UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

Charles Seife ***Plaintiff*,** **v.** **Food and Drug Administration and Department of Health and Human Services** ***Defendants*** **and** **Sarepta Therapeutics, Inc.** ***Defendant-Intervenor*.**	**Case No. 1:17-cv-3960 (JMF)**

SAREPTA THERAPEUTICS, INC.'S RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND REPLY IN FURTHER SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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ORAL ARGUMENT REQUESTED

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

INTRODUCTION

Plaintiff's rhetoric aside, this is a case about competitive harm under FOIA Exemption 4. In its moving papers, Sarepta demonstrated that it faces actual competition in the market for exon-skipping and Duchenne muscular dystrophy ("DMD") treatments. Sarepta also explained how release of the withheld information is likely to cause the company substantial competitive harm. To address the misrepresentations and misunderstandings in Plaintiff's motion papers, Sarepta now has submitted a second declaration, which further details the competitive harm that Sarepta is likely to face from disclosure of the withheld information. Sarepta thus has met its burden under the well-established law governing FOIA Exemption 4, and the case should end there.

In an effort to avoid summary judgment in Sarepta and the FDA's favor, Plaintiff has raised a host of issues that are beyond the scope of this straightforward FOIA case, inundated the court with unnecessary exhibits, and even filed a duplicative motion to strike. Plaintiff apparently seeks to transform its FOIA suit into a different kind of case altogether, a referendum on Sarepta, the FDA, and eteplirsen, Sarepta's groundbreaking drug for the treatment of DMD. Plaintiff's inflammatory allegations are both unsupported and irrelevant.

Not a single court in the country applies Plaintiff's proposed balancing test for the disclosure under FOIA of confidential commercial information. And the reason for that is clear: the public interest balancing test that Plaintiff wants is inconsistent with the balance of private

and public interests Congress struck in FOIA Exemption 4. Plaintiff simply cannot bolster its case for disclosure by claiming additional public benefit. Where there is a showing of likely competitive harm, there can be no disclosure.

Plaintiff's desired balancing test is not the only sideshow in which Plaintiff indulges. Plaintiff attaches to his motion 800+ pages of public material he believes reveals redacted information, even while Sarepta and the FDA readily acknowledge that material that has been publicly released cannot be withheld. Plaintiff could have identified this information during the meet-and-confer period but instead elected to remain silent for months and only now raise the issue. Nonetheless, Defendants reviewed Plaintiff's assertions regarding public information and have provided contemporaneously with this filing revised pages with any inadvertent redactions removed. This issue is moot and does not present a matter for judicial resolution.

The information that Sarepta seeks to withhold under Exemption 4 is not public and its release is likely to cause competitive harm to Sarepta, notwithstanding Plaintiff's claims to the contrary. Plaintiff claims that the withheld data will not be useful to competitors because it may not, standing alone, justify FDA approval of a new drug. But this proves nothing; as demonstrated in the declarations of Ian Estepan, Sarepta's competitors are likely to make many uses of the data short of relying entirely on it for an FDA application. And if, as Plaintiff asserts, release of the data will enable researchers to replicate and audit Sarepta's studies, then it will permit Sarepta's competitors to do the same.

The flurry of FOIA cases cited by Plaintiff show what failure to meet the legal standard for substantiating competitive harm actually looks like. They are a telling contrast to this case, where Sarepta has submitted two detailed declarations establishing the competitive harm it is likely to experience from release of the redacted information. Sarepta has met its burden on the

only matter at issue in this case—competitive harm—and is entitled to summary judgment in its favor.

ARGUMENT

I. Plaintiff Does Not Disprove Sarepta's Assertions of Competitive Harm.

A. Sarepta Has Met Its Evidentiary Burden.

The bar for showing competitive harm is not as high as Plaintiff suggests (Dkt. No. 86, Pl. Br. at 13-22), but it is set. (*See* Dkt. No. 78, Sarepta Br. at 10-11 (citing *Continental Stock Transfer & Trust Co. v. SEC*, 566 F.2d 373, 375 (2d Cir. 1977) (adopting the D.C. Circuit's test in *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974)).) Sarepta's burden is to show that disclosure of the withheld information is likely to cause substantial competitive harm. *National Parks*, 498 F.2d at 770. A case cited by Plaintiff, *National Parks & Conservation Ass'n v. Kleppe*, makes clear that under FOIA Exemption 4 "[n]o actual adverse effect on competition need be shown, nor could it be, for the requested documents have not been released." 547 F. 2d 673, 683 (D.C. Cir. 1976). Submitters and the government need demonstrate only a likelihood of competitive harm to justify withholding. *See id.* Detailed economic analysis, such as might be required in an elaborate antitrust case, is unnecessary in a FOIA Exemption 4 case. *Id.* at 681, n. 24.

Each and every redaction in the 35,000+ page production does not need a separate paragraph in a declaration to prove a likelihood of competitive harm. As the D.C. Circuit has explained, while conclusory and generalized allegations of exemption are insufficient, a sufficiently detailed analysis does "not have to contain factual descriptions that if made public would compromise the secret nature of the information" and can "be composed without excessive reference to the actual language" sought to be released. *Vaughn v. Rosen*, 484 F.2d

820, 826-27 (D.C. Cir. 1973). Under this well-established standard, the *Vaughn* index produced to Plaintiff has more than sufficient specificity.

Over and over again in FOIA Exemption 4 cases involving pharmaceuticals, courts have recognized that a party meets its burden of establishing competitive harm where, as here, the party demonstrates that actual competition exists for the drug under review and shows that "release of certain information from a drug application could direct a competitor … to pursue the same avenues of research and development." *Pub. Citizen Health Research Grp. v. Food & Drug Admin.* ("*PCHRG I*"), 185 F.3d 898, 905 (D.C. Cir. 1999). *See also Webb v. HHS*, 696 F.2d 101, 103 (D.C. Cir. 1982) ("If a manufacturer's competitor could obtain all the data in the manufacturer's [New Drug Application], it could utilize them in its own NDA"); *Citizens Commission on Human Rights v. Food and Drug Admin.*, 1993 WL 1610471, *9 (C.D. Cal. May 10, 1993) ("[I]f all research data and results were released to the public, a competitor . . . could also use the information to submit its own NDA to FDA for the same or similar drug product"). While Sarepta has the burden to produce evidence demonstrating that release of withheld information would be competitively harmful, "it need not demonstrate precisely how the release of the information would case competitive harm." *General Electric Co. v. Dept. of Air Force*, 648 F. Supp. 2d 95, 103 (D.D.C. 2009).

The Declaration of Ian Estepan submitted in support of Defendant's motion ("First Estepan Declaration") for summary judgment amply demonstrates the existence of actual competition in the market for DMD treatments (*see* Dkt. No. 72 ¶¶ 44-60 (discussing specific competitors)). The First Estepan Declaration also amply demonstrates that release of the redacted information is likely to cause Sarepta substantial competitive harm (*see id.* ¶¶ 22-43). While the First Estepan Declaration easily satisfies Sarepta's burden under FOIA Exemption 4,

Mr. Estepan has submitted a second declaration ("Second Estepan Declaration") that responds to misunderstandings and misrepresentations in the Plaintiff's motion papers, including in the Declaration of Plaintiff (Dkt. No 87, "Seife Decl.") and the Declaration of Dr. Peter Lurie in support of Plaintiff (Dkt. No. 88, "Lurie Decl.").[1] As is clear from the record of this case, along with the response to Plaintiff's unnecessary motion to strike filed concurrently with this brief, Sarepta has more than met its burden in justifying appropriate withholding under FOIA Exemption 4.

B. Sarepta Would Likely Suffer Competitive Harm if the Redacted Materials Were Released.

Before addressing Plaintiff's specific arguments, it is worth noting that Plaintiff's position on competitive harm contains an irreconcilable contradiction. On one hand, Plaintiff insists that the withheld data cannot be used by competitors "in any meaningful way." (Pl. Br. at 19, citing Lurie Decl. ¶ 24.) On the other hand, Plaintiff insists that the withheld data "will enable independent evaluation of whether the data overall 'clearly show, using adequate controls, that the drug increases dystrophin protein production in some of the patients'" (*id.* at 40, citing Seife Decl. ¶ 112), and that "scientists" will be able to "fully assess" the FDA process, and by extension the drug itself (*id.*). Dr. Lurie insists that "[r]elease of the withheld data would also allow researchers to validate the trials by seeing if Sarepta made any obvious analytical errors with respect to setting and testing the secondary endpoints, and if the endpoints support efficacy" (Lurie Decl. ¶ 10), and states that data regarding adverse outcomes is "particularly valuable to patients and researchers" (*id.* ¶ 13).

[1] Plaintiff also submitted a declaration from Diana Zuckerman, but that declaration is entirely dedicated to various objections to the FDA's process of approval for Exondys-51. (*See* Dkt. No. 89.) As discussed in § II, *infra*, the Plaintiff's objections to the FDA's approval process are not relevant to the legal issues before the Court.

Of course, Sarepta's competitors also employ scientists and researchers. If a "researcher" trying to audit the Sarepta research method will be substantially aided by release of the withheld information, then so will a "researcher" trying to imitate that method. Thus, Plaintiff essentially concedes that the withheld data is "particularly valuable" to Sarepta's competitors.

Dr. Lurie's Declaration fails to establish that the withheld data could not be used by competitors "in any meaningful way." (Pl. Br. at 19, quoting Lurie Decl. ¶ 24.) Regarding dosing, Dr. Lurie asserts only that the Exondys-51 label contains dosing information. (Lurie Decl. ¶ 22.) Yet Sarepta is not seeking to protect the dosing information on the label of its drug, but rather the analysis of dosing levels that it undertook during its study. (First Estepan Decl. ¶ 25; Second Estepan Decl. ¶ 29. *See*, *e.g.*, FDACER00099.) Regarding clinical endpoints, Dr. Lurie asserts only that the broad universe of endpoints are known to industry, and that many companies use the 6-minute walk test ("6MWT"), so it is public. (Lurie Decl. ¶ 23.) Sarepta is not seeking to withhold that it used the 6MWT, but rather the specific analysis of the 6MWT and other endpoints undertaken by Sarepta in the course of its work on eteplirsen. (First Estepan Decl. ¶ 34-39; Second Estepan Decl. ¶ 31. *See*, *e.g.*, FDACDER_SAR_0006476.) Dr. Lurie himself states in the same declaration that with the withheld 6MWT data, researchers can "validate the trials" conducted by Sarepta. (Lurie Decl. ¶ 10.)

Regarding the largest category of redactions, withholding the de-identified patient-level data from Study 201 and 202, Dr. Lurie states only his belief that the "redacted [*i.e.* de-identified] data would not be reliable enough to support FDA approval." (Lurie Decl. ¶ 24. *See also id.* ¶ 25 (claims that de-identified data could not support head-to-head testing "to the level of detail required for FDA approval.").) Even if this were true, Sarepta has shown that its competitors may make many uses of the data short of relying directly upon it to gain approval of

a competing drug. As with the data Sarepta obtained for the same purpose, the de-identified data will be integrated into a larger control set, and will be invaluable for that purpose even if it may not be cut and pasted directly from Sarepta's submission into a competitor's. (First Estepan Decl. ¶¶ 30-32; Second Estepan Decl. ¶ 34 (explaining "Sarepta spent many years and millions of dollars obtaining, vetting, and using the *anonymized* control data of the type Plaintiff seeks" and that "competitors can still take advantage of such [anonymized] data in the process of developing their own historical external control datasets and designing their own clinical trials").)

As discussed below, Sarepta has not raised any serious questions about the competitive harm that is likely to result from release of the information Plaintiff seeks.

1. Study Procedures

Sarepta has requested the redaction of the nonpublic and proprietary elements of its clinical study procedure so as to protect its investment and prevent its competitors from mirroring its approaches. (Sarepta Br. at 16-18; First Estepan Decl. ¶¶ 22-28; Second Estepan Decl. ¶¶ 29-32, 34.) Plaintiff asserts that he "is not seeking step-by-step clinical protocol details, but rather the narrative description of the tests conducted and their results presented in the CSRs." (Pl. Br. at 29.) This is a distinction without a difference. The narrative descriptions of the study protocols include detailed descriptions of the steps Sarepta followed in its clinical studies. (Second Estepan Decl. ¶ 41 ("The information is confidential and competitively sensitive in both places").) Thus, the material is appropriately withheld under Exemption 4 no matter in where it appears.

Plaintiff's discussion of study procedures also misrepresents case law. For example, *Public Citizen Health Research Group, v. FDA ("PCHRG III"),* 964 F. Supp. 413, 415-16 (D.D.C. 1997) did not, as Plaintiff claims, "conclude[] that protocols are not CCI and that a public interest in their release must be taken into account" (Pl. Br. at 29). *PCHRG III* never

made any such categorical statement. In that case, the court ordered disclosure of the protocols requested, because the record did "not present a clear picture as to the competitive injury, if any, that would result from releasing the protocol." 964 F. Supp. at 416. Specifically, the court found that the submitter had not "answer[ed] the question posed by Plaintiff," *i.e.* how competitors could benefit from details of a study protocol that was tailored for Metformin, at the time a new diabetes treatment. *Id.* In this case, however, Plaintiff has not asserted that the unique nature of eteplirsen renders the requested study details irrelevant to competitors. (*See* Pl. Br. at 29-30.) To the contrary, Mr. Estepan has described how various competitors are performing work on exon-skipping treatments and would benefit from guidance on how to conduct a study of such treatments, both in basic details such as timing of certain procedures and measurements, and more complex issues such as the manner of effectively characterizing dystrophin production. (First Estepan Decl. ¶¶ 22-28; Second Estepan Decl. ¶ 29.)

Plaintiff's objection to the specific redaction on Bates page FDACDER_SAR00058 is mere disagreement with Sarepta's characterization of the document's contents. (Pl. Br. at 29-30.) Sarepta cannot further "explain what was unique or unknown to the industry about the techniques it used" (*id.* at 30) without giving away precisely what Sarepta seeks to protect. Moreover, Sarepta is not obligated to show that every participant in the pharmaceutical industry is unaware of a given scientific precept or testing protocol or to provide Plaintiff with an "evidentiary basis" of such a showing to Plaintiff's satisfaction. Rather, Sarepta must show, and has shown, (a) actual competition in the marketplace, and (b) likelihood of substantial competitive injury. *National Parks*, 498 F.2d at 770. Sarepta has demonstrated the existence of a group of active competitors pursuing drug research in the same space as eteplirsen, and

identified multiple ways that these competitors could use the nonpublic elements of Sarepta's clinical study protocols.

2. Study Results

Plaintiff argues that Sarepta's study results, which Sarepta completed only after years of investment and effort, should be publicly released. (Pl. Br. at 30-31.) Plaintiff puts forth Dr. Lurie in an effort to rebut Mr. Estepan's explanations of the competitive value of Sarepta's results. But as demonstrated in Mr. Estepan's Second Declaration and throughout this brief, Plaintiff and Dr. Lurie's contentions are without any evidentiary basis and in many instances defy common sense.

Plaintiff incongruously claims that he needs de-personalized data "to assess the effectiveness of Exondys 51" but that "this information cannot be used by competitors because it will not contain the demographic information they would need." (*Id*. at 31.) His assertion that "CSR data in the partially redacted form requested … is unusable by competitors" (*id.*) is both untrue and unsupported by Dr. Lurie's declaration. In fact, Dr. Lurie merely states that the de-identified data from Sarepta's Studies 201 and 202 cannot serve as a historical control group for purposes of FDA approval. (Lurie Decl. ¶¶ 24-25.) As Mr. Estepan explains, however, "[e]ven if the de-identified data alone cannot satisfy the FDA's requirements for historical controls in DMD studies, 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." (Second Estepan Decl. ¶ 34.) Furthermore:

> Dr. Lurie wrongly presumes that only data that is independently sufficient to satisfy FDA requirements is competitively valuable. The redacted data tables at issue here include not only individual patient-level information but also statistical analyses of its significance. Data in a rare disease population is sparse and therefore any data is incredibly important to inform development decisions. A consortium was formed to evaluate depersonalized and de-identified data to get a better understanding of the natural history of the DMD.

(Second Estepan Decl. ¶ 36.) Sarepta has never released the de-identified patient-level data that Plaintiff seeks publicly. (Second Estepan Decl. ¶ 40; First Estepan Decl. ¶¶ 31, 33.) Plaintiff's suppositions that competitors could not utilize this data are belied by Plaintiff's own declarant's acknowledgment that researchers could utilize this data to "validate" Sarepta's trials. (Lurie Decl. ¶ 10.) This information is valuable, which is precisely why Plaintiff seeks access to it.

Next, Plaintiff claims that disclosure of Sarepta's study results will not undercut the company's competitive advantage in the European Union because the results will "eventually" be released under the European Medicines Agency ("EMA") "policy to publish CSRs." (Pl. Br. at 31; Seife Decl. ¶ 159.) This again misstates the relevant law. Seife bulk-cites 104 pages of European Union ("EU") guidance, but neglects to cite any specific regulation "requir[ing] proactive disclosure." (Seife Decl. ¶ 102, citing pages "2-106".) In fact, the EU guidance explicitly provides for submitters to review and redact material that conveys confidential commercial information. (Dkt. No. 90-28, Kenney Decl. Ex. AA at 16-18 ("Content of the Redaction Proposal Document package").) Sarepta is aware of these rules and will participate in the EMA process at the proper time. (Second Estepan Decl. ¶ 42.) Even if some data is eventually released, this does not eliminate the harm of a release in the United States now. (*Id.*)

Further, Seife is simply wrong that the de-identified data he requests—data about 12 individuals stripped only of details such as height and weight but otherwise unaltered—will be automatically released under EU rules. The EMA regulations include extensive rules for processing de-identified data using, *inter alia*, automated processes to further anonymize it until there is "no possibility" of linking a result with an individual. (Dkt. No. 90-28, Kenney Decl. Ex. AA at 67-68.) As specifically relevant here, the EMA regulations state that "in the case of

small studies with few patients it might be more likely to single out individuals and therefore this criterion may not be fulfilled." (*Id*. at 67.)

Finally, Plaintiff seeks to leaven its case for disclosure with unsubstantiated allegations about falsified study results that supposedly would not be of any use to competitors. (Pl. Br. at 31.) This argument again betrays that Plaintiff's FOIA suit is a thinly veiled effort to litigate the merits of the FDA approval process or the efficacy of eteplirsen, neither of which is an issue in this case. Plaintiff acknowledges throughout his motion papers that anyone with access to the withheld data could utilize the data to audit, analyze, and replicate Sarepta's work. Sarepta has detailed the competitive harm it would suffer should the Court allow this to take place.

3. Exploratory Endpoints

Plaintiff likewise fails to disprove that substantial competitive harm would likely result from unauthorized release of redacted information concerning the exploratory endpoints Sarepta used in its clinical studies. Plaintiff contends in one scant paragraph that the exploratory endpoints redacted in the requested materials are not protectable under FOIA Exemption 4 because "many of the endpoints disclosed by Sarepta were developed by its competitors or are standard measures used in the community of muscular dystrophy researchers." (Pl. Br. at 32.) Plaintiff cites Dr. Lurie's statement that the community of DMD researchers is aware of the existence of a set of commonly used endpoints from which the endpoints for specific studies are selected. But, Sarepta is not seeking to withhold the listing of endpoints under study in either Study 201 or 202; such information is found, unredacted, in both study documents. (*See* FDACDER00028 (Study 201) and FDACDER_SAR_0006474 (Study 202).) The information Sarepta is seeking to withhold relates to the specific implementation of such tests. For example, Sarepta seeks redaction of information regarding its use of the Maximum Voluntary Isometric Contraction Test ("MVICT") in its studies. The MVICT involves the use of an electronic tool to

measure the amount of force that can be exerted by a muscle in a patient. That other researchers are aware of the existence of this tool is neither surprising nor relevant. The designers of clinical studies determine how this measurement tool will be used in their particular study, *i.e.* how frequently subjects will be tested, what position subjects will be in, and what muscles will be tested.[2] There is no fixed schedule for such tests, or required set of muscles that must be tested in order for the test to comply with clinical standards. Sarepta seeks to withhold the details of the choices its scientists made regarding the implementation of the MVICT. (*See, e.g.*, FDACDER00060-61.) Plaintiff does not respond at all to Sarepta's contention that undisclosed information of this kind regarding Sarepta's use and analysis of exploratory endpoints constitutes competitively sensitive information under FOIA Exemption 4; Plaintiff merely relies on its incorrect assertion that the redacted "information about Sarepta's so-called exploratory endpoints are public." (Pl. Br. at 32.)

As repeatedly stated, Sarepta does not claim that public information should be withheld. The existence of public information regarding clinical endpoints does not in any way impact the protectability of nondisclosed details of how Sarepta specifically effectuated its clinical testing and the results Sarepta obtained.

Dr. Lurie's statements about the competitive harm associated with the release of nonpublic exploratory endpoints are similarly unavailing for Plaintiff. First, Dr. Lurie contends that "the efficacy endpoints that are most commercially valuable are already known in the research community." (Lurie Decl. ¶ 23.) This statement wrongly presumes that no other potential endpoints might one day become commercially valuable. (*See, e.g.*, First Estepan Decl.

[2] *See, e.g.*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3602208/ (study describes its own set of MVICT standards and muscle groups, including testing every 6 months, common positions, and a set of 10 muscles to be tested).

¶ 37 (explaining that "a particular endpoint may reveal a future objective for the company's development of eteplirsen or other drugs").) Second, Dr. Lurie claims that, in light of the amount of publicly released data about clinical endpoints, "it is extremely improbable" that any undisclosed data "would be of great commercial value." (Lurie Decl. ¶ 23.) This vague assertion misconstrues the applicable legal standard, and cannot overcome the specific descriptions of the competitive value Sarepta assigns the redacted information, as described in both Estepan declarations. (*See* First Estepan Decl. ¶¶ 34-39; Second Estepan Decl. ¶¶ 30-31 ("the disclosure of unpublished information regarding Sarepta's exploratory endpoints for eteplirsen would be commercially valuable to Sarepta's competitors, who could use the information both to reproduce Sarepta's prior research and to predict areas of Sarepta's future research").) In sum, Sarepta met its burden to demonstrate a likelihood of substantial competitive harm from release of the withheld information, and none of Plaintiff's arguments or declarations demonstrate otherwise.

4. Adverse Events

Plaintiff's statement that the redacted information is "*precisely*" what "researchers, patients, and doctors" need to verify whether Sarepta's determinations were "correct" (Pl. Br. at 32 (emphasis in original)) again seeks to convert this FOIA lawsuit into a tussle over the efficacy of eteplirsen as a DMD treatment, and again acknowledges that the withheld information reveals significant information regarding Sarepta's analysis of the study results. Yet, this lawsuit is not a vehicle to audit whether Sarepta's assessments regarding the adverse events experienced in its eteplirsen clinical studies were correct. Rather, the question before the Court is whether Sarepta's competitors could derive competitively useful information from the release of Sarepta's nonpublic, proprietary descriptions and measurements of these adverse events. Plaintiff's arguments only confirm Sarepta's position that this information would be valuable to researchers,

including those employed by Sarepta's competitors. (*See* Second Estepan Decl. ¶ 32 ("Sarepta's competitors could take advantage of data relating to AEs found not to be drug-related, AEs occurring with a variety of compounds Sarepta studied, and Sarepta's methods of testing and analyzing AEs—all without making the significant investments of time and money that Sarepta made").)

Sarepta has demonstrated the competitive harm that would result from publication of nonpublic elements of its clinical study reports speaking to adverse events. (First Estepan Decl. ¶¶ 40-43; Second Estepan Decl. ¶¶ 32-33.) In fact, Sarepta's stock price suffered last year from the abuse of a similar type of information that was released. (Second Estepan Decl. ¶ 33.) The fact that the FDA "routinely releases Adverse Event datasets to the public" has no bearing on Sarepta's particular proprietary interest in nonpublic elements of its clinical studies. (Pl. Br. at 33.) Plaintiff's attempts to demonstrate that this information should be released are without any basis in law and fail to disprove Sarepta's fulsome demonstration of competitive harm.[3]

[3] Plaintiff falsely and irresponsibly claims that Sarepta's position on adverse event data puts children in harm's way. (Pl. Br. at 33, citing First Estepan Decl. ¶ 25.) This baseless swipe at Sarepta misrepresents both Sarepta's position and the actual impact of nondisclosure of Sarepta's proprietary information. As explained in the Second Estepan Declaration:

> Sarepta has provided the FDA with the proprietary information [Plaintiff] seeks, and the FDA can use that information in exercising its authority to prevent any clinical trials that it believes would expose subjects to unreasonable and significant risks. Moreover, if competitors cannot rely on re-treading the ground that Sarepta has already broken, they are more likely to develop new treatments and therapies that may provide benefit to the DMD population….

(Second Estepan Decl. ¶ 45.) As discussed further below, Plaintiff's allegation, besides being untrue, is irrelevant for purposes of a FOIA Exemption 4 analysis.

C. Plaintiff's Cited Cases Do Not Justify Disclosure.

Plaintiff cites multiple cases discussing the requirements for demonstrating competitive harm. (Pl. Br. at 19-21, *passim*.) These cases either do not help or actively undercut Plaintiff's case.

Plaintiff provides no reason why this Court should equate the inadequate declarations submitted in *AIDS Healthcare Foundations v. FDA*, No. 11-cv-07925 (C.D. Cal. Aug. 6, 2013)[4] with the detailed declarations submitted by Sarepta in the instant case. Far from undermining Sarepta's assertions of competitive harm, *AIDS Healthcare Foundations* makes clear that Sarepta has properly focused its evidentiary showing not only on the scientific aspects of the data, but on the impacts of that data on the specific competitive marketplace in which Sarepta participates. Plaintiff seeks to belittle Mr. Ian Estepan as a mere "marketing professional"—ignoring that he is Chief of Staff and Head of Corporate Affairs at Sarepta—and diminish his knowledge of the current marketplace for DMD treatments because—even though he has many years of experience with drug development and approval—he is not an "expert" in FDA procedures or drug study design. (*See*, *e.g.*, Pl. Br. at 18; Dkt. No. 94, Pl. Motion to Strike at 1.) But *AIDS Healthcare Foundation* illustrates that what is necessary for a showing of competitive harm is not simply testimony regarding study design and FDA procedures but rather information about the ***relevant market***, *i.e.* a demonstration that the submitter faces actual competition in the market to which the withheld data related. *Id.* at 12. Here, Sarepta provided consistent, highly relevant testimony

[4] Plaintiff did not provide a link to, or copy of, this case, which is unavailable on Westlaw, but it may be found at www.law360.com/dockets/download/5202698a153245271e000022?doc_url=https%3A%2F%2Fecf.cacd.uscourts.gov%2Fcgi-bin%2Fshow_doc.pl%3Fcaseid%3D513026%26de_seq_num%3D165%26dm_id%3D16043028%26doc_num%3D60&label=Case+Filing.

from Mr. Estepan on both the relevance of the data to the development and approval of competing drugs, and the clear existence of an active, current competitive market for drugs of this type.[5]

Plaintiff also misstates the import of the holding in *Physicians Comm. for Responsible Med. v. NIH*, 326 F. Supp. 2d 19, 26-27 (D.D.C 2014). While the court there did find that competitive harm was not established "despite evidence that three other labs were working on similar projects," Plaintiff does not tell the whole story. (Pl. Br. at 20.) The submitter in *Physicians Committee* was an individual researcher seeking to protect the contents of his grant application from disclosure. The court denied protection under Exemption 4 primarily because the researcher "is a noncommercial scientist who has never manufactured or marketed any drug relating to neuroAIDS that was produced as a result of his research" and because "none of [his] research results have been marketed or used and subsequently subjected to additional study." *Physicians Committee*, 326 F. Supp. 2d at 25 (explaining that "a noncommercial scientist's research design [was] ... not [an] item of commercial information" (citation omitted)). Because the researcher in that case was unaffiliated with any commercial enterprise, and because he had only identified three other similarly situated individual researchers working on similar topics, the court found that he had failed to qualify for Exemption 4 protection. *Id*. at 26. In the instant case, of course, Sarepta is in the commercial market for drugs of this kind, and provided multiple examples of actual commercial competitors currently developing competitive DMD treatments. (*See* First Estepan Decl. ¶¶ 45-49, 58-59.)

[5] The *AIDS Healthcare Foundation* court also found that where the FDA's declarants had, like Estepan in the instant case, identified ***both*** a relevant market and the existence of competitive medications and companies, the FDA had "adduced sufficient evidence showing that there is actual competition in the market." *Id*. at 13.

Plaintiff offers another telling contrast by citing *Pub. Citizen Health Research Grp. v. Food & Drug Admin.* ("*PCHRG II*"), No. CIV.A. 99-0177 (JR), 2000 WL 34262802, at *2 (D.D.C. Jan. 19, 2000). In that case, the submitter sought protection of certain raw patient data presented to an FDA committee. The Court found that the submitter had inadequately justified its assertion of competitive harm. This result was not surprising, given that the submitter in *PCHRG II* provided only two sentences in support of its assertion of competitive harm. *PCHRG II* at *2. In the instant case, Sarepta has provided vastly more than the two conclusory sentences in *PCHRG II*.

The court in *PCHRG II* helpfully described the components of a sufficient showing of competitive harm in a different case, a showing that bears many similarities to the showing Sarepta has made here:

> Although comparing the specificity of proffers is necessarily a subjective task, it appears to me that the (successful) proffers made by Schering demonstrated how other companies could take advantage of Schering's research efforts: Schering had "just commenced clinical testing on a successor [drug] which was designed based on information learned during development of [the drugs described in those INDs];" its expert noted that the company's "basic research revealed that the particular type of fungal infection for which this product was designed was not one that was relatively well-controlled by existing products;" and "[t]he development and marketing of new antifungal products is ... being actively engaged in by a number of other drug companies."

Id. at *2 (citing *PCHRG I*, 185 F.3d at 905-06 (D.C. Cir. 1999)). Sarepta's submissions in this case clearly pass muster under *PCHRG II*. Sarepta identified both its historical as well as current and future research efforts (First Estepan Decl. ¶¶ 10-21, 52-54); established that eteplirsen was effective for a disease that was not widely treatable (*id*. ¶¶ 12, 26, 34, 38, 41, 44-45) and had led to new interest in drugs of its type (*id*. ¶ 45, 58-59); and identified the players and relevant research efforts in this emerging competitive market (*id*. ¶¶ 45-49, 58-59).

Plaintiff then cites *PCHRG I* itself. (Pl. Br. at 21.) In that case, the D.C. Circuit upheld withholding of several Investigational New Drug ("IND") applications the agency sought to protect, citing the appropriate support offered by the Agency for those withholdings (*i.e.* the test discussed in *PCHRG II*, *supra*). Plaintiff, however, argues that Sarepta's submission bears a similarity to the inadequate support provided by the FDA for the one IND that the court in *PCHRG I* ordered released. Plaintiff invites the Court to "compare" the affidavit found insufficient in *PCHRG I* with the assertions in the Sarepta submission. (*Id.*) Sarepta invites the Court to do the same.

The rejected affidavit in *PCHRG I* consisted of a flat, unsubstantiated assertion that release would "reveal substantial basic research . . . developed by Schering at a great expense." *PCHRG I* at 906. Sarepta, by contrast, detailed the various components of its research, such as dosing procedures (First Estepan Decl. ¶¶ 25, 28); methods for quantifying dystrophin including development of western blot and immunohistochemistry methods (*id* ¶ 26); and many other details of the research implications of the withheld data. The inadequate *PCHRG I* affidavit stated only that "disclosure 'would have substantial commercial value to any company attempting to develop cardiovascular therapies generally.'" *PCHRG I* at 906. Sarepta specifically identified its competitors and their research, and the market in which those competitors operated. (First Estepan Decl. ¶¶ 44-45, 58-59.) The inadequate *PCHRG I* affidavit stated vaguely that "disclosure would reveal [submitter's] . . . judgment as to what requirements will be necessary in order to establish the drug's safety and effectiveness." *PCHRG I* at 906. Sarepta provided an extensive discussion of adverse event data and effectiveness-measuring endpoints, including specific ways in competitors could use this data. (First Estepan Decl. ¶¶ 22-43.)

Plaintiff cites yet a third Public Citizen case, *PCHRG III*, relating to a request for study details related to the diabetes drug Metformin. In *PCHRG III*, the court denied protection over some data because the submitter had made general statements that the requested data contained important proprietary information, but failed to identify "[w]hat advantage would a competitor gain from the protocol for a study that is uniquely tailored to the characteristics of Metformin." 964 F. Supp. at 416. Sarepta, on the other hand, provided details regarding the commonalities between the Study 201 and 202 data and the ongoing research efforts of its competitors, and identified the advantages that would accrue to specific competitors if specific information were released:

> Dosing in exon skipping therapeutics is a matter of considerable interest in the industry, and other companies, including Wave Life Sciences and Nippon Shinyaku, are currently studying dosing. Those companies are studying a variety of doses and have yet to determine a final therapeutic dose for their drug candidates. Selection of a final dose, and ultimately a competitive drug candidate, could be informed by data relating to the multiple doses and dosing administration evaluated by the Company in its studies.

(First Estepan Decl. ¶ 25; *see also, e.g.*, *id.* ¶ 26 (competitors could use Sarepta information regarding detection of dystrophin levels for non-eteplirsen dystrophin-increasing drugs), *id.* at ¶ 26-27, 33, 38 (FDA guidance creates common interest in dystrophin level detection and other areas where eteplirsen data would be relevant to non-eteplirsen studies), and many more.) Again, Plaintiff's cited case serves only to demonstrate the sufficiency of the Sarepta discussion of competitive harm.

Plaintiff also claims the instant case is comparable to the circumstances in *Teich v. Food & Drug Admin.*, 751 F. Supp. 243 (D.D.C. 1990). (Pl. Br. at 20-21.) But in *Teich*, the submitter provided no explanation at all as to why the withheld documents—20-year old medical studies—would still be relevant to the submitter's competitors. 751 F. Supp. at 254. ("The FDA admits that protocols have changed substantially in the intervening years and that the documents have

not been analyzed for their continued relevance. Defendants have introduced no evidence which would demonstrate the current significance of these tests."). *Teich* thus stands for the unremarkable proposition that when a submitter fails to provide any information in support of withholding, withholding is improper. It has nothing to do with the instant case, however, where Sarepta has provided extensive discussion of the relevance of recent testing data.

Finally, Plaintiff several times cites *Gov't Accountability Project v. HHS* ("*GAP*"), 691 F. Supp. 2d 170, 180 (D.D.C. 2010) as relevant (and, indeed, "fatal") to Sarepta's position. (Pl. Br. at 19, 21.) It is nothing of the sort, and provides yet another illustration of just how far short Plaintiff has fallen in its attempt to undercut Sarepta's argument regarding competitive harm. The court in *GAP* did indeed find that the submitter's case for competitive harm was insufficient, but that was because the entirety of the submitter's assertion of harm was found in a single paragraph:

> Defendants' sole evidence that disclosure of the information in dispute would likely result in "substantial competitive injury" is as follows, reprinted in full:
>
> > If [the] FDA were to disclose the information that the agency has withheld as confidential consumer information, 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. In addition, 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.

691 F. Supp. 2d at 178. Thus, the submitter in *GAP* provided only a single sentence about its competitors and a threat to file a reverse-FOIA suit. Sarepta, however, filed an extensive declaration (and with this filing, a second declaration) detailing the facts surrounding the withheld data and the scientific and competitive basis for Sarepta's assertion of withholding. The

comparison may be fatal to Plaintiff's argument, but it leaves Defendants' arguments utterly untouched.

It is not sufficient for Plaintiff to merely cite, as he has, a series of cases where the submitters provided little or no support for their assertions of withholding, and declare that these cases dictate the result he wants here. Nor is it sufficient for Plaintiff to assert, as he does repeatedly, that Sarepta and the FDA's argument is "untethered to any factual record" (Pl. Br. at 17); provides "no concrete examples" (*id*. at 18); and "fail[s] to provide supporting detail" (*id*. at 19). Simply saying it does not make it so. The many cases cited by Plaintiff provide an illustration of what real failure to substantiate competitive harm looks like. These cases identify inadequate submissions that bear no resemblance to Sarepta's and FDA's showing, and expound standards for sufficient showings that, as shown above and discussed further *infra*, Sarepta and FDA meet or surpass.

D. Sarepta Need Not Show But Has Shown "Imminent" Competitive Harm.

Plaintiff's attempt to require a showing of "imminent" competitive harm (Pl. Br. at 17; *id.* at 34-35) is unavailing. As an initial matter, the Second Circuit does not require that competitive harm be "imminent" in order for Exemption 4 to apply. While Plaintiff cites a district court case for the proposition that competitive harm must be imminent, that case turned on the agency's failure to show how competitors will use the information sought, not on the timing of the alleged harm. *See Bloomberg L.P. v. Board of Governors of the Fed. Reserve Sys.*, 649 F. Supp. 2d 262, 279 (S.D.N.Y. 2009) (citing *Iglesias v. C.I.A.*, 525 F. Supp. 547, 559 (D.D.C. 1981)). Notably, the Second Circuit's affirmance of *Bloomberg* made no reference to a requirement of "imminent" harm. *See* 601 F.3d 143 (2d Cir. 2010).

More recent D.C. District Court decisions have explicitly declined to impose a requirement of "imminent" harm in FOIA Exemption 4 cases. In *Judicial Watch, Inc. v. U.S.*

Dep't of Treasury, for example, the D.C. District Court plainly stated that the defendant "is not required to prove imminent harm" and "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.'" 802 F. Supp. 2d 185, 207 (D.D.C. 2011) (citing *Nat'l Parks*, 498 F.2d at 770). *See also Judicial Watch, Inc. v. U.S. Dep't of Treasury*, 796 F. Supp. 2d 13, 36 (D.D.C. 2011) (rejecting plaintiff's argument that defendant must "prove imminent harm").

Were this court to consider imminence, the record demonstrates that Sarepta has met even this elevated standard. Sarepta has identified multiple immediate or near-term impacts from the release of the redacted material. For example, Sarepta identified three companies with exon-skipping treatments under clinical study now and six companies that are currently pursuing various dystrophin-producing therapies, and noted that 27 DMD treatments are currently in clinical development. (*See* First Estepan Declaration ¶¶ 45-49, 59.) While Plaintiff takes issue with the fact that Sarepta's competitors may not receive approval for their competing drugs before 2020 (Pl. Br. at 34), Sarepta's competitors' research and trials are underway now. (First Estepan Decl. ¶¶ 45-49, 58-59; Second Estepan Decl. ¶¶ 29-30.) The likely dates of FDA approval for any of these competitors, whether 18 months or five years away, are beside the point. Sarepta also has described how recent FDA Guidelines regarding DMD treatments now make elements of Sarepta's data more valuable. (*See* First Estepan Decl. ¶ 27 (dystrophin levels as surrogate endpoint), ¶¶ 31, 33 (historical control data sets), ¶ 38 (endorsement of use of multiple exploratory endpoints).) The information requested by Plaintiff is useful to Sarepta's competitors now, and any reasonable calculation of the harm must include the fact that release of this information will accelerate the current and ongoing progress of these competitors.

II. Public Interest Is Not A Factor Under FOIA Exemption Four.

Plaintiff has dedicated a significant portion of its briefing, including the overwhelming majority of the testimony presented in the declarations submitted with its Summary Judgment filing, to an issue that is not before this Court, *i.e.* to an imagined public interest balancing test that would transform this straightforward FOIA case into a broad challenge to the FDA and Sarepta. (Pl. Br. at 13-17; *id.* at 36-44; Seife Decl. ¶¶ 29-40, 93-149; Lurie Decl. ¶¶ 10-18, 26; Zuckerman Decl. ¶¶ 8-21.) While Plaintiff would like to litigate the merits of the FDA's decision to approve eteplirsen, this is a straightforward FOIA case about whether the FDA is justified under Exemption 4 in withholding from public release the information it has proposed for redaction.

From the start of its brief, Plaintiff misconstrues this action before the Court. The cross-motions for summary judgment do not "present the issue of whether defendants are permitted to withhold information about the safety and efficacy of an approved drug," as claimed by Plaintiff. (Pl. Br. at 11.) Rather, these cross-motions present the issue of whether the redacted information constitutes competitively sensitive information that qualifies for withholding under FOIA Exemption 4. There is no elevated burden on FDA or Sarepta to justify withholding "information that inherently informs about both FDA activity and drug safety and effectiveness," and the Court should decline Plaintiff's invitation to create one.

Plaintiff's wish that public interest in a company's proprietary business materials weigh in favor of disclosure under FOIA Exemption 4 is not supported by the law, and Plaintiff recognizes as much: "The Second Circuit has not considered the issue of public interest balancing under FOIA's Exemption 4." (*Id.* at 14.) Indeed, no court in the Second Circuit has ever suggested that such a balancing would be appropriate. Plaintiff bases its call for a new balancing test on a misconstruction of a Ninth Circuit case that is not even followed within the

Ninth Circuit and a concurrence in a D.C. Circuit case that is at odds with the law of the D.C. Circuit. (*Id.* at 14-15.)

Plaintiff's selective discussion of *GC Micro Corp. v. Def. Logistics Agency*, 33 F.3d 1109 (9th Cir. 1994), *overruled*, *in part,* by *Animal Legal Def. Fund v. Food & Drug Admin.*, 836 F.3d 987 (9th Cir. 2016), is highly misleading. In *GC Micro*, the Ninth Circuit recognized, as other circuits do, that "evidence revealing (1) actual competition and (2) a likelihood of substantial competitive injury is sufficient to bring commercial information under Exemption 4." *Id.* at 1113 (internal citation omitted). The court also recognized "[t]hose seeking to prevent disclosure of certain information under FOIA have the burden of proving that the information is confidential." *Id.* at 1115. Applying this well-established test, the court found "questionable whether the declarations submitted by the [government contractors seeking to prevent disclosure] show any potential for competitive harm, let alone *substantial* harm." *Id.* at 1115. For this reason, the Ninth Circuit concluded in *GC Micro* that "FOIA's strong presumption in favor of disclosure trumps the contractors' right to privacy." *Id.* The Ninth Circuit never held that the public interest in disclosure can overcome a showing of substantial competitive harm under FOIA Exemption 4.

Far from "adopting" Plaintiff's purported public interest balancing test, courts in the Ninth Circuit have declined to engage in such an exercise when assessing assertions of Exemption 4. *See, e.g.*, *Lahr v. NTSB*, 453 F. Supp. 2d 1153, 1176 (C.D. Cal. 2006), *rev'd in part on other grounds*, 569 F. 3d 964 (9th Cir. 2009) (rejecting plaintiff's argument that "for any record falling under Exemption 4, the Court must apply a balancing test between the public interest in disclosure and the private interests protected by the exemption," and holding instead that the "only test" that it may apply "is that found in *National Parks*"). Plaintiff fails to cite any

case even from the Ninth Circuit applying the balancing test the Ninth Circuit supposedly "adopted." (Pl. Br. at 14.)

The one Second Circuit decision that cites *GC Micro* makes no mention of the public interest as a factor to consider when applying Exemption 4. *See Nadler v. FDIC*, 92 F.3d 93 (2d Cir. 1996). Rather, the *Nadler* court uses the two-part test formulated by the D.C. Circuit in *National Parks*, 498 F.2d at 770, endorsed by the Second Circuit in *Continental Stock Transfer & Trust Co.*, 566 F.2d at 375, and cited in Sarepta's moving brief. *Nadler,* 92 F.3d at 95-96.[6]

Moreover, while Plaintiff points to a concurring opinion in *PCHRG I*, 185 F.3d 898 (D.C. Cir. 1999) in support of its desired balancing test, the D.C. Circuit's majority opinion in that case ***expressly rejected*** a public interest balancing test for Exemption 4 cases. The majority explained that "a consequentialist approach to the public interest in disclosure is inconsistent with the balance of private and public interests the Congress struck in Exemption 4," a balance that "is accurately reflected in the test of confidentiality set forth in *National Parks I*, which was known and acquiesced in by Congress when it enacted" Exemption 4. *Id.* at 904 (internal quotations and citations omitted). Thus, the court held that a FOIA plaintiff suing the FDA cannot, as Plaintiff seeks, "bolster the case for disclosure by claiming an additional public benefit in that, if the

[6] In a footnote, Plaintiff acknowledges that the Second Circuit "rejected a test designed to consider the public interest in *withholding* information" in *Bloomberg, L.P. v. Board of Governors of the Fed. Reserve Sys.*, 601 F.3d 143 (2d Cir. 2010). (Pl. Br. at 14 n.4.) In *Bloomberg*, the Second Circuit held that the requested information did not qualify as material received "from a person" under Exemption 4 and that, even if it did, the court did not have the power to make "public interest" a reason for withholding otherwise releasable information. Even though Plaintiff here is arguing that the public interest favors disclosure, the point remains that an alleged public interest is not a relevant factor in a FOIA Exemption 4 analysis.

information is disclosed, then other drug companies will not conduct risky clinical trials of the drugs that [have been abandoned]." *Id.*[7]

Congress struck the balance it wanted when it drafted Exemption 4, and this is expressed in the straightforward tests developed by the D.C. Circuit and endorsed by the Second Circuit. *See PCHRG I*, *supra* at 904 (ruling that case-specific public interest balancing tests are "inconsistent with the balance of private and public interests the Congress struck in Exemption 4."). Any change in FOIA law must come through Congress, not through the end-run that Plaintiff attempts.

As a last Hail Mary, Plaintiff argues in a footnote that "Courts in other contexts have recognized that a public interest in health and safety can outweigh a private interest in confidentiality." (Pl. Br. at 16 n.6.) These cases from "other contexts" do not apply here, where a specific statutory scheme determines what information becomes public and what does not. For example, Plaintiff cites court orders mandating information-sharing amongst the parties to enable a settlement of opioid-related multi-district litigation. (*Id.* at 17 n.6.) But these information-sharing orders had nothing to do with any public release and, indeed, were followed by strict protective orders that limited distribution of any confidential material. *See In re: National Prescription Opiate Litigation*, Case Management Order No. 2: Protective Order, 2018 WL 2392968 at § IV.

Plaintiff chose to attempt to gain access to Sarepta's documentation via FOIA, and Plaintiff is bound by FOIA's disclosure rules. Those rules do not require balancing allegations of

[7] The court noted, however, that "were a competitor to submit an IND involving a risk known to the FDA because of its experiences with … INDs [withheld from disclosure], the agency could and presumably would refuse to permit that company to begin clinical testing." *Id.* at 905. *See also id.* at 901 (noting that the FDA may place clinical testing on hold at any time (citing 21 C.F.R. §§ 312.40(b), 312.42)).

harm to the public interest against application of the confidential commercial information exemption. Cases discussing what documents Plaintiff could or could not obtain in discovery during a case of another kind are irrelevant. Just because a business submitted information to the government does not render that information up for grabs in any FOIA request; rather, FOIA Exemption 4 specifically protects that information. Plaintiff's proposed public interest balancing simply has no basis here, as even its own declarant has observed.[8]

Sarepta and the FDA seek summary judgment on the application of FOIA Exemption 4, under this Court's well-established test. As Sarepta has explained, in deciding whether information is "privileged or confidential" for purposes of Exemption 4, the Second Circuit asks whether disclosure is likely to (1) impair the government's ability to obtain information in the future or (2) cause substantial harm to the competitive position of the person from whom the information was obtained. (Sarepta Br. at 10-11 (citing *Continental Stock* and *National Parks*).) Plaintiff's allegations that the public interest would be served by disclosure do not change the analysis.[9]

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[8] Testimony of Peter Lurie, MD, MPH and Hillary Peabody, MPH Health Research Group at Public Citizen Before the FDA Transparency Task Force (June 24, 2009), *available at* https://www.citizen.org/sites/default/files/1883.pdf ("Courts have held that the exemption does not provide for a balancing of the commercial interest against the public interest. That is, if the material sought is confidential commercial information, the exemption is triggered, regardless of the strength of the public interest in the disclosure of that information." (citing *PCHRG I*)).

[9] Plaintiff's statements regarding the Trade Secrets Act, 18 U.S.C. § 1905, are similarly off-base. (Pl. Br. at 12 n.3.) Plaintiff selectively quotes Second Circuit precedent to read Exemption 4 as allowing permissive, not mandatory, withholding. (*Id.*) These cases can just as easily be read to state that Exemption 4 requires withholding. *See, e.g.*, *Nadler v. FDIC*, 92 F.3d 93, 95 (2d Cir. 1996) ("Exemption Four applies if a tripartite test is satisfied…"). Furthermore, both Second Circuit cases cited by Plaintiff themselves cite the D.C. Circuit's precedent on FOIA matters.

III. Sarepta Does Not Seek to Protect Public Information.

A. The Public Information Plaintiff Now Cites Is Not at Issue on This Motion.

Despite having multiple opportunities during the meet-and-confer process to do so, Plaintiff failed previously to identify the public information it believes reveals information proposed for redaction by Sarepta and the Government. Instead, Plaintiffs waited until its summary judgment motion before this Court to show its hand. By so doing, it has sought to create a legal controversy where there is none. Plaintiff's attachment of nearly 900 pages of public documents to its filings does not present a matter for judicial resolution. Sarepta does not seek, and has never sought, to protect public information. Sarepta and the FDA engaged in a good-faith review of the documents and proposed for redaction only those materials they believed to not be publicly available. The FDA made rolling productions to Plaintiff over the course of Fall 2017, giving Plaintiff months to analyze the materials and raise any objections based on public information. (Declaration of Amanda Sherwood ("Sherwood Decl.") ¶¶ 3-4.) Yet, Plaintiff instead chose to lay in wait, instead only raising its objections as part of a voluminous summary judgment filing. By doing so, Plaintiff improperly blurs the issues and requests this Court rule on a matter not actually in contention between the parties.

Sarepta has never asserted a desire to protect publicly available information. Sarepta carefully reviewed the materials attached to Plaintiff's summary judgment motion, and has revised the challenged redactions accordingly, just as it would have done had these materials been forwarded during the months of meet-and-confer exchanges. (*See* Sherwood Decl. ¶¶ 6-59.) There is no dispute for this Court to resolve.

Plaintiff's apparent insinuation—that any errors in the redactions, whereby publicly available material was redacted, render the entire review process unreliable—is not credible. Sarepta and the FDA have expended significant resources in conducting a thorough review of the

thirty thousand pages of documents that Plaintiff requests. (*See* Sherwood Decl. ¶¶ 3-4) This review was methodical and extensive and, if anything, demonstrates Sarepta's and the FDA's good faith in releasing all information not legally protectable. (*Id.*) By bringing forward additional public documentation only now, many months after the completion of this review, Plaintiff attempts to distract from the real matter at issue before this Court: the application of FOIA Exemption 4. Again, Sarepta does not assert any right to protect publicly available information.

B. That Certain Drug Trial Information Is Released By Law Does Not Mean All Drug Trial Information Must Be Released.

Plaintiff's improper focus on publicly available information does not end with its voluminous attachments. Plaintiff devotes a substantial portion of its brief to the contention that "so much information about approved drugs must be disclosed by law that any incremental competitive harm from disclosing the CSR information would not be substantial." (Pl. Br. at 22-27.) This assertion is logically flawed.

First, Plaintiff is operating under the mistaken assumption that at least some of what Sarepta seeks to protect is already public information by operation of law. (*See id.* at 24-25, citing 42 U.S.C. § 282(j) (FDA statute mandating disclosure of certain drug information).) Sarepta is not seeking to protect any information that must be disclosed by statute. *Inner City Press/Comty. On the Move v. Bd. of Governors of Fed. Reserve Sys.*, 463 F.3d 239, 249 (2d Cir. 2006), which held that information required to be disclosed in SEC filings are ineligible for Exemption 4, is accordingly inapplicable, as Sarepta is not seeking to protect information that has been released in SEC filings or elsewhere.

Plaintiff identifies only three examples of such supposedly required public material in its actual brief, referring to two spaghetti plot graphs and information regarding Sarepta's

implementation of the North Star Ambulatory Assessment ("NSAA") endpoint. (Pl. Br. at 25-26.) As detailed in the Sherwood Declaration, however, these examples miss the mark. Contrary to Plaintiff's claims, the released spaghetti plot data is ***not*** the same as the redacted data, and none of the descriptive detail redacted regarding the NSAA has been publicly released. (*See* Sherwood Decl. ¶¶ 7, 14.) Plaintiff's citations, to cases mandating disclosure under FOIA of information that is already public, are irrelevant. (*See* Pl. Br. at 23.)[10]

Second, the amount of information about approved drugs that must at some point be disclosed by law has no bearing on whether release of the specific redacted materials would cause Sarepta competitive harm. Sarepta does not dispute that much information regarding Exondys-51 is required to be made public. The regulatory scheme also explicitly provides that while some material will be made public, and other material will ***not*** be. Just because similar types of information, or high-level summaries of specific information, have been released does not in any way diminish the protectability of the detailed redacted information at issue here. (*See* Pl. Br. at 26-27.) Plaintiff's argument essentially asks the Court to find the distinctions made by Congress and the FDA to be meaningless.

But this request has no bearing on the actual issue of this case: the applicability of FOIA Exemption 4 to the redacted information. Sarepta and the FDA have worked cooperatively to

[10] Plaintiff also makes a superficial analogy to patent law, citing cases where inclusion of trade secrets in a patent application ended the ability of an inventor to protect a trade secret, even though such applications remain confidential during the initial stages of review by the government. Plaintiff claims that these cases mean that just because a rule states that certain information is non-public, that "does not make them automatically exempt." (Pl. Br. at 23 n.11.) But those cases are explicitly based on the fact that all patent submissions are ***intended for***, indeed have no value without, eventual public disclosure. *See*, *e.g.*, *BondPro Corp. v. Siemens Power Generation, Inc.* 463 F.3d 702, 706–07 (7th Cir. 2006) ("Publication in a patent destroys the trade secret, [...] because patents are intended to be widely disclosed."). These cases have no application to rules, like the FDA's, that are explicitly designed to protect information that submitters have no intention of releasing.

release all information that is already public, and have continued to do so as Plaintiff releases its piecemeal challenges. The matter properly before this Court is whether the non-public, redacted information is exempt from production under FOIA. Plaintiff's protestations regarding public information are a distraction.

IV. Plaintiff Does Not Disprove that Release of the Redacted Information Would Impair the Government's Ability to Obtain Such Detailed Material in the Future.

Under the test adopted by the Second Circuit in *Continental Stock Transfer & Trust Co.*, withholding under FOIA Exemption 4 is appropriate if disclosure would "impair the Government's ability to obtain necessary information in the future." *National Parks*, 498 F.3d at 770. In its response, Plaintiff points to the Government's note that the Second Circuit has not yet addressed a D.C. Circuit opinion establishing a different standard for release of voluntary submissions. (Pl. Br. at 35, citing Dkt. No. 75, FDA Br. at 7 n.6.)

This is a nonresponse to Sarepta's argument. The fact that companies are required to submit clinical data to receive drug approval does not on its own defeat any impairment argument. Just because the FDA mandates the general contents of new drug applications does not eliminate any and all discretion in the level of detail companies include in those applications. Plaintiff cites the FDA statute requiring submission of clinical study reports as if that ends the matter (Pl. Br. at 35); yet this statute only requires drug manufacturers to submit "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1). While the associated regulations provide some additional detail regarding what manufacturers must include in these reports, 21 C.F.R. § 314.50(d)(5), the types of materials a company choses to include in its reports, the level of detail, and how it presents its findings are all matters of discretion, discretion which would be

impacted should the company know that these reports would later be made public for all its competitors to review.

Federal courts have recognized that drug manufacturers invest significantly in their FDA applications and do so under an expectation of confidentiality. *Judicial Watch, Inc. v. Food & Drug Admin.*, 449 F.3d 141, 148 (D.C. Cir. 2006) ("FDA could not expect full and frank disclosure if it later released such proprietary information into the public domain"). This case is no different.

V. The Redactions Reasonably Segregate Exempt from Non-Exempt Information.

Having failed to demonstrate that FOIA Exemption 4 does not properly exempt Sarepta's proprietary information from disclosure, Plaintiff complains that the redactions are too broad and do not reasonably segregate releasable from protected information. (Pl. Br. at 44-45.) Plaintiff cites only two specific examples, neither of which demonstrates that more limited redactions are proper.

First, Plaintiff points to the redactions of certain words and phrases from the Study Report tables of contents. (*Id.* at 45, citing Seife Decl. ¶ 42.) Plaintiff cites no authority for its proposition that the disclosure of phrases revealing proprietary information that appear in tables of contents cannot cause competitive injury. (*Id.*) Counsel for Sarepta conducted a detailed review of the material and determined that only nonpublic information, including nonpublic titles appearing in the table of contents, were redacted, and the justification for these redactions was set forth in the *Vaughn* index provided to Plaintiff. (Sherwood Decl. ¶¶ 3-5.) Plaintiffs have failed to provide any specific objection to that justification.

Second, Plaintiff alleges that Sarepta and FDA "black[ed] out materials that are easily accessible in other CSRs, for example one released in the FDA's pilot program." (Pl. Br. at 45, citing Seife Decl. ¶ 43.) Plaintiff cites to another company's study report—Aragon

Pharmaceuticals—that was released pursuant to the FDA's pilot program. (Seife Decl. ¶¶ 43-44; Sherwood Decl. ¶ 10.) What another company considers to be proprietary, and a voluntary program in which Sarepta was not a participant, have no bearing here. *See Liberty Glob. Logistics LLC v. U.S. Mar. Admin.*, No. 13-CV-0399 ENV JMA, 2014 WL 4388587, at *10 (E.D.N.Y. Sept. 5, 2014) (noting a lack of Second Circuit case law "supporting the argument that the government must be deemed to have waived its right to redact confidential information (of a third party) properly subject to FOIA Exemption 4 by failing to redact other, allegedly similar, information in response to a FOIA request of an unrelated party in an unrelated matter.").

As Sarepta has repeatedly explained, Sarepta conducted an in-depth review of the documents and selectively redacted only the information it believes is competitively sensitive and nonpublic. (Sherwood Decl. ¶¶ 4-5.) That the nonpublic information in the requested documents is extensive does not mean defendants failed to reasonably segregate the releasable information. Sarepta engaged in a rigorous review and released as much information as it could ascertain had been publicly released. That is all that is required, even under the case law cited by Plaintiff. *See Lead Indus. Ass'n, Inc. v. Occupational Safety & Health Admin.*, 610 F.2d 70, 86 (2d Cir. 1979) (recognizing the "inordinate burden" associated with further parsing redactions and reversing district court order to disclose information under FOIA).

CONCLUSION

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

Dated: July 30, 2018

Respectfully Submitted,

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