressing no reservation with any portion of its reasoning. FDA's citation to other authority is equally misdirected: *Inner City Press/Cmty. on the Move v. Bd. of Governors of Fed. Reserve Sys.*, 463 F.3d 239 (2d Cir. 2006), dealt with information in the public domain, and public interest again was not raised as an issue. *See* Brief of Plaintiff-Appellant-Cross-Appellee, 2005 WL 5326508 (2d Cir. 2006) (making no public interest argument). *Bloomberg* is addressed fully in Seife's opening brief. *See* Seife Br. 14, n.4.

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criminalized by judicial fiat). To the extent this Court has concerns about the relevance of the Trade Secrets Act, Seife would request an opportunity to brief that issue separately.

Defendants are also wrong to read *National Parks* and *GC Micro* as rejecting any balancing if competitive harm is demonstrated. The D.C. Circuit has made clear that its *National Parks* test allows a court to balance the public's interest against any competitive harm. *See, e.g., Nat'l Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 768 (D.C. Cir. 1974) (quoting 88th Cong., 1st Sess., at 102 (1964), that even where a company proves a competitive harm the public interest might still justify disclosure); *Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1289 & n.25 (D.C. Cir. 1983) (describing need to balance "the interest of the public in disclosure and the protection of innovation incentives"); *see also Washington Post Co. v. HHS*, 690 F.2d 252, 268-69 (D.C. Cir. 1982) (noting that an Exemption 4 impairment case "necessarily involves a rough balancing of the extent of impairment and the importance of the information against the public interest in disclosure"); *Washington Post Co. v. HHS*, 865 F.2d 320, 325-28 (D.C. Cir. 1989) (remanding to the district court to consider public interest in applying the *National Parks* impairment prong). As Judge Garland has explained, both *National Parks* and *GC Micro* agree that "in making our determination [of competitive harm under Exemption 4], we must balance the strong public interest in favor of disclosure against the right of private businesses to protect sensitive information." *Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 908-10, & n.2, n.3 (D.C. Cir. 1999) (Garland, J., concurring) (brackets in original); *see also Utah v. U.S. Dep't of Interior*, 256 F.3d 967, 971 (10th Cir. 2001) (reading D.C. Circuit precedent as recognizing "a rough 'balancing of interests' test under Exemption 4"). Given this precedent, district courts in the Ninth and D.C. Circuits unsurprisingly weigh the public interest when it is asserted to outweigh the need for confidentiality under Exemption 4.[3]

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[3] *See AT & T Info. Sys., Inc. v. Gen. Servs. Admin.*, 627 F. Supp. 1396, 1403 (D.D.C. 1986) (noting the "strong" public interest in release); *Teich v. FDA*, 751 F. Supp. 243, 253 (D.D.C. 1990) (holding disclosure would reveal safety issues that outweigh the "negligible competitive harm"); *Pub. Citizen Health Research Group v. FDA*, 964 F. Supp. 413, 415 (D.D.C. 1997) (considering "whether there is a strong public interest in release of the information"); *Pub. Citizen Health Research Group v. NIH*, 209 F. Supp. 2d 37, 45 (D.D.C. 2002) (noting "the central role a rough balancing must play between the private and public interests when considering a withholding under exemption 4"); *see also JCI Metal Prod. v. U.S. Dep't of the Navy*, No. 09-cv-2139, 2010 WL

Judge Garland differed with the *Public Citizen* majority largely on the issue of whether Exemption 4 allows the "collateral interest" in disclosure of CCI to be weighed in addition to the interest in knowing what an agency is doing, as defendants recognize. *See* FDA Opp. Br. at 16 (discussing *Public Citizen*'s interpretation of *DOJ v. Reporters Comm. For Freedom of Press*, 489 U.S. 749, 772 (1989)); *see also* Seife's Br. at 14-17. Judge Garland's concurrence notes that the majority's citation to *Reporters Committee* underscores FOIA's core purpose is to shed light "on what the government is up to," 489 U.S. at 780, and therefore "'[o]fficial information that sheds light on an agency's performance of its statutory duties falls squarely within that statutory purpose' and may be weighed in the balance," *Pub. Citizen,* 185 F.3d at 909-10 (Garland, J., concurring) (brackets and quotes in original).

This authority demonstrates that Exemption 4 properly permits weighing the competitive harm from the disclosure of CCI against the extent to which disclosure will shed light on agency action.[4] Defendants do not dispute that the withheld data will do just that. It unambiguously will inform the public about whether the FDA is properly performing its duty to protect public health, and particularly whether the Exondys 51 approval process was infected with scientific and/or agency misconduct. Allegations of such improprieties cannot be fully evaluated without the withheld information. This alone justifies disclosure.

The better view, as articulated by Judge Garland, is that this Court is also free to consider "collateral interests" in disclosure, particularly those that reflect on the FDA's mission of promoting

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2925436, at *7 (S.D. Cal. July 23, 2010) ("public interest in disclosure outweighs any confidentiality concerns [plaintiff] might have in its unit prices").

[4] The FDA cites to inapposite cases where plaintiffs fail to assert a public interest in the information. *See* FDA Opp. Br. 15 (citing *Torres Consulting Law Grp v. NASA*, 666 F. App'x 643, 644 (9th Cir. 2016), and *Watkins v. U.S. Bureau of Customs & Border Protection*, 643 F.3d 1189, 1195 (9th Cir. 2011)). Also note that in *Lahr v. Nat'l Transp. Safety Bd.*, 453 F. Supp. 2d 1153, 1176 (C.D. Cal. 2006), *aff'd in part, rev'd in part and remanded*, 569 F.3d 964 (9th Cir. 2009), the plaintiff did not appeal the Exemption 4 ruling, and so the Ninth Circuit had no occasion to correct the district court's misstatements of law.

public health. Defendants do not dispute the important collateral value of disclosure for informed decision making by doctors, patients, and others. Sarepta expressly acknowledges this collateral interest. *See* Sarepta Counter Rule 56.1 Statement ¶¶ 128, 130-131, 134-37, 140, 144-145, 149.[5] This further underscores the impropriety of withholding the information under Exemption 4.

B. Defendants' Supplemental Evidence Still Fails to Justify Their Refusal To Disclose Data Provided in Sarepta's Clinical Study Reports

While the public interest would compel disclosure even if significant competitive harm had been established, defendants fall far short of meeting their burden to demonstrate such harm.

1. Defendants still offer only generalized claims of harm that are insufficient as a matter of law

To meet their burden, defendants initially provided a single declaration by a Sarepta marketing professional claiming release of the withheld details from the CSRs would likely cause substantial competitive injury. *See* Estepan Decl., ECF No. 72. After Seife challenged both the declarant's qualifications and the lack of factual support for his conclusory assertions of harm, Seife Br. at 17-22, defendants attempted to resuscitate the claims with a second declaration by the same employee, Ian Estepan. Estepan 2d Decl., ECF No. 105. The new declaration should be rejected because it is more of the same.

Defendants attempt to distinguish case law revealing the legal insufficiency of their evidence as "bear[ing] no resemblance to Sarepta's and FDA's showing." Sarepta Opp. Br. at 21. They must not have examined the evidence in the main case they invoke, *Public Citizen Health Research Group v. FDA*, 185 F.3d at 906, where the court found inadequate a far more detailed affidavit from a far more qualified affiant. There, the affiant, Dr. Ronald Garutti, received an M.D. from Georgetown University and practiced medicine for ten years before working for Schering Corporation where he

[5] Sarepta mistakenly contends that the information cannot be released by citing a regulation based upon 21 U.S.C. § 355(l), a statute providing for release of information not *already* publicly disclosed. *See* Sarepta Rule 56 Counterstatement ¶ 148. It has no application to a release under FOIA.

had direct responsibility over clinical research and design and implementation of clinical trials, including the drug at issue. Garutti Decl. ¶ 3.[6] The court still rejected his conclusory statements—parroted by Sarepta, Estepan Decl. ¶ 41; Estepan 2d Decl. ¶ 29—that the data "would be directly applicable to any drug product any of whose metabolites were identical or similar to those of IND 18113," Garutti Decl. at ¶ 31. Dr. Garutti specifically declared that:

> [T]his would be the case not only for the remaining three isomers of Schering's marketed product, but for other drugs in a similar chemical type, such as other drugs which alpha and beta blocking properties. Such products are under active investigation by many research-based drug companies.

Id. Garutti also went further than Estepan in providing specific examples from the *Vaughn* Index to explain the source of the asserted value of each category of withheld information. *E.g.*, *id.* at ¶¶ 27-29 (stating that the value of the pharmacological information derives from two sources and describing each). The court nonetheless found the affidavit insufficient because it "contain[ed] only conclusory assertions that disclosure would cause substantial competitive harm." *Pub. Citizen*, 185 F.3d at 906.

The Estepan declarations also fall short when compared with the type of evidence other courts have found to be *adequate*. In *Public Citizen Health Research Group v. FDA*, 704 F.2d at 1291, for example, the court found sufficient evidence to establish substantial competitive harm where defendants submitted a "lengthy expert report" and "numerous depositions" supported by declarations from a professional economist, a Ph.D. in biostatistics, a marketing and sales expert, and five different ophthalmic surgeons. *Id; see also* Corp. Defendants' Memorandum in Support of Their Motion for Preliminary Injunction at ii-iii.[7] In contrast, defendants' conclusory assertions of harm come solely from a witness who cites frequent interactions with scientific, medical, and technical personnel as the

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[6] The Garutti Declaration can be found as part of the district court docket. *See Public Citizen v. FDA*, No. 94-cv-0018 (D.D.C. Apr. 18, 1997), ECF No. 42.

[7] Although this document is not available on PACER, Seife was able to obtain a partial copy and can furnish it for the Court should that prove useful along with the declarations from this case cited *infra* at 9.

basis for his opinions. *See* Estepan 2d Decl. ¶¶ 6, 12-13, 15, 25 ("I have seen exhibitions of Sarepta's proprietary technology."). While Estepan may regularly converse with physicians and clinicians, he is not a physician and lacks the expertise necessary for his conclusions, nor can he convey hearsay. *See infra* at 15-19.

In addition, the declarants in the 1983 *Public Citizen* case substantiated their factual claims with documentary evidence, statistical analysis, and concrete examples. One declarant, a well-established economic professional and academic, conducted a comprehensive economic study and based his affidavit on the findings it produced. *See* Affidavit of Stanley Nehmer ¶¶ 1-6. His report describes multiple sources of competitive harm, and provides details such as the severity, particular actors, and short and long-term economic consequences. *See id.* ¶¶ 8-13. A biostatistician specializing in the design and analysis of clinical trials supported the claim. *See* Affidavit of Frank L. Hurley, Ph.D. ¶ 1. The declaration provides a concrete example of a previous FDA disclosure of similar data, which put a specific manufacturer's competitive position in jeopardy. *See id.* ¶ 4(e).

In sharp contrast, defendants offer only summary assertions of harm from a lay witness unsupported by specific facts. If defendants' generalized claims of harm in this case are sufficient, *any* CSR data can be withheld and the ability of FOIA to allow public oversight of the FDA's actions will be eviscerated. Defendants' claim of competitive harm is plainly insufficient.

2. Defendants still have no real answer to Seife's showing that the withheld information is largely public, or easily discerned by competitors

Despite the length of their submissions, defendants have failed to address a core tenet of Seife's argument: so much information about the drug and its development is public by operation of law, voluntary disclosures, and FDA proceedings that release of additional granular details would not cause any *substantial* and *imminent* competitive harm to Sarepta, much less harm that is reasonably foreseeable, as required by the 2016 FOIA amendments. Seife Br. 22-24 (collecting cases from the Second Circuit and SDNY). With so much information already public, the more granular supporting

data would provide little incremental value to competitors working on different drugs; their utility is in allowing independent scientists to test *Sarepta's* claims about *this* drug. *See infra* at 11-13; Lurie 2d Decl. ¶¶ 2-5, 10. Defendants would convert the inquiry into whether any information Sarepta spent money to develop is currently unavailable to the public, which is simply not the standard for competitive injury. *See* Sarepta Opp. Br. at 29-31; FDA Opp. Br. at 12-13.

Exhibit A, attached to the Seife Reply Declaration, cross-references each of defendants' claims of confidentiality to its publicly-available counterpart. As this exhibit shows, defendants' claims remain largely unsupported and contradicted by the record. For example:

- **Functional measures, including exploratory endpoints.** Contrary to defendants' depiction, the names and trial procedures for functional measures, including exploratory endpoints, used in Study 201/202 have been publicly disclosed by Sarepta and its researchers. Seife 2d Decl. ¶ 9; *see also id.*, Ex. A, 2; *id.*, Ex. B, 2-5. The timing of measure administration has also been publicly disclosed. Seife 2d Decl. ¶ 9; *see also id.*, Ex. A, 2-3. The FDA and Sarepta have released tables as well as plots and figures containing both summary and individual results for many of the functional measures. (*See* Exhibit A and B to the Seife Reply Declaration for a detailed breakdown.) It is relatively straightforward for competitors to extract the patient-level results on functional measures for each time point through week 216 from publicly available figures, plots and tables. *See* Seife 2d Decl. ¶¶ 11-13. The methods used by Sarepta for the functional methods are also publicly available or readily ascertained. (See Exhibits A and B to the Seife Reply Declaration for a detailed breakdown.)

- **Biopsies and dystrophin measurements.** The precise schedule and methods for muscle biopsies for Study 201/202 and Sarepta's other studies is public as well. *See* Seife 2d Decl., Ex. A, 3-4. Sarepta has published multiple scientific articles regarding its procedure for quantifying dystrophin. *Id.* at 4. The results of Western Blot and IHC tests for Study 201/202 are public.

- **Adverse events.** Sarepta has already released extensive information regarding the adverse events in Study 201/202. Adverse events were discussed by Sarepta in published scientific articles, in briefing information prepared for the FDA Advisory Committee, and also in the FDA's Medical Reviews. (*See id.*, Ex. A, 9-12; *id.*, Ex. B, 6-7, for detailed breakdown.)

Moreover, defendants now admit that the sample subset of documents submitted to the Court for review on the pending cross-motions contained many inaccurate and unjustified claims of confidentiality, proving Seife's point about defendants' failure to adequately separate exempt from

non-exempt information, Seife Br. at 44-45, and calling into question the accuracy of the rest of the withheld CSR information. In response to Seife's motion, defendants acknowledged that fully 54% of the fifty representative pages challenged by Seife on these motions contained indefensible redactions, and substitute pages were provided. Seife 2d Decl. ¶ 5. It is inconceivable that similar errors did not occur in thousands of pages with redactions in the approximately 30,000 pages at issue. (Seife's color-coded index, ECF No. 90-1, that is organized by the Table of Contents shows thousands of pages have been redacted in full or in part.)

3. Defendants still have no answer to Seife's showing that a competitor could not make any meaningful affirmative use of the withheld information

Defendants do not even address Seife's "affirmative use" argument—namely that because Sarepta's trials may have been tainted, competitors could use further CSR information only to embarrass Sarepta or to call into question its test results, which are not cognizable harms under Exemption 4. *See* Seife Br. at 27-28 (collecting cases). To establish that competitors could meaningfully make use of the withheld data, Sarepta needed to address the factual allegations that its data are of questionable scientific utility; instead, Sarepta simply states the documentary evidence Seife submitted "speaks for itself." Sarepta Counter Rule 56 Statement ¶¶ 102-110, 112-117, 119-120, 133, 135. Sarepta does make certain points in support of its science, mostly related to the 6-minute walk test and other endpoints, but these claims are refuted by Seife's documentary evidence, as shown in Exhibits A and B. *See* Seife 2d Decl., Exs. A & B. Given the lack of any showing that the withheld data is useful, defendants have not carried their heavy burden to show that substantial competitive harm is both likely and "reasonably foreseeable," as required by the 2016 FOIA amendments, 5 U.S.C. § 552(a)(8)(A)(i)(I); *see also* Seife Br. at 12.

Nor does Sarepta rebut Seife's showing that even if competitors could use the CSR data, it would not cause substantial competitive harm because the data could not support a competitor's new

drug approval application, which defendants' own authority takes as the bar for Exemption 4. *See* Seife Br. at 21-22 & n.9, 27-33; *Webb v. HHS*, 696 F.2d at 103. Dr. Lurie, with more than thirty years' experience as a public health researcher, including as the head of the FDA's Transparency Initiative, testifies that the withheld information has little commercial value because it does not meet FDA standards under guidelines that defendants themselves point to, Estepan Decl. ¶ 27 (discussing FDA guidance), and has "a relatively small incremental value to competitors," Lurie Decl. ¶¶ 24-25, ECF No. 88; *see also* Lurie 2d Decl. ¶ 10. For example, Estepan mistakes the nature of the information Seife requests, and without the demographic information Seife is not seeking, the data could not be used to create a historical control dataset or for head-to-head trials "because they could not be adjusted to account for differences in age, weight, height, and demographic information." Lurie Decl. 2d ¶ 8.

In addition, Dr. Lurie shows defendants' remaining arguments about Adverse Events and protocols are incorrect. First, the procedures for collecting and categorizing adverse events are standardized across the industry, so competitors would not benefit by studying Sarepta's description and categorization of adverse events. *Id.* ¶ 6; Seife 2d Decl., Ex. B, 6-7. Second, the functional measures, including method of administration, used by Sarepta are standard across neuromuscular disorder research. *See* Seife 2d Decl., Ex. B, 2-5. Third, Sarepta has patents on its methods for exon skipping, and according to these patents, the dosing information can readily be discerned by skilled practitioners. *See* U.S. 9,018,368 at 30:50-52 ("a skilled practitioner will be able to determine readily the optimum route of administration and any dosage for any particular animal and condition."); *see also* U.S. 8,486,907 at 29:9-11 (same). This admission seriously calls into question Estepan's credibility in asserting that the CSRs carry non-obvious information to competitors, Estepan 2d Decl. ¶ 29; *see also* Sarepta Therapeutics, *Sarepta Therapeutics Announces USPTO Decision in Patent Interference Case with BioMarin Pharmaceutical* (2015), http://investorrelations.sarepta.com/news-releases/news-release-

details/sarepta-therapeutics-announces-uspto-decision-patent (describing the '368 as "Sarepta's primary patent protection for eteplirsen [Exondys 51]" and attributing source to Ian Estepan).

Finally, Dr. Lurie's reply declaration addresses the "contradiction" Sarepta attempts to create. Sarepta Opp. Br. 5. He demonstrates that most of the commercially valuable data is now public, either through voluntarily disclosures or through operation of law, and the withheld details will only be useful to validate whether Sarepta's studies are "accurate" and useful to "clinicians monitoring patients and patients taking Exondys 51." Lurie 2d Decl. ¶ 10. Dr. Lurie explains that competitors' drugs "are different compounds, with different pharmacological profiles and different absorption rates" that would require separate clinical trials even if they are in the same class. *Id.* ¶ 3. "On the other hand, the information could help validate a concern raised by FDA reviewers—in particular Dr. Unger—that the data showed that Sarepta's dosing was sub-therapeutic." *Id.* ¶ 4. The record establishes both the absence of meaningful competitive value for the withheld data, and its essential importance for an evaluation of what the FDA has done and whether it is fulfilling its statutory mandate.

II. THE MOTION TO STRIKE THE ESTEPAN DECLARATION SHOULD BE GRANTED

Far from shoring up his first declaration, Estepan's second attempt—trying to recast himself as presenting the qualified views of others at Sarepta—makes clear that both declarations lack personal knowledge and are "blatantly inadmissible hearsay" that should be struck. *C.G. ex rel. B.G. v. New York City Dept. of Edu.*, 752 F. Supp. 2d 355, 360-61 (S.D.N.Y. 2010).

A. Seife's Objections And Motion to Strike Are Properly Before the Court Through The Instant Motion

It is common practice for courts to consider motions to strike supporting evidence presented in support of a motion for summary judgment. *See Richmond v. General Nutrition Centers Inc.*, No. 08-cv-3577, 2011 WL 2493527, *6 (S.D.N.Y. June 22, 2011) (granting defendants' motion to strike exhibits to opposition to summary judgment); *Kramsky v. Chetrit Group, LLC*, Nos. 10-cv-2638, 10-cv-9458,

2011 WL 2326920, *2 (S.D.N.Y. June 13, 2011) (considering motion pursuant to Federal Rule of Civil Procedure Rule 56(e) to strike affidavits and documents submitted by defendants in support of their motion for summary judgment); *see also Faulkner v. Arista Records LLC*, 797 F. Supp. 2d 299, 305 (S.D.N.Y. May 26, 2011) (stating that a motion to strike should be considered before a motion for summary judgment). Here, Seife properly served his objections to and motion to strike the improper portions of the Estepan Declaration pursuant to Rule 56. Sarepta is simply off-base in arguing that the motion "needlessly multiplies the number of briefs in this case" which "burden[s] Defendants and the Court." Sarepta Opp. Mot. Strike at 2, ECF No. 102.

Sarepta's argument that the Court should deny Seife's motion ignores the form of the pleading and context in which it is made. When faced with a motion to strike, courts in this District "may strike those portions, or may simply disregard them." *Rus, Inc. v. Bay Industries, Inc.*, 322 F. Supp. 2d 302, 307 (S.D.N.Y. 2003). That is exactly the relief for which Seife prays: "to strike or disregard the cited portions of those declarations pursuant to those sustained objections," in addition to "any other and further relief to which [Seife] may be entitled." Seife Mot. to Strike at 21, ECF No. 94. Furthermore, where "a decision on the motion to strike may affect [the movant's] ability to prevail on summary judgment, it is appropriate to consider the Motion to Strike prior to" resolution of the motions for summary judgment. *Rund v. JPMorgan Chase Group Long Term Disability Plan*, No. 10-cv-5284, 2012 WL 1108003, at *1 (S.D.N.Y. Mar. 30, 2012) (citing *Century Pacific, Inc. v. Hilton Hotels Corp.*, 528 F. Supp. 2d 206, 213 (S.D.N.Y. 2007)). That is the case here.

Sarepta's belief that this motion is "unnecessary," Sarepta Opp. Mot. Strike at 2, is not an adequate ground to defeat the motion, and is belied by Estepan's inadequate declaration. Given the extent of objectionable material in Estepan's Declaration, and the central nature of the Declaration to Sarepta's arguments, it is critical that the objections and request to strike are resolved prior to the summary judgment motions.

B. Sarepta Has Not Cured The Flaws In Its Initial Estepan Declaration By Submitting The Second Estepan Declaration, And The Court Should Strike Or Disregard Both

As fully described in the motion to strike, Seife's objections to the first Estepan declaration center on the fact that Estepan is fundamentally not competent to opine on the highly technical and scientific matters at the heart of this litigation. He lacks the training and expertise of a declarant who would otherwise be able to opine on these matters based on personal knowledge. Seife Mot. to Strike at 3-14. Estepan's inclusion of additional detail about his background in his second declaration only highlights the fact that his statements do not meet the requirements of a lay declarant (much less an expert), particularly when contrasted with the declarations submitted by Dr. Peter Lurie, Seife's uncompensated expert.

If a lay affidavit is not based on personal knowledge, it is considered "blatant[] inadmissible hearsay when used to prove the truth of the matters referenced" and, thus, cannot be considered in support of a motion for summary judgment. *C.G. ex rel. B.G.*, 752 F. Supp. 2d at 360-61; *see also Cooper v. Niagara Cmty. Action Program*, No. 08-cv-468S, 2010 WL 1407238, *4 (W.D.N.Y. Mar. 31, 2010). Sarepta's belated attempt to analogize Estepan to a record keeper who reviewed records in his official capacity also fails, because the documents that Estepan claims to have reviewed (which is in itself doubtful given mistakes in his testimony) require more than a casual knowledge of science to understand. *See Searles v. First Fortis Life Ins. Co.*, 98 F. Supp. 2d 456, 461-62 (S.D.N.Y. 2000) (corporate officer responsible for overseeing company's life and disability business had personal knowledge of the matters in her affidavit after reviewing administrative records and an insurance policy). Sarepta has not cured the flaws in the first Estepan declaration by introducing the second Estepan declaration, and the Court should strike both.

Sarepta claims that Estepan's personal knowledge can "easily be inferred" from his title at Sarepta—"the Chief of Staff and Head of Corporate Affairs, Overseeing Investor Relations,

Corporate Communications, and Program Management." Sarepta Opp. to Strike at 4. This conclusory assertion is emblematic of Sarepta's entire argument that Estepan, through his experience in "healthcare investing," somehow has the technical, scientific, or medical expertise to opine on highly technical distinctions in clinical study protocols relevant to other compounds. Sarepta Opp. to Strike at 5; Estepan 2d Decl. ¶ 4.

The caselaw Sarepta cites in support of its reply underscores that, in order to be considered personal knowledge, the subject matter of a lay witness must be within that witness's "sphere of responsibility." *DIRECTV, Inc. v. Budden*, 420 F.3d 521, 531 (5th Cir. 2005). As a corporate officer with experience in healthcare investing, the specific underlying technical and scientific concepts of clinical study protocols are not within Estepan's sphere of responsibility, rendering him incompetent to testify on those issues. Estepan's statements of his actual responsibilities further illustrate this point. *See, e.g.,* Estepan 2d Decl. ¶¶ 11 ("A significant portion of my time at Sarepta has been devoted to Program Management. In this role, I have led the development of Sarepta's strategic plan and execution of corporate strategic initiatives."); 15 ("I have seen exhibitions of Sarepta proprietary technology."). As a corporate officer, Estepan claims he frequently consulted with "scientific, medical, and technical personnel," not that he is one. *Id.* ¶ 13. Nor can he convey their hearsay.

Moreover, even if Estepan were competent to testify on the issues at hand, he still has not cured the numerous conclusory and speculative statements in his first and second declarations, for which he has failed to state a basis. *See* Seife Mot. to Strike at 14-17; *see, e.g.,* Estepan 2d Decl. at ¶¶ 29 ("Sarepta's competitors are studying a variety of dosing questions and have yet to determine a final therapeutic dose amount, timing, form, and strength for their drug candidates."); 31 ("the disclosure of unpublished information regarding Sarepta's exploratory endpoints for eteplirsen would be commercially valuable to Sarepta's competitors . . ."); 32 ("Sarepta's competitors could take advantage

of data relating to AEs found not to be drug-related . . ."); 33 ("AE data may intentionally be taken out of context and exploited to discourage investment in Sarepta.").

The additional assertions that Estepan makes in his second declaration demonstrate that he lacks the knowledge to opine on these issues. As described in the reply declaration of Peter Lurie, Estepan incorrectly states scientific and technical aspects of Seife's request and demonstrates a lack of understanding of scientific concepts. For example:

- Estepan 2d Decl. ¶ 44: "Under such circumstances, the initial study (Study 201) looked at multiple endpoints to assess the safety of the drug and to create a context in which the effectiveness of the compound could be assessed. For phase two (Study 202), the focus turned to efficacy, as Sarepta sought to establish a measure of efficacy sufficient to obtain FDA approval. . . Sarepta's analysis was publicly disclosed in its NDA."

- **Response**: Sarepta had already completed two clinical trials of eteplirsen (Exondys 51) that focused on safety and dosing prior to commencing Study 201. Kenney Decl., Ex. X, 26-64, 73-90. Study 201 was not an "initial study" designed to assess safety. Study 201 was a Phase Two trial, designed to assess efficacy, and Study 202 was a continuation of Study 201 that also focused on efficacy. Kenney Decl., Ex. P, 31; *id.*, Ex. O, 3; *id.*, Ex. S, 2. Sarepta's NDA is not public. The CSRs that Seife seeks were filed as part of the NDA. *See* FDA Br. at 2, n.2, 3, ECF No. 75.

Through his second declaration, Estepan also demonstrates a lack of knowledge about issues that are dispositive on his assertions of competitive harm. For example:

- Estepan 2d Decl. ¶ 32: "Sarepta's competitors could take advantage of data relating to AEs found not to be drug-related, AEs occurring with a variety of compounds Sarepta studied, and Sarepta's methods of testing and analyzing AEs—all without making the significant investments of time and money that Sarepta made."

- **Response**: Adverse Event (AE) data would not be useful to Sarepta's competitors because the small study size means that determinations as to whether a drug caused the AE would be done clinically, not based on statistics. Lurie 2d Decl. ¶ 5. It is highly unlikely that Sarepta invented a novel statistical method for analyzing or testing AEs since the testing and analysis has been well-studied for decades and the method of recording and identifying adverse events is standard throughout industry. *Id.* ¶ 6; *see also* Seife 2d Decl., Ex. B, 6-7.

Moreover, the inclusion in the second Estepan declaration of the specific scientific documents that Estepan reviewed further illustrates the impropriety of relying on his testimony. Estepan 2d Decl.

¶¶ 15-19, 43. As described above, Estepan simply does not have the requisite expertise to review and interpret these documents—his one year of medical school is hardly sufficient to establish a basis of knowledge with which to do so. *See id.* ¶ 4. That Estepan was reviewing scientific documents in his role as the Head of Corporate Affairs does not translate into personal knowledge with which he could assess how withheld information could or could not be used by scientists at Sarepta's competitors. Estepan notes in his second declaration that he completed one year of medical school and has a "Bachelor of Science" (but does not indicate which program he completed), yet does not describe how these give him the background necessary to give competent testimony on the issues at hand. *Id.* at ¶ 5.

The only case Sarepta cites in support of its argument on this point, *DIRECTV, Inc. v. Budden*, cuts against its own argument. 420 F.3d 521, 531 (5th Cir. 2005). In *DIRECTV*, the court noted that subjects of the affiant's testimony were "reasonably within [his] position," in other words, "his sphere of responsibility." *Id.* The affiant was the Senior Director for Signal Integrity, and therefore had personal knowledge of investigations into potential illegal access of DIRECTV programming, including the investigation at issue in the litigation. *Id.* That kind of personal knowledge is a far cry from Estepan's alleged "knowledge" of clinical study protocols and data, as a corporate executive with no role in any clinical team at Sarepta. Sarepta's reliance on *DIRECTV* is therefore misplaced.

Finally, Sarepta's attempt to analogize Estepan to a record keeper who reviewed records in his official capacity fails. The cases Sarepta cites in which affiants properly testified to the contents of records reviewed in an employee's official capacity are distinguishable because none of those cases involved highly technical and scientific matters of the kind that are in dispute here. For example, in *Searles*, the affiant at issue was a "corporate officer" and was responsible for overseeing the company's life and disability businesses. *Searles*, 98 F. Supp. 2d. at 461-62. In preparing her affidavit, she reviewed "various administrative materials and files, as well as the [relevant insurance] policy, and so had direct

personal knowledge of the facts and circumstances set forth therein." *Id.* This is in sharp contrast to Estepan's lack of a medical degree or other scientific training that would enable him competently to review and opine on the technical matters at the heart of this case, namely highly sophisticated clinical research and trial design. Estepan cannot convert his experience in healthcare investing into the expertise required to opine on the clinical and scientific issues that dominate this litigation.

CONCLUSION

For each and all the foregoing reasons, and in the reasons set forth in Seife's initial motion papers, defendants' motions for summary judgment should be denied, and Seife's cross-motion for summary judgment granted. Further, Seife's objections to Estepan's two declarations should be sustained and those declarations should be stricken or disregarded. Seife prays for such other and further relief to which he is entitled.

Dated: August 30, 2018

Respectfully submitted,[8]

/s/Cortelyou C. Kenney
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[8] This memorandum has been partially prepared by the Media Freedom and Information Access Clinic, a program of the Abrams Institute for Freedom of Expression at Yale Law School, and by the First Amendment Clinic at Cornell Law School. Nothing in this memorandum should be construed to represent the institutional views of these law schools, if any.

Certificate of Service

On August 30, 2018, a copy of the foregoing document was served on all counsel of record via the Court's Electronic Case Filing (ECF) system.

By: */s/ Cortelyou Kenney*
One of Counsel