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, Inc.** ***Defendant-Intervenor*.**	**Case No. 1:17-cv-3960 (JMF)**

SAREPTA THERAPEUTICS, INC.'S SUPPLEMENTAL MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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Defendant-Intervenor Sarepta Therapeutics, Inc. ("Sarepta") submits this supplemental memorandum of law in support of its and the Food and Drug Administration's ("FDA" or the "Agency") Motions for Summary Judgment, on the ground that, pursuant to 5 U.S.C. § 552(b)(4) ("Exemption 4"), the FDA has properly withheld from release information redacted in response to Plaintiff's Freedom of Information Act ("FOIA") request.

I. INTRODUCTION

The Supreme Court fundamentally changed the FOIA Exemption 4 landscape in *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356 (2019) (*hereinafter* "*Argus Leader*"). Under the Supreme Court's simplified test, "where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4." *Id.* at 2366. Plaintiff Charles Seife ("Plaintiff" or "Seife") stipulated early in this matter that Sarepta keeps the information at issue in this case confidential, and the factual record confirms that these stipulations were appropriate. Moreover, the parties have engaged in multiple reviews to ensure that only confidential, nonpublic information remains behind the disputed redactions. Finally, the FDA has throughout this case acted in accordance with its regulations and maintained the confidentiality of the redacted material, and the Plaintiff has stipulated to (and identified public statements of the FDA confirming) the FDA's policy of withholding precisely the information at issue in this case. This case is on all fours with *Argus Leader*, and the redactions should be upheld.

By way of background, this litigation stems from the request of Plaintiff that the FDA release Clinical Study Reports 201 and 202 and supporting documentation (collectively, the "CSRs") submitted to the FDA by Sarepta in 2015. Sarepta submitted the CSRs in order to seek the FDA's approval to market the drug eteplirsen (trade name EXONDYS 51®) for the treatment

of Duchenne muscular dystrophy ("DMD"), a rare disease afflicting young males. The information contained in Sarepta's New Drug Application ("NDA"), of which the CSRs were a part, reflects more than a decade of work and an investment of millions of dollars. Sarepta submitted the CSRs to the FDA, its regulator, in order to obtain regulatory approval to market eteplirsen, and did so pursuant to its reasonable understanding that the FDA would maintain the confidentiality of certain portions of the CSRs. Neither the FDA nor Sarepta customarily releases unredacted CSRs.

As evidenced by the existence of this litigation, FDA has maintained the confidentiality of portions of the CSRs, pursuant to its regulations, both before and after the commencement of this litigation. In accordance with the government's long-established procedures governing FOIA releases, the FDA and Sarepta worked together to create a publicly releasable version of the requested CSRs in response to Plaintiff's FOIA request. This publicly releasable version redacts all confidentially-held information from the CSRs—and only the confidentially-held information. The FDA and Sarepta together have striven to develop a version of the requested materials that both responds to Plaintiff's FOIA request and also protects Sarepta's interest in its confidentially-held proprietary information. In doing, so, the FDA has released thousands of pages of material to the Plaintiff.

The remaining redactions in the released materials protect confidential information and therefore are proper under FOIA Exemption 4, as recently clarified by the Supreme Court in *Argus Leader*. Accordingly, this Court should grant summary judgment in favor of the FDA and Sarepta.

II. STATEMENT OF FACTS

A. Sarepta's Research

Sarepta began researching possible treatments for DMD patients in the 2000s. (First Decl. of Ian Estepan dated April 6, 2018 ("First Estepan Decl."), Dkt. 72 ¶¶ 11[1].) DMD is a progressively debilitating and ultimately fatal neuromuscular disease affecting approximately 9,000 to 12,000 young males in the United States. (*Id.* ¶ 4-5.) DMD is caused by mutations in the dystrophin gene that result in a lack of dystrophin in a patient's body. (*Id.* ¶ 6.) Dystrophin is a protein that plays a vital role in the structure of muscle cells, and the lack of dystrophin causes a progressive loss of muscle tissue and function. (*Id.*)

While the mutations in the dystrophin gene causing DMD vary, for more than half of patients, DMD is caused by the deletion of one or more exons (a sequence within the gene that will be expressed once transcribed by RNA). (*Id.* ¶ 8.) "Exon skipping" is a molecular biological process used to treat genetic diseases such as DMD; in simplest terms, exon skipping instructs the body's cellular machinery to "skip over" a segment of the gene sequence during the translation process. (*Id.* ¶ 9.) In the context of DMD, exon skipping can cause the body to skip over the mutation on the dystrophin gene, resulting in the production of functional, albeit shortened, form of the gene. (*Id.*)

Scientists at Sarepta, in collaboration with others, created a modified version of DNA suitable for exon skipping in a therapeutic setting. (*Id.* ¶¶ 10-12.) The result of this multi-year collaboration was eteplirsen, a type of compound designed to cause exon 51 to be skipped during processing in patients with mutations amenable to such skipping. (*Id.* at ¶ 12.) These mutations

[1] For the convenience of the Court, a copy of this previously filed Estepan Declaration, as well as copies of the previously filed Ittig and Sherwood Declarations (discussed below), are attached as exhibits to the Declaration of Amanda Sherwood dated September 30, 2019 filed in connection with this supplemental memorandum of law. (Ex. C.)

occur in approximately 13% of DMD patients. (*Id.* ¶ 13.) Sarepta submitted an Investigational New Drug ("IND") Application to the FDA for the use of eteplirsen to treat DMD in 2007. (*Id.* ¶ 14.) IND approval is necessary to conduct clinical trials, but is by no means a guarantee that the investigational drug will ever reach the market. The percentage of drugs subject to Phase 1 clinical testing that eventually complete the approval process is only 9.6%.[2] Having achieved preliminary success in proof-of-concept (known as "Phase 1") clinical studies, Sarepta initiated a 28-week double-blind, placebo-controlled "Phase 2" study in 2011 ("Study 201"). (*Id.* ¶ 15.) Twelve patients, each with DMD mutations amenable to exon 51 skipping, participated in this study. (*Id.* ¶ 17.) Sarepta transitioned Study 201 into a longer-term "Phase 2b" study in 2012 ("Study 202"). (*Id.* ¶ 16.)

Clinical trials compare a historical control group of untreated DMD subjects[3] to the study participants, whose progress is compared to "endpoints" to measure drug efficacy. "Clinical" endpoints consider direct effects on patients, and "surrogate" endpoints use lab measurements to track a marker affiliated with a disease. (*Id.* ¶ 35.) During the course of these studies, Sarepta measured and analyzed multiple endpoints, some of which—such as certain lymphocyte counts, the "timed 4-step test," and the North Star Ambulatory Assessment—have been publicly released, while other similar endpoints have not, and remain part of Sarepta's proprietary research and methodological knowledge. (CSR Excerpts, Decl. of Kristen Ittig dated April 6, 2018 ("Ittig Decl."), Ex. B, Dkt. 73-2 at FDACDER00028 ("Bates 28"); Bates 6474.) After much research and expense, Sarepta chose an increase in dystrophin (measured via muscle

[2] *See* "Clinical Development Success Rates 2006-2015," Biotechnology Innovation Organization, *available at* www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf.

[3] Data regarding untreated DMD subjects is obtained via contract with third parties. (First Estepan Decl., Dkt. 72 ¶ 33.)

biopsies taken at designated points during the study) as a surrogate endpoint and patients' ability to complete a six-minute walk test as a clinical endpoint. (*Id.* at Bates 28-29; First Estepan Decl., Dkt. 72 ¶ 36.) The surrogate endpoint was the ultimate basis for FDA approval. (First Estepan Decl., Dkt. 72 ¶ 26.) The FDA recently publicly confirmed that dystrophin is an acceptable surrogate endpoint to achieve accelerated approval, rendering Sarepta's research into correct measurement of dystrophin extremely valuable. (*Id.* ¶ 27.)[4]

The CSRs that Plaintiff requests document the results of Studies 201 and 202. Each CSR consists of an approximately 100-page narrative document, accompanied by thousands of pages of attachments containing supporting data and background information. Dissemination of CSRs, and study results in general, is carefully controlled, even within Sarepta. Disclosure is limited to certain members of Sarepta's clinical development, regulatory, biostatistics, and data-management functions along with certain members of the executive committee. (*Id.* ¶ 19; Ex. A, Decl. of William Thornton dated Sept. 30, 2019 ("Thornton Decl.") ¶¶ 9-13; Ex. B, Decl. of Christopher Verni dated Sept. 30, 2019 ("Verni Decl.") ¶¶ 4-6.) Clinical trials and the research that supports them are a costly undertaking, requiring the investment of hundreds of millions of dollars. The clinical trials themselves are conducted under strict confidentiality terms, including nondisclosure agreements executed with any third-party providers. (Ex. B, Verni Decl. ¶ 6.) Confidentiality is of utmost importance to Sarepta not only to preserve its competitive advantage but also to protect itself from allegations of prior disclosure that could weaken Sarepta's intellectual property protections. (*See generally* First Estepan Decl., Dkt. 72.)

[4] *See* https://www.fda.gov/media/92233/download at 10-11.

B. The FDA's New Drug Approval Process

An ultimate goal of commercial drug development is FDA approval to market the resulting drug. The primary stage of the approval process is the submission by the company, and review by the FDA, of the New Drug Application. 21 U.S.C. § 355; 21 C.F.R. Part 314. NDAs are comprehensive reports of what the submitting company knows about its drug, including "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1); *see also* 21 C.F.R. § 314.50. The documents to which Plaintiff requests access through this FOIA action were submitted to the FDA as attachments to Sarepta's NDA for eteplirsen. (First Estepan Decl., Dkt. 72 ¶ 20.)

The FDA approval process can take years. But, the law allows for accelerated approval of drugs that treat a "serious or life threatening disease[]" and provide "meaningful therapeutic benefit to patients over existing treatments," if the manufacturer directly demonstrates the drug provides a "clinical benefit" or if the manufacturer indirectly does so by using a "surrogate endpoint." 21 U.S.C. § 356(c)(1)(A). Sarepta followed this established process to receive accelerated FDA consideration of eteplirsen. After the success of Studies 201 and 202, Sarepta submitted an NDA on June 26, 2015; on September 19, 2016, the FDA granted EXONDYS 51® accelerated approval to treat DMD patients.

C. Fierce Competition in the Market for DMD Treatments Mandates that Sarepta Protect Confidential Data

Sarepta has achieved a hard-earned competitive advantage as the first company to earn FDA approval of exon-skipping therapy for treatment of DMD. (*See* First Estepan Decl., Dkt. 72 ¶¶ 44-60.) The principle of exon skipping is reproducible, and the limited public release of information regarding Sarepta's application of this principle to DMD has led many other pharmaceutical companies to work to develop their own DMD treatments specifically utilizing

exon skipping. (*Id.* ¶¶ 44-45.) All companies developing DMD treatments compete for the same small patient population, within which only a percentage of DMD patients are potentially responsive to a drug, such as Exondys 51, that causes skipping of a particular exon (exon 51). (*Id.* ¶¶ 13, 50-51.) While Sarepta's eteplirsen studies were designed to induce exon 51 skipping, testing methods and study design are portable across exons. (*Id.*) For these reasons, Sarepta must carefully guard all non-public information regarding its Studies 201 and 202. (*See, e.g.*, *id.* ¶¶ 22-60.)

Despite its small size, Sarepta has made strategic investments and achieved early innovations in the utilization of exon skipping for DMD treatment. (*Id.* ¶¶ 55, 10-20, 52.) This has generated a significant competitive advantage for Sarepta with respect to both its existing drug and as Sarepta moves to expand its DMD treatment portfolio. Sarepta's competitive advantage would be severely jeopardized by publication of sensitive and confidential details of Sarepta's eteplirsen clinical trials, the very information Plaintiff seeks through this FOIA action.

III. PROCEDURAL POSTURE

In response to Plaintiff's FOIA request and subsequent lawsuit, the FDA and Sarepta produced redacted versions of CSRs 201 and 202 that withheld confidential material, along with a *Vaughn* index justifying each redaction, in late 2017. Plaintiff then provided the FDA and Sarepta with an annotated version of the *Vaughn* index identifying a subset of FOIA Exemption 4 redactions that Plaintiff wished to challenge through this litigation. The parties filed their original summary judgment briefings, focused on these selected redactions, in 2018.

Plaintiff's summary judgment brief argued, *inter alia*, that the redactions improperly withheld information that had been released publicly, identifying a set of example redactions, and attaching various public documents related to eteplirsen Plaintiff claimed released the

redacted material. Sarepta was not (and is not) seeking to protect any public information, and so reviewed Plaintiff's assertions, unredacting information where appropriate. (Dkt. 104.)

After the briefs were filed, but before the cross motions were decided, on January 11, 2019, the U.S. Supreme Court granted *certiorari* in *Food Marketing Institute v. Argus Leader Media*, No. 18-481, a case that called into question the validity of the test set forth in *National Parks v. Morton*, 498 F.2d 756 (D.C. Cir. 1974), upon which the parties based their original briefing. This Court then administratively terminated the parties' original summary judgment motions and suspended further briefing pending the Supreme Court's decision in *Argus Leader*. (Dkt. 129.) The Court determined, however, that because Sarepta discovered and unredacted public information in response to the specific examples raised in Plaintiff's summary judgment briefing, Sarepta and the FDA should perform a full review of the requested documents to determine if any other public information was being improperly redacted. (*Id.* at 4-5.) Sarepta thus re-reviewed the entirety of the requested materials. (Ex. C, Second Declaration of Amanda Sherwood ("Second Sherwood Decl.") ¶ 9.)

The Supreme Court issued its decision in *Argus Leader* on June 24, 2019, overturning the *National Parks* test. 139 S. Ct. 2356 (2019). This Court ordered supplemental summary judgment briefing addressing the *Argus Leader* decision. (Dkt. 137). Sarepta hereby timely files its supplemental summary judgment motion in accordance with that order.

IV. STANDARD OF REVIEW

Summary judgment is appropriate when "there is no genuine issue as to any material fact." Fed. R. Civ. P. 56(c). In a FOIA case, to warrant summary judgment, "the agency need only submit 'affidavits or declarations' that demonstrate (1) that the agency 'has conducted a thorough search,' and (2) 'giving reasonably detailed explanations why any withheld documents fall within an exemption.'" *Gertskis v. U.S. E.E.O.C.*, 2013 WL 1148924 at *14 (S.D.N.Y.

March 20, 2013) (Furman, J.) (quoting *Long v. Office of Pers. Mgmt.*, 692 F.3d 185, 190-91 (2d Cir. 2012)). A court should grant summary judgement in a FOIA case based on submitted declarations or affidavits "when the affidavits describe the justifications for nondisclosure with reasonably specific detail, demonstrate that the information withheld logically falls within the claimed exemption, and are not controverted by either contrary evidence in the record nor by evidence of agency bad faith. Ultimately an agency's justification for invoking a FOIA exemption is sufficient if it appears logical or plausible." *Wilner v. Nat'l Sec. Agency*, 592 F.3d 60, 73 (2d Cir. 2009) (quoting *Larson v. Dep't of State,* 565 F.3d 857, 861-62 (D.C. Cir. 2009)).

V. ARGUMENT

The redactions to the requested material in this case plainly meet the test set out in *Argus Leader*. Plaintiff has stipulated that Sarepta keeps its CSR information confidential, and these stipulations are consistent with the record. The parties have engaged in multiple reviews to ensure that no public information is included in the redactions. Regarding "assurance of confidentiality," while the Supreme Court's dicta may have some eventual relevance in cases where an agency contests a submitter's assertions of protection, it cannot apply where the FDA participated in withholding the documents and concurs in the redactions. In any event, as cited by the Plaintiff, the FDA has repeatedly confirmed that its policy is not to release CSR information of the type at issue. *Argus Leader* therefore mandates that the FDA and Sarepta's motions for summary judgment be granted.

FOIA Exemption 4 shields from disclosure "commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). As the FOIA statute does not define the term "confidential," courts in many circuits—including this one—previously looked to the D.C. Circuit's test created in *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974), which hinged on whether disclosure would either

"(1) impair[] the government's ability to obtain information—necessary information—in the future, or (2) caus[e] substantial harm to the competitive position of the person from whom the information was obtained." *Cont'l Stock Transfer & Trust Co. v. SEC*, 566 F.2d 373, 375 (2d Cir. 1977) (per curiam) (adopting the *National Parks* test).

In *Argus Leader*, however, the Supreme Court noted that the phrase "substantial competitive harm" appears nowhere in the text of the FOIA statute and condemned the *National Parks* test as a "relic from a bygone era of statutory construction," evincing an inappropriately "casual disregard of the rules of statutory interpretation." 139 S. Ct. at 2364 (quotation omitted). The Supreme Court emphasized that, instead of judicially creating new meanings not present in a statute's text, "a court's proper starting point lies in a careful examination of the ordinary meaning and structure of the law itself." *Id.* The Court accordingly looked to the "ordinary, contemporary, common meaning" of the term "confidential," "when Congress enacted the FOIA in 1966," finding it "meant then, as it does now, 'private' or 'secret.'" *Id.* (quotations omitted). The Court then found "two conditions that might be required for information communicated to another to be considered confidential:

> In one sense, information communicated to another remains confidential whenever it is customarily kept private, or at least closely held, by the person imparting it. In another sense, information might be considered confidential only if the party receiving it provides some assurance that it will remain secret.

Id. at 2363 (citations omitted). The submitting company clearly met the first condition in *Argus Leader*: "uncontested testimony established that the Institute's retailers customarily do not disclose [the requested information] or make it publicly available in any way." *Id.* (citation omitted). The Court found there to be "no need to resolve" the question of whether confidentially held information can "*lose* its confidential character for purposes of Exemption 4

if it's communicated to the government without assurances that the government will keep it private," because that condition was met in *Argus Leader* as well. *Id.* (emphasis in original).

While the *Argus Leader* decision changes the FOIA Exemption 4 landscape, it actually sharpens the focus of the Court's inquiry in this case. No longer does the requested disclosure of Sarepta's sensitive clinical study reports rest on whether the Court accepts that Sarepta would likely suffer substantial competitive harm from such a disclosure. Instead, *Argus Leader* protects Sarepta's proprietary materials from release *precisely because they are confidential*. FOIA Exemption 4 protects from disclosure "commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). Under the ordinary meaning of those terms, and as confirmed through multiple declarations, Sarepta's clinical study reports and attachments are confidential and therefore must be protected from disclosure.[5]

A. Sarepta Customarily Keeps the Requested Information as Confidential

Under the new standard announced in *Argus Leader*, this Court need only consider whether Sarepta customarily keeps the requested information as confidential in order to find withholding under FOIA to be proper. Plaintiff does not dispute that this standard has been met by Sarepta. Plaintiff has explicitly stipulated multiple times that Sarepta keeps these materials confidential. These stipulations should be sufficient to resolve the matter, but as an additional measure to provide the Court with context in which to consider the new test, Sarepta supports this filing with declarations demonstrating Sarepta's proactive, actual, and effective efforts to maintain the requested materials' confidentiality. This showing is more than sufficient under

[5] While FOIA Section 552(b) permits agencies to withhold requested information that falls within 9 exemptions, the Trade Secrets Act removes this discretion for Exemption 4. 18 U.S.C. § 1905; *see McDonnell Douglas Corp. v. Nat'l. Aeronautics & Space Admin.*, 180 F.3d 303, 305 (D.C. Cir. 1999); *Pacific Architects & Eng'rs, Inc. v. Dep't of State*, 906 F.2d 1345, 1347 (9th Cir. 1990).

existing FOIA case law informing the bar for confidentiality, and Plaintiff cannot deny Sarepta's efforts to segregate confidential from non-confidential information for release.

1. Plaintiff Does Not Dispute that Sarepta Keeps the Requested Documents as Confidential.

As an initial (and dispositive) matter, Plaintiff does not dispute that Sarepta in fact kept the requested documents confidential:

> 27. Sarepta's clinical studies for eteplersen [sic] were conducted under strict confidentiality terms, including nondisclosure agreements executed with any third-party providers. (Estepan Decl. ¶ 19.)
>
> **Seife Response: Undisputed.**

(Pl.'s Resp. to Def.'s Statement of Material Facts, Dkt. 91 ¶ 27.)

> 37. Sarepta has limited the dissemination of the CSRs for eteplersen [sic], even within the company itself. (*Id.* ¶ 19.)
>
> **Seife Response: Undisputed.**

(*Id.* ¶ 37.) Finally, Plaintiff explicitly does not dispute the confidentiality prong which has always been, and remains under *Argus* an element of the FOIA Exemption 4 test, stating "Seife does not dispute that Sarepta has limited the dissemination of the CSRs for eteplirsen and that the stated reason for from Sarepta is that such limited dissemination is to protect proprietary information." (*Id.* ¶ 38 (emphasis added).)

Because Plaintiff has not controverted these statements of fact that are supported by a declaration from Sarepta, they are deemed admitted. *See Giannullo v. City of N.Y.*, 322 F.3d 139, 140 (2d Cir. 2003) ("If the opposing party . . . fails to controvert a fact so set forth in the moving party's Rule 56.1 statement, that fact will be deemed admitted."); *Hoodho v. Holder*, 558 F.3d 184, 191 (2d Cir. 2009) (facts admitted by a party are judicial admissions that bind the party throughout the litigation); *see also Cohan v. Movtady*, 751 F. Supp. 2d 436, 443 (E.D.N.Y. 2010)

(citing *Hoodho v. Holder* for the proposition that "parties are bound by their concessions in Rule 56.1 Statements"). Plaintiff therefore is bound by his admissions that Sarepta actually treated the requested documents as private.

No justification exists for allowing Plaintiff to withdraw its admissions, if he seeks to do so, or to request some kind of audit of Sarepta's internal operations. The underlying facts, confirmed by declarations from Sarepta, have not changed since Plaintiff acknowledged that Sarepta "customarily and actually treated" the requested information "as private." *Argus Leader*, *supra* at 2366. All that has changed is the legal significance of those facts. Plaintiff must live with its plain statements, however inconvenient they may be now that the Supreme Court has clarified the law of the land.

2. Sarepta Has Demonstrated That It Maintains the Requested Documents As Confidential.

Even if Plaintiff's stipulations are not enough to resolve the issue (but they should be), Sarepta has more than sufficiently demonstrated that it keeps the requested materials confidential, both under existing case law and common sense.

Even before *Argus Leader*, many circuits adopted a more straightforward confidentiality test for "voluntary" submissions to the government. *See Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 879 (D.C. Cir. 1992) (*en banc*).[6] Notably, the *Critical Mass* decision resulted from an *en banc* rehearing triggered by two D.C. Circuit judges' criticism that the *National Parks* test was "fabricated, out of whole cloth," a criticism which is

[6] The Second Circuit has never expressly accepted or rejected the *Critical Mass* test. *See Inner City Press/Community on the Move v. Board of Governors of Fed. Reserve Sys.*, 463 F.3d 239, 245 n.6 (2d Cir. 2006) (declining to "adopt nostra sponte the *Critical Mass* test" when the parties did "not argue for its adoption"); *see also Nadler v. FDIC*, 92 F.3d 93, 96 n.1 (2d Cir. 1996) (declining to consider whether the *Critical Mass* test should apply to voluntary submissions because the submission in question was involuntary).

markedly similar to the Supreme Court's critique of the test in *Argus Leader*. The *Critical Mass* court reasoned that, at least when a document was submitted to the government voluntarily, it "is 'confidential' for the purpose of Exemption 4 if it is of a kind that would customarily not be released to the public by the person from whom it was obtained," without regard to the "competitive harm" *National Parks* standard which *Argus Leader* recently overturned. *Id.* Cases in the vein of *Critical Mass* therefore serve as uniquely useful precedent on the confidentiality standard for FOIA purposes, a standard Sarepta easily meets.

Courts applying the *Critical Mass* confidentiality standard agree that "in assessing customary disclosure, the court will consider how the particular party customarily treats the information, not how the industry as a whole treats the information." *Center for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 244 F.3d 144, 148 (D.C. Cir. 2001). This showing is most often—and most persuasively—made through company declarations. For example, the court in *Defenders of Wildlife v. U.S. Dep't of Interior* relied on a declaration submitted by the President and founder of a company averring that the company "considers severance agreements to be 'proprietary financial information that it has never made available to the public,' and he could think of no other occasion when the company had disclosed such an agreement" to establish confidentiality under Exemption 4. 314 F. Supp. 2d 1, 17 (D.D.C. 2004). *Cf. Inner City Press/ Community on the Move v. Bd. Of Governors of Fed. Reserve Sys.*, 380 F. Supp. 2d 211, 217-18 (S.D.N.Y. 2005) (granting summary judgment in favor of withholding documents from disclosure under FOIA Exemption 4 on the basis of a bank vice president's declaration stating "in the ordinary course" the bank would not disclose the requested information).

Sarepta has submitted two such declarations here (in addition to the prior two declarations submitted by Mr. Ian Estepan). Mr. Christopher Verni is Sarepta's Vice President

and Chief Intellectual Property Counsel and is responsible for all intellectual property related legal matters for Sarepta. (Ex. B, Verni Decl. ¶¶ 1-2.) His declaration describes the legal steps Sarepta takes to ensure the confidentiality of materials such as those requested by Plaintiff. Namely, every single Sarepta employee—including those who worked on clinical studies 201 and 202—sign confidentiality agreements that prohibit the disclosure, by any means, of any Sarepta confidential information without Sarepta's prior written consent. (*Id.* ¶ 4.) This obligation extends even after the term of employment and covers the broad category of information that Sarepta considers to be confidential, including future product development plans, technical know-how, and information that Sarepta is otherwise obligated to keep confidential. (*Id.*)

Not only do Sarepta employees sign these confidentiality agreements, every consultant that Sarepta engages to work on clinical studies signs a similar agreement. (*Id.* ¶ 5.) Furthermore, clinical studies 201 and 202 were conducted pursuant to clinical trial agreements that also protect confidential information, defined to include (but not be limited to) information such as study protocols, information relating to the study drug, and information generated in connection with the clinical study. (*Id.* ¶ 6; First Estepan Decl., Dkt. 72 ¶ 19.) These non-disclosure obligations survive the end of the clinical study and apply to all third parties who participate in the conduct of the study. (Ex. B, Verni Decl. ¶ 6.) Similarly, Sarepta only shares clinical study information with research consortia under strict confidentiality terms. (*Id.* ¶¶ 8-10.)

The case law is clear that these "limited disclosures, not made to the general public, do not preclude Exemption 4 protection." *Parker v. Bureau of Land Mgmt.*, 141 F. Supp. 2d 71, 79 (D.D.C. 2001) (finding confidential documents to be protected under Exemption 4). That is, "[a]

party can voluntarily make protected disclosures of information, and as long as the disclosures are not made to the general public, such disclosures do not constitute customary disclosures." *Center for Auto Safety*, 244 F.3d at 148; *id.* at 151 (agreeing that "the mere sale of a product to the public does not constitute customary disclosure"). This includes information revealed to a "third party contractor" under "confidentiality agreements." *Parker*, 141 F. Supp. 2d at 79.

Here, too, Sarepta never disclosed the withheld materials to the "general public." While the clinical study process requires cooperation with and participation by third parties, Sarepta consciously and carefully only shared information with such entities under binding agreements containing strict confidentiality terms. Not even Sarepta's own employees have access to the sort of data requested by Plaintiff except under binding confidentiality agreements. The fact that the research and development process required the participation of many entities does not mean the inputs and results of that process cannot be confidential, when all those involved took great pains to curtail dissemination of the materials in question and prohibited public sharing of the data without Sarepta's prior consent. *See, e.g.*, *Eli Lilly and Co. v Emisphere Techs., Inc.*, 408 F. Supp. 2d 668, 691-92 (S.D. Ind. 2006) (enforcing confidentiality provisions in pharmaceutical research agreement between two research partners).

Sarepta also submits a declaration from Mr. William Thornton, the Chief Information Officer. (Ex. A.) Mr. Thornton is responsible for Sarepta's global information technology ("IT") function, including the implementation, support, and operations of all the company's computer systems. (Thornton Decl. ¶ 2.) Mr. Thornton's declaration describes how, from an IT perspective, Sarepta protects its confidential information, all of which is electronically stored. Namely, Sarepta restricts access to confidential information saved on its systems to only those

employees authorized to view or with a need to use the information, based on their job role and function. (*Id.* ¶ 5.)

At Sarepta, any department-level information is stored so as to only be accessible to the members of the specific department in question. (*Id.* ¶ 6.) Granting access to department data is a manual process, requiring a manager to authorize an individual to access the data and then the IT department or a local system administrator to execute the manager's direction, in accordance with established policies and procedures. (*Id.* ¶ 7.) Access to clinical study data—including the data contained in clinical study reports 201 and 202—is controlled by a clinical study lead, who must approve employees for access to the data. (*Id.* ¶ 8; *see also id.* ¶¶ 9-11 (describing how clinical study data is saved within Sarepta's systems); First Estepan Decl., Dkt. 72 ¶ 19.) Prior to finalization, the live clinical study data is maintained in a restricted access database that is controlled by Sarepta's Clinical Data Management Group. (Ex. A, Thornton Decl. ¶ 21.) Access is not only limited to the underlying clinical study data; access to Sarepta's FDA submissions incorporating and referencing that data is also limited to employees in Sarepta's Regulatory Affairs department, which assembles the final packages to be submitted to the FDA. (*Id.* ¶ 12.) Since the time that Sarepta submitted clinical studies 201 and 202 to the FDA, none of the confidential data and final results associated with those studies has been released, and it "continues to be maintained in Sarepta's IT systems as confidential." (*Id.* ¶ 21.)

These restrictions are important and probative under established case law to whether the materials should be treated as confidential for purposes of FOIA. In considering whether a company holds requested information as confidential, courts will find relevant that "[d]istribution within the company of these withheld documents was on a limited 'need to know' basis to prevent public dissemination." *Parker*, 141 F. Supp. 2d at 79. *See also McDonnell*

Douglas Corp. v. U.S. E.E.O.C., 922 F. Supp. 235, 242 (D. Mo. 1996) (finding persuasive that the company "guarded [the documents'] disclosure even within the corporate structure," namely that "[a]ll the documents were stamped 'confidential'" and "they were not disseminated beyond those with a need to know their contents"); *Airline Pilots Ass'n, Intern. v. U.S. Postal Service*, 2004 WL 5050900, at *5 (D.D.C. June 24, 2004) (relying on company declaration that "the Transportation Agreement is subject to very limited disclosure within the organization, with access provided to only a few individuals below the corporate officer level . . . and employees with a 'need to know' receiving access only to relevant portions of the document"). *Argus Leader* itself confirmed that whether "within a company . . . only small groups of employees usually have access to" the information is probative of whether that information is confidential. 139 S. Ct. at 2363. That was certainly the case here, as established by Mr. Thornton's declaration.

In Sarepta's prior briefings, Sarepta has referred to four categories of redactions: clinical study procedures, clinical study results, exploratory endpoints, and adverse events. Sarepta maintains that redaction of these four types of information is appropriate, because Sarepta does not customarily release these types of information. (*See* First Estepan Decl., Dkt. 72 ¶¶ 22-43; Decl. of Ian Estepan dated July 30, 2018 ("Second Estepan Decl."), Dkt. 105 ¶ 40.) The simple fact that Plaintiff has so vigorously sought the FDA's release of these four types of information demonstrates that Plaintiff does not currently have access to this information. The reason for this is simple: Sarepta customarily keeps, and has kept, this information confidential, rendering it protected under the *Argus Leader* test for withholding under FOIA Exemption 4. *See Argus Leader*, 139 S. Ct. at 2363 ("uncontested testimony established that the Institute's retailers customarily do not disclose store-level SNAP data or make it publicly available 'in any way.'").

3. Sarepta Does Not Seek to Protect Non-Confidential Information.

Sarepta only seeks to protect confidential information properly withheld under the new standard announced in *Argus Leader*. Sarepta's actions throughout this case demonstrate its commitment to withholding only information that it actually keeps and maintains as confidential.

Sarepta has undertaken multiple reviews of the requested documents. First, Sarepta performed an initial review of all of the documents in conjunction with the FDA. (*See* Dkt. 77-14 at 3 ("Sarepta carefully coordinated and cross-checked its redactions against publicly available documents describing its eteplirsen-related studies, namely the information on the FDA website from the Advisory Committee proceedings and Exondys 51's NDA approval documents. Sarepta only proposes redacting information that has not elsewhere been publicly released, and thus complies with FDA regulations in this regard."); Ex. C, Second Sherwood Decl. ¶¶ 6-7.) Next, Sarepta reviewed the specific assertions that Plaintiff made in its summary judgment briefing, and revised its redactions on some of the challenged pages.[7] (Declaration of Amanda

[7] In the court's order regarding this subsequent review, the court cited Plaintiff's claim that 54% of the challenged pages required removal of some redactions. (Dkt. 129 at 4.) Plaintiff's claim is misleading, however. As described in the initial declaration of A. Sherwood, regarding the documents identified in Exhibit C to the Kenney Declaration, Sarepta unredacted a line from the table of contents that was made in error (Dkt. 104 ¶12) and corrected an inconsistency where information unredacted in one place was redacted elsewhere (*id.* ¶ 17). Sarepta also noted that Plaintiff was citing documents from the original FDA release that had since been corrected to remove inappropriate redactions in February 2018, months before Plaintiff's summary judgment filing. (*Id.* ¶13.) Regarding the documents identified in Ittig Exhibit B (Dkt. 73-2), the majority of the unredactions to these documents related to (1) inconsistencies between pages, and so resulted in no new information being revealed (First Sherwood Decl., Dkt. 104 ¶¶ 24, 28, 33, 34, 35, 42); (2) chart titles and cross-references that were arguably public, and were released out of an abundance of caution, though Plaintiff's claims that underlying data was public were incorrect and such data remained redacted (*id.* at ¶¶ 32, 39); and (3) general descriptions of test methods without any unredaction of test results. (*Id.* at ¶¶ 23, 39, 40.) In three instances, in fact, while Plaintiff's allegations were wrong, Sarepta independently identified different public documents that contained some redacted information, and provided corrected redactions to reflect this. (*Id.* at ¶¶ 25, 26, 38.) Sarepta employed its best efforts at all times, and Sarepta certainly has no objection to the unredaction of public information. But, the vast majority of the unredactions were minor, and related only to administrative details rather than substantive information. In his declaration, Plaintiff chose to characterize these unredactions as damning admissions and include them in his percentage count, but that is not appropriate. These unredactions are rather evidence

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Sherwood dated July 30, 2018 ("First Sherwood Decl."), Dkt. 104, ¶¶ 11-43; Ex. C, Second Sherwood Decl. ¶ 8.) Finally, in response to this Court's instruction, Sarepta compared the public documents provided by Plaintiff line-by-line to every one of the 35,000 requested pages, resulting in additional unredactions. (Ex. C, Second Sherwood Decl. at ¶ 9 (describing unredaction review process and unredacted material).)

This Court has already rejected Plaintiff's "contention that the exception to Exemption 4 for publicly available information applies to information that is 'largely public' or can be 'easily discerned' based on public information. *See* Pl. Reply 9." (Dkt. 120 at 4 n.3.) This Court instead correctly found that the alleged "publicly available information must be 'identical.'" (*Id.*, quoting *Inner City Press*., 463 F.3d at 244.) Furthermore, courts in this Circuit agree that there is no obligation to release "information that is inextricably intertwined with exempt information." *Inner City Press*, 463 F.3d at 249 n.10 (internal quotation and citation omitted). Sarepta therefore has met its obligations to cull public information from the requested documents, and Plaintiff cannot reasonably assert that these exchanges and reviews undermine the reality that Sarepta has "customarily and actually treated as private" the data remaining behind the redactions in the requested materials. *Argus Leader*, 139 S. Ct. at 2366.

B. Sarepta Only Submitted the Requested Information to the FDA Under Assurances of Confidentiality.

As the Supreme Court explained in *Argus Leader*, the proper starting point for statutory interpretation is in the ordinary meaning of the term used in the statute. Where the language of the statute yields a clear answer, no further inquiry is appropriate. As to FOIA, the Supreme

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that Sarepta has been diligent and responsive in pruning the redactions in this matter since the beginning.

Court "has repeatedly refused to alter FOIA's plain terms on the strength only of arguments from legislative history."

Here then, the question at hand is what, in the context of the FOIA statute, does the term "confidential" mean? The Supreme Court found that the term carries its "ordinary, contemporary, common meaning," which is that the information is "private" or "secret." *Argus*, 139 S. Ct. at 2362-63. That holding suggests that confidentiality is the beginning and the end of the inquiry: Is the information private or secret? If so, then it is confidential. *Argus* nevertheless posited that there *may* be a secondary inquiry; namely, whether privately held information may lose its confidential character if it is relayed to the government without assurances that the government will keep it private. *Id.* at 2363. But the Supreme Court found that it did not need to reach that question to decide the case before it, and left it unanswered. *Id.*

This Court need not reach that question either. The Sarepta information is both private and secret, and as in *Argus Leader*, the FDA's regulations provide assurance that the government will keep it private. Moreover, finding that this secondary inquiry is an integral part of the analysis would improperly expand the bounds of statutory interpretation espoused by the Supreme Court, sending the parties into the very atextual territory that the Supreme Court declared off limits.

Still, to the extent that any requirement for assurance of confidentiality from the government is required, it cannot be seriously contested that the Agency in this case has lived up to a commitment to confidentiality expressed in its regulations, its actions, its public statements, and, frankly, the very existence of the case at hand. If the Agency had not intended to keep, and had not in fact kept, these documents confidential, this case would not exist, and Plaintiff would have received the withheld data long ago.

Like in *Argus Leader*, this Court need only refer to the published regulations governing the Agency's treatment of submitted materials such as the clinical study reports at issue here. The CSRs and CSR data in question were submitted to the FDA on June 26, 2015 as part of the NDA for eteplirsen. (First Estepan Decl., Dkt. 72 ¶ 20.) Sarepta marked these submissions as containing confidential information as provided by 21 C.F.R. § 20.61. That application was approved on September 19, 2015.[8] As such, the requested data is subject to the regulations defining the FDA's treatment of submissions in support of a NDA after the NDA is approved, found at 21 C.F.R. § 314.430. These regulations identify a specific set of NDA documents that the Agency will release, making no provision for release of documents not identified.

Plaintiff is not challenging the FDA's application of these regulations,[9] and cannot deny their existence or their clear commitment to maintaining confidentiality over significant quantities of submitted data. The FDA's categorization of particular data as non-releasable under its regulations is not the subject of Plaintiff's suit, which is limited to an assertion that the Agency misapplied FOIA Exemption 4 to allow withholding of Sarepta-submitted documents. The significance of these regulations, in the wake of *Argus Leader*, is the assurance of confidentiality over new drug data submitted by Sarepta, as to all submitters of such data under these regulations.

Notably, Plaintiff himself has acknowledged that the FDA offers its submitters an assurance of confidentiality, specifically over CSR information. Indeed, in his declaration,

[8] https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-first-drug-duchenne-muscular-dystrophy.

[9] Nor could he, in this action, as a challenge to the Agency's application of its regulations would presumably proceed under the Administrative Procedure Act ("APA").

Plaintiff discussed a voluntary pilot program offering extensive CSR disclosures for a small group of NDAs (not including Sarepta's). (Seife Decl., Dkt. 87 ¶ 97.) Plaintiff recounts the statement of FDA administrator Gottlieb acknowledging the FDA's current practice of maintaining confidentiality over NDA study data:

> In an accompanying press release, Commissioner Gottlieb acknowledged that information currently disclosed by the FDA upon approval of a New Drug Application (NDA) does not provide an adequate level of transparency for medical professionals or the public at large. Without disclosure of CSRs, it is difficult for external audiences to extract all of the detailed clinical evidence that supported the FDA's approval decisions.

(Seife Decl., Dkt. 87 ¶ 100.) In the 2018 public statement cited by Mr. Seife, Commissioner Gottlieb described the pilot program involving nine drugs "whose sponsors volunteer to participate" as "the first time that FDA is proactively disclosing clinical summary reports from sponsors to the public." (Kenney Decl. Ex. Z, Dkt. 90-27 at 6-7 (emphasis added); Seife Decl., Dkt. 87 ¶ 100.) In other words, Plaintiff has throughout this case insisted that as of 2018, the FDA's public policy (for all but the nine pilot program volunteers) was not to disclose such reports. While it is clear that Plaintiff would *prefer* this pilot program to extend to all CSR submissions to the FDA, and would prefer if Sarepta had participated in it, the fact remains that it does not so extend, and Sarepta did not volunteer to participate.

Thus, Sarepta is among the main stream of applicants for whom the FDA's regulations and practices extend an assurance of confidentiality, consistent with the actions of the FDA in managing the thousands of NDAs it handles every year. Sarepta did in fact understand and expect that its confidential information, when submitted to the FDA, would be kept confidential. (Ex. B, Verni Decl. ¶ 12.) The FDA's regulations, operating procedures, and course of conduct all justified Sarepta's expectation of confidentiality. The position of the Government here is unmistakable, both from the statements discussed above, and from its conduct and briefing

throughout this matter. *Cf.* Restatement (Second) Contracts § 19 cmt. A ("Conduct may often convey as clearly as words a promise or an assent to a proposed promise."); *Brown Bros. v. Beam Constr. Corp.*, 41 N.Y.2d 397, 399 (1977) ("In determining whether the parties entered into a contractual agreement and what were its terms, it is necessary to look . . . to the objective manifestations of the intent of the parties as gathered by their expressed words and deeds.").

Sarepta's submission of the information under the circumstances of this case (and, indeed, any case where the Agency cooperated in and agrees with the challenged withholding) amply satisfies any requirement related to Government assurance of confidentiality.

VI. CONCLUSION

Sarepta therefore respectfully renews its request that the Court grant its and the FDA's Motions for Summary Judgment and deny Plaintiff's Motion.

Dated: September 30, 2019

Respectfully Submitted,

/s/ Daniel R. Bernstein

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