20-4072

In the
United States Court of Appeals
For the Second Circuit

CHARLES SEIFE,
Plaintiff-Appellant,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION and
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendants-Appellees,

- and -

SAREPTA THERAPEUTICS, INC.,
Intervenor-Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT NEW YORK

REPLY BRIEF FOR PLAINTIFF-APPELLANT

THOMAS S. LEATHERBURY
VINSON & ELKINS LLP
2001 Ross Avenue, Suite 3900
Dallas, Texas 75201
(214) 220-7792

JARED K. CARTER
CORTELYOU C. KENNEY
FIRST AMENDMENT CLINIC
CORNELL LAW SCHOOL
Myron Taylor Hall
Ithaca, New York 14850
(607) 255-8897

DAVID A. SCHULZ
MEDIA FREEDOM & INFORMATION ACCESS CLINIC
YALE LAW SCHOOL
P.O. Box 208215
New Haven, Connecticut 06520
(203) 432-4366

Attorneys for Plaintiff-Appellant

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Other Authorities

PRELIMINARY STATEMENT

At its core, this appeal involves one question: What is the "interest protected by" Exemption 4 under the FOIA Improvement Act of 2016? The answer, as Plaintiff-Appellant Professor Seife has demonstrated, is that Exemption 4 protects the submitter's interest in the economic value of its intangible property. Seife's Br. at 20. Appellees have no real response to this answer, which is rooted firmly in the text and purpose of the FOIA Improvement Act (FIA) and Exemption 4.

The lesson from *Food Marketing Institute v. Argus Leader Media* ("*FMI*") is crystal clear: statutory interpretation begins with "a careful examination of the ordinary meaning and structure of the law itself." 139 S. Ct. 2356, 2364 (2019). Under the text of the FIA, an agency seeking to withhold information under an applicable FOIA exemption must show that it "reasonably foresees that disclosure would harm an interest protected by [that] exemption." 5 U.S.C. § 552(a)(8)(A)(i).[1] Appellees fail to "careful[ly] examin[e]" the text of Exemption 4 or the text of the FIA, *FMI*, 139 S. Ct. at 2364, let alone "harmoniz[e]" them. *Citizens for Resp. & Ethics in Wash. v. Fed. Election Comm'n*, 711 F.3d 180, 188–89 (D.C. Cir. 2013).

[1] An agency is also permitted to withhold documents where disclosure is "prohibited by law," but that provision is not at issue here and, as Professor Seife points out below, Appellees' argument that it should apply broadly here is unavailing based on the text and purpose of the FIA. 5 U.S.C. § 552(a)(8)(A)(i)(II).

Appellees instead simply assert that Exemption 4 *only* protects an interest in confidentiality and then wholly ignore the text of the FIA itself, when harmonizing the two plainly requires accounting for the other words in each provision.

The FIA requires an agency to reasonably foresee "*harm*," 5 U.S.C. § 552(a)(8)(A)(i)(I) (emphasis added), and as demonstrated in Appellant's opening brief, this requires an agency invoking Exemption 4 to show that disclosure will measurably impact the submitter's intangible property interests. *See* Seife's Br. at 20; *see also*; *Harm*, Black's Law Dictionary (11th ed. 2019) (defining "harm" as "injury, loss, damage; *material or tangible* detriment" (emphasis added)). Appellees' contrary reading of the law deeply offends the indisputable purpose of both FOIA and the FIA: to encourage *more* disclosures, not fewer disclosures.

In Appellees' view, once an agency shows that commercial or financial information is "confidential," such that Exemption 4 applies, nothing else would be required of the agency under the FIA. FDA's Br. at 24-25. That is quite the opposite of the independent and meaningful burden Congress intended. *See* Seife's Br. 31-33; *see also Nat. Res. Def. Council v. EPA*, No. 17-CV-5928, 2019 WL 3338266, at *1 (S.D.N.Y. July 25, 2019) (citing *Judicial Watch, Inc. v. U.S. Dep't of Commerce*, 375 F. Supp. 3d 93, 100 (D.D.C. 2019)). Appellees' argument renders the FIA mere surplusage and reflects the kind of "casual disregard of the rules of statutory interpretation" the Supreme Court has cautioned against. *See FMI*, 139 S. Ct. at 2364.

Furthermore, Appellees improperly conflate Professor Seife's interpretation of the law with the abrogated *National Parks* "competitive harm" test. *See, e.g.*, FDA's Br. 2, 23, 31. As a result, they never explain how disclosure of the information at issue in this case would foreseeably harm Sarepta's intangible property interests. The claims of harm Appellees do advance are conclusory, speculative, and refuted by the record evidence. FDA's Br. 37–42; Sarepta's Br. 34–43. Moreover, Appellees' conclusory assertions of harm rest entirely on the declarations of Mr. Ian Estepan, who may have years of experience in "healthcare investing," *see* Sarepta's Br. at 37, but is neither a proper expert witness nor an appropriate lay witness. Even if Mr. Estepan were appropriately classified as a lay witness, his testimony is not based on first-hand knowledge or his own perception. The district court's reliance on Mr. Estepan's declarations and its failure to properly weigh the evidence are further grounds for reversal.

ARGUMENT

I. "Confidentiality" is Not an Interest Protected by Exemption 4.

A. Appellees Ignore *FMI*'s Clear Instruction and Canons of Statutory Construction by Looking to Only One Word in the Statute.

Based on *FMI* and basic principles of statutory construction, this Court should reject Appellees' argument that "confidentiality" is the interest protected by Exemption 4. Appellees repeatedly cite *FMI* but do the opposite of what it instructs. Instead of "careful[ly] examin[ing] the ordinary meaning and structure" of FOIA, as *FMI* requires,

Appellees narrow in on one word, "confidential," and brush the rest of the statute aside. Although, as Sarepta points out, confidentiality was "included among the exemption's spare fifteen words," *see* Sarepta's Br. at 26, Appellees ignore the other fourteen words entirely.

The correct analysis acknowledges that every term in the exemption—including but not limited to "confidential"—is important, as is its relation to the FIA and the rest of FOIA. *See U.S. Nat'l. Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) (explaining that courts "look to the provisions of the whole law" rather than being "guided by a single sentence or member of a sentence").

Appellees further offend *FMI* by failing to consider the "structure" of FOIA, which includes the FIA. *See FMI*, 139 S. Ct. at 2364. Congress passed the FIA and added an additional independent and meaningful burden that agencies must meet because it believed agencies were excessively withholding information and acting counter to FOIA's fundamentally pro-disclosure purpose.[2] *See* S. Rep. No. 114-4, at 2–3 (2015). If Appellees prevail, and agencies can meet their FIA burden by showing a reasonably foreseeable harm to information's "confidentiality," no trade secrets or confidential commercial or financial information will *ever* be released. Appellees' position would destroy the independent and meaningful burden to establish harm *or* to show that such

[2] Notably, Professor Seife's argument that the "foreseeable harm standard imposes a stringent new burden on the agency" does not in fact "alter the scope of information" covered under Exemption 4, as the FDA claims. *See* FDA's Br. at 26.

harm is reasonably foreseeable. This is not what *FMI* directs nor is it consistent with basic principles of statutory interpretation that say when Congress amends a statute, "it intends its amendment to have real and substantial effect." *See Stone v. INS*, 514 U.S. 386, 397 (1995).

B. *FMI*'s Focus on Defining "Confidentiality" for Exemption 4 Eligibility Does Not Mean that Confidentiality is the "Interest Protected by" Exemption 4.

Appellees propose morphing *FMI* into something that it is not. In *FMI*, the Court held that Exemption 4 protects information if it would not customarily be released to the public by the person from whom it was obtained. *See FMI*, 139 S. Ct. at 2364, 2366. According to Appellees, that language demonstrates that the interest protected by Exemption 4 is the confidentiality of the record maintained by the person who submitted that record to the government. This argument does not hold up. *FMI* involved one narrow issue: the definition of the term "confidential" for the purpose of determining whether information falls within the scope of Exemption 4. *See FMI*, 139 S. Ct. at 2360. Appellees admit that the Court did *not* interpret the FIA or the "interest protected by" Exemption 4 "because the FOIA request in that case was filed prior to 2016." Sarepta at 16; *see also Ctr. for Investigative Rep. v. U.S. Customs & Border Protection*, 436 F. Supp. 3d 90, 113 (D.D.C. 2019). *FMI* does not hold that confidentiality is the interest protected by Exemption 4 and neither should this Court.

C. Appellees Fail to Refute Professor Seife's Demonstration of the "Interest Protected by" Exemption 4.

Not only do Appellees fail to offer a logical interpretation of the "interest protected by" Exemption 4, but they also fail to rebut Professor Seife's showing of the protected interest manifest in the language and purpose of Exemption 4. Notably, Appellees never dispute Exemption 4's focus on protecting the value of intangible property. In fact, Sarepta notes that "Exemption 4 protects *proprietary* information that commercial enterprises keep confidential." Sarepta's Br. at 26 (emphasis added). Sarepta directly argues in favor of Professor Seife's understanding without even realizing it. Sarepta states: "Confidentiality . . . is a commercial objective, for which business [sic] expend resources directed at protecting *assets* that have *business value*." Sarepta's Br. at 28 (emphasis added); *see also Asset*, Merriam-Webster Online Dictionary (2021) https://www.merriam-webster.com/dictionary/asset (defining "assets" in terms of "property"). Precisely. That is exactly what Exemption 4 protects—the underlying "business value" of information, not merely its confidential status. Put another way, confidentiality is necessary, but not sufficient, to invoke Exemption 4.

Appellees further fail to refute the fact that likely diminution of the information's economic value is the most logical way to measure the foreseeable harm to an intangible property interest. Their only response, relegated to a footnote, is that "courts have recognized property interests that lack economic value." FDA's Br. at 32 n.12. Yet Appellees' own citations belie this conclusion. For example, in one case, the court *rejected*

the government's argument that "tenure rights have no economic value" and explicitly found that the tenure rights had "value to the faculty member to whom tenure has been granted." *North Dakota State Univ. v. United States*, 255 F.3d 599, 605 (8th Cir. 2001).

Sarepta asserts that, under Professor Seife's reading, a "submitter must demonstrate that the specific information at issue has a quantifiable dollar value, and that release of that information will lower that value." Sarepta's Br. at 26. But Professor Seife has not argued as much, and this Court need not now decide the exact means by which an agency must establish foreseeable harm, as it could vary from case to case. In this case, however, providing evidence of a *relative* diminution in the information's value is not beyond Appellees' capabilities. Yet, they failed to make that showing notwithstanding Seife's record evidence that no such diminution is foreseeable here. Seife's Br. at 33. Indeed, measuring harm to an intangible property interest in economic terms is a tale as old as time. For example, damages for trade secret misappropriation are measured in terms of the "economically measurable effects" of the wrongful use. *See* 4 Milgrim on Trade Secrets § 15.02[3][a]; *A.F.A. Tours, Inc. v. Whitchurch*, 937 F.2d 82, 87 (2d Cir. 1991). In other words, the "harm" is measured in terms of the information's economic value. Appellees' efforts to paint Professor Seife's understanding of the law as "brand new" are entirely unavailing. Sarepta's Br. at 10.

In addition, Appellees' confidentiality argument impermissibly treats the foreseeable harm showing as an "on/off" switch: either the harm occurs (upon disclosure) or it does not (upon withholding). Appellees would therefore render the

reasonably foreseeable harm requirement in the FIA meaningless—the agency would not have to reasonably foresee anything. Rather, under Appellees argument, the agency would just have to state that "[d]isclosure would necessarily destroy the private nature of the information." *See* FDA's Br. at 28 (quoting *Am. Small Bus. League v. U.S. Dep't of Def.*, 411 F. Supp. 3d 824, 836 (N.D. Cal. 2019)).

Finally, the intangible property interest standard does not, as Appellees claim, "reinject" the *National Parks* standard, FDA's Br. at 31, or "impose a harm test more stringent than the *National Parks* test," Sarepta's Br. at 25. Professor Seife has never urged a "competitive harm" standard, yet it appears in Appellees' most recent briefs a combined total of 59 times. The discrepancy is no mystery. Presumably, Appellees are attempting to tar Professor Seife's position with the recent rejection of the *National Parks* approach to Exemption 4. *See* FDA's Br. at 33. This simply mischaracterizes his position.

In short, Appellees simultaneously defy established principles of statutory construction, render the FIA mere surplusage, misconstrue the Supreme Court's holding in *FMI*, and both misinterpret and fail to refute Professor Seife's argument.

II. The FDA Has Not Met Its Independent and Meaningful Burden Under the FIA to Establish Foreseeable Harm.

To meet its FIA-required burden, the FDA must establish that disclosure of the requested information would cause a reasonably foreseeable diminution in the

economic value of the information. The FDA has failed to even make that argument, let alone do so successfully.

A. Appellees' Claims of "Competitive Harm" Are Conclusory and Speculative, and Thus Unsatisfactory Under the FIA.

Appellees make two equally unconvincing types of foreseeable harm arguments: that the "pharmaceutical industry is highly competitive" and that "Sarepta has invested a significant amount of time and expense in developing Exondys 51." *See* Sarepta's Br. at 34–35, 38–40; *see also* FDA's Br. at 34–35, 37. These arguments suffer from multiple flaws. Even assuming that Appellees connected the dots between Sarepta's past investment in Exondys 51 and its claimed future competitive harm—which they did not—Sarepta's investment is not relevant to the type of harm Appellees are required to show. Furthermore, since all pharmaceutical companies invest time and resources when developing drugs, the implication of this argument is that no information about FDA-approved drugs can ever be obtained through a FOIA request—the company can always reference their "significant" investment in developing the drug. Surely Congress did not pass the FIA with that result in mind.

Furthermore, Appellees airlift their "time and expense" argument from *Public Citizen Health Research Group v. FDA*, 185 F.3d 898, 905–06 (D.C. Cir. 1999), but that case does more harm than good for Appellees. The 1999 D.C. Circuit case involved the *National Parks* competitive harm standard and thus is irrelevant to the current analysis and not binding on this Court. Even worse for Appellees, the court specifically required

the FDA to release one category of documents because the company's affiant offered only "conclusory assertions" similar to the claims Appellees make here. *See Pub. Citizen Health Research Grp.*, 185 F.3d at 906.

Appellees' "generic" assertions of harm are not permitted in a foreseeable harm analysis. *See Ctr. for Investigative Reporting*, 436 F. Supp. 3d at 106. Simply claiming that a submitter's industry is "highly competitive" is far from satisfying the independent and meaningful burden Congress imposed in the FIA. And Appellees' repeated incantation of "economic common sense," *see* Sarepta's Br. at 36, 38, 47; FDA's Br. at 15, is the poster child for impermissible "boilerplate" and "generic" claims. *See Ctr. for Investigative Reporting*, 436 F. Supp. 3d at 106. Instead, the FDA was required to ""identify specific harms to the relevant protected interests that it can reasonably foresee would actually ensue from disclosure of the withheld materials' and 'connect[ ] the harms in [a] meaningful way to the information withheld."' *Ctr. for Investigative Reporting*, 436 F. Supp. 3d at 106; *see also Judicial Watch*, 375 F. Supp. 3d at 100. Appellees' assertions of harm are neither "specific," nor connected to the withheld information in any meaningful way.

Furthermore, nearly all of Appellees' claims of harm are speculative. For example, Sarepta asserts that "[t]he value of an as-yet unknown endpoint . . . c*ould* be significant." Sarepta's Br. at 40 (emphasis added). And Sarepta mentions that "its stock price has fallen in the past when similar information was released and misconstrued," Sarepta's Br. at 41—but offers no evidence to suggest that its stock price *would* fall as a

result of disclosure of *this* information. This is precisely the type of meaningless speculation that has been rejected in the foreseeable harm context. *See Center for Investigative Reporting v. U.S. Dep't of the Interior*, No. 18-CV-1599 (DLF), 2020 WL 1695175, at *1 (D.D.C. Apr. 7, 2020) (explaining that under the FIA an agency must show "that disclosure *would* cause reasonably foreseeable harms" rather than merely stating "what *could* happen"). Appellees' purely speculative claims are inadequate and cannot stand in the way of the public's right to know "what [the FDA] is up to" and to understand potential risks associated with Exondys 51. *See DOJ v. Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 773 (1989).

B. Disclosure of the Withheld Information Will Not Harm Sarepta's Intangible Property Interests Because the Information Lacks Economic Value.

Appellees have not shown that disclosure of the requested information would harm Sarepta's intangible property interests. Specifically, they have not shown that the information has any economic value that would decline as a result of disclosure. Appellees argue that Sarepta will suffer "competitive harm" because its competitors would be able to use the withheld information in their own studies, research, and marketing campaigns. Sarepta's Br. at 38–41; FDA's Br. at 39. And they claim, without any elaboration, that "it defies credulity that information so valuable to public health researchers (and to Seife himself) would be without value to private sector researchers." Sarepta's Br. at 33. Professor Seife's evidence thoroughly refuted these arguments from the beginning.

Professor Seife submitted multiple declarations from Dr. Peter Lurie, a medical physician, epidemiologist, former medical school professor, and former Associate Commissioner of the FDA. Seife's Br. at 36(citing JA 290–334). Dr. Lurie has explained at length how the requested information would be valuable to public health researchers but not to Sarepta's competitors.

For example, while Sarepta argues that competitors could use information regarding dosing to determine a "final therapeutic dose amount, timing, form, and strength for their drug candidates," Sarepta's Br. at 38, Dr. Lurie has explained that competitors are designing different drugs, which are made of "different compounds, with different pharmacological profiles and different absorption rates," Seife Br. at 38 (citing JA 299). Thus, even if "the same dosage would [not] be applied to the new drug," *see* FDA's Br. at 39, competitors will have to perform new studies on their particular compounds with or without the information sought here,[3] Seife's Br. at 38. Dr. Lurie bases his conclusions on his decades-long experience in public health and clinical trial design, which Mr. Estepan does not possess.

[3] In *Teich v. FDA*, the court ordered the disclosure of information despite the defendants' argument that the company's competitors "could use [the] test results . . . as a road map to facilitate their own testing, thus taking advantage of the research funds and time expended by [the company]." 751 F. Supp. 243, 253 (D.D.C. 1990). The court explained that "a manufacturer must submit not only the protocols and test results, but the raw data supporting those results. In the absence of the raw data, an applicant cannot demonstrate the requisite safety and effectiveness necessary to obtain FDA approval." *Id.* (citation omitted).

Appellees continue to assert that competitors could use the de-identified patient level data "in the process of developing their own historical external control datasets and designing their own clinical trials, and to inform development decisions. FDA's Br. at 39–40(quotations omitted). For this, Appellees rely on Mr. Estepan, who has demonstrated a fundamental misunderstanding of the type of data Seife seeks. Seife Br. at 38 (citing JA 148, 302–03). Meanwhile, Professor Seife has shown that competitors could not use such data, which lacks *all identifying data*, "in any meaningful way." Seife's Br. At 38–39 (citing JA 301–03). Moreover, Appellees' claim is wholly conclusory, as they never explain *how* competitors could do so. And, even if the FDA were correct, the argument still says absolutely nothing about harm to Sarepta's property interests.

Additionally, Appellees' apparent concern for patient privacy is unfounded. Mr. Estepan himself suggests that the alleged "risk to patient privacy" derives from social media, not the data itself. *See* Estepan 2d Decl. ¶ 35. He never explains how *this de-identified data* would reveal patient identities. Indeed, Professor Seife specifically requested de-identified data in order to preserve patient privacy—his goal is to help DMD patients, not harm them in any way. *See* Seife's Br. at 38 (citing JA 301).

As for the information regarding clinical endpoints, Appellees argue that disclosure would give Sarepta's "competitors its full 'playbook'" and allow competitors to reproduce Sarepta's prior research and predict its future research. Sarepta's Br. at 40. Once again, Appellees never explain *how*. As Professor Seife has established, however, this information would not give competitors "an advantage" because the "most

commercially valuable" endpoints are already widely known and "routinely used" in the field. Seife's Br. at 39–40. Beyond inadequate conclusory assertions, Appellees has not explained how harm would flow from information that is commonly known and freely shared in the scientific community.

Finally, Appellees misrepresent Professor Seife's demonstration that the information lacks value because so much is already known about Exondys 51. The FDA erroneously states that Professor Seife argues "the information has no value to Sarepta because it is already publicly available." FDA's Br. at 35. Professor Seife's argument is *not* that "identical information" is already public, and therefore disclosure will not harm Sarepta's intangible property interests. Sarepta's Br. at 31–32. It is that because so much *similar* information is already known about the drug, Sarepta's intangible property interests would not be harmed by the release of the remaining *non-public*, non-valuable information.

Yet Appellees continue to assert, unnecessarily, that "'similar' public information is of no import" *to the question of whether Exemption 4 applies*. Sarepta's Br. at 32. Appellees correctly note that Exemption 4 only "does not apply if *identical* information is otherwise in the public domain." *Id.* (citing *Inner City Press v. Board, Fed. Res. System,* 463 F.3d 239, 244 (2d Cir. 2006)) (emphasis added). But this appeal is not about whether Exemption 4 applies. Thus, *Inner City Press* is irrelevant, and certainly not the "controlling case law" Appellees suggest. *See* FDA's Br. at 36. Although substantially similar information is not relevant to whether Exemption 4 *applies*, it is highly relevant to whether release of

"granular details" with "incremental value" will cause a reasonably foreseeable harm to Sarepta's intangible property interests under the FIA. Appellees have not refuted this. *See* Seife's Br. at 33 (citing JA 303).

Appellees also assert that "Sarepta is in the best position to know whether release of the information would cause it harm." Sarepta's Br. at 33–34. Even a basic understanding of FOIA reveals how weak this argument is. To accept that a private company that submits information to a government agency is the authority on when crucial health and safety information should be released is to accept that such information will never be released except when the company is feeling charitable—or at least when it is absolutely sure it will be safe from backlash. The same is true for the agency when, as in this case, the requested information has the potential to reveal wrongdoing. Such deference to either the submitter or the agency contradicts FOIA's purpose to let the public know what their government is up to. *See Reporters Comm. for Freedom of the Press*, 489 U.S. at 773 (1989).

In short, Appellees have not met the required independent and meaningful burden under FIA and this court should reject their arguments to the contrary.

III. This Court Should Reverse or Remand Because the District Court Failed to Weigh Professor Seife's Evidence.

A. The District Court Erred in Failing to Consider Professor Seife's Evidence.

The district court is required to consider the record as a whole on summary judgment. *See* Fed. R. Civ. P. 56(c); *Matsushita Elec. Indus. Co v. Zenith Radio Corp.,* 475

U.S. 574, 585 (1986). By failing to take into consideration the declarations of Dr. Lurie, Dr. Zuckerman, or Professor Seife, the district court committed an evidentiary error. Accordingly, this Court should remedy the district court's abuse of discretion with a reversal.

Sarepta and the FDA contend that the district court correctly disregarded the declarations of Dr. Lurie and Dr. Zuckerman because they had no relevance to the legal issues before the court. Appellees, however, misconstrue the relevant legal inquiry in this case. Appellees erroneously focus only on the confidential nature of the information sought and the competitiveness of the pharmaceutical industry. *See* Sarepta's Br. at 48. But as explained, the FIA and Exemption 4 protect Sarepta's interest in the economic value of its intangible property.

The declarations of Dr. Lurie, Dr. Zuckerman, and Professor Seife all were directly relevant to whether disclosure of the requested information would harm Sarepta's intangible property interests by causing the information's economic value to depreciate. *See* Seife's Br. at 43. Appellees' attempt to discredit Dr. Lurie's declaration on the basis that it did not dispute the highly competitive nature of the pharmaceutical industry is a complete red herring. Professor Seife has never disputed that the pharmaceutical industry is competitive, but his experts establish that, despite this competition, disclosure of the information at issue would not harm Sarepta's intangible property interests. Dr. Lurie's and Dr. Zuckerman's declarations provide evidence

relevant to the inquiry the district court should have made, and thus it was error not to take them into consideration.

B. The District Court Erred in Relying on the Estepan Declaration.

The district court erred in relying on the declaration of Mr. Estepan, who is not qualified to provide the expert testimony required to support Sarepta's claims of "competitive harm."

1. Mr. Estepan is Not a Lay Witness and is Not Qualified to Offer Expert Testimony.

Federal Rule of Evidence 701 constrains opinion testimony of lay witnesses. *See* Fed. R. Evid. 701. Lay witness opinion testimony is limited to that which is: (a) rationally based on the *witness's perception*; (b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and (c) *not based on scientific, technical, or other specialized knowledge* within the scope of Rule 702. Fed R. Evid. 701 (emphasis added). On the other hand, Rule 702 lays out the requirements of expert testimony: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case. Fed. R. Evid. 702.

Here, Sarepta attempts to make an end-run around the evidentiary standard for opinion testimony by disguising Mr. Estepan as a lay witness yet utilizing him to draw

conclusions on complex economic and scientific conditions requiring expert testimony. Sarepta's Br. at 51. It is uncontroversial that testifying to market and scientific conditions requires expert testimony under Rule 702. *See, e.g.*, *Washington v. Kellwood Co.*, 105 F. Supp. 3d 293, 308–09 (S.D.N.Y 2015) (expert offered to testify to business valuations); *McIntire v. China MediaExpress*, 38 F. Supp. 3d 415, 427–28 (S.D.N.Y. 2014) (expert offered to testify on market efficiencies); *S.E.C. v. Tourre*, 950 F. Supp. 2d 666, 676–79 (S.D.N.Y. 2013) (expert offered to testify to economically material information); *IBEW Loc. 90 Pension Fund v. Deutsche Bank AG*, No. 11 CIV. 4209 KBF, 2013 WL 5815472 (S.D.N.Y. Oct. 29, 2013), at *13–15 (expert offered to testify on damages, loss causation, and market efficiency). Mr. Estepan's speculative conclusions regarding the economic value of the withheld information land outside the acceptable boundaries of Rule 701 and lay witness testimony. *See* Fed. R. Evid. 701. Instead, Rule 702 controls Mr. Estepan's contested declaration.

The district court recognized this. In denying Mr. Seife's motion to strike, the district court analyzed Mr. Estepan's declaration as though he were providing expert testimony but made erroneous conclusions on his qualifications and reliability. *Seife v. Food & Drug Admin.*, 17-CV-3960 (JMF), 2019 WL 1382724, at *2 (S.D.N.Y. Mar. 27, 2019). Citing Mr. Estepan's experience in healthcare investing, the district court answered the "threshold question" for Rule 702 and held that Mr. Estepan was qualified to testify as an expert. *See id.*; *523 IP LLC v. CureMD.Com*, 48 F. Supp. 3d 600, 642 (S.D.N.Y. 2014). However, Mr. Estepan was in fact unqualified because he lacks the

requisite education and experience to opine on market conditions and scientific valuations. *Cf. Kellwood Co.*, 105 F. Supp. 3d at 308–09 (S.D.N.Y 2015); *McIntire*, 38 F. Supp. 3d at 427–428 (S.D.N.Y. 2014); *Tourre*, 950 F. Supp. 2d at 676–79 (S.D.N.Y. 2013); *Deutsche Bank AG*, 2013 WL 5815472 at *13–15.

The district court also erred in assuming Mr. Estepan's conclusions were reliable. The court leaned on Mr. Estepan's declaration "even if [Mr. Estepan] does not understand the precise scientific value of the disclosures." *Seife,* 2019 WL 1382724 at *2. Taking Mr. Estepan's declaration at face value, the district court sidestepped the "general gatekeeping obligation" to vet the reliability of expert testimony. *See In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 540 (S.D.N.Y. 2004). Mr. Estepan's expert competency may be as an executive with expertise in business development and marketing—but not clinical research or biomedical science—precluding his testimony on the potential economic costs of the disputed disclosures.

Sarepta's sleight of hand in portraying Mr. Estepan as a lay witness runs afoul of the common understanding that Rule 701 exists to "eliminate the risk that the reliability requirements set forth in Rule 702 will be evaded through the simple expedient of proffering an expert witness in lay witness clothing." *Bank of China, N.Y. Branch v. NBM LLC*, 359 F.3d 171, 181 (2d Cir. 2004) (quoting Fed. R. Evid. 701 advisory committee notes). Furthermore, "[i]f a witness is testifying as an expert, and the party offering the expert testimony did not properly identify the witness as an expert, then the Court may preclude the testimony of that witness." *Lujan v. Cabana Mgmt., Inc.*, 284 F.R.D. 50, 77

(E.D.N.Y. 2012) (citing *United States v. City of New York*, No. 07–CV–2067 (NGG)(RLM), 2010 WL 2838386, at *2 (E.D.N.Y. July 19, 2010)). Thus, this Court is free to disregard Mr. Estepan's declaration in its entirety.

Sarepta grasps at a distinction between *Schonfeld* and *In re Pfizer* and the present dispute but comes up empty handed. While Sarepta astutely points out that *Schonfeld* lies outside the FOIA context, the case remains contextually applicable for expert testimony. *See* Sarepta's Br. at 53. Like the "expert" executive in *Schonfeld*, Mr. Estepan "failed to establish the high degree of correlation between [Sarepta] and the proffered firms . . . upon which the probative quality of this [economic cost] evidence depends." *Schonfeld v. Hilliard*, 218 F.3d 164, 174 (2d Cir. 2000). This Court in *Schonfeld* correctly rejected the same speculative market conditions testimony that Mr. Estepan offers here. *See id.* at 173–175.

Sarepta also asks this Court not to "throw the good out with the bad," as cautiously advised in *In re Pfizer*. *See* 819 F.3d 642, 665 (2d Cir. 2016); Sarepta's Br. at 54. That principle, established by this Court, is predicated on there being *some* meritorious evidence of competitive harm. As noted by Sarepta, the experts in *In re Pfizer* performed extensive economic analyses to arrive at their expert opinions, a fact conspicuously absent in Mr. Estepan's conclusory declaration. *See* Sarepta's Br. at 53–54; Estepan Decl. ¶¶ 22-43; Estepan 2d Decl. ¶¶ 27–42.

2. Even if Mr. Estepan Were a Proper Lay Witness, His Testimony is Outside His Own Perception.

While Mr. Estepan's declaration can be disregarded as inadmissible expert testimony, even if Mr. Estepan could properly be considered a lay witness, it was error to rely on his testimony because it was not based on his own perception. The district court erred in permitting Mr. Estepan to testify to actions he merely "supervises, rather than directly conducts." *Seife*, 2019 WL 1382724, at *2.

Lay witness opinions must be rationally based on the witness's perception. Fed. R. Evid. 701. Opinions within a witness's perception are cabined by the "familiar requirement of first-hand knowledge or observation." *Bank of China*, 359 F.3d at 182. Mr. Estepan's experience in "healthcare investing" and role as Sarepta's "Chief of Staff and Head of Corporate Affairs, overseeing Investor Relations, Corporate Communication, and Program Management," in which he supervised marketing operations, places his conclusions well outside any economic or scientific observation concerning the value of the disputed scientific disclosures. *See* Estepan Decl. ¶¶ 1–2; Estepan 2d Decl. ¶ 4. Mr. Estepan cites no observation he makes on *how* competitors could use the disclosed information. *See* Mem. of Law in Supp. re: 93 Mot. to Strike Doc. No. 72 Decl. of Ian Estepan, ECF No. 94, at 7–13. In place of first-hand knowledge or perception are conclusions only an expert can opine. *See* Fed. R. Evid. 701; *see also* Fed. R. Evid. 702. For these reasons, it was error for the district court to rely on Mr. Estepan's declaration.

C. The District Court Erred in Failing to Afford Professor Seife an Adversary Hearing.

If nothing else, this Court should remand and afford Professor Seife his right to a full evidentiary hearing on all genuine issues of material fact. Contrary to Appellees' assertion, this argument is not untimely nor was it waived. Seife did not raise the issue of an evidentiary hearing below because the district court ensured him that it would properly weigh all of the evidence, including by making credibility determinations. *See* Mem. Op. and Order re: Motions, ECF No. 129, at 3–4. Because the court failed to do so, Seife had no choice but to raise this issue on appeal.

This Court reviews issues raised for the first time on appeal when it is "necessary to avoid a manifest injustice or where the argument presents a question of law and there is no need for additional fact-finding." *Bogle-Assegai v. Connecticut*, 470 F.3d 498, 504 (2d Cir. 2006). If this Court does not reverse the district court outright, then remand for an evidentiary hearing is the only way to avoid manifest injustice. Whether a court should remand for an evidentiary hearing is a purely legal question and requires no additional fact-finding, which favors hearing an issue raised for the first time on appeal. *See Everytown for Gun Safety Support Fund v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 984 F.3d 30, 38 n.4 (2d Cir. 2020). Here, the only question is whether, under the Federal Rules of Civil Procedure and FOIA caselaw, Professor Seife had a right to a full evidentiary hearing. This is a question of law that must be answered in the affirmative.

Despite Sarepta's assertion that FOIA cases are "typically" resolved on motions for summary judgment, Sarepta's Br. at 43, "some FOIA cases require resolution of disputed facts." *See Animal Legal Def. Fund v. FDA*, 836 F.3d 987, 989–90 (9th Cir. 2016). Such hearings are warranted in FOIA cases where dueling affidavits contain disputed facts or factual discrepancies, as in this case. *See Long v. ICE*, 464 F. Supp. 3d 409, 417 (D.D.C. 2020). Here, the declarations directly contradict each other with regard to clinical study results, endpoints, and adverse events as well. *Compare* Estepan Decl. ¶¶ 29–33, *with* Lurie Decl. ¶¶ 24–25, *and* Lurie Reply Decl. ¶ 8; *compare* Estepan Decl. ¶ 37, *with* Lurie Decl. ¶ 23; *compare* Estepan Decl. ¶¶ 40–43, *and* Estepan 2d Decl. ¶¶ 32–33, *with* Lurie Reply Decl. ¶¶ 5–7.

At a minimum, Seife is entitled to a remand so that the district court can weigh the evidence and make credibility determinations at an evidentiary hearing.

IV. Because 21 C.F.R. § 20.61 is Not "Law" for the Purposes of the FIA, the FDA is Not Relieved of Its Obligation to Demonstrate Foreseeable Harm as to the Information at Issue on Appeal.

Appellees alternatively argue that no foreseeable harm inquiry is required because disclosure of the requested information is "prohibited by law." FDA's Br. at 24–26. Although the district court held that disclosure of only one category of information, "clinical study procedures," was prohibited by law,[4] Appellees maintain that disclosure of the remaining three categories of information at issue in this appeal is similarly

[4] As Appellees both acknowledge, Professor "Seife does not challenge this aspect of the district court's decision." Sarepta at 23; *see also* FDA's Br. at 13 n.3.

prohibited. *See* FDA's Br. at 26 n.8. They assert that an FDA regulation, 21 C.F.R. § 20.61, exempts the information at issue from disclosure such that disclosure is "prohibited by law" within the meaning of the FIA. FDA's Br. at 25. This argument is plainly incorrect.

The text of the FIA says that the foreseeable harm standard does not apply to information exempt under FOIA only where such disclosure is otherwise "prohibited by law." 5 U.S.C. § 552(a)(8)(A)(i). The FDA points to its *own regulations* providing that "[d]ata and information submitted or divulged to [FDA] which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure" to argue that disclosure of the information at issue is thus "prohibited by law" and therefore no foreseeable harm analysis is required. FDA's Br. at 25–26.

Appellees ask this Court to conclude that the FDA can avoid the foreseeable harm analysis required by the FIA simply by using its own regulations to define what is "prohibited by law." They argue that when Congress crafted the "prohibited by law" provision, it really meant prohibited by *regulation,* not *law.* Appellees' reading of the "prohibited by law" phrase as encompassing random statutes and their regulations would treat agency regulations or a statute mentioned in legislative history as authorizing withholding—effectively treating the "prohibited by law" provision as if it were a new exemption in the withholding subsection of FOIA. This is not only logically untenable but, as the U.S. Supreme Court held in the context of disclosure under TSA

regulations, agency regulations are not "law." *Dep't of Homeland Sec. v. MacLean*, 574 U.S. 383, 391 (2015).[5] While "prohibited by law" might in some instances be read to include agency regulations, the structure, history, and purpose of FOIA provide the "clear showing of contrary legislative intent" required to establish a narrower meaning of "law" that excludes agency regulations. *See id.*, 574 U.S. 383, 393–94 (2015) (citing *Chrysler Corp. v. Brown*, 441 U.S. 281, 295–96 (1979)). Furthermore, there is a strong presumption "against construing a statute as containing superfluous or meaningless words or giving it a construction that would render it ineffective." *See Auburn Hous. Auth. v. Martinez*, 277 F.3d 138, 146 (2d Cir. 2002) (quoting *United States v. Blasius*, 397 F.2d 203, 207 n.9 (2d Cir. 1968)). The "prohibited by law" provision in the FIA means a *law* passed by Congress—not an agency regulation.

[5] Not only is Appellees' argument inconsistent with the U.S. Supreme Court's analysis in *MacLean*, but it also inconsistent with how many states have interpreted their own open records laws with provisions analogous to FOIA's. *See, e.g. Zuckerman v. N.Y. Bd. of Parole*, 53 A.D.2d 405, 407 (N.Y. App. Div. 1976) ("exemptions can only be controlled by other *statutes*, not by *regulations* which go beyond the scope of specific statutory language."); *see also Indus. Found. of the S. v. Texas Indus. Accident Bd.*, 540 S.W.2d 668, 677 (Tex. 1976) ("While a rule may have the force and effect of a statute in other contexts, we do not believe that a governmental agency may bring its information within exception 3(a)(1) by the promulgation of a rule. To imply such authority merely from general rule-making powers would be to allow the agency to circumvent the very purpose of the Open Records Act."); *Wis. Newspress, Inc. v. Sch. Dist. of Sheboygan Falls*, 546 N.W.2d 143, 147 (Wis. 1996) ("[T]here are no blanket exceptions [to the open records law] other than those provided by the *common law* or *statute*." (emphasis added)).

CONCLUSION

For these reasons, this Court should reverse the decision of the District Court and conclude that Appellant is entitled to summary judgment.

Dated: September 23, 2021

Respectfully submitted,

Thomas S. Leatherbury
Vinson & Elkins
2001 Ross Avenue, Suite 3700
Dallas, TX 75201
Tel: (214) 220-7792
tleatherbury@velaw.com

/s/ Jared K. Carter
Jared K. Carter
Cortelyou C. Kenney
Lily A. Coad (*First Amendment Clinic Intern*)
First Amendment Clinic
Cornell Law School
Myron Taylor Hall
Ithaca, NY 14850
Tel: (207) 319-6050
jc2537@cornell.edu

David A. Schulz
Media Freedom & Information
Access Clinic
Yale Law School
P.O. Box 208215
New Haven, CT 06520
Tel: (203) 432-4366
david.schulz@yale.edu

Counsel for Plaintiff-Appellant Charles Seife

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Brief of Appellant Charles Seife, with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system on September 23, 2021.

All counsel of record in this case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Jared K. Carter

Jared K. Carter

Counsel for Appellant Charles Seife

Dated: September 23, 2021

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Local Rule 32.1(a)(4)(A) because it contains 6998 words, exclusive of the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). This brief complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Garamond and 14 point font.

/s/ Jared K. Carter

Jared K. Carter

Counsel for Appellant Charles Seife

Dated: September 23, 2021