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' COMBINED MEMORANDUM OF LAW IN (1) FURTHER SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT, (2) OPPOSITION TO PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT, AND (3) OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE

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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 memorandum of law in further support of their motion for summary judgment, ECF No. 74, in opposition to Plaintiff Charles Seife's cross-motion for summary judgment, ECF No. 85, and in opposition to Plaintiff's motion to strike the Declaration of Ian Estepan, ECF No. 93.[1]

PRELIMINARY STATEMENT

The narrow issue before the Court in the parties' cross-motions for summary judgment is whether FDA properly withheld from release, pursuant to Freedom of Information Act ("FOIA") Exemption 4, certain information contained in Clinical Study Reports ("CSRs") submitted by Defendant-Intervenor Sarepta Therapeutics, Inc. ("Sarepta") to FDA in connection with its new drug application for Exondys 51. Despite Plaintiff's best efforts to make it so by submitting voluminous declarations based on suppositions and innuendos extrapolated from FDA's 45,000 page FOIA production to him—this is not a referendum on whether Exondys 51 should have been approved or a challenge to FDA's approval process. Accordingly, much of Plaintiff's voluminous filing is simply an irrelevant attempt to disparage FDA and Sarepta and should not even be considered by the Court.

The only issue that this Court must decide is whether the redacted information is confidential commercial information. Commercial information obtained from an entity is confidential for the purposes of Exemption 4 if disclosure would likely cause substantial harm to the competitive

[1] In accordance with the Court's June 12, 2018 Order that "Defendants and Defendant-Intervenors shall each file no more than one brief—that is, a consolidated brief in opposition and reply, as applicable," ECF No. 96, Defendants include their opposition to Plaintiff's motion to strike in this memorandum of law.

position of the entity from which the information was obtained. That test is clearly met here. Release of the withheld information would cause Sarepta significant harm in the highly competitive market for Duchenne muscular dystrophy ("DMD") drug treatment development. As detailed in the declaration of Sarepta employee Ian Estepan, access to this information would allow Sarepta's competitors to reap the benefits of Sarepta's clinical studies and Sarepta's significant resources invested in those studies to develop Exondys 51 by using proprietary information from the studies to develop competing therapies without the same level of investment.

To the extent that Plaintiff has belatedly identified certain information that has previously been made available publicly (despite having ample opportunity to inform Defendants of the publicly-available information during the Parties' meet and confers prior to summary judgment briefing), that information is now being released in this case as well. Plaintiff's speculation that the withheld information is publicly available is simply incorrect.

Plaintiff devotes the majority of his voluminous filing to arguing that disclosure of Sarepta's confidential information would be in the public interest, and therefore, should be released on that basis alone. That is not, and has never been, a relevant inquiry in this Circuit, as Plaintiff acknowledges. This Court is bound to follow established Second Circuit precedent and find, based on the detailed declaration submitted by Sarepta explaining the competitive harm it would suffer if the information were to be disclosed, that the Government properly withheld the redacted information pursuant to Exemption 4.

Plaintiff's motion to strike the initial declaration of Sarepta employee Ian Estepan is likewise without merit. The information presented in Mr. Estepan's declaration regarding Sarepta's research and development activities and expected competitive harm if the withheld information is released is clearly based on his personal knowledge. In the event that was not clear from his initial

declaration, Sarepta is now submitting a supplemental declaration from Mr. Estepan providing further detail regarding the basis for his knowledge. Plaintiff's motion to strike should be denied.

ARGUMENT

I. The Court Should Grant Defendants' Motion for Summary Judgment With Respect to the Exemption 4 Withholdings

As explained in Defendants' opening brief, summary judgment is appropriate in a FOIA case when a government agency demonstrates that no material facts are in dispute and that the search was adequate and that any withheld documents fell within an Exemption to FOIA. *See* ECF No. 75 ("Defs' Br.") 5.[2] Plaintiff's cross-motion fails to rebut Defendants' showing that Exemption 4 prohibits the disclosure of the CSR information because Sarepta is likely to suffer substantial harm to its competitive position should the information be released. Defendants, therefore, have met their burden and are entitled to summary judgment.

A. FDA Properly Withheld Confidential Information Submitted by Sarepta Pursuant to FOIA Exemption 4

"To establish competitive harm, the Government must show that 'the person who submitted the information faces both (1) actual competition and (2) a likelihood of 'substantial' competitive injury if the information were released.'" *NRDC v. U.S. Dep't of Interior*, 36 F. Supp. 3d 384, 402 (S.D.N.Y. 2014) (quoting *Inner City Press v. Bd. of Governors*, 380 F. Supp. 2d 211, 219 (S.D.N.Y. 2005), *aff'd sub nom Inner City Press/Cmty. On the Move v. Bd. of Governors of the*

[2] The Government has not submitted a counterstatement to Plaintiff's Local Rule 56.1 statement nor did the Government submit a Local Rule 56.1 statement in connection with the Government's motion because, as explained in the Government's opening brief, the general rule in this Circuit is that such statements are not necessary in FOIA actions. *See* Defs' Br. 2 n.1. Moreover, Plaintiff's 56.1 statement constitutes a lengthy recitation of alleged facts that are immaterial to the actual issues to be decided by the Court, and accordingly the Government objects to Plaintiff's 56.1 statement on this basis. If, however, the Court believes that a response to Plaintiff's 56.1 statement would be appropriate in this FOIA case, the Government will of course provide one.

Fed. Res. Sys., 463 F.3d 239 (2d Cir. 2006)); *see also* Defs' Br. 6-7. The initial declaration of Sarepta employee Ian Estepan, *see* ECF No. 72 ("Estepan Decl."), and his supplemental declaration that Sarepta is filing with its combined opposition/reply, *see* Second Declaration of Ian Estepan ("2d Estepan Decl."), readily supports both of these prongs. None of Plaintiff's arguments to the contrary, *see* ECF No. 86 ("Pl's Br.") 17-22, 27-35, or the Declaration of Peter Lurie (which is the only declaration that Plaintiff has submitted that actually addresses these points),[3] *see* ECF No. 88 ("Lurie Decl.") ¶¶ 21-26, undermine this conclusion.

As explained in the Government's opening brief, the Court need not conduct a "sophisticated economic analysis of the likely effects of disclosure" and Defendants are not required to show "actual competitive harm" or "actual adverse effect on competition." Defs' Br. 7-8 (quoting *Pub. Citizen Health Research Grp v. FDA*, 704 F.2d 1280, 1291 (D.C. Cir. 1983) and *Customs & Int'l Trade Newsletter v. U.S. Customs & Border Prot.*, 588 F. Supp. 2d 51, 55 (D.D.C. 2008)). Indeed, a company "need not demonstrate precisely how the release of the information would cause competitive harm" so long as it offers more than "mere conclusory opinion testimony," *Gen. Elec. Co. v. Dep't of Air Force*, 648 F. Supp. 2d 95, 103-04 (D.D.C. 2009)—a standard that is more than met here based on Estepan's two detailed declarations.

[3] Although Plaintiff's declaration includes a section entitled "Lack of Competitive Harm," Plaintiff does not purport to have any expertise or personal knowledge regarding how this information could be used by Sarepta's competitors. Instead, this section consists of argument (more properly made in a memorandum of law) and recitation of public sources of factual information about Sarepta's participation in industry collaborative research and conferences regarding DMD. *See* ECF No. 87 ("Seife Decl.") ¶¶150-156. Whether Sarepta participated in such conferences and collaboration does not undermine the fact that the specific information at issue here is non-public and has not been shared freely with Sarepta's competitors and the public, *see* 2d Estepan Decl. ¶¶ 37-39. Likewise, Seife's argument that the information is publicly available, *see* Seife Decl. ¶¶ 157-59; *see also id.* ¶¶ 54-92, is for the most part simply incorrect, *see* pp. 12-13 *infra.*

Although Plaintiff asserts that Defendants must show that the "competitive harm" will be "imminent" based on Judge Preska's decision in *Bloomberg L.P v. Board of Governors of the Federal Reserve System*, 649 F. Supp. 2d 262, 279 (S.D.N.Y. 2009), *see* Pl's Br. 14, 34-35, that heightened standard has not been adopted in either this district or this Circuit. Indeed, in affirming the district court's judgment in *Bloomberg*, the Second Circuit did not reference or apply an "imminence" standard. *See* 601 F.3d 143 (2d Cir. 2010). And the D.C. District Court specifically rejected an attempt to add such a requirement to the *National Parks* standard—the same standard applied in the Second Circuit[4]—holding that the defendant agency "is not required to prove imminent harm. The agency only must show that release of the withheld documents 'is *likely* . . . to cause substantial harm to the competitive position of the person from whom the information was obtained.'" *Judicial Watch, Inc. v. U.S. Dep't of Treasury*, 796 F. Supp. 2d 13, 36 (D.D.C. 2011) (emphasis and alterations in original) (quoting *Nat'l Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974)).[5]

1. The Estepan Declarations Provide The Necessary Specificity and Detail

Defendants' and Intervenors' opening briefs and supporting declarations established that the release of the redacted information is likely to cause competitive harm and consequently the information should be exempt from disclosure under 5 U.S.C. § 552(b)(4). *See* Def's Br.; ECF

[4] *See Inner City Press/Cmty. On the Move v. Bd. of Governors of the Fed. Res. Sys.,* 463 F.3d 239, 244 (2d Cir. 2006) (quoting *Cont'l Stock Transfer & Trust Co. v. SEC,* 566 F.2d 373, 375 (2d Cir. 1977), which adopted the standard set forth in *National Parks & Conservation Ass'n v. Morton,* 498 F.2d 765, 770 (D.C. Cir. 1974)).

[5] Plaintiff's reliance on *Bristol-Myers Squibb Co. v. Shalala*, 892 F. Supp. 295, 297-98 (D.D.C. 1995), in which FDA argued that the drug manufacturer had not made a sufficient showing of imminent harm *for standing purposes*, is misplaced. Unlike in the Exemption 4 context, the requirement that plaintiff make a showing of "not merely potential but 'actual or imminent'" harm is a necessary element of the test for Article III standing as expressly articulated by the Supreme Court. *Id.* at 298 (quoting *Lujan v. Def. of Wildlife*, 504 U.S. 555, 560 (1992)).

No. 76 ("Kotler Decl"); ECF No. 77 ("Sager Decl"); ECF No. 70; Estepan Decl. The detailed explanation of how the release of each disputed category of information would cause competitive harm to Sarepta, *see, e.g.,* Estepan Decl. ¶¶ 22-43; 2d Estepan Decl. ¶¶ 29-36, provides ample specificity to establish the applicability of Exemption 4, especially when compared to the limited evidence proffered in the cases Plaintiff relies upon, *see* Pl's Br. 19-21,

For example, in *AIDS Healthcare Foundation v. FDA*, No. 11-cv-07925, Dkt. No. 60 (C.D. Cal. Aug. 6, 2013), Slip Op. at 19, the Central District of California found that the declarations were insufficient to demonstrate competitive harm because they did not address competitive harm in the market for which they had established actual competition, but instead focused on harm in a market for which they did not establish competition. This is readily distinguishable from the facts here. As explained below, there is no dispute here that there is actual competition for the development of a DMD drug, *see* pp. 8-9 *infra*, and that is the market that Estepan's declarations focus on.

Likewise, in *Physicians Committee for Responsible Medicine v. NIH*, a noncommercial scientist merely alleged that "several laboratories [were] currently working on similar projects"—without explanation of how those laboratories could make use of his information—and offered the conclusory allegation that the release would impair his ability to have his own research published in journals. 326 F. Supp. 2d 19, 26-27 (D.D.C. 2004). Here, in contrast, Sarepta is indisputably a commercial enterprise and Estepan explains in detail how the information at issue could be used by its competitors and cause substantial harm to Sarepta.

In *Public Citizen Health Research Grp. v. FDA*, the D.C. Circuit found that that a description very similar to that provided in the Estepan declaration was sufficient to support a finding of competitive harm with respect to all but one of the Investigational New Drug ("IND") applications.

See 185 F.3d 898, 905-06 (D.C. Cir. 1999). With respect to the one IND as to which the D.C. Circuit found there had been an insufficient showing, the statements in the declaration stand in contrast to what is offered by Estepan here. The declaration in *Public Citizen* had merely offered:

> conclusory assertions that disclosure would cause substantial competitive harm. For example, the affiant states that disclosure "would reveal substantial basic research" as well as "disease models . . . that have been developed by Schering at a great expense," and that "[t]oxicology data . . . have significant value beyond the compound under investigation . . . . [and would be applicable] to any drug product any of whose metabolites were identical or similar to those of IND 18113 . . . . [and] other drugs [of] a similar chemical type." Dr. Garutti attests that the clinical protocols also "have applicability beyond the specific drug being tested" and that disclosure "would have substantial commercial value to any company attempting to develop cardiovascular therapies generally." The arguments in Schering's brief are even more general: disclosure would reveal its "assessment of regulatory requirements and its experience with FDA in this area, as well as [its] judgment as to what requirements will be necessary in order to establish the drug's safety and effectiveness."

Id. at 906. In contrast, here, the Estepan declarations explain, *inter alia,* that Sarepta has invested significant resources and years in developing its clinical studies, and that competitors would be able to: use Sarepta's timing for certain tests and details regarding the tests to copy Sarepta's study designs or selectively modify them, Estepan Decl. ¶¶ 22-23; use Sarepta's dosing research to bypass years of expensive trial and error work, *id.* ¶ 25; use Sarepta's work on immunohistory techniques to aid in the rapid development and approval of competing products, *id.* ¶¶ 26-27; use testing results to get the benefit of having conducted a clinical study without actually having to do so or such results as control datasets, *id.* ¶¶ 29-31, 33; use nonpublic exploratory endpoints to gain insight into Sarepta's future research, to save time by not pursuing avenues that Sarepta ultimately did not utilize or to pick up Sarepta's research where Sarepta left off, *id.* ¶¶ 37-39; and leverage

nonpublic eteplirsen adverse event data as being representative of the chemical class of PMO compounds in their own approvals, *id.* ¶ 41. *See also* 2d Estepan Decl. ¶¶ 30-36.[6]

2. Actual Competition Exists in the DMD Drug Market

Sarepta presented Estepan's detailed declaration and supplemental declaration that establish that actual competition exists within the drug industry for development of drugs to fight DMD. Estepan Declaration, *see* Estepan Decl. ¶¶ 44-49, 58-59. Neither in his opposition brief nor in the Lurie Declaration, does Plaintiff offer anything to rebut the showing made in Defendants' opening brief, *see* Defs' Br. 8-10, and the Estepan Declaration, *see* Estepan Decl. 44-49, 58-59, that actual competition exists for the development of a DMD drug. Plaintiff merely challenges the foundation of Estepan's knowledge of Sarepta's competitors' plans. *See* Pl's Br. 18 n.8. However, as explained in response to Plaintiff's motion to strike, Estepan's initial declaration and his supplemental declaration lay out the basis of his knowledge. *See* pp. pp. 19-21 *infra.* This is a

[6] The other cases that Plaintiff cites similarly stand in stark contrast to the Estepan declarations. *See, e.g., Gov't Accountability Project v. U.S. Dep't of Health & Human Servs*., 691 F. Supp. 2d 170, 178 (D.D.C. 2010) (holding that a sole paragraph stating that "a competitor could use that [ ] information to support its own new drug application [ ] without having to incur the time and expense involved in developing the information itself" and that "the owner of the protected-but-improperly-released information could sue [the] FDA on the grounds that [the] FDA's release jeopardized its competitive market by providing competitors with critical information that could speed up the development of a competing project" was conclusory and insufficient to establish competitive harm); *Pub. Citizen Health Research Grp. v. FDA*, 99-177 (JR), 2000 WL 34262802, at * 2 (D.D.C. Jan. 19, 2000) (finding that declaration that *only* contained assertion that one of the company's competitors could use raw patient data in support of NDA and that it would allow competitors to save time and expense was insufficiently specific, as compared to other declarations that were found to be sufficient which "demonstrated *how* other companies could take advantage of [the company's] research efforts" (emphasis added)); *Pub. Citizen Health Research Grp. v. FDA*, 964 F. Supp. 413, 416 (D.D.C. 1997) (rejecting declaration stating that disclosure of protocol would permit competitors to "piggypack" study design because it "does not answer the question. . . What advantage would a competitor gain from the protocol for a study that is uniquely tailored to the characteristics of Metformin?"); *Teich v. FDA*., 751 F. Supp. 243, 253–54 (D.D.C. 1990) (finding it "unlikely that competitors would look in any meaningful way to studies undertaken . . . over 20 years ago" and that "Defendants have introduced no evidence which would demonstrate the current significance of these tests.").

sufficient basis for the Court to credit Estepan's representations about the state of competition in the DMD market.[7] *See Searles v. First Fortis Life Ins. Co.,* 98 F. Supp. 2d 456, 461 (S.D.N.Y. May 24, 2000) ("An affiant's conclusions based on personal observations over time. . . may constitute personal knowledge."). Mr. Estepan's representations more than support the Court's finding that actual competition exists in the DMD market.

3. Defendants Have Established that Disclosure of the Redacted Information Is Likely To Cause Substantial Competitive Harm to Sarepta

Defendants' opening briefs established that the release of the information withheld from the Clinical Study 201 and 202 CSRs would provide an advantage to Sarepta's competitors and cause substantial competitive injury to Sarepta and consequently the information is exempt from disclosure under 5 U.S.C. § 552(b)(4). *See* Defs' Br. 10-15. Likewise, the Court should find that in this highly competitive market the release of the information withheld from Clinical Study 201 and 202 CSRs would provide an advantage to Sarepta's competitors and cause substantial competitive injury to Sarepta. *See* Defs' Br. 10-15. None of Plaintiff's arguments undermines Defendants' showing that release of the withheld information in the four categories described below would cause substantial competitive harm to Sarepta.[8]

[7] The standard that Plaintiff is suggesting would be impossible for any company to meet in defending the release of its competitively sensitive information, as it would effectively require the company to proffer declarations from its competitors in which the competitors explain how they intend to use the information (either requiring the company to actually disclose the competitively sensitive information to its competitors, thereby defeating the purpose of defending against its release, or speculation on the part of the competitors).

[8] As Plaintiff recognizes, *see* Pl's Br. 27, although the Government and Sarepta use slightly different terminology to refer to these four categories, they are both referring to the same four categories of withheld information.

a. Granular-Level Detail Regarding Clinical Study Procedures

As detailed in Defendants' opening brief, FDA properly withheld certain portions of the CSRs because release of the withheld information would reveal granular-level detail of Sarepta's clinical study procedures—including information regarding Sarepta's for certain tests and details regarding the tests themselves, dosing information,[9] the proper method to quantify dystrophin and patient selection criteria—which would allow Sarepta's competitors to copy Sarepta's study design, or selectively modify it, without having invested the time and resources into producing their own studies. *See* Def's Br. 11-12 (citing Sager Decl. Ex. O at 2-18); *see also* Estepan Decl. ¶¶ 23-28.

Neither of Plaintiff's arguments in response undermines this conclusion. First, although Plaintiff asserts that he is not seeking "step-by-step clinical protocol details, but rather the narrative descriptions," Pl's Br. at 29, the withheld information from the narrative descriptions would reveal the very same type of information, *see* 2d Estepan Decl. ¶ 41. Second, Plaintiff inaccurately asserts that *Public Citizen Health Research Group v. FDA*, 964 F. Supp. at 416-17, stands for the proposition that study protocols are not confidential information. *See* Pl's Br. 29. Instead the D.C. District Court found was that the submitter had not explained "[w]hat advantage . . . a competitor [would] gain from the protocol." *Pub. Citizen*, 964 F. Supp. at 416. Here, by contrast, Mr. Estepan explains that in detail. *See* pp. 7-8 *supra.*

[9] Contrary to Plaintiff's claims, *see* Lurie Decl. ¶ 22; Seife Decl. ¶ 157, the withheld dosing information is not the same information that is available on the Exondys-51 label. As Estepan explains, the withheld information includes unpublished data relating to multiple dose amounts, timing, forms and strengths evaluated by Sarepta in its studies. *See* 2d Estepan Decl. ¶ 29. Sarepta's competitors are studying a variety of dosing questions, and disclosure of the withheld information would allow them to bypass years of expensive work that Sarepta undertook. *Id.*; *see also* Estepan Decl. ¶ 25.

b. Patient-Level Data Regarding Study Results and Patient Characteristics

Defendants also amply demonstrate that release of the study results would cause competitive harm to Sarepta. *See* Def's Br. 12-13. Plaintiff's claim that competitors cannot use Sarepta's study results in "any meaningful way," *see* Pl's Br. 30-32; Lurie Decl. ¶ 24-25, is contradicted by Mr. Estepan's declarations. As he explains, even if the de-identified data alone cannot be used for historical controls to be submitted to FDA, "competitors can still take advantage of such data in the process of developing their own historical external control datasets and designing their own clinical trials," 2d Estepan Decl. ¶ 34, and to inform development decisions, *id.* ¶ 36. *See also* Estepan Decl. ¶¶ 29, 32. Additionally, the withheld study results data contains statistical analysis of its significance, which likewise is important to Sarepta's competitors in making drug development decisions. *See* 2d Estepan Decl. ¶ 36. Plaintiff has offered nothing to rebut this evidence.

c. Information Regarding Endpoints

Contrary to Plaintiff's assertion, FDA has only withheld *non-public* information regarding clinical study endpoints from the CSRs. *See* Defs' Br. 13-14. Accordingly, Plaintiff's assertions that many of the endpoints were either "developed by [Sarepta's] competitors" or "are standard measures used in the community of muscular dystrophy researchers," Pl's Br. 32; Lurie Decl. ¶¶ 22-23; Seife Decl. ¶¶ 60-84, do not actually address the withheld information. What Estepan's declarations describe is the commercial harm that would be suffered if *non*-public exploratory endpoints are revealed, *see* Estepan Decl. ¶¶ 35-39; 2d Estepan Decl. ¶¶ 30-31, and Plaintiff again offers nothing to rebut that evidence.

d. Information Regarding Nonpublic Adverse Events

Finally, Defendants properly withheld information regarding non-public adverse events due to the competitive harm that would result to Sarepta if this information were released. *See* Defs' Br. 14-15; *see also* 2d Estepan Decl. ¶ 32. Plaintiff does not appear to dispute that release of this information would cause competitive harm to Sarepta, but instead returns to his public interest argument. *See* Pl's Br. 32-33. As explained below, the alleged existence of a public interest in the information is not a relevant factor in determining whether information is properly withheld pursuant to Exemption 4. *See* pp. 14-18 *infra.* The only other argument that Plaintiff offers is that Sarepta has enjoyed the "first mover advantage" for long enough, Pl's Br. 33, but Plaintiff cites no authority for the proposition that Exemption 4 only protects commercial information for a limited period of time to protect first in-time applications. Nor are Defendants aware of any such authority. Thus, the Court need not consider this argument.

B. Defendants Have Only Withheld Information They Believe to Not Be Publicly Available.

Defendants are not withholding information from the FOIA production that is publicly-available from other sources. Before the summary judgment motions were filed, the parties engaged in extensive meet and confers and FDA released additional information in response to concerns raised by Plaintiff during those meet and confers. *See* Sager Decl. ¶ 23. Notably, despite ample opportunity to do so, Plaintiff never raised any of the purported "public disclosures" that he now presents to the Court.[10] Counsel for Sarepta has gone through the voluminous materials

[10] For example, Plaintiff did not flag the fact that in making one of its re-releases FDA inadvertently added an additional redaction to the Table of Contents on document FDACDER00033 (which was reproduced with the A suffix added to the Bates number). *See* ECF No. 90-3 at 6-7; Pl's Br. 45. If Plaintiff had pointed this out during the meet and confer process, FDA would have corrected this error as it has now done.

submitted by Plaintiff, compared those materials to the withheld information and identified any documents that have indeed previously been made public. *See* Declaration of Amanda Sherwood, ECF No. ___ ("Sherwood Decl."). Any publicly available information has now been released to Plaintiffs. *See id.* ¶¶ 12, 22-26, 28, 31, 33-35, 38-39, 42; *see also* Declaration of Howard R. Philips ("Philips Decl.") ¶ 5. As detailed in the Sherwood Declaration, Plaintiff is simply incorrect in his speculation that the remaining information has been made public or is information that Sarepta was required to make public by operation of law. *See generally* Sherwood Decl.; *see also* 2d Estepan Decl. ¶¶ 37-40.

Plaintiff's argument that the withheld material is *similar* to information that other manufacturers have made public—including those released under FDA's pilot program, *see* Pl's Br. 45; Seife Decl. ¶¶ 43-45—does nothing to undermine the showing of competitive harm with respect to the Sarepta materials at issue in this litigation. As Plaintiff himself notes in his declaration, materials are made public pursuant to FDA pilot program "with consent of the manufacturer." *See* Seife Decl. ¶ 43. Sarepta has not given its consent here—to the contrary it is actively defending these withholdings. Moreover, Plaintiff has not shown how the market for the drug for which a different drug manufacturer authorized the CSR for release and the released information in that CSR are analogous to the facts at issue in this case.[11]

[11] Plaintiff makes much of the European Medicines Agency's ("EMA") policy on the publication of CSRs as proof that the redacted information "will" be released someday and therefore Sarepta cannot suffer economic harm today due to the CSRs' release. *See* Seife Decl. ¶ 159. Even apart from the temporal problem with this argument, Plaintiff misstates the measures that EMA takes to protect drug applicants from any commercial harm that would be caused by a competitor accessing and using the released information. First, prior to publication, drug applicants are allowed to redact CCI from CSRs, which EMA defines as "any information contained in the clinical reports submitted to the Agency by the applicant/marketing authorization holder (MAH) that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH." *See* "Questions and answers on the European Medicines Agency policy on publication of clinical data for medicinal products for human use," EMA/357536/2014

C. Public Interest Balancing is Not Part of the Exemption 4 Legal Test

Plaintiff devotes much of his brief and declarations to arguing that disclosure of the withheld information would be in the public interest, *see* Pl's Br. 2, 4-7, 8-11, 13-17, 36-44; Seife Decl. ¶¶ 9-22, 29-40, 93-149; ECF No. 89 ("Zuckerman Decl.") ¶¶ 8-29; Lurie Decl. ¶¶ 8-20. The public interest's interest in the disclosure of the information, however, is not a relevant factor in the Second Circuit's Exemption 4 analysis, as Plaintiff admits. *See* Pl's Br. 14. In an attempt to make it relevant, the plaintiff requests this Court to break new ground and weight the purported public interest against the likely competitive harm that Sarepta will suffer should its confidential information be released. Plaintiff's request is unfounded and unsupported by even the case law on which he relies, and accordingly should be rejected.

First, contrary to Plaintiff's assertion, the Ninth Circuit in *Micro Corp. v. Def. Logistics Agency*, 33 F.3d 1109 (9th Cir. 1994), did not "adopt[]" an Exemption 4 test that balances competitive harm against a purported public interest in disclosure. *See* Pl's Br. 14-15. The Ninth Circuit, however, merely stated that the balance of the public interest in disclosure against the right of private businesses to protect their sensitive information had already been considered and was embodied in the D.C. Circuit's test in *National Parks*, 498 F.2d at768-69. *See Micro Corp.*, 33 F.3d at 1115. *National Parks* requires that the party seeking to withhold the information

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Rev. 1, at 6 (June 8, 2015) *available at* http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/10/WC500174378.pdf. Further, any person wishing to access the unredacted data (whenever it is published), is required pursuant to the Terms of Use ("ToU") to register with the Agency and agree that the information will only be used for non-commercial purposes. *Id.* Any user who wishes to download the information must, according to the ToU, provide their name, date of birth, and passport or ID card number. *See id.* at 5. The ToU specifically states that "no unfair commercial uses shall be made of such information." *Id.* A watermark is applied to the published information to "emphasize the prohibition of its use for commercial purposes." *Id.* There are no comparable restrictions on the use of materials obtained under FOIA.

demonsrtate that it is confidential by showing that its release is likely either: "(1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained." *Id.* (quoting *Nat. Parks*, 498 F.2d at 1113). The Ninth Circuit further noted that "*[t]o the extent that releasing [the withheld information] does not cause substantial harm to the competitive positions* of federal contractors involved, while encouraging federal contractors in general to set higher SDB subcontracting goals, congressional intent in passing both FOIA and the Small Business Act Amendment will be furthered." *Id.* (emphasis added).). Furthering other public goals, according to the Ninth Circuit was relevant only "to the extent" that the release did not cause substantial competitive harm. *See id.* Because the defendants in *Micro Corp.* failed to show competitive harm, the court ordered the withheld information's release. *Id.* at 1115.

Notably, since *Micro Corp.*, the Ninth Circuit has continued to apply the *National Parks* test without adding the "public interest" balancing test that Plaintiff advocates. *See, e.g.*, *Torres Consulting Law Grp v. NASA*, 666 F. App'x 643, 644 (9th Cir. 2016); *Watkins v. U.S. Bureau of Customs & Border Protection*, 643 F.3d 1189, 1195 (9th Cir. 2011). Indeed, at least one district court in the Ninth Circuit has expressly rejected the argument that the court "apply a balancing test between the public interest in disclosure and the private interests protected by the exemption," stating that "[t]he only test the Court may apply is that found in *National Parks*" and reiterating that the "*National Parks* test *is* the balancing test." *Lahr v. Nat'l Transp. Safety Bd.*, 453 F. Supp. 2d 1153, 1176 (C.D. Cal. 2006) (emphasis in original, citing *Pub. Citizen Health Research Grp v. FDA,* 185 F.3d 898, 904 (D.C. Cir. 1999)), *aff'd in part, rev'd in part and remanded*, 569 F.3d 964 (9th Cir. 2009).

Second, Plaintiff asks this Court to disregard the D.C. Circuit's majority opinion in *Public Citizen Health Research Group v. FDA*, and, instead, follow *dicta* in Judge Garland's concurrence in that matter. *See* Pl's Br. 15-16. The majority opinion expressly rejected the approach that Plaintiff advocates here because "a consequentialist approach to the public interest in disclosure is inconsistent with the '[b]alanc[e of] private and public interests' the Congress struck in Exemption 4." *Pub. Citizen Health Research Grp*, 185 F.3d at 904 (citations omitted). As the majority opinion explained "[i]t is not open to [the requester], however, to bolster the case for disclosure by claiming an additional public benefit." Quoting the Supreme Court's opinion in *DOJ v. Reporters Committee for Freedom of Press*, 489 U.S. 749, 773 (1989), the D.C. Circuit explained:

> "[W]hether disclosure of a . . . .document . . . is warranted must turn on the nature of the requested document and its relationship to the basic purpose of the Freedom of Information Act to open agency action to the light of public scrutiny . . . rather than on the particular purpose for which the document is being requested." In other words, the public interest side of the balance is not a function of the identity of the requester, . . . , or of any potential negative consequences disclosure may have for the public, . . . , nor likewise of any collateral benefits of disclosure.

Pub. Citizen, 185 F.3d at 904 (internal citations omitted). Plaintiff also overstates Judge Garland's concurring opinion. *See* Pl's Br. 15-16. While Judge Garland recognized the appeal of considering the public interest, the thrust of his concurrence was that the question of whether it should be considered was "an important issue . . . that should be decided only after full briefing and argument," which is why he wrote a separate concurrence. *Pub. Citizen*, 185 F.3d at 907 (Garland, J., concurring); *see also id.* at 910.

In any event, to the extent this Court looks to D.C. Circuit case law in FOIA matters for guidance, what is persuasive authority is the majority opinion, not a concurrence that has not been followed since, even in the D.C. Circuit. *See Skybridge Spectrum Found. v. F.C.C.*, 842 F. Supp. 2d 65, 82 (D.D.C. 2012) (rejecting plaintiff's suggestion that any "public interest in the particular

information covered by its requests should outweigh the private interest in the non-disclosure of confidential commercial information" because "Exemption 4 embodies a congressional determination that the public disclosure of confidential commercial information *does* outweigh the public interest in disclosure, and it is not the district court's role to second-guess that judgment on a case-by-case basis." (emphasis in original)); *cf. Pub. Citizen Health Research Grp. v. NIH*, 209 F. Supp. 2d 37, 45 (D.D.C. 2002).[12]

The old or unpublished cases Plaintiff cites in footnote 6, *see* Pl's Br. 16-17 n.6, likewise do not advance his cause and have no bearing on the appropriate test for Exemption 4 withholding in the FOIA context or on the facts before the Court in this case. *See Corn Prod. Refining Co. v. Eddy*, 249 U.S. 427 (1919) (holding that state boards of health could require certain labeling on cans of corn syrup disclosing their contents); *Nat'l Prescriptions Opiate Litig.*, 17:MD:02804, Dkt. No. 199, Order Regarding Settlement Discussions (N.D. Ohio Mar. 27, 2018) (in the context of settlement discussions ordering parties share any confidential and proprietary information as necessary); (*Kentucky v. Merck*, No. 09-CI-1671, Opinion & Order at 10-14 (Ky. Cir. Ct. Mar. 23, 2018)) (finding that Merck's interests were insufficient to maintain confidentiality designation of the documents because the other party to the contract, which was the party whose commercial interests the confidentiality designations were intended to protect, had done nothing in the litigation to protect those interests) (submitted by Plaintiff herein at ECF No. 90-36).

[12] The D.C. Circuit's majority opinion in *Public Citizen* was also followed by the District of New Hampshire in *New Hampshire Right to Life v. Department of Health & Human Services*, which found the "reasoning persuasive—if for no other reason than it simply applies the [Freedom of Information] Act as written. . . . So [the] court reject[ed] [the plaintiff's] suggestion that, even if material is "confidential" under § 552(b)(4)—in the accepted sense that its disclosure would likely 'cause substantial harm to the competitive position of' the person who submitted it—that exemption is nevertheless inapplicable so long as that harm is outweighed by the public interest in the material. 976 F. Supp. 2d 43, 55 (D.N.H. 2013), *aff'd sub nom. N.H. Right to Life v. U.S. Dep't of Health & Human Servs.*, 778 F.3d 43 (1st Cir. 2015).

The Second Circuit's test for Exemption 4 is clear: "information is 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/On the Move*, 463 F.3d at 244 (quoting *Cont'l Stock Transfer & Trust Co.,* 566 F.2d at 375). Accordingly, the Court should disregard the bulk of Plaintiff's filing, *see* Pl's Br. 2, 4-7, 8-11, 13-17, 36-44; Seife Decl. ¶¶ 9-22, 29-40, 93-149; Zuckerman Decl. ¶¶ 8-29; Lurie Decl. ¶¶ 8-20, as irrelevant to the question before the Court.[13] And find, for the reasons set forth above, that because release of the withheld information would cause substantial competitive harm to Sarepta, the information was properly withheld pursuant to Exemption 4.

D. FDA Has Released All Reasonably Segregable 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. DOJ*, 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, after discussions with Plaintiff during the Parties' meet and confers, FDA did a secondary review, and released additional previously redacted information, *see* Sager Decl. ¶ 23, and yet again

[13] In particular, the Court should disregard the vast majority of Plaintiff's declaration, which consists largely of argument and a summary of information purportedly learned from public sources or FDA documents provided in response to his FOIA request. *See, e.g.,* Seife Decl. ¶¶ 9-22, 29-40. Not only is such argument properly part of a memorandum of law rather than a declaration, it is not based on Plaintiff's personal knowledge. Moreover, while the Government disagrees with Plaintiff's characterization of the FDA documents as "smoking gun" documents, *see id.* ¶ 29, that is simply not relevant to the question before the Court—whether the information withheld from two CSRs submitted by Sarepta to FDA is confidential and properly withheld pursuant to Exemption 4. Plaintiff is not challenging any withholdings from the FDA documents—and, if anything, Plaintiff's lengthy recitation of facts he claims to have learned from those documents supports the conclusion that FDA has been forthcoming in its FOIA response.

released additional information based on the public disclosures newly identified by Plaintiff in his summary judgment briefing, *see* Philips Decl. ¶ 5.

E. There is No Need for *In Camera* Review.

The Court should decline Plaintiff's request for *in camera* review of the documents, as the *Vaughn* index and declarations are sufficient for the Court to conduct its review of the basis of the withholdings. *See Carney v. DOJ*, 19 F.3d 807, 812-13 (2d Cir. 1994); *see also Associated Press v. DOJ*, 549 F.3d 62, 67 (2d Cir. 2008) ("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."). Plaintiff's suggestion that an *in camera* review is warranted because the "agency has something to hide," Pl's Br. 46, is belied by the massive nature of FDA's production (which Plaintiff acknowledges exceeds 45,000 pages of documents, *see* Seife Decl. ¶ 29), and the fact that Plaintiff is not challenging any of the withholdings in FDA documents, *see* ECF No. 66 at 1. FDA has been transparent in its FOIA productions, and has demonstrated that the limited withholdings challenged by Plaintiff are exempt from disclosure under Exemption 4. There is simply no reason for the Court to conduct an *in camera* review of the Sarepta materials.

II. Plaintiff's Motion to Strike The Estepan Declaration Should Be Denied

Adding to the large volume of his filings, Plaintiff has also filed a 21-page memorandum of law in support of his motion to strike the Declaration of Sarepta employee Ian Estepan. *See* ECF No. 94 ("Pl's Motion to Strike Br."). As an initial matter, Plaintiff's motion to strike is not contemplated by Rule 56 of the Federal Rules of Civil Procedure. Although, Rule 56(c)(2) allows a party to "object that the material cited to support . . . a fact cannot be presented in a form that would be admissible in evidence," Fed. R. Civ. P. 56(c)(2), "there is no need to make a separate motion to strike," Advisory Committee Note to 2010 Amendment. *See also Martin v. Town of*

Westport, 558 F. Supp. 2d 228, 230 (D. Conn. 2008) ("Rule 56, which governs summary judgment, does not provide a 'motion to strike' as a tool in the summary judgment process."). To the extent Plaintiff's motion is filed pursuant to Federal Rule of Civil Procedure 12(f), that rule applies only to motions to strike information from pleadings, and "[d]eclarations and affidavits are not pleadings." *Nat'l Union Fire Ins. Co. of Pittsburgh, PA v. Hicks, Muse, Tate & Furst, Inc.*, 02 Civ. 1334 (SAS), 2002 WL 1482625, at *6 (S.D.N.Y. July 10, 2002) (denying motion to strike declaration submitted in connection with reply brief); *Granger v. Gill Abstract Corp.*, 566 F. Supp. 2d 323, 335 (S.D.N.Y. 2008) ("[T]he Court recommends denying all of Plaintiff's motions to strike [motion for summary judgment and supporting papers] because they do not comport with the restrictions of Rule 12(f).").

Even if it were procedurally proper, Plaintiff's motion fails on its merits. Contrary to Plaintiff's assertion, Mr. Estepan's declaration was made based on his personal knowledge and experience based on his current role at Sarepta as well as his 16 years of experience in healthcare investing, related to the development of promising drug candidates. *See* Estepan Decl. ¶¶ 1-2; *see also* 2d Estepan Decl. ¶¶ 3-10. Although the information contained in the initial declaration was sufficient to establish the basis for Estepan's knowledge, *Searles*, 98 F. Supp. 2d at 461 ("The test for admissibility is whether a reasonable trier of fact could believe the witness had personal knowledge."), and to the extent there was any doubt in that regard, he has now submitted a supplemental declaration identifying the particular activities in these roles that led him to gain the knowledge set forth in his declarations. *Id.* ¶¶ 11-26.

As Mr. Estepan details in his supplemental declaration, as part of his work responsibilities as Chief of Staff and Head of Corporate Affairs at Sarepta, overseeing Investor Relations, Corporate Communication, and Program Management, he has led the development of Sarepta's

strategic plan and execution of corporate initiatives. *See* 2d Estepan Decl. ¶¶ 10-11. This role has led him to gain first-hand knowledge about Sarepta's work in developing esteplirsen. *Id.* ¶¶ 12-23. He has reviewed the information at issue in this litigation. *Id.* ¶¶ 25-26. Moreover, he has ample basis to form a belief as to work of Sarepta's competitors: he regularly reviews medical literature regarding DMD and therapies for the disease; regularly discusses such publications with scientists and clinicians; reviews reports and nonclinical and clinical trials; reviews submissions to FDA; communicates with and reads the reports of financial analysts covering Sarepta's competitors; communicates with Sarepta's investors and prospective investors about investments in Sarepta vis-à-vis its competitors; reviews competitors' SEC filings, filings with foreign regulators, and press releases; listens to competitors' webinars and earnings presentations, reviews analysis reports; follows media coverage; and attends industry conferences. *See* 2d Estepan Decl. ¶¶ 16-24.

As explained in the Government's opening brief, numerous courts have recognized in the FOIA context that employees of a company whose information is at issue in an Exemption 4 challenge possess the personal knowledge to attest to the competitive harm that will result to the company if the information is released. *See* Def's Br. 6 n.5. Defendants also join in the arguments made in Defendant-Intervenor Sarepta's opposition to Plaintiff's motion to strike.

CONCLUSION

For the foregoing reasons and those set forth in Defendants' opening brief, (1) Defendants' motion for summary judgment should be granted, (2) Plaintiff's cross-motion for summary judgment should be denied, and (3) Plaintiff's motion to strike should be denied.

Date: New York, New York
July 30, 2018

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