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. Intervenor-Defendant.	Case No. 1:17-cv-3960 ORAL ARGUMENT REQUESTED May 29, 2018

NOTICE OF PLAINTIFF'S OBJECTIONS TO THE DECLARATION OF IAN ESTEPAN AND MOTION TO STRIKE

PLEASE TAKE NOTICE that, upon the accompanying Memorandum of Law in Support of this Motion, Plaintiff Charles Seife, by his attorneys, the Media Freedom & Information Access Clinic, Abrams Institute for Freedom of Expression, Yale Law School and Vinson & Elkins, L.L.P., respectfully moves this Court, before the Honorable Jesse M. Furman, United States District Judge, United States District Court, Southern District of New York, at the Thurgood Marshall United States Courthouse, 40 Foley Square, Courtroom 2202, City of New York, at a date and time to be set by the Court, for an order pursuant to Rule 56(c)(2),(4) of the Federal Rules of Civil Procedure and other applicable authority, striking or disregarding the cited portions of the Declaration of Ian Estepan, ECF No. 72, and the related ¶ 37 of the Declaration of Nancy B. Sager, ECF No. 77, filed in support of

the defendants' motions for summary judgment, as detailed in the accompanying Memorandum of Law in Support of this Motion.

Dated: May 29, 2018

Respectfully Submitted,

MEDIA FREEDOM &
INFORMATION ACCESS CLINIC

By: */s/ Cortelyou Kenney*

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On May 29, 2018, a copy of the foregoing document was served on all counsel of record via the Court's Electronic Case Filing (ECF) system.

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One of Counsel

UNITED STATES DISTRICT COURT
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MEMORANDUM IN SUPPORT OF PLAINTIFF'S OBJECTIONS TO THE DECLARATION OF IAN ESTEPAN AND MOTION TO STRIKE

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ORAL ARGUMENT REQUESTED

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MEMORANDUM IN SUPPORT OF PLAINTIFF'S OBJECTIONS TO THE DECLARATION OF IAN ESTEPAN AND MOTION TO STRIKE

Pursuant to Federal Rule of Civil Procedure 56(c)(2),(4), Plaintiff Charles Seife (Seife) objects as follows to the Declaration of Ian Estepan, ECF No. 72 (the Estepan Declaration) and respectfully moves the Court to sustain those objections and strike the cited portions of the declaration.

Introduction

Estepan appears to be a marketing professional who opines on highly technical and scientific matters. He does not claim to testify based on personal knowledge, nor does he establish how he has personal knowledge of these scientific and technical conclusions. He opines in conclusory fashion on the scientific and regulatory utility of certain types of data to competing scientists, without foundation. He speculates on the activities of competitors without explaining how he acquired this information or whether it is based on inadmissible hearsay. Because the Estepan Declaration contains incompetent evidence, those portions should be stricken.

Background

Intervenor-Defendant Sarepta Therapeutics, Inc. (Sarepta) submitted the Estepan Declaration in support of its Motion for Summary Judgment and supporting memorandum. *See* ECF Nos. 69-70, 78. Defendants the Food and Drug Administration and Department of Health and Human Services (together, the FDA) adopted and relied upon the Estepan Declaration in their Motion for Summary Judgment and supporting memorandum. *See* ECF Nos. 74, 75 at 6-7, 9-15.

The FDA's Declarant Sager also relied upon the Estepan Declaration, explaining that the FDA made the redactions at issue *"[b]ased upon Sarepta's representations* that its proposed redactions contained confidential commercial information" (emphasis added) and citing only the Estepan Declaration in support of the conclusory statement: "The information redacted from Study 201 and Study 202 is exempt from disclosure under FOIA Exemption 4 because, *as Sarepta claims in the Declaration of Ian Estepan* submitted along with its motion for summary judgment, the information is confidential

commercial information that would cause competitive harm to Sarepta if disclosed." *See* Sager Decl. ¶¶ 32, 37, ECF No. 77 (emphasis added).

Legal Standard

Federal Rule of Civil Procedure 56(c)(4) states: "An affidavit or declaration used to support or oppose a motion [for summary judgment] must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." Federal Rule of Evidence 602 likewise states: "A witness may testify to a matter only if evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter." A court may "strike portions of an affidavit that are not based upon an affiant's personal knowledge, contain inadmissible hearsay or make generalized and conclusory statements." *Searles v. First Fortis Life Ins. Co.*, 98 F. Supp. 2d 456, 461 (S.D.N.Y. 2000); *see also Rus, Inc. v. Bay Indus., Inc.*, 322 F. Supp. 2d 302, 307 (S.D.N.Y. 2003) (courts may strike or disregard such portions).

Personal knowledge is required in Exemption 4 cases to establish a substantial likelihood of competitive injury and of actual competition—and if the declarant lacks such knowledge the defendant cannot carry its burden. *See*, *e.g.*, *Nat'l Parks & Conservation Ass'n v. Kleppe*, 547 F.2d 673, 683 (D.C. Cir. 1976) (rejecting district court reliance on "conjecture" by Exemption 4 witness not based upon "personal knowledge"); *Teich v. FDA*, 751 F. Supp. 243, 254 (D.D.C. 1990) (ruling that "[d]efendants have simply not sustained their claim of substantial competitive injury with specific and direct evidence" after the court was "forced to strike the declaration of [the intervenor-defendant] Dow Corning's principal witness" and holding it could not accept "Dow Corning's contention of competitive harm when it is based on unsupported allegations.")

Argument

Seife objects to the Estepan Declaration because the statements in question are not admissible evidence. Specifically: (1) the statements were not made on personal knowledge; (2) they are

conclusory as to the scientific and regulatory utility of the data to competing scientists; and (3) they are speculative as to the activities and intent of competitors.

1. Declaration not made on personal knowledge

Before making several highly technical and scientific conclusions, the Estepan Declaration provides only three sentences explaining Estepan's background and experience. These high-level descriptions of experience in "healthcare investing" and "executing corporate strategic initiatives" do not explain how the declarant has personal knowledge to testify about the highly scientific and technical claims at the heart of his declaration. Estepan Decl. ¶¶ 1, 2.

To provide contrast, Plaintiff Seife addressed the same issue—the utility of de-identified patient data in clinical study reports to other scientists—through the declaration of an independent, uncompensated expert, Dr. Peter Lurie, who details his personal knowledge, including serving as the FDA's former Associate Commissioner for Public Health and Strategy and Analysis; representative to the Department of Health and Human Services (HHS) on Data Management and Verification, Evaluation and Evidence, and Social Determinants of Health; and agency lead on transparency and streamlined patient access to experimental medications; as well as publishing peer-reviewed work on clinical trial design and access to experimental medications, and serving as principal investigator of a National Institutes of Health (NIH) funded multi-site study. Lurie Decl. ¶¶ 2, 4, 7. That declaration also describes Dr. Lurie's medical training, multiple post-doctoral fellowships, more than one-hundred articles in medical journals, and other relevant foundational information, establishing his personal knowledge and the competence of his testimony on these issues.

The Estepan Declaration contains no such foundation, even for lay testimony. Nowhere does it assert that it was made on personal knowledge. Nowhere does it explain with any detail or specificity Estepan's role at Sarepta or how it connects to his scientific claims. Nowhere does it explain where his information came from.

In the first of just three sentences describing Estepan's foundation for testifying, he states that he is Sarepta's "Chief of Staff and Head of Corporate Affairs, overseeing Investor Relations, Corporate Communication, and Program Management." Esteban Decl. ¶ 1. No detail is provided about these positions or what they entail. In general practice, "Investor Relations" is a marketing position; indeed, the *Wall Street Journal* lists Estepan's title as "Head–Investor & Media Relations at Sarepta Therapeutics, Inc."[1] *See also, e.g.*, *Absolute Activist Value Master Fund Ltd. v. Ficeto*, 677 F.3d 60, 64 (2d Cir. 2012) ("As Head of Investor Relations and Marketing at ACM, defendant [] was responsible for courting investors around the globe"); *Obeid ex rel. Gemini Real Estate Advisors LLC v. La Mack*, No. 14 CV 6498-LTS-HBP, 2018 WL 2059653, at *10 (S.D.N.Y. May 1, 2018) (describing "consult[ations] with . . . Gemini's Vice President of Marketing and Investor Relations, on future marketing programs"). Likewise, the declaration provides no explanation for the role of "Corporate Communications" or how it provides a foundation for personal knowledge of technical and scientific claims. According to the *Financial Times*, "Corporate Communication" is a modern synonym for "Public Relations" and typically involves activities like communication strategy and reputation management.[2] Nor does the declaration provide any explanation for the role of "Program Management." It is silent on what any such programs are or how they were managed. A public definition of the phrase from the Project Management Institute reflects the generic nature of the title: "Program management is the application of knowledge, skills, tools and techniques to meet program requirements."[3] None of this provides a foundation to opine on the highly technical, scientific matters upon which Estepan purports to testify in his Declaration.

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[1] *See* Sarepta Therapeutics, Inc., Wall Street Journal, https://quotes.wsj.com/SRPT/company-people/executive-profile/134031256 (last accessed May 25, 2018).

[2] *See* Financial Times, *Definition of corporate communication*, http://lexicon.ft.com/Term?term=corporate-communication (last accessed May 25, 2018).

[3] *See* Project Management Institute, Program Management, https://www.pmi.org/learning/featured-topics/program (last accessed May 25, 2018).

In the second of three foundation sentences, Estepan asserts: "I have 16 years of experience in healthcare investing, specifically relating to the development of promising drug candidates, and over the past 5 years I have focused on speeding the clinical development of new therapies for patients with Duchenne muscular dystrophy." Estepan Decl. ¶ 1. There is no explanation of what tasks Estepan performed during those years, or where. The "development of promising drug candidates" could refer to basic science, clinical research, and trial design; it could just as easily refer to non-scientific areas such as administrative, corporate, or legal functions, or—as suggested by his job titles and reference to "healthcare investing"—it could indicate marketing, fundraising, communications, investor relations, or finance. "Speeding the clinical development" of treatments is likewise vague and lacking in useful information. The declaration provides no descriptions of prior training, educational background, field of study, past companies or roles, publications, or other experience, rendering it impossible to assess any basis for personal knowledge of scientific opinions and conclusions.

Finally, the declarant states in the third and last foundation sentence: "In my current role, I am responsible for executing corporate strategic initiatives with the goal of expediting the advancement of clinical compounds through the regulatory process, and as a result I closely track the rapidly evolving competitive landscape in Duchenne muscular dystrophy." Estepan Decl. ¶ 2. Again, the "corporate strategic initiatives" are undefined, as is the nature and method of their "execution." The "goal of expediting the advancement of clinical compounds through the regulatory process" is the goal of every drug company stated at the highest, most generic level: to get drugs to market as quickly as possible. This statement again tells nothing about Estepan's training, skills, knowledge, background, experience, or information upon which his testimony is based.

In the same vein, saying that one "closely track[s] the rapidly evolving competitive landscape in Duchenne muscular dystrophy" is wholly conclusory and entirely vague. Is he tracking the "competitive landscape" as an economist, a physician, a clinical researcher, a marketer, a publicist, a

fundraiser, a regulatory compliance officer, or something else? Is he defining the "competitive landscape" in economic terms (by market share, consumer demand, private investment, public funding?), in legal terms (patents, trade secrets, regulatory, antitrust?), or in scientific terms? Whichever landscape he is referring to, how does he track it? Through medical journals, research grants, marketing materials, industry conferences, regulatory submissions? Did he personally review these? Which facts did he learn from which sources, and were those respective sources valid? Or were they speculative, conclusory, or hearsay? It is impossible to know and thus impossible to assess and admit these opinions as competent evidence based on personal knowledge.

"The test for admissibility is whether a reasonable trier of fact could believe the witness had personal knowledge." *Searles*, 98 F. Supp. 2d at 461. Here, a reasonable trier of fact has no basis to tell. By way of example, the court in *Searles* found that a declarant established personal knowledge to testify about her company's insurance policy by explaining that (1) she was a corporate officer "responsible for overseeing its life and disability insurance businesses"; (2) "in preparing her affidavit she reviewed various administrative materials and files, as well as the [insurance] policy, and so had direct personal knowledge of the facts and circumstances set forth therein"; and (3) the "statements contained in her affidavit are supported by documentary evidence that she would be competent to introduce at trial. In consequence, her affidavit is admissible." *Id.* at 462.

In contrast, the Estepan Declaration lacks any of the above indicia of personal knowledge. He does not connect his corporate role to the specific knowledge alleged. He does not aver to reviewing any relevant documents, nor does he even testify that he reviewed the clinical study reports at issue, much less the disputed redactions, or that he has the basis to review and parse the reports at that level of scientific detail. Virtually none of his statements are supported by documentary evidence, much less demonstrably admissible evidence. Estepan cites only 2 documents in his entire 18-page,

60-paragraph declaration (one is the CSRs and one is the FDA's website). No evidence is cited for the vast majority of assertions.

In addition to this lack of foundation, Estepan makes several statements for which he has not established personal knowledge. Seife objects to Estepan's Declaration as follows:

- **To the declaration as a whole**, because it fails to establish any basis for personal knowledge. The role of the PR function is not that of an operator with first-hand personal knowledge, but rather a communicator who hears information from others and puts the best spin possible on it. Because Estepan provides no basis in the declaration for assessing where his information came from, what he knew personally, or how this information was verified, the entirety of the declaration is untestable, speculative, conclusory, potentially hearsay, lacking in foundation, not based on personal knowledge, and thus incompetent evidence that should not be admitted.

- **To ¶ 18**, because Estepan has not established his competence in or personal knowledge of technical details of those clinical studies. The claim at ¶ 18 that "changes in dystrophin were evaluated using proprietary techniques that were developed through ongoing regulatory interaction with the FDA over the course of years" is wholly conclusory, and Estepan does not explain how he has knowledge of different methodologies for measuring changes in dystrophin, nor how he knows that this technique is proprietary or materially distinct from other techniques.

- **To ¶¶ 22-28 (Competitive Harm Resulting From Disclosure of Sarepta's Clinical Study Procedures)**, because Estepan has not established his competence or personal knowledge of technical details for scientific study design, or how results from one study could be used by competitors in any meaningful way. For example, there is no basis for:

    - The claim at ¶ 22 that Sarepta "spent over three years perfecting its clinical study procedure." Estepan has shown no basis for personal knowledge about whether study protocols were "perfect" or even correct in any scientifically meaningful sense. (By contrast,

persons with actual deep personal knowledge, such as the FDA's lead reviewer of Sarepta's data, found not perfection but concerns about "scientific misconduct.").[4]

- The claim at ¶ 22 that "[s]pecific aspects of the study protocols proposed for redaction could be applied to other exon skipping drugs." Estepan has shown no basis for personal knowledge on the technical issues of which "specific aspects" of study protocols could and could not be applied across different drugs, nor even testified that he read the proposed redactions or had a basis to analyze whether the proposed redactions related only to such specific aspects of the study design.

- The claim at ¶ 22 that "Providing Sarepta's competitors with the results of Sarepta's labor would be to provide an enormous competitive advantage, both in terms of time required to advance a conceptual drug to market and the expense required to do so." Estepan has shown no basis for personal knowledge on the technical issues of why these study protocols would not be readily determinable by a skilled practitioner. Indeed, Estepan provides an example in ¶ 25 that is refuted by Sarepta's own patent application. Estepan testifies: "The development of Sarepta's testing procedures involved researching *complicated issues* such as (i) how to dose, (ii) how much to dose, (iii) how often to dose, and (iv) whether the dosing should be fixed or variable." Estepan Decl. at ¶ 25 (emphasis added). Estepan has demonstrated no personal knowledge as to the complexities of dosing, and Sarepta's own publicly-available, granted patent for Exondys 51 says the opposite: "a skilled practitioner will be able to determine *readily* the optimum route of administration *and any dosage* for any particular animal and condition."[5]

[4] *See* Kenney Decl., Exs. L, 10 & GG, 10.
[5] U.S. 8,486,907 at 29:9-11 (emphasis added).

- The claims in ¶¶ 23-24 are similarly without basis in personal knowledge, and Estepan has established no foundation for speaking to the technical and scientific issues of whether the "timing" within a particular study is clinically relevant to competitors considering other studies, or whether certain research endpoints were "previously recognized" in the scientific literature, which Estepan does not state whether he has personally reviewed.

- The claims in ¶ 25 about dosing are similarly unfounded and without apparent personal knowledge or citation to any underlying documents, such as the Sarepta patent refuting the declaration.

- The claims in ¶¶ 26-27 are highly technical and scientific in nature, and Estepan has established no personal knowledge of the intricacies of "immunohistochemistry techniques," "western blot techniques," "dystrophin localization," and so forth, much less which versions of those technologies are "proper," "optimized," "appropriate," or "not publicly available."

- The claims in ¶ 28, including opining on how "de-identified" data would be "tremendously beneficial" to competitors, "as an aid to designing clinical studies having a higher likelihood of succeeding." Estepan has established no personal knowledge in how details of one study are applicable or not to studies of different drugs by competitors. Dr. Lurie, who actually has personal knowledge of this issue, states the opposite and explains why. *See* Lurie Decl. ¶¶ 21-25. But Estepan provides no basis for personal knowledge of his highly technical and scientific opinions and conclusions.

- **To ¶¶ 29-33 (Competitive Harm Resulting From Disclosure of Sarepta's Clinical Study Results)**—which claims in conclusory fashion that "[a] scientist could make productive use of the data"—because Estepan has not established that he has personal knowledge in the utility of de-identified patient data to scientists studying other drugs, including:

- The claims in ¶¶ 29-31, 33 that "a competitor could simply use the results of Sarepta's clinical study to conduct a head-to-head study" or that "[e]ven when de-identified, data of this kind can contribute to development of historical external control datasets of the kind that the FDA authorized in February 2018." Estepan has not established any personal knowledge to testify on (in Dr. Lurie's words) "the FDA's extensive requirements for historical controls" or for "a head to head trial," for which the demographic and age information Seife is not seeking "would be critical to establish that the control group was prospectively well matched to the treatment group." Lurie Decl. at ¶ 24. For comparison, Dr. Lurie based his testimony (that Sarepta's competitors cannot use this data for such comparison studies "in any meaningful way," *id.* at ¶ 19) on personal knowledge of study design acquired, not only as a former Associate Commissioner of the FDA, but as a published peer-reviewed author on clinical trial design and as the principal investigator of a NIH funded multi-site case control study, *id.* at ¶ 4. Estepan provides no such basis for personal knowledge, and his claims on point are not competent evidence.

- The claim in ¶ 32 that the data could be used purportedly to "undermine Sarepta's patent positions," because Estepan has not established any personal knowledge of IP law or patent law, much less knowledge of the legal standards for "undermining" or invalidating patents, nor has he explained how he knows that releasing data from a clinical study would invalidate Sarepta's patents. He does not state that he has read Sarepta's patents, or the grounds for invalidating patents, nor does he identify which of Sarepta's patent claims he believes would be invalidated by release of the withheld clinical data or why.

- **To ¶¶ 34-39 (Competitive Harm Resulting From Disclosure of Sarepta's Clinical Study Endpoints)** because Estepan has not established that he has personal knowledge of

the scientific process of selecting direct and surrogate endpoints in clinical trial design or how they "are a critical to measure [sic] and evaluate drug efficacy," including:

- The claims in ¶ 34 that "the ideal outcomes for the patient population are not well-known" and "[w]hat would be the effect of a 'successful' treatment is not commonly understood . . . ." Estepan has not established that he has any personal knowledge of any consensus in the scientific literature or medical community that ideal outcomes for the affected patents are or are not characterized or well-known, or why commonly-used measures such as the 6-minute walk test are not "ideal" or viable. Nor has he demonstrated a basis for opining what "is not commonly understood" to the medical community.

- The claims in ¶¶ 35-37 regarding different types of endpoints, their use, and the scientific process and decision-making behind selection and role in a study, including the assertion that "[u]npublished exploratory endpoints would therefore be valuable to Sarepta's competitors . . . ." Estepan has not established any personal knowledge regarding the utility of different types of endpoints for Sarepta's competitors, or whether such endpoints would not already have been known or readily obvious to other scientists.

- The claims in ¶¶ 38-39 that the FDA "encourages companies to be creative in the selection of which clinical endpoints to pursue and consider," that such endpoints "constitute highly proprietary aspects of a company's approach," and that "potential competitors would be spared the significant investment of time and resources Sarepta incurred and could simply pick up where Sarepta's research left off." Estepan has not established personal knowledge of what the FDA does or does not encourage, has not detailed any personal interaction with the FDA or competent basis to comment from personal knowledge on its requirements and preferences as to study design, and has not demonstrated personal knowledge of whether the specific endpoints at issue here were

"highly proprietary," nor how or to what extent Sarepta's competitors could (or would want or need) to use them.

- **To ¶¶ 40-43 (Competitive Harm Resulting From Disclosure of Nonpublic Adverse Events)** because Estepan has not established that he has personal knowledge of the highly scientific and technical claims about DNA structure, similarities or differences between adverse events across different exon skipping modalities, and what allowances the FDA would or would not make upon those highly technical distinctions, including:
    - The claims in ¶ 40 that "[i]f this information were released, Sarepta's competitors would have a record of Sarepta's analysis of which adverse events occurred and did not rise to the level of drug-related adverse reactions, which they could apply to their own studies without making similar investments." Estepan has demonstrated no personal knowledge in whether this data would have applicability to scientists studying different drugs such that a viable study of another drug could occur and pass regulatory muster without testing its own adverse events, or, as Dr. Lurie pointed out, without even being able to serve as a comparison because the data would lack all demographic information.
    - The claims in ¶ 41 in their entirety because they deal with highly technical and scientific opinions about what information "could be leveraged by a competitor to facilitate the approval of its own PMO for DMD irrespective of the exon" based on the scientific assertion that "a given PMO, irrespective of the exon to which it targets, generally has the same chemical backbone structure with the same DNA bases (A, T, C, G), albeit with a different order and length. As such, a competitor seeking approval for its own PMO – for exon 51 or otherwise - can leverage the eteplirsen adverse event data as being representative of the chemical class of PMO compounds." Whether "what events arise from that chemical action and what events do not" are translatable and create "an efficient shortcut" is a claim

for which Estepan has established no personal knowledge. He has demonstrated no basis to opine on whether the "generally . . . same chemical backbone" alone is relevant to adverse events or whether other differences may matter, and that is without even reaching the other limitations on comparing de-identified data already mentioned.

- **To ¶¶ 44-60 (Competition in Marketplace)** because Estepan has not established that he has personal knowledge, including:
    - The claims in ¶¶ 45-49 about what other companies are doing, because he has not established that he knows any of those asserted facts based on personal knowledge, nor does he cite any external evidence corroborating these statements about third parties to demonstrate that his knowledge is based on competent sources and not inadmissible hearsay.
    - The claim in ¶ 50 that "all companies developing DMD treatments compete for the same small patient population, and while these compounds differ significantly, testing methods are portable across exons, as is study design." Estepan has not established personal knowledge that other approaches are applicable to (and in competition for) the "same small patient population"; indeed, his own earlier testimony states the opposite: that different approaches apply to different sub-populations. *See, e.g.*, *id.* at ¶¶ 13, 51.
    - The claim in ¶ 52 that "other pharmaceutical companies have requested access to Sarepta's clinical trial data and testing methodologies" does not establish personal knowledge of the alleged request and is inadmissible hearsay.
    - The claims in ¶ 55 that "[p]ermitting Sarepta's competitors access to detailed information regarding its clinical studies could allow Sarepta's competitors to leapfrog Sarepta in the international marketplace," for all the reasons above that Estepan has not established personal knowledge to attest to the data's utility to other scientists.

- The claim in ¶ 57 that "[i]f Sarepta's competitors with established international infrastructures are granted access to Sarepta's proprietary information, those competitors could advance their clinical development programs more quickly in these countries," for all the reasons above that Estepan has not established personal knowledge to attest to the data's utility to other scientists.

- The claim in ¶ 58 that "[r]elease of the Sarepta information will accelerate the development of these trials," again for all the reasons already shown that Estepan has not established personal knowledge to attest to the data's utility to other scientists.

Because the Estepan Declaration does not establish a basis for personal knowledge of the above statements, and separately because no foundation or competence for the testimony is established, those statements should be stricken.

2. Declaration conclusory as to the utility of the data to competitors

Even if Estepan had established personal knowledge, that would not rehabilitate his wholly conclusory statements, which offer no basis, explanation, defense, or analysis for the assertions. Even an expert, much less a lay witness, cannot simply state conclusions. *See, e.g., Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 311 (2d Cir. 2008).

In contrast to Estepan's testimony, Dr. Lurie explains in detail why the requested data is, in fact, not useful to competitors, including that "Seife is seeking de-identified data from Studies 201 and 202, where information related to patient age, height, weight, and demographic information is redacted to preserve patient privacy. But such redacted data would not be reliable enough to support FDA approval based on the FDA's extensive requirements for historical controls in studies of Duchenne Muscular Dystrophy that Sarepta itself cites, which mandate patients be compared to an extremely similar population demographically." Lurie Decl. ¶ 24. Estepan, however, makes the following

conclusory and unsupported statements as to the withheld information's utility to other scientists, without explanation, rationale, or documentary evidence:

- ¶ 18: "[C]hanges in dystrophin were evaluated using proprietary techniques that were developed through ongoing regulatory interaction with the FDA over the course of years." Estepan simply asserts the techniques are "proprietary" without any basis.

- ¶ 22: "Providing Sarepta's competitors with the results of Sarepta's labor would be to provide an enormous competitive advantage, both in terms of time required to advance a conceptual drug to market and the expense required to do so." Estepan asserts "enormous competitive advantage" in the trial design without basis, never explaining why or how Sarepta's study design would be different, non-obvious, or useful to other companies studying different drugs. The sentences that follow, at ¶¶ 24-25, are equally conclusory, with vague references to "timing" and "procedures" and "how to dose," merely asserting and speculating that those aspects would apply to different studies of different drugs, thus providing no support for this conclusory statement.

- ¶ 22: "Sarepta's testing protocols and procedures are proprietary."

- ¶ 23: "Release of this information would cause Sarepta competitive harm because Sarepta's competitors would be able to copy Sarepta's study design, or selectively modify it, without having invested the resources into producing their own study." It is unclear how Estepan concludes this when asserting later that his competitors' studies are already well underway, but it is conclusory nonetheless.

- ¶ 28: "Detailed information about each patient in the eteplirsen clinical trials and external controls - even if patient data is de-identified - would be tremendously beneficial . . . as an aid to designing clinical studies having a higher likelihood of succeeding thereby curtailing development ordinarily needed for FDA approval." Again, the statement is unsupported and

conclusory for the reasons above, as are the following statements, which assert without explanation or basis that such de-identified data would be useful to other scientists studying other drugs.

- ¶ 30: "The release of de-identified patient-level study results can result in competitive harm. A scientist could make productive use of the data."
- ¶ 31: "Therefore release of this data will directly help our competitors build the type of control dataset that Sarepta spent years and millions of dollars producing."
- ¶ 32: Release of the data could be used to "undermine Sarepta's patent positions."
- ¶ 33: "Even de-identified results could be utilized as part of a historical control set."
- ¶ 35: "Such endpoints define what is being investigated in a study, and are a critical [*sic*] to measure and evaluate drug efficacy."
- ¶ 38: "Essential to this roadmap are clinical endpoints with a demonstrated record of improvement and how those endpoints are measured, both of which constitute highly proprietary aspects of a company's approach."
- ¶ 39: "[P]otential competitors would be spared the significant investment of time and resources Sarepta incurred and could simply pick up where Sarepta's research left off."
- ¶ 40: "If this information were released, Sarepta's competitors would have a record of Sarepta's analysis of which adverse events occurred and did not rise to the level of drug-related adverse reactions, which they could apply to their own studies without making similar investments."
- ¶ 41: "Therefore, a complete record of analysis in these studies distinguishing what events arise from that chemical action and what events do not represents an efficient shortcut to any Sarepta competitor working with exon skipping drugs."
- ¶ 43: "If this information is released, it will free Sarepta's competitors from a years-long process of building the necessary understanding to meaningfully study drugs of this kind."

- ¶ 55: "Sarepta must build up its infrastructure globally before it can benefit from its investments in the application of exon skipping treatments to DMD." Estepan never states why, or why immediate licensing or direct exclusive distribution given its patents would not be a "benefit."

Because the above statements are conclusory and unsupported, the Court should strike them.

3. Declaration speculative as to the activities of competitors

Estepan also speculates without evidence about the state of knowledge, past practices, and future plans and intent of competitors. One striking example is his accusation that the withheld data should not be released because competitors would "mischaracterize[e]" it and "subject [it] to . . . potential manipulation." Estepan Decl. ¶¶ 32, 51. This is ironic speculation, given that the only evidence of actual manipulation implicates Sarepta, as documented in the FDA's own internal correspondence. *See, e.g.*, Kenney Decl., Ex. L. (Dr. Farkas warning western blot images seemed "heavily manipulated photographically" and that the images in the clinical study reports did not match those presented earlier to the FDA). Estepan also speculates about what his competitors do and do not already know internally, what they have or have not already done internally, and what would be difficult for them to discern in their own studies, all without any stated basis, foundation, evidence, citation, or support. Such speculation is incompetent evidence and should be stricken, including:

- ¶ 23: "Release of this information would cause Sarepta competitive harm because Sarepta's competitors would be able to copy Sarepta's study design, or selectively modify it, without having invested the resources into producing their own study."

- ¶ 25: "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 . . . Were these companies to gain insights into the unpublished data regarding Sarepta's unsuccessful and successful dosing approaches, it would allow

them to bypass the years of expensive trial and error work that Sarepta undertook."

- ¶ 26: "In the absence of such technology, these companies would have to develop their own validated procedures at great time and expense to demonstrate dystrophin production in a manner sufficient for regulatory approval."

- ¶ 26: "Many of these methods are not publicly available and have been requested by companies to aid in the rapid development and approval of competing products or other products in DMD by utilizing our proprietary techniques to establish dystrophin production."

- ¶ 27: "Making the methods, or aspects of the methods, available would provide competitor companies a basis to quickly conduct dystrophin analyses with accurate and reliable methodologies that would not otherwise be available to them and, under recent guidance, could directly result in the approval of competing drugs under expedited timelines."

- ¶ 28: "In essence, the eteplirsen clinical trial data would facilitate a competitor to "retrospectively" design its clinical trials. Being better informed, competitors could design their clinical trials with inclusion and exclusion criteria to facilitate their success."

- ¶ 29: "If provided access to the data tables excerpted in the clinical study report narratives or provided in full in the appendices, a competitor could simply use the results of Sarepta's clinical study to conduct a head-to-head study, without ever having administered the dosages of eteplirsen to patients as did Sarepta or run a pivotal stage clinical study."

- ¶ 31: "Therefore release of this data will directly help our competitors build the type of control dataset that Sarepta spent years and millions of dollars producing."

- ¶ 32: "Third parties could also use the data to further their sales and marketing campaign to claim that its product was superior, undermine Sarepta's patent positions, or interfere with patient recruitment in subsequent studies."

- ¶¶ 32, 51: "Release, with or without patient data, would allow competitors to mine the data and to characterize it in the most unfavorable light possible, whilst their own patient level data would remain safely hidden and not subject to the same potential manipulation."; "Mischaracterizations of Sarepta's data by competitors could tremendously impact Sarepta's ability to enroll patients in its clinical studies."

- ¶ 33: "De-identified patient-level data could also be used by a competitor as a historical control set."

- ¶ 37: "Unpublished exploratory endpoints would therefore be valuable to Sarepta's competitors because they provide insight into which endpoints Sarepta is pursuing, information which Sarepta's competitors could use to either mirror Sarepta's approach or to predict the areas in which Sarepta is focusing its research."

- ¶ 39: "[P]otential competitors would be spared the significant investment of time and resources Sarepta incurred and could simply pick up where Sarepta's research left off."

- ¶ 40: "If this information were released, Sarepta's competitors would have a record of Sarepta's analysis of which adverse events occurred and did not rise to the level of drug-related adverse reactions, which they could apply to their own studies without making similar investments."

- ¶ 43: "If this information is released, it will free Sarepta's competitors from a years-long process of building the necessary understanding to meaningfully study drugs of this kind."

- ¶ 44: "The principle of exon skipping is reproducible, and other companies are using the concept to develop their own DMD treatments."

- ¶ 45: "Since clinical development of eteplirsen was initiated, other companies have been developing antisense oligonucleotides for DMD in the US, including: [bullet list omitted]."

- ¶¶ 46-49: "The following companies and institutions are also currently pursuing

development of drug therapies to cause DMD patients to produce dystrophin: Daiichi Sankyo, PTC Therapeutics, Nippon Shinyaku Pharma, Wave Life Science, Solid Biosciences, Bamboo Therapeutics (acquired by Pfizer)."

- ¶ 50: "All companies developing DMD treatments compete for the same small patient population."
- ¶ 51: "Companies also compete for patients to participate in clinical studies, particularly in view of the small patient numbers. . . Mischaracterizations of Sarepta's data by competitors could tremendously impact Sarepta's ability to enroll patients in its clinical studies."
- ¶ 58: "There are currently dozens of planned trials for other exon skipping DMD treatments."
- ¶ 59: "The competitive landscape in DMD includes 27 DMD assets in clinical development with expected US market approval between 2020 and 2027."

Because the above statements are speculative and unsupported, the Court should strike them.

4. Portion of Sager Declaration Reliant on Estepan Declaration

Paragraph 37 of the Sager Declaration, ECF No. 77, is wholly conclusory and relies entirely on the Estepan Declaration for its conclusion that the requested information is "exempt from disclosure under FOIA Exemption 4 because, as Sarepta claims in the Declaration of Ian Estepan submitted along with its motion for summary judgment, the information is confidential commercial information that would cause competitive harm to Sarepta if disclosed." Sager Decl. ¶ 37. Because ¶ 37 of the Sager Declaration relies entirely on the Estepan Declaration, which is inadmissible and thus no evidence on point, and also on its face, ¶ 37 of the Sager Declaration should be struck or disregarded as conclusory, speculative, lacking foundation, and lacking personal knowledge.

Conclusion

For the foregoing reasons, Plaintiff Seife respectfully moves the Court to sustain Seife's objections herein to the Declaration of Ian Estepan, ECF No. 72, and to the related ¶ 37 of the Declaration of Nancy B. Sager, ECF No. 77, reliant thereon, and to strike or disregard the cited portions of those declarations pursuant to those sustained objections. Seife respectfully asks the Court to grant any other and further relief to which he may be entitled.

Dated: May 29, 2018

Respectfully Submitted,

MEDIA FREEDOM &
INFORMATION ACCESS CLINIC[6]

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[6] This memorandum has been partially prepared by the Media Freedom and Information Access Clinic, a program of the Abrams Institute for Freedom of Expression at Yale Law School. Nothing in this memorandum should be construed to represent the institutional views of the law school, if any.

Certificate of Service

On May 29, 2018, the foregoing document was served on all counsel of record via the Court's Electronic Case Filing (ECF) system.

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