UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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| CHARLES SEIFE,<br><br>Plaintiff,<br><br>-v-<br><br>FOOD AND DRUG ADMINISTRATION, et al.,<br><br>Defendants. | 17-CV-3960 (JMF)<br><br>OPINION AND ORDER |

JESSE M. FURMAN, United States District Judge:

Plaintiff Charles Seife, a science writer and journalism professor, sues the Food and Drug Administration ("FDA") and Department of Health and Human Services ("HHS") under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, seeking documents and records regarding the testing and approval process for eteplirsen (which is sold under the trade name Exondys 51), a drug created by Sarepta Therapeutics, Inc. ("Sarepta") for the treatment of Duchenne Muscular Dystrophy ("DMD"), a rare neuromuscular disease. See ECF No. 1 ("Compl."). Pursuant to a stipulation between the parties, the FDA produced over 35,000 pages of documents to Seife, some of which were redacted pursuant to FOIA's Exemption 4 ("Exemption 4"), which applies to documents containing "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). Now pending are renewed cross-motions for summary judgment regarding the propriety of the FDA's redactions. For the reasons that follow, the Court grants Defendants' and Sarepta's motions for summary judgment and denies Seife's motion.

## BACKGROUND

The relevant facts are drawn from the parties' affidavits and are undisputed for purposes of this motion. DMD is a progressively debilitating and ultimately fatal neuromuscular disease that affects only about 9,000 to 12,000 young males in the United States. See ECF No. 72 ("Estepan Decl."), ¶¶ 4-5. DMD is caused by genetic mutations that result in a lack of dystrophin, a protein that plays a vital role in the structure of muscle cells and ultimately leads to the progressive loss of muscle tissue and function. Id. ¶ 6. While the mutations 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 RNA translation process. Id. ¶ 9.

Sarepta, a pharmaceutical company, began researching possible treatments for DMD patients in the early 2000s. After several years of research, Sarepta, in collaboration with others, created eteplirsen, a compound designed to cause exon 51 to be skipped during processing in patients with mutations amenable to such skipping. Id. ¶ 12. Approximately thirteen percent of DMD patients have this mutation. Id. ¶ 13. Accordingly, in 2007, Sarepta initiated the pre-drug approval process with the FDA. First, it submitted an Investigational New Drug ("IND") Application to the agency for the use of eteplirsen to treat DMD, which, after approval, allowed Sarepta to conduct clinical trials. Id. ¶ 14. The company conducted the clinical trials with strict confidentiality protocols, including nondisclosure agreements executed with any third-party providers. Id. ¶ 19. After Sarepta achieved preliminary success in proof-of-concept (that is, "Phase 1") clinical studies, it initiated a twenty-eight-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 the study. Id. ¶ 17. Sarepta transitioned Study 201 into a longer-term "Phase 2b" study in 2012 ("Study 202"). Id. ¶ 16.

Throughout its studies, Sarepta followed certain timing and dosing procedures and adopted certain "endpoints" to measure the drugs' efficacy. Id. ¶ 35. The endpoints consisted of both "clinical" endpoints that considered direct effects on patients and "surrogate" endpoints that used lab measurements to track markers affiliated with a disease. Id. After much research and expense, Sarepta chose an increase in dystrophin (measured via muscle 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. ¶ 36. The results of Studies 201 and 202 were documented in clinical study reports ("CSRs"), which were submitted to the FDA as part of Sarepta's New Drug Application ("NDA") in June 2015, thus initiating the primary stage of the drug approval process. 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.

On September 19, 2016, the FDA granted eteplirsen accelerated approval to treat DMD patients. See Compl. ¶ 34. The decision, however, was not without controversy. Although accelerated approval is allowed for drugs that treat a "serious or life-threatening disease[]" and provide "meaningful therapeutic benefit to patients over existing treatments," the manufacturer must either directly demonstrate that the drug provides a "clinical benefit" or indirectly do so by

using a surrogate endpoint. 21 C.F.R. 314.500; see 21 U.S.C. § 356(c)(1)(A). The FDA's advisory committee tasked with ascertaining whether Sarepta's studies showed "substantial evidence" that eteplirsen would provide a clinical benefit ultimately concluded that the studies were deficient. See ECF No. 153-4. Nevertheless, Dr. Janet Woodcock, head of the Center for Drug Evaluation and Research, intervened and unilaterally granted accelerated approval for the drug. See ECF No. 153-5.

On December 5, 2016, Seife submitted a FOIA request to the FDA seeking records related to the accelerated approval of eteplirsen. See Compl. ¶¶ 1-3; see also ECF No. 76 ("Kotler Decl."), ¶¶ 11, 13 & Ex. A. Seife requested, among other things, materials submitted by Sarepta to the FDA to support its approval application, as well as internal Government communications and deliberations regarding the approval. See Kotler Decl. Ex. A. On May 25, 2017, after the FDA denied his appeal for expedited processing, Seife initiated this lawsuit. Just over one month later, Seife filed a motion for partial summary judgment seeking expedited processing. See ECF No. 15. He and the Government then reached agreement on a schedule for the production of documents responsive to the FOIA request (as refined during the course of the parties' negotiations), which was so ordered by the Court on July 27, 2017. See ECF No. 39. On September 15, 2017, Sarepta moved to intervene as a Defendant. See ECF Nos. 43-44. Sarepta's motion was granted on September 18, 2017. See ECF No. 47.

Pursuant to 21 C.F.R. § 20.61, the FDA consulted with Sarepta regarding the confidentiality of Study 201 and Study 202, which were subject to Seife's FOIA request. See ECF No. 77 ("Sager Decl."), ¶¶ 25-26 & Exs. K-N. Sarepta proposed redactions to the two Studies and provided a draft index to the FDA explaining the bases for the proposed redactions. See id. ¶¶ 28, 31. The FDA removed a few of the redactions, but adopted the rest based on

Sarepta's representation that they covered confidential commercial information that would cause competitive harm to Sarepta if disclosed. See id. ¶¶ 29, 32, 37. In accordance with the agreed-upon production schedule, between July 24, 2017, and December 8, 2017, the FDA produced a total of approximately 45,000 pages to Seife. See id. ¶¶ 13, 15-23. In December 2017 and January 2018, in response to specific questions raised about the productions, the FDA re-produced some documents with redactions removed. See id. ¶ 23. On January 8, 2018, Seife provided the FDA and Sarepta with an annotated version of the FDA's Vaughn index identifying a subset of FOIA Exemption 4 redactions from the Studies and their appendices that Seife wished to challenge in this litigation — specifically, redactions of all adverse event reports; descriptions of adverse events; charts, graphs, and tables; descriptions of test results, clinical endpoints; and titles and identifiers of specific documents. See ECF No. 63. Seife does not challenge the adequacy of the Government's search, nor does he challenge any other redactions. See ECF No. 66, at 2.

Thereafter, the parties filed cross-motions for summary judgment, see ECF Nos. 69, 74, 85, and Seife filed a motion to strike a declaration submitted by Sarepta in connection with its motion for summary judgment, ECF No. 93. While these motions were pending, the Supreme Court granted certiorari in Food Marketing Institute v. Argus Leader Media, 139 S. Ct. 915 (2019), which concerned the FOIA Exemption 4 standard. On March 27, 2019, this Court issued an opinion and order denying Seife's motion to strike and reserving judgment on the cross-motions for summary judgment pending the Supreme Court's decision in Argus Leader. See Seife v. FDA, No. 17-CV-3960 (JMF), 2019 WL 1382724, at *1 (S.D.N.Y. Mar. 27, 2019) (ECF No. 129). At the same time, the Court directed Sarepta to re-review the redactions to verify that all publicly available information had been released to Seife. Id. at *2-3. Between May and

August 2019, Sarepta conducted the re-review ordered by the Court, and Defendants produced unredacted versions of certain previously withheld information on the ground that it was publicly available. See ECF No. 133. On June 24, 2019, the Supreme Court decided Food Marketing Institute v. Argus Leader Media, 139 S. Ct. 2356 (2019) ("Argus Leader"). Thereafter, the parties submitted supplemental briefs. See ECF Nos. 140-62.

**LEGAL STANDARD**

FOIA mandates disclosure of agency records unless those records fall within an enumerated exception. See, e.g., Tigue v. U.S. Dep't of Justice, 312 F.3d 70, 76 (2d Cir. 2002) (Sotomayor, J.). The exemptions notwithstanding, an agency must also produce any non-exempt portions of a record that are "reasonably segregable" from portions that are exempt. 5 U.S.C. § 552(b).

Summary judgment is the procedural vehicle by which most FOIA actions are resolved. See, e.g., Grand Cent. P'ship, Inc. v. Cuomo, 166 F.3d 473, 478 (2d Cir. 1999). "In resolving summary judgment motions in a FOIA case, a district court proceeds primarily by affidavits in lieu of other documentary or testimonial evidence . . . ." Long v. Office of Pers. Mgmt., 692 F.3d 185, 190 (2d Cir. 2012). As the Second Circuit has explained, "Summary judgment is warranted . . . 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." 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, 862 (D.C. Cir. 2009)). Although the agency's determination that requested information falls within a FOIA exemption is reviewed de novo, see 5 U.S.C. § 552(a)(4)(B); Dep't of Air Force v. Rose, 425 U. S. 352, 379 (1976), the affidavits submitted by

the agency in support of its determination "are accorded a presumption of good faith," Carney v. U.S. Dep't of Justice, 19 F.3d 807, 812 (2d Cir. 1994) (internal quotation marks omitted). Ultimately, "the agency's justification is sufficient if it appears logical and plausible." ACLU v. U.S. Dep't of Def., 901 F.3d 125, 133-34 & n.9 (2d Cir. 2018), as amended (Aug. 22, 2018); accord Wilner, 592 F.3d at 73.

## DISCUSSION

The sole issue in this case is the propriety of Defendants' redactions pursuant to Exemption 4, which "shields from mandatory disclosure 'commercial or financial information obtained from a person and privileged or confidential.'" Argus Leader, 139 S. Ct. at 2362 (quoting 5 U.S.C. § 552(b)(4)). In particular, four categories of redactions from Studies 201 and 202 (and their associated appendices) are at issue: (1) clinical study procedures, (2) clinical study results, (3) exploratory endpoints, and (4) unrelated adverse events. There is no dispute that these categories of information are commercial or financial in nature, that they were obtained from a "person" within the meaning of FOIA (here, Sarepta), see 5 U.S.C. § 551(2) (defining a person as "an individual, partnership, corporation, association, or public or private organization other than an agency"), and that they are not privileged, see ECF No. 148 ("Pl.'s Mem."), at 2-3; ECF No. 146 ("Defs.' Mem."), at 8; ECF No. 140 ("Sarepta's Mem."), at 1; ECF No. 65 ("Joint Stip."), at 1. Thus, the principal dispute is whether they qualify as "confidential" within the meaning of Exemption 4.

### A. Confidentiality

At the time the parties completed their first round of briefing in this case, the Second Circuit — like many courts in the country — adhered to the test of "confidentiality" adopted by the D.C. Circuit in Nat'l Parks & Conservation Ass'n v. Morton, 498 F.2d 765, 768 (D.C. Cir.

1974) ("National Parks"). Pursuant to that test, commercial or financial information submitted to the government was deemed "confidential for the purposes of Exemption 4 if its disclosure would have the effect either: (1) of impairing the government's ability to obtain information — necessary information — in the future, or (2) of causing substantial harm to the competitive position of the person from whom the information was obtained." Inner City Press/Cmty. on the Move v. Bd. of Governors of Fed. Reserve Sys., 463 F.3d 239, 244 (2d Cir. 2006) (internal quotation marks omitted); see Cont'l Stock Transfer & Tr. 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 rejected National Parks as "a relic from a bygone era of statutory construction," condemning the decision for formulating its test by "inappropriately resort[ing] to legislative history before consulting the statute's text and structure" and "rel[ying] heavily on statements from witnesses in congressional hearings years earlier on a different bill that was never enacted into law." 139 S. Ct. at 2364 (internal quotation marks omitted).

In place of the National Parks test, the Supreme Court adopted a more straightforward test. To qualify as "confidential" within the meaning of Exemption 4, the Court held, commercial or financial information communicated to the government had to be "customarily [and actually] kept private, or at least closely held, by the person imparting it." Id. at 2363. The Court noted that for Exemption 4 to apply, a second condition might also be required: that the information "was provided to the government under an assurance of privacy." Id. Ultimately, however, the Court refrained from deciding whether that second condition was required because it found that it was satisfied in the case before it. Id. The Court thus summed up its decision as follows: "At least 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; see Ctr. for Investigative Reporting v. U.S. Customs & Border Prot., No. 18-2901 (BAH), 2019 WL 7372663, at *12 (D.D.C. Dec. 31, 2019) (affirming that the test for customary confidentiality is "objective" and "the agency invoking Exemption 4 must meet the burden of proving the provider's custom" (internal quotation marks omitted)).

This Court need not decide whether the test is one- or two-pronged either because, as with the information at issue in Argus Leader, both conditions are satisfied here. Sarepta's chief of staff and head of corporate affairs, for example, attests that the company customarily and actually kept the information at issue confidential at all stages of the clinical study process and thereafter because release would allow its competitors to more easily conduct their own DMD-related studies — by "copy[ing] Sarepta's study design, or selectively modify[ing] it," "build[ing] the type of control dataset that Sarepta spent years and millions of dollars producing," discovering which exploratory endpoints Sarepta might pursue in the future, and gaining insight into Sarepta's analysis of which adverse events occurred — all "without having invested the resources into producing their own study." Estepan Decl. ¶¶ 23, 31, 37, 40. And even though Sarepta has published some information related to Studies 201 and 202, it has not disclosed specific information regarding the timing of certain tests, the dosing methods used, specific data tables that include statistical analysis of patient-level indicators, certain exploratory endpoints, and details about the adverse events. See id.

Moreover, as Sarepta's chief intellectual property counsel Christopher Verni avers, such information is subject to strict confidentiality protocols both within and outside of Sarepta. See ECF No. 143 ("Verni Decl."), ¶¶ 4-6, 8-11. For instance, Sarepta (1) limits access to the information to members of specific departments and third-party providers who are bound by

nondisclosure agreements; (2) grants access to department data only after a manager authorizes an individual to access the data and the IT department or a local system administrator executes the manager's direction in accordance with established policies and procedures; and (3) stores the live clinical study data in a restricted access database that is controlled by Sarepta's Clinical Data Management Group. See id.; ECF No. 142 ("Thornton Decl."), ¶¶ 5-12, 21. And "context shows" that Sarepta supplied the information to the FDA under an implied assurance of confidentiality. Besson v. U.S. Dep*'t* of Commerce, — F. Supp. 3d —, No. 18-CV-2527 (APM), 2020 WL 4500894, at *5 (D.D.C. Aug. 5, 2020). The nature of the pharmaceutical industry and the FDA regulations themselves support this inference, as does testimony from Verni. See Verni Decl. ¶ 12 ("Sarepta understands and expects that its trade secret and other confidential information submitted to FDA will be kept confidential in accordance with FDA's regulations."); see also, e.g., Citizens for Responsibility & Ethics in Wash. *v. U.S. Dep't of Commerce*, No. 18-CV-3022 (CJN), 2020 WL 4732095, at *4 (D.D.C. Aug. 14, 2020) ("The context in which [the company] provided [the Department of] Commerce information — to grow its business in foreign markets — supports the notion that it did so under an implied assurance of confidentiality."). Notably, since the time that Sarepta submitted Studies 201 and 202 to the FDA, none of the confidential data and final results associated with those studies has otherwise been publicly released, and the information "continues to be maintained in Sarepta's IT systems as confidential." Thornton Decl. ¶ 21.

Seife does not actually dispute that the FDA gave Sarepta assurances of privacy when the company submitted the information at issue pursuant to the FDA's regulations. See Pl.'s Mem. 34 n.17. Nor does Seife dispute that Sarepta conducted its clinical studies under strict confidentiality terms. See ECF No. 91 ("Pl.'s 56.1 Counter-Statement"), ¶¶ 27, 37-38. Instead,

Seife's primary argument is that the information is not "confidential" because Sarepta publicized it when submitting an application for market approval of Exondys 51 to the European Medicines Agency ("EMA") "with the knowledge that, regardless of the outcome, the EMA would publish the submitted data." Pl.'s Mem. 37; see also id. at 36 n.20, 37-41. But while the EMA did publish an assessment report of the drug when it later denied Sarepta's application, Seife provides no evidence that the report contains information identical to the withholdings at issue. In the alternative, Seife contends that Sarepta publicly shared the information at issue when it collaborated with third parties. But "[t]hese types of limited disclosures," subject to nondisclosure agreements and "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).[1] In short, Seife offers nothing to undermine the conclusion, based on declarations from those with firsthand knowledge of Sarepta's actual practices, that Sarepta has consistently maintained the confidentiality of the information.

Finally, Seife's contention that some of the information at issue was made public after the FDA processed his FOIA request is unavailing. "[A]s a general rule, a FOIA decision is evaluated as of the time it was made and not at the time of a court's review." ACLU v. NSA, 925 F.3d 576, 602 (2d Cir. 2019) (quoting N.Y. Times v. U.S. D*ep't of* Justice, 756 F.3d 100, 110 n.8 (2d Cir. 2014)). As the Second Circuit has explained, "[t]o require an agency to adjust or modify its FOIA response based on post-response occurrences could create an endless cycle of judicially

[1] Seife also argues that similar information is publicly available and that he can reconstruct or guess at what is behind the redactions. See Pl.'s Mem. 39. But the Court has already rejected these arguments. See Seife, 2019 WL 1382724, at *2 n.3 (rejecting Seife's argument that Exemption 4 does not apply to "information that is 'largely public' or that can be 'easily discerned based on public information'" and affirming that "[t]he publicly available information must be 'identical'" (quoting Inner City Press, 463 F.3d at 244)).

mandated reprocessing each time some circumstance changes" and "FOIA does not subject agencies or the courts to such 'an endlessly moving target.'" Id. (first quoting Florez v. CIA, 829 F.3d 178, 188 (2d Cir. 2016); then quoting Bonner v. U.S. Dep't of State, 928 F.2d 1148, 1153 (D.C. Cir. 1991) (Ginsburg, J.)). Here, the FDA completed its production of information responsive to Seife's FOIA request on December 8, 2017. See Sager Decl. ¶ 23. Thus, the Court need — indeed, may — look only to the information that was public as of that date to evaluate whether the information was properly withheld by the FDA on the basis of Exemption 4. In any event, as noted in the declaration submitted by Sarepta with its opposition and reply brief, Sarepta has compared the withheld information to the post-December 8, 2017 materials that Seife points to in his brief (namely, Sarepta's May 3, 2018 filing with the Securities and Exchange Commission and the EMA assessment report dated September 21, 2018) and has confirmed that the withheld information is different from the information that was publicly released in these publications. See ECF No. 155 ("Third Sherwood Decl."), ¶¶ 6-7. Accordingly, the Court concludes that Defendants have established that the information withheld is confidential under Exemption 4. See, e.g., Am. Small Bus. League v. U.S. Dep't of Def., 411 F. Supp. 3d 824, 831 (N.D. Cal. 2019); Parker, 141 F. Supp. 2d at 79.

**B. Foreseeable Harm**

That is not the end of the matter, however, because Congress amended FOIA in 2016 to add an additional "foreseeable harm" requirement. See FOIA Improvement Act of 2016 ("FIA"), Pub. L. No. 114-185, 130 Stat. 538; see also Ctr. for Investigative Reporting, 2019 WL 7372663, at *7-9. Specifically, FOIA now provides that an agency "shall . . . withhold information . . . only if . . . (I) the agency reasonably foresees that disclosure would harm an interest protected by an exemption . . . ; or (II) disclosure is prohibited by law." 5 U.S.C.

§ 552(a)(8)(A)(i).[2] By its terms, this provision applies to Exemption 4. See, e.g., Ctr. for Investigative Reporting, 424 F. Supp. 3d at 780. And as this Court has held, it "imposes an independent and meaningful requirement on agencies before they may withhold a record under one of FOIA's exemptions." NRDC v. EPA, No. 17-CV-5928 (JMF), 2019 WL 4142725, at *3 (S.D.N.Y. Aug. 30, 2019); see Judicial Watch, Inc. v. U.S. Dep't of Commerce, 375 F. Supp. 3d 93, 100 (D.D.C. 2019) ("[E]ven if an exemption applies, an agency must release the document unless doing so would reasonably harm an exemption-protected interest.").

This provision does not call for disclosure here. First, the Court agrees with Defendants that disclosure of the confidential clinical study procedures "is prohibited by law." 5 U.S.C. § 552(a)(8)(A)(i)(II). The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., authorizes the FDA to promulgate substantive regulations regarding the drug approval process. See 21 U.S.C. § 371; *Nat'l Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 696-97 (2d Cir. 1975). To the extent relevant here, the FDA regulations provide that, "[a]fter FDA sends an approval letter to the applicant" certain information in the NDA is "immediately available for public disclosure, unless the applicant shows that extraordinary circumstances exist" or an enumerated exception applies. 21 C.F.R. § 314.430(e). The regulations specify that "[a] protocol for a test or study" is subject to disclosure "unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in [Section] 20.61." Id. § 314.430(e)(3). Section 20.61(b) provides, in turn, that "[c]ommercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and

[2] In Argus Leader, the Supreme Court did not address the foreseeable harm standard because the FOIA request there was filed before the FIA was enacted. See Ctr. for Investigative Reporting v. U.S. Dep't of Labor, 424 F. Supp. 3d 771, 780 (N.D. Cal. 2019); see also Ctr. for Investigative Reporting, 2019 WL 7372663, at *14.

not disclosed to any member of the public by the person to whom it belongs." Id. § 20.61(b). Although the FDA has discretion under Section 20.61(e)(3) to reject a submitter's designations and disclose the information, if the designations are accepted the confidential information is not subject to public disclosure. See id. § 20.61(c) ("Data and information submitted or divulged to the [FDA] which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.").

These regulations have the "force and effect of law," Chrysler Corp. v. Brown, 441 U.S. 281, 295-96 (1979) (internal quotation marks omitted); accord Dep't of Homeland Sec. v. MacLean, 574 U.S. 383, 392-93 (2015), and preclude disclosure of the confidential clinical study procedures at issue here. Sarepta submitted the Studies as part of its NDA on June 26, 2015, and marked its submissions as containing confidential information pursuant to Section 20.61. After the FDA approved the application on September 19, 2015, the requested data become subject to Section 314.430(e) of the regulations, and the FDA has not provided any reason to disclose the clinical study procedures that Sarepta re-identified as confidential in response to this FOIA litigation. See Sarepta's Mem. 22. Thus, under its own regulations, the FDA does not have discretion to disclose Sarepta's non-public clinical study procedures, and the foreseeable harm standard set forth in Section 552(a)(8)(A)(i)(I) does not apply.

The Court, however, will apply the foreseeable harm requirement to the non-patient-level study results, endpoints, and adverse events, as their disclosure is not prohibited by statutory or regulatory law.[3] In the four years since the FIA was enacted, few courts have addressed how the

[3] Sarepta suggests that the information is protected by the Trade Secrets Act, see Verni Decl. ¶ 7, which arguably would render them non-discretionary withholdings not subject to the foreseeable harm requirement. See, e.g., *McDonnell Douglas Corp. v. Nat'l Aeronautics & Space Admin.*, 180 F.3d 303, 305 (D.C. Cir. 1999). But because the information satisfies the foreseeable harm requirement, the Court need not and will not decide whether the information at issue is covered by the Trade Secrets Act. See ECF No. 157 ("Defs.' Reply"), at 11.

foreseeable harm requirement applies to Exemption 4, but nevertheless a split has already developed. Compare Am. Small Bus. League, 411 F. Supp. 3d at 836, with Ctr. for Investigative Reporting, 436 F. Supp. 3d at 113. In American Small Business League, the court rejected an argument, relying on National Parks, that the agency must show that disclosure would cause foreseeable competitive harm to the submitter, calling the argument an attempt to "circumvent" the Supreme Court's rejection of the discredited opinion's "reliance on the legislative history in determining the scope of the term 'confidential.'" 411 F. Supp. 3d at 836. The court held, instead, that, under Argus Leader, "the plain and ordinary meaning of Exemption 4 indicates that the relevant protected interest is that of the information's confidentiality — that is, its private nature." Id. By contrast, in Center for Investigative Reporting, the court relied in part on National Parks to conclude that the agency may satisfy the foreseeable harm requirement by showing that disclosure would cause "genuine harm to [the submitter's] economic or business interests, and thereby dissuad[e] others from submitting similar information to the government." 436 F. Supp. 3d at 113 (internal quotation marks and citations omitted).[4]

The Court need not and does not decide which approach is correct because, either way, Defendants and Sarepta satisfy the foreseeable harm requirement. Under the American Small Business League approach, the requirement is satisfied because, by definition, disclosure would destroy the confidential nature of the information at issue. And under the Center for Investigative Reporting approach, the requirement is satisfied because Defendants and Sarepta

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[4] Seife eschews both of these standards in favor of a third, arguing that because the interest Exemption 4 seeks to protect "is fundamentally economic in nature" and "relates to the intrinsic value of the withheld information itself," the agency must "demonstrate that disclosure would result in . . . a diminution in value of the information at issue to Sarepta." Pl.'s Mem. 16-17 (emphasis omitted). But this standard is too narrow and is supported by neither the statute's text nor any relevant precedent.

show through affidavits that Sarepta's competitive interests would be harmed if the non-public clinical study results, exploratory endpoints, and adverse events were disclosed. As an initial matter, it is indisputable that the pharmaceutical industry is highly competitive. See Estepan Decl. ¶¶ 11, 14-21; see Pub. Citizen Health Research Grp. v. NIH, 209 F. Supp. 2d 37, 47 (D.D.C. 2002) (recognizing that the "pharmaceutical industry is a highly competitive market where companies routinely attempt to discover a possible advantage over their competitors"); Citizens Comm'n on Human Rights v. FDA, No. 92-CV-5313, 1993 WL 1610471, at *7-9 (C.D. Cal. May 10, 1993) ("Actual competition in the drug manufacturing business is evident from the record before the Court. Drug manufacturers must invest enormous time and capital to 'pioneer' a new drug. . . . After a new drug is approved for marketing, actual competition also exists among manufacturers seeking approval to market the drug in a 'generic' form."), aff'd in part, remanded in part, 45 F.3d 1325 (9th Cir. 1995). In addition, the record makes plain both that Sarepta has invested a significant amount of time and expense in developing Exondys 51 and that Sarepta's competitors are hot on its tail working to develop their own DMD treatments. See Estepan Decl. ¶¶ 44-49.

As Sarepta details in its declaration, for example, since 2016, at least three other drug manufacturers have been developing antisense oligonucleotides (short, single-stranded DNA molecules) for DMD as part of a potential treatment. See id. ¶¶ 45, 47-49. Additionally, six companies are pursuing development of drug therapies to cause DMD patients to produce dystrophin. See id. ¶ 46. At the time initial briefing in this matter was completed, there were dozens of planned trials for other exon-shipping DMD treatments and twenty-seven DMD assets in clinical development with expected United States market approval between 2020 and 2027. See id. ¶¶ 58-59. This record is more than sufficient to establish that competition exists for the

development of a DMD drug. See, e.g., Gov't Accountability Project v. FDA, 206 F. Supp. 3d 420, 439 (D.D.C. 2016). And between Defendants' and Sarepta's declarations, and economic common sense, the Court has no trouble concluding that release of the information at issue would advantage Sarepta's competitors and cause substantial competitive injury to Sarepta, as other companies could make use of that information to "eliminate much of the time and effort that would otherwise be required to bring to market" a competitive product. Judicial Watch, Inc. v. FDA, 449 F.3d 141, 148-49 (D.C. Cir. 2006) (quoting Pub. Citizen Health Research Grp. v. FDA, 185 F.3d 898, 905 (D.C. Cir. 1999)); see also Webb v. *U.S. Dep't of* Health & Human Servs., 696 F.2d 101, 103 (D.C. Cir. 1982) ("If a manufacturer's competitor could obtain all the data in the manufacturer's NDA, it could utilize them in its own NDA without incurring the time, labor, risk, and expense involved in developing them independently.").

Seife's policy arguments in favor of disclosure are insufficient to overcome the language of the statute. The FDA's approval of Exondys 51 has been subject to its fair share of criticism and controversy: The FDA's own scientists accused Sarepta of scientific impropriety and ethical misconduct, and one top review-team scientist quit in protest when the drug was approved. See ECF No. 149 ("Pl.'s Decl."), ¶¶ 15-21, 30-40. Disclosure of Sarepta's clinical trial data would undoubtedly help to "assess whether the FDA followed its statutory mandates and . . . inform doctors, patients, and researchers about health matters of immense public interest." ECF No. 162 ("Pl.'s Reply"), at 1. But the Court's task is to apply the law and the law is clear: There is no public policy or public health exception that allows for disclosure where, as here, Exemption 4 and the foreseeable harm requirement (to the extent it applies) are met. See, e.g., Pub. Citizen v. U.S. Dep*'t* of Health & Human Servs., 66 F. Supp. 3d 196, 209 (D.D.C. 2014) ("[T]he Court . . . rejects the plaintiff's argument that when disputed records reflect facts that may lead to the

conclusion that an unlawful act occurred, those records are stripped of eligibility for Exemption 4 withholding."). Put simply, "[t]he statute as written by Congress sets forth no basis for the exemption [Seife] asks [the Court] to read into it." Bloomberg, L.P. v. Bd. of Governors of the Fed. Reserve Sys., 601 F.3d 143, 151 (2d Cir. 2010). "If [Seife] believes such an exemption would better serve the national interest, [he] should ask Congress to amend the statute." Id.

**C. Segregability**

Finally, the Court finds that, despite Seife's assertions to the contrary, in camera review of Defendants' redactions is not warranted. "Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt." 5 U.S.C. § 552(b); see also id. § 552(a)(8)(A)(ii)(II) ("An agency shall . . . take reasonable steps necessary to segregate and release nonexempt information . . . ."). The Court previously held that Defendants' original redactions and withholdings were riddled with errors and thus ordered Defendants and Sarepta to re-review the documents and produce all publicly available information to Seife. See Seife, 2019 WL 1382724, at *2. Defendants have since reviewed the documents and, through counsel's sworn affidavit, attest that the only information marked for redaction was not publicly available, and thus is exempt. See Third Sherwood Decl. ¶ 3. This time around, Seife has not fulfilled his burden of showing that the reproduced documents contain withheld information that is "identical" to what was publicly available at the time Defendants completed their production. Inner City Press, 463 F.3d at 244. Nor has he provided any other reason besides his own speculation for the Court to doubt Defendants' most recent redactions. Instead, Defendants' Vaughn index and affidavits are sufficient for the Court to hold that the withheld information is subject to Exemption 4 and barred from disclosure by law. See Associated Press v. *U.S. Dep't of Justice*, 549 F.3d 62, 67 (2d Cir. 2008) (per curiam)

("Only if the government's affidavits make it effectively impossible for the court to conduct de novo review of the applicability of FOIA exemptions is in camera review necessary.").

**CONCLUSION**

For reasons stated above, the Court GRANTS the summary judgment motions of Defendants and Sarepta and DENIES Seife's cross-motion for summary judgment. As the parties explained in their March 22, 2018 joint letter — and as noted in Defendants' brief — the "FDA also withheld information in the documents on the basis of patient privacy pursuant to FOIA Exemption 6," but Seife did not challenge the Exemption 6 withholdings in his cross-motion. Defs.' Mem. 4 n.3; see ECF No. 66, at 1-2. In any event, given that the redactions were proper under Exemption 4, any remaining issues regarding Exemption 6 are moot.

The Clerk of Court is directed to terminate ECF Nos. 139, 145, and 147, and to close this case.

SO ORDERED.

Dated: October 6, 2020
New York, New York

JESSE M. FURMAN
United States District Judge