UNITED STATES DISTRICT COURT
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.	1:17-cv-3960 (JMF)

DEFENDANTS' SUPPLEMENTAL MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGEMENT

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In accordance with the Court's orders, *see* ECF Nos. 133 & 137, Defendants the United States Food and Drug Administration ("FDA") and the Department of Health and Human Services ("HHS") (collectively "Defendants" or the "Government") respectfully submit this supplemental memorandum of law in support of their motion for summary judgment with respect to the Complaint filed by Plaintiff Charles Seife.

PRELIMINARY STATEMENT

The narrow issue before the Court in the parties' cross-motions for summary judgment is whether the FDA properly withheld, pursuant to Freedom of Information Act ("FOIA") Exemption 4, certain confidential information regarding clinical studies that Defendant-Intervenor Sarepta Therapeutics, Inc. ("Sarepta") submitted to the FDA in connection with its New Drug Application ("NDA") for Exondys 51. Specifically, the FDA redacted from the FOIA production granular-level details of Sarepta's clinical studies, detailed study result information, certain study end-point information, and certain adverse event information. Although Sarepta had previously publicly released some information regarding its clinical studies, Sarepta has consistently maintained the confidentiality of the withheld information. When Sarepta submitted the confidential commercial information to FDA in connection with its NDA, it marked the contents of the application as confidential, and it reasonably expected, based on the applicable regulations, that the FDA would maintain the confidentiality of that information. Thus, the withheld information readily satisfies the test for confidentiality recently articulated by the Supreme Court in *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356 (2019). Accordingly, Defendants' motion for summary judgment should be granted.

BACKGROUND[1]

This action pertains to a FOIA request received by Defendants from Plaintiff on December 14, 2016, that sought records related to FDA's September 19, 2016, approval of the drug eteplirsen manufactured by Sarepta and marketed as Exondys 51 for treatment of Duchenne muscular dystrophy ("DMD"). *See* ECF No. 1 ("Compl.") ¶¶ 1-3 & Ex. A; *see also* ECF No. 76 (Declaration of Sarah Kotler ("Kotler Decl.")) ¶¶ 11, 13 & Ex. A. The requested documents included, *inter alia*, materials submitted by Sarepta to FDA to support the approval of the application for the new drug,[2] as well as internal Government communications and deliberations regarding the approval. *See* Kotler Decl. Ex. A. FDA's Center for Drug Evaluation and Research ("CDER") maintains the requested information. *Id.* ¶ 13.

Plaintiff initiated this lawsuit on May 25, 2017, after FDA denied his appeal for expedited processing. *See* ECF. No. 1. Plaintiff then filed a motion for partial summary judgment seeking expedited processing on June 21, 2017. *See* ECF No. 15. Plaintiff and the Government agreed on

[1] Although this is a supplemental brief submitted in response to the Court's directive to address the impact of the new legal standard articulated by the Supreme Court in *Argus Leader*, in accordance with the Court's order to "simplify things," ECF No. 137, at 2, the Government repeats all facts and arguments that remain relevant. As before, the Government is not submitting a Local Rule 56.1 statement because "the general rule in this Circuit is that in FOIA actions, agency affidavits alone will support a grant of summary judgment" and a Local Rule 56.1 statement "would be meaningless." *Ferguson v. FBI*, 89 Civ. 5071 (RPP), 1995 WL 329307, at *2 (S.D.N.Y. June 1, 1995), *aff'd*, 83 F.3d 41 (2d Cir. 1996); *N.Y. Times Co. v. DOJ*, 872 F. Supp. 2d 309, 314 (S.D.N.Y. 2012); *ACLU v. Office of the Dir. of Nat. Intelligence,* 10 Civ. 4419 (RJS), 2011 WL 5563520, at *1 n.1 (S.D.N.Y. Nov. 15, 2011).

[2] As part of a manufacturer's application for approval to market a new drug, the manufacturer must submit substantial and detailed information about the drug, including data concerning the drug's safety and effectiveness obtained through both preliminary research and investigations, including, but not limited to, pertinent animal and *in vitro* studies of the drug. *See* 21 U.S.C § 355(b)(1); 21 C.F.R. § 314.50. The results of those studies are submitted as part of the NDA when the manufacturer seeks marketing approval for the new drug. *See generally* 21 C.F.R. part 314.

a production schedule, which was entered by the Court on July 27, 2017. *See* ECF No. 39. As a result, Plaintiff withdrew his motion for partial summary judgment. *Id.*

Immediately thereafter, pursuant to 21 C.F.R. § 20.61(f)(4), FDA notified Sarepta of Plaintiff's FOIA request and gave Sarepta the opportunity to object to the disclosure of certain information Sarepta had submitted to the FDA in connection with the NDA for Exondys. *See* ECF No. 77 (Declaration of Nancy B. Sager ("Sager Decl.")) ¶¶ 25-26 & Exs. K-N. Specifically, on July 28, 2017, FDA sent Sarepta copies of the Clinical Study Reports for Study 201 and 202 ("CSRs"), totaling 35,579 pages, that Sarepta had included in its NDA to FDA. *Id.* ¶ 25 & Ex. K. FDA provided the CSRs to Sarepta to give the company—which had created the reports and conducted the studies—an opportunity to identify any proprietary information. *See id.*¶ 25. Sarepta responded that it "wanted to ensure that its trade secret and commercial or financial information is adequately protected" and requested that FDA refrain from releasing further information until Sarepta could review the material. *See id.* ¶ 26 & Ex. L.

A CSR is a full report of an individual drug study onducted in human patients. The report discusses how the critical design features of the study were chosen and includes enough information on the plan, methods, and conduct of the study so that there is no ambiguity in how the study was carried out. The report also contains detailed information concerning individual patient data and analytical methods to allow replication of the critical analyses. *See Guideline for Industry: Structure and Content of Clinical Study Reports*, available at https://www.fda.gov/downloads/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/UCM073113.pdf (last accessed Mar. 21, 2018).

On September 15, 2017, Sarepta moved to intervene in this matter to further protect the information. *See* ECF Nos. 43 & 44. Sarepta's motion was granted on September 18, 2017. *See*

ECF No. 47. Sarepta then reviewed the CSRs and proposed redactions, providing a draft index to FDA explaining the bases for the proposed redactions. *See* Sager Decl. ¶¶ 28, 31. Prior to producing the materials to Plaintiff, FDA reviewed the proposed redactions and made certain changes. *See id.* ¶¶ 29, 32.

In accordance with the agreed-upon production schedule, between July 24, 2017, and December 8, 2017, FDA made nine productions and produced a total of approximately 45,000 pages of documents in response to Plaintiff's FOIA request. *See* Sager Decl. ¶¶ 13, 15-27. On December 8, 2017, FDA made its final document production in response to Plaintiff's FOIA request. *Id.* ¶ 23. Thereafter, the parties engaged in a number of discussions in an effort to narrow the issues that Plaintiff raised regarding FDA's productions. *See* ECF Nos. 49, 63 & 66. In December 2017 and January 2018, in response to specific questions raised about the productions, FDA re-produced certain documents with certain redactions removed. *See* Sager Decl. ¶ 23.

The only redactions Plaintiff now challenges pertain to specific confidential commercial information contained in the Study 201 and Study 202 CSRs withheld from the FOIA response pursuant to FOIA Exemption 4. *See* ECF No. 66 at 1.[3] These challenged redactions are reflected on the *Vaughn* index. *See* Sager Decl. Ex. O. The general categories of redacted information include: (1) granular-level details of Sarepta's clinical studies; (2) patient-level data regarding study results and patient characteristics; (3) certain adverse event information; and (4) certain exploratory endpoint information. *See* Sager Decl. ¶ 35; Ex. O. Plaintiff does not challenge the

[3] As the parties explained in their March 22, 2018, joint letter, FDA also withheld information in the documents on the basis of patient privacy pursuant to FOIA Exemption 6. At this time, Plaintiff does not challenge the Exemption 6 withholdings. In the event the Court were to rule in Plaintiff's favor on the Exemption 4 withholdings, the parties would meet and confer on redactions that would ensure patient privacy before the documents are released. All parties have reserved their rights to raise issues related to Exemption 6 in the event that they are unable to reach agreement. *See* ECF No. 66 at 1-2.

adequacy of the Government's search, nor does he challenge any withholdings from any other documents in the production. *See* ECF No. 66 at 2.

The parties filed cross-motions for summary judgment, *see* ECF Nos. 69, 74, 85, and Plaintiff filed a motion to strike the declaration submitted by Sarepta in connection with its motion for summary judgment, ECF No. 93. During the course of the briefing, the FDA released additional previously withheld information to Plaintiff. *See* ECF No. 100 ("Philips Decl.") ¶ 5. While the parties' motions were pending, the Supreme Court granted certiorari in *Food Marketing Institute v. Argus Leader Media*, No. 18-481, 139 S. Ct. 915 (Jan 11, 2019), which raised questions regarding the appropriate legal test for confidentiality under FOIA Exemption 4. On March 27, 2019, this Court issued an order denying Plaintiffs' motion to strike and reserving judgment on the cross-motions for summary judgment pending the Supreme Court's decision in *Argus Leader*. *See* ECF No. 129, at 1. The Court also directed Sarepta to re-review the redactions to verify that all publicly available information had been released to the Plaintiff. *Id.* at 5. The Court further asked that the parties submit a joint letter once the Supreme Court decided *Argus Leader*, to address whether supplemental briefing would be necessary. *Id.* at 6. Between May and August 2019, Sarepta conducted the re-review requested by the Court, and Defendants produced unredacted versions of certain previously withheld information on the basis that it was publicly available. *See* ECF No. 133.

On June 24, 2019, the Supreme Court decided *Food Marketing Institute v. Argus Leader Media*, which rejected the prevailing standard for determining whether information was confidential within the meaning of Exemption 4. 139 S. Ct. 2356 (2019). Accordingly, the parties agreed that supplemental briefing is necessary, and agreed upon a briefing schedule. ECF No. 136.

ARGUMENT

A. Legal Standards for Summary Judgment in FOIA Actions

The Freedom of Information Act, 5 U.S.C. § 552, represents a balance struck by Congress "'between the right of the public to know and the need of the Government to keep information in confidence.'" *John Doe Agency v. John Doe Corp.*, 493 U.S. 146, 152 (1989) (quoting H.R. Rep. No. 1497, 89th Cong., 2d Sess., 6 (1966)); *New York Times Co. v. DOJ*, 872 F. Supp. 2d 309, 314 (S.D.N.Y. 2012). Thus, while FOIA requires disclosure under certain circumstances, the statute recognizes "that public disclosure is not always in the public interest," *CIA v. Sims*, 471 U.S. 159, 166-167 (1985), and mandates that records need not be disclosed if "the documents fall within [the] enumerated exemptions." *DOI v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 7 (2001) (citations omitted); *see also John Doe Agency*, 493 U.S. at 152 (FOIA exemptions are "intended to have meaningful reach and application"); *Martin v. DOJ,* 488 F.3d 446, 453 (D.C. Cir. 2007) ("Recognizing, however, that the public's right to information was not absolute and that disclosure of certain information may harm legitimate governmental or private interests, Congress created several exemptions to FOIA disclosure requirements.").[4]

Most FOIA actions are resolved by summary judgment. *See Carney v. DOJ*, 19 F.3d 807, 812 (2d Cir. 1994); *N.Y. Times v. DOJ*, 915 F. Supp. 2d 508, 531 (S.D.N.Y. 2013). Summary judgment is warranted if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A defendant is entitled to summary judgment in a FOIA case when it demonstrates that its search was adequate and that any withheld documents fell within an Exemption to FOIA. *See Carney*, 19 F.3d at 812. The defendant agency

[4] Courts in this Circuit frequently cite FOIA decisions from the D.C. Circuit, "a jurisdiction with considerable experience on FOIA matters." *Main Street Legal Servs., Inc. v. Nat'l Sec. Council,* 13 Civ. 948 (ENV), 2013 WL 4494712, at *2 (E.D.N.Y. Aug. 7, 2013) (citing cases).

bears the burden to demonstrate that any information it withheld is exempt from disclosure. *See* 5 U.S.C. § 552(a)(4)(B). The agency can satisfy this burden using "[a]ffidavits or declarations supplying facts indicating that the agency has conducted a thorough search and giving reasonably detailed explanations why any withheld documents fall within an Exemption." *See Carney,* 19 F.3d at 812.

FDA supports this motion with declarations from three FDA employees: Sarah Kotler, Director of the Division of Freedom of Information ("DFOI"), FDA's Office of the Executive Secretariat; Nancy B. Sager, Director of the Division of Information Disclosure Policy ("DIDP"), in FDA's Center for Drug Evaluation and Research ("CDER") (whose declaration attaches a *Vaughn* index), and Howard R. Philips, Deputy Director of DIDP. The FDA also supports its motion with the original and supplemental declarations of three Sarepta employees: Ian Estepan, *see* ECF No. 72 ("Estepan Decl.") & 105 (2d Estepan Decl."), Christopher Verni ("Verni Decl."), and William J. Thornton ("Thornton Decl.").[5] These declarations establish that FDA properly withheld the redacted information in the Study 201 and Study 202 CSRs because it was confidential commercial information.

[5] Courts in this District and elsewhere have accepted and considered declarations from the third-party submitters of information at issue in Exemption 4 cases. *See, e.g.*, *NRDC v. U.S. Dep't of Interior*, 36 F. Supp. 3d 384, 401 n.10 (S.D.N.Y. 2014) (finding that such declarations are "relevant and based on personal knowledge," and thus that "[t]he Court is . . . at liberty to consider the declarations"); *Pub. Citizen v. HHS*, 66 F. Supp. 3d 196, 208 (D.D.C. 2014) (Defendant-Intervenor's "declarants make a strong case as to why the information contained in these documents could be used to cause substantial commercial harm."); *Utah v. U.S. Dep't of Interior*, 256 F.3d 967, 970 (10th Cir. 2001) (considering declarations from the two private entities whose information was sought to be disclosed).

B. Legal Standard for FOIA Exemption 4 Confidentiality Post-*Argus Leader*

Exemption 4 protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. § 552(b)(4). This exemption covers two distinct categories of information: (1) trade secrets; or (2) information that is (a) commercial or financial, and (b) obtained from a person, and (c) is privileged or confidential. *Nadler v. FDIC*, 92 F.3d 93, 95 (2d Cir. 1996). In this case, the second category applies. Plaintiff does not dispute that the withheld information is commercial or financial; nor does he dispute that it was obtained from "a person." *See* ECF No. 66 at 1. The only question before the Court is whether the commercial information is confidential under the recently announced standard in *Argus Leader*.

In *Argus Leader* the Supreme Court stated that "confidential," as it is used in Exemption 4, must be given its "ordinary, contemporary, common meaning" at the time the statute was enacted in 1966 and that "[t]he term 'confidential' meant then, as it does now, 'private' or 'secret.'" 139 S. Ct. at 2362-63 (quoting *Perrin v. United States*, 444 U.S. 37, 42 (1979)). In so doing, the Court rejected the "competitive harm" standard, which had required a showing that disclosure of the information was "likely to cause substantial harm to the competitive position of the person from whom the information was obtained." *Argus Leader*, 139 S. Ct. at 2367 (quoting *Nat'l Parks & Conservation Ass'n v. Morton,* 498 F.2d 765, 770 (D.C. Cir. 1974)). The Court stated that there was no textual or historical support for the prior "competitive harm" standard —articulated in the D.C. Circuit's decision in *National Parks & Conservation Association* (and adopted in the Second Circuit in *Cont'l Stock Transfer & Trust Co. v. SEC,* 566 F.2d 373, 375 (2d Cir. 1977). The Court further explained that "FOIA expressly recognizes that 'important interests [are] served by [its] exemptions,' . . . and '[t]hose exemptions are as much part of [FOIA's] purpose[s and policies] as the [statute's disclosure] requirements.' . . . So just as we cannot properly *expand* Exemption 4 beyond what its terms permit, we cannot arbitrarily *constrict* it either by adding limitations found

nowhere in its terms." *Argus Leader*, 139 S. Ct. at 2366 (citations omitted, alterations and emphasis in original).

The Supreme Court observed (without deciding) that, in some instances, it might be possible for "privately held information [to] *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." *Id.* at 2363. However, nothing in Exemption 4 suggests that government assurances are *necessary* to establish confidentiality in the absence of a reason to anticipate disclosure. The legislative history confirms this reading. The House and Senate Reports that accompanied FOIA's enactment explained that Exemption 4 generally exempts information "if it would not customarily be made public by the person from whom it was obtained by the Government." H.R. Rep. 89-1497, at 10; *accord* S. Rep. 89-813, at 9. Thus, the way a particular type of information is typically treated by its owner usually suffices to settle the inquiry. The House Report explains that, in addition to the foregoing, the exemption "would *also* include information which is given to an agency in confidence, since a citizen must be able to confide in his Government." H.R. Rep. 89-1497, at 10 (emphasis added). That is because "where the Government has obligated itself in good faith not to disclose documents or information which it receives, it should be able to honor such obligations." *Id.*

Nothing in the statute's text or history suggests that, for information that is typically treated as confidential by its owner, the government must in each instance show that it made assurances of confidentiality in order to establish that the information would be exempt. It is also consistent with FOIA's purpose that commercial information is confidential, and thus exempt from disclosure, if it is generally kept private. The statute is intended to require disclosure when it will "contribute significantly to public understanding *of the operations or activities of the government*."

United States Dep't of Justice v. Reporters Comm. for Freedom of the Press, 489 U.S. 749, 775 (1989) (quoting 5 U.S.C. § 552(a)(4)(A)(iii) (emphasis added)). Congress did not design FOIA generally to require disclosure of the commercial or financial information of nongovernment entities. Just as the "disclosure of records regarding private citizens, identifiable by name, is not what the framers of the FOIA had in mind," *id.* at 765, the disclosure of commercial or financial information about private individuals, businesses, and other organizations is not what Congress intended FOIA to address. Exemption 4's protection for confidential information is consistent with FOIA's purposes of shedding light on government functions because it applies only if the information is commercial or financial information "obtained from a person," 5 U.S.C. § 552(b)(4), meaning that the information must be "obtained [from] outside the Government," *Federal Open Mkt. Comm. of the Fed. Reserve Sys. v. Merrill*, 443 U.S. 340, 360 (1979). The standard of confidentiality adopted in *Argus Leader* is thus clearly applicable to these facts.

C. The Information at Issue Readily Meets the Test for Confidentiality Articulated in *Argus Leader*.

Here, the information at issue was kept private or closely held by Sarepta. No evidence suggests that this confidentiality was somehow lost when Sarepta provided the information to FDA in an NDA. Sarepta reasonably expected that the Government would maintain the confidentiality of the closely-held information, and FDA did so.

As detailed in Sarepta's original and supplemental declarations, the redacted Study 201 and Study 202 CSRs' information is customarily and actually kept private or closely-held by Sarepta. The information at issue has not been shared outside Sarepta and is closely controlled within the company—dissemination of study results is limited to certain members of the clinical development, regulatory, biostatistics, and data management functions, select reporting functions, as well as certain members of the executive committee. *See* Estepan Decl. ¶ 19, 22. Notably,

when other pharmaceutical companies requested access to Sarepta's clinical trial data and testing methodologies, Sarepta refused such access, maintaining the confidentiality of this information. *Id.* ¶ 52. Sarepta also conducts its clinical trials, including clinical studies 201 and 202, pursuant to clinical trial agreements that protect confidential information, specifically including but not limited to the clinical study protocols, information relating to the study drug itself, and information generated in connection with the clinical study. *See* Verni Decl. ¶ 6; *see also* Estepan Decl. ¶ 19. These clinical trial agreements contain non-disclosure obligations that are binding on non-Sarepta third parties who participate in the conduct of the clinical studies and survive the end of the study. *See* Verni Decl. ¶ 6. Sarepta regards all non-publicly disclosed aspects of its clinical study process (which are not disclosed in patents or otherwise publicly disclosed) as trade secrets developed with company resources and does not share such information with anyone outside the company without appropriate, effective measures to ensure that confidentiality is maintained. *See* Verni Decl. ¶ 7. Within Sarepta's computer system, access to clinical study data is controlled by the clinical study lead, who grants access only to those employees working on those studies and require access to specific study data. *See* Thornton Decl. ¶¶ 8, 12. Sarepta limited access to the NDA submission containing the confidential CSR studies to employees within Sarepta's Regulatory Affairs department. *Id.* ¶ 12. Sarepta requires employees and consultants to sign confidentiality or non-disclosure agreements. *See* Verni Decl. ¶¶ 4-5. To the extent that Sarepta participates in research consortia and shares study information in such contexts, consortia participants are required to maintain the confidentiality of such information. *Id.* ¶¶ 8-10. Moreover, Sarepta has technological controls in place to ensure that unauthorized persons, both inside and outside the company, do not access clinical study data. *See* Thornton Decl. ¶¶ 9-21. When the clinical study process requires parties external to Sarepta to review and analyze clinical study data, such third parties are never

given unsecured access to Sarepta proprietary data and must execute confidentiality agreement that ensure that they maintain IT security over the data. *Id.* ¶ 20. Thus, Sarepta's declarations readily establish that the information at issue has been "customarily kept private, or at least closely held" by Sarepta. *Argus*, 139 S. Ct. at 2363.

This showing alone is sufficient to establish that the information is confidential within the meaning of Exemption 4 and that FDA properly withheld it from the FOIA production. While *Argus Leader* left open the question whether, in some circumstances, "privately held information *lose[s]* its confidential character for purposes of Exemption 4 if it's communicated to the government without assurances that the government will keep it private." 139 S. Ct. at 2363, this Court need not decide that open question, because here Sarepta had good reason to believe, based on assurances set forth in FDA regulations, that the government would not disclose the information. Whether privately held information loses its confidential character when it is disclosed to the government depends on an objective inquiry into the circumstances surrounding the disclosure. *Cf. United States Dep't of Justice v. Landano*, 508 U.S. 165, 179 (1993) (adopting an objective, context-based test of confidentiality under Exemption 7(D)). The circumstances in this case thus demonstrate that Sarepta had a reasonable expectation, based on the applicable regulations, that FDA would maintain the information as confidential.

The information at issue was provided to FDA in connection with Sarepta's NDA and that submission was designated on its face as "confidential" by Sarepta. The FDA regulation, 21 C.F.R. § 314.430 governs when FDA may disclose information contained in an NDA. This provision states, *inter alia*, that FDA will not publicly disclose even the existence of the application prior to approval unless the submitter has publicly acknowledged the NDA and, even if it has been publicly acknowledged, "no data or information in the application . . . is available for public disclosure."

21 C.F.R. § 314.430(b)-(d). After approval, limited specific information is "immediately available for public disclosure." 21 C.F.R. § 314.430(e), including "all safety and effectiveness data previously disclosed to the public" and a "Summary Basis of Approval (SBA) document that contains a summary of the safety and effectiveness data and information evaluated by FDA during the drug approval process." 21 C.F.R. § 314.430(e)(2). With respect to "protocol[s] for a test of study" such information is to be made public "*unless it is shown to fall within the exemption established for trade secrets or confidential commercial information* in § 20.61." 21 C.F.R. § 314.430(e)(3) (emphasis added). Under 21 C.F.R. § 20.61, trade secrets and commercial or financial information qualify as privileged or confidential and are "not available for public disclosure" when submitted to FDA. *See* 21 C.F.R. § 20.61(c). The regulation further defines confidential commercial information as "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 not disclosed to any member of the public by the person to whom it belongs." 21 C.F.R. § 20.61(b).

Thus, when Sarepta provided the information at issue to FDA and designated it as confidential, it did so with ample assurance that it would remain confidential. Specifically, any information that did not appear in the SBA after approval was considered confidential and would remain so unless previously disclosed to the public. *See, generally*, 21 C.F.R. § 314.430(e). Moreover, FDA further confirmed this expectation of confidentiality when it provided notice to Sarepta of a FOIA request for the records. *See* Sager Decl. ¶¶ 25-26. FDA gives such notice when it "has substantial reason to believe that information in the records could reasonably be considered exempted under exemption 4 of [FOIA]." 21 C.F.R. § 20.61(e). The existence of this procedure—and the fact that FDA followed it here—gives further support to the reasonableness of Sarepta's belief that FDA would protect confidentiality of the information.

FDA has also satisfied its obligation to provide plaintiff with "[a]ny reasonably segregable portion" of the requested records "after delet[ing those] portions which are exempt . . . ." 5 U.S.C. § 552(b); *see, e.g., Billington v. U.S. Dep't of Justice*, 233 F.3d 581, 586 (D.C. Cir. 2000); *Fla. Immigrant Advocacy Ctr. v. National Security Agency,* 380 F. Supp. 2d 1332, 1337 (S.D. Fla 2005). Indeed, FDA has continued releasing previously redacted information when it has determined that it is appropriate to do so. *See* Sager Decl. ¶ 23, Philips Decl. ¶ 5, ECF No. 133.

CONCLUSION

For the foregoing reasons, Defendants' motion for summary judgment should be granted.

Date: New York, New York
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