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,

Intervenor-Defendant.

Case No. 1:17-cv-3960 (JMF)

November 4, 2019

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF CHARLES SEIFE'S COMBINED CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Regulations

Other Authorities

PRELIMINARY STATEMENT

This combined cross-motion for and in opposition to summary judgment by plaintiff Charles Seife (Seife) challenges the authority under the Freedom of Information Act (FOIA) of defendant Food and Drug Administration (FDA) to withhold key scientific information about Exondys 51: a controversially-approved, incredibly expensive, and potentially unsafe and ineffective drug.

The FDA approved the drug over the heated disapproval of scientific experts on the basis of what the President of the National Center for Health Research called "the skimpiest evidence [she had] ever seen in the approval of a drug," Zuckerman Decl. ¶ 15,[1] and despite a warning by the FDA's Director of the Office of Drug Evaluation that approval would "definitely" lead to "serious infections and possibly deaths," Seife Decl. ¶ 126, Kenney Decl., Ex. F, 22. The FDA departed so wildly from its regular procedures in approving Exondys 51 that the FDA's own scientists raised accusations of scientific impropriety and ethical misconduct, and, when the drug was approved, one top review-team scientist quit in protest while another appealed the approval to the FDA's commissioner. Seife Decl. ¶¶ 15-21, 30-40.

Despite serious questions about the drug's effectiveness and safety, intervenor-defendant Sarepta Therapeutics, Inc. (Sarepta), the drug's manufacturer, charges each patient over one million dollars per year to use it. Zuckerman Decl. ¶ 28; Kenney Decl., Ex. GG, 18. And Sarepta has yet to conduct the post-approval studies required to confirm Exondys 51's effectiveness, even though the

[1] All references to supporting declarations, exhibits, or attachments filed in conjunction with this memorandum of law have been updated and refer to present, re-filed declarations in support of this combined cross-motion and opposition, rather than the declarations in support of the previous summary judgment motions administratively terminated by this Court. To the extent this memorandum references declarations, attachments, or exhibits by the FDA or Sarepta, it refers for the Court's convenience to ECF numbers associated with those respective documents.

drug was approved over three years ago on the condition that such studies would occur. Failure to conduct these studies has led patients' families to suspect that "Sarepta doesn't want to know if [Exondys 51] really works" because its sales are bankrolling other products. Kenney Decl., Ex JJ, 13-18.

In this action, noted science writer and professor of journalism Charles Seife seeks to compel disclosure of key clinical trial data contained in the two studies upon which Exondys 51 was approved. The disclosure of this information will shed important light on whether the FDA followed statutory procedures in authorizing the sale of the drug and whether in approving Exondys 51 the FDA fulfilled its statutory mandate to protect public health and safety. This information is precisely the type of information needed to monitor agency action that Congress intended to make public under FOIA, and no proper basis exists for the FDA's refusal to disclose it.

Defendants' renewed summary judgment motions claim the information may be kept secret under FOIA's Exemption 4 as confidential "commercial or financial information" in light of the recent Supreme Court decision in *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356 (2019) (*FMI*). This is not so. As recognized by this Court in *NRDC v. EPA*, No. 17-CV-5928, 2019 WL 3338266 at *1 (S.D.N.Y. July 25, 2019) (Furman, J.), the government is obligated by FOIA amendments passed in 2016 to disclose even FOIA-exempt information unless doing so would cause a reasonably foreseeable harm to an interest the exemption seeks to protect. 5 U.S.C. § 552(a)(8)(A)(i) (2018). This obligation to demonstrate particular harm was not addressed in *FMI* because that case involved a pre-2016 FOIA request. This case involves a post-2016 request, but defendants fail to even mention their additional statutory burden.

As demonstrated below, defendants have not and cannot meet their new burden. They have not demonstrated that disclosing the information at issue is likely to cause the type of economic harm

Exemption 4 seeks to protect against, and certainly have not demonstrated foreseeable harm sufficient to vanquish entirely the public's basic right under FOIA to know "what [the FDA] is up to." *See DOJ v. Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 773 (1989). The FDA fails even to demonstrate that the information at issue falls within the scope of Exemption 4 in the first place. Contrary to defendants' contention, much of that information is not "confidential" within the meaning of Exemption 4 because it has not been customarily kept secret by Sarepta and is widely known within the industry.

Having failed to meet either of their two independent statutorily-required showings, defendants' motions for summary judgment should be denied and Seife's motion for summary judgement should be granted. The FDA should be ordered to disclose the withheld information underlying its approval of Exondys 51.

STATEMENT OF FACTS

A. The CSR Safety and Efficacy Information at Issue

The records at issue are reports of two clinical trials of Exondys 51 conducted by its manufacturer, Sarepta. These standardized clinical study reports, or CSRs, are required documents that every applicant for new drug approval must submit to the FDA. The FDA uses CSRs as its primary means for evaluating drugs, Lurie Decl. ¶ 14, per its statutory mandate to determine whether "drugs are safe and effective," 21 U.S.C. § 393(b)(2)(c)(B) (2018).

A CSR contains both a narrative summary of the clinical trial and underlying data about the drug's safety and effectiveness. Researchers across the board agree that CSR data is vital to public health and "relevant to clinical care." Kenney Decl., Ex. BB, 36. The European Union, which denied the approval of Exondys 51, proactively releases CSRs after all regulatory decisions, regardless of

approval, to promote greater accountability in medicine, and has already released much or most of the information at issue in this case. Seife Decl. ¶¶ 44, 119; Kenney Decl., Ex. AA. The public interest in disclosing Sarepta's withheld information is particularly compelling given the significant controversy surrounding Exondys 51's approval.

B. The Controversy Surrounding the Approval of Exondys 51

Exondys 51 was developed to treat Duchenne Muscular Dystrophy (Duchenne), a fatal neuromuscular disorder that primarily affects young boys and adolescents and is believed to be caused by a lack of the protein dystrophin. Seife Decl. ¶ 9. Sarepta sought accelerated approval for the drug based primarily on two clinical trials involving a total of just twelve patients, Study 201 and Study 202.[2] *Id.* ¶¶ 10, 13.

Sarepta's public lobbying campaign for approval of Exondys 51 began with misinformation. In Sarepta's initial reports, researcher Dr. Jerry Mendell claimed that the drug had brought patients' proportion of dystrophin-expressing muscle fibers to within 47% of normal after 48 weeks of treatment. Kenney Decl., Ex. N; Seife Decl. ¶ 11. Because patients with Duchenne typically have dystrophin levels that are less than 1% of normal, an actual 46 percentage point increase within a year of treatment would have signaled a breakthrough. *Id.*; Kenney Decl., Exs. E, 3-4 & D, 20. Sarepta trumpeted this initial finding in a press release that received great attention and generated widespread

[2] Study 201 was a single-center, double-blinded, randomized-controlled trial involving twelve patients with Duchenne, four of whom received a placebo. Seife Decl. ¶ 10. This study used the change in the percentage of dystrophin-positive fibers over time as a surrogate marker, or proxy, for neuromuscular health by analyzing the levels of dystrophin in patients. *Id.* Researchers also measured the distance patients walked in a 6-minute walk test (6MWT). *Id.* After twenty-four weeks, the four patients initially given placebos were then given a regimen of Exondys 51. *Id.* After forty-eight weeks, the study was extended to an "open-label phase," meaning that all test-givers and all patients were aware that all patients were receiving the study drug. *Id.* This extended phase was Study 202. *Id.*

hope in the Duchenne community that Exondys 51 provided a miracle cure. Seife Decl. ¶ 11; Kenney Decl., Exs. O, 3 & F, 16.

The internal FDA team disagreed. FDA review team scientists tasked with reviewing the CSR data questioned Sarepta's interpretation of the study results. One of the lead reviewers on the team, Dr. Ronald Farkas, expressed "strong doubts" about the accuracy of Sarepta's findings and concerns about possible "scientific misconduct" and results that appeared to "have been heavily manipulated photographically." Seife Decl. ¶¶ 14, 40; Kenney Decl., Exs. L & GG, 9. After requesting and reviewing Sarepta's interim results from a third ongoing trial of the drug, Study 301, five separate FDA offices *uniformly* recommended against approval. Seife Decl. ¶ 14; Kenney Decl., Ex. D, 4. Separately, the FDA Advisory Committee—a team of outside experts tasked with reviewing the drug—was unconvinced and voted not to approve the drug despite enormous lobbying to greenlight it. Seife Decl. ¶ 13; Kenney Decl., Ex. GG, 21.

At this point, something extraordinary happened: Dr. Janet Woodcock, head of the Center for Drug Evaluation and Research (CDER), intervened and acted on her own to approve the drug. Seife Decl. ¶ 15; Kenney Decl., Ex. E. In taking this step, Dr. Woodcock expressed concern that Sarepta's "stock went down after the [Advisory Committee] meeting" and worried that Sarepta "needed to be capitalized"—extra-statutory factors that are inappropriate when evaluating a drug's safety and efficacy. Seife Decl. ¶ 16; Kenney Decl., Ex. G, 17. Although Dr. Woodcock later denied to then-Commissioner Robert Califf that these financial concerns influenced her decision, Seife Decl. ¶ 16; Kenney Decl., Ex. H, 10, n.23, concerns persisted that Dr. Woodcock only approved the drug in response to external pressures, Seife Decl. ¶ 16; Zuckerman Decl. ¶ 24-25.

Dr. Ellis Unger, Director of the Office of Drug Evaluation-I, disagreed with Dr. Woodcock so vehemently that he appealed her decision to an FDA scientific review body. Seife Decl. ¶ 17;

Kenney Decl., Ex. F. Dr. Unger called attention to procedural flaws in the approval process, including that Dr. Woodcock made clear to the review team that she intended to approve Exondys 51 before she had read the review memoranda. Seife Decl. ¶ 17; Kenney Decl., Ex. F, 27. Dr. Unger also challenged Dr. Woodcock's analysis of the Sarepta studies, Seife Decl. ¶ 18; Kenney Decl., Ex. F, 5-7. Through his own statistical analyses, Dr. Unger demonstrated that the dystrophin increases that Sarepta had reported did not correlate with measures of patient muscle health, meaning that the drug had produced no meaningful clinical result. Seife Decl. ¶ 18; Kenney Decl., Ex. F, 17-20. In contrast to the lack of evidence of efficacy, Dr. Unger underscored the "certain" risk of side effects from the drug, including possible death from infection caused by the drug's method of administration. Seife Decl. ¶ 19; Kenney Decl., Ex. F, 22. In his view, the drug was merely an "elegant placebo" that would give vulnerable patients "false hope in exchange for hardship and risk." Seife Decl. ¶ 19; Kenney Decl., Ex. F, 22. Dr. John Jenkins, Director of the FDA's Office of New Drugs, agreed with Dr. Unger. He found "no rational basis" to approve Exondys 51 and urged that doing so would "def[y] any sense of scientific reason." Seife Decl. ¶ 33; Kenney Decl., Ex. I, 3.

The appeals committee confirmed that Dr. Woodcock "orally communicated her intention to grant accelerated approval" before reading the review team's draft memorandum, and before data from the ongoing Study 301 had even been requested. Kenney Decl., Ex. G, 23. The committee concluded that a further independent scientific review of the drug was necessary. *Id.* The head of the committee (and Acting Chief Scientist of the FDA) wrote separately to express support for Dr. Unger's view of the problems with Sarepta's science. He further faulted Sarepta for "misleading communications" that "led to unrealistic expectations and hope for [Duchenne] patients and their families." *Id.* at 26-28.

In yet another extraordinary turn of events, then-FDA Commissioner Robert Califf upheld Dr. Woodcock's approval decision despite the appeals committee's opinion. Even though Commissioner Califf found flaws in Sarepta's clinical trials that "made it impossible to use much of the resulting data as reliable evidence in regulatory decision-making," *id.*, Ex. H, 5, and even though he called for Sarepta to correct or retract Dr. Mendell's original dubious claims, he nonetheless approved the drug, *id.* at 12, n.28; Kenney Decl., Ex. M.

C. Background to This Lawsuit and Procedural History

Exondys 51's unprecedented approval provoked an outcry in the scientific community and generated intense media coverage. It was reported by *The Washington Post*, *The New York Times*, *NPR*, *Forbes*, and *STAT* (a news site run by the *Boston Globe*) and criticized in at least one major medical journal. Seife Decl. ¶ 23; Kenney Decl., Ex. GG, 23-24. If ever there were a need for full transparency around the basis of the FDA's action, it is in this case of the approval of Exondys 51.

As an investigative reporter with a focus on science, data and mathematics, Seife followed the Exondys 51 approval process closely and began his own journalistic investigation into its highly unusual approval. Seife Decl. ¶¶ 4, 8, 23-25. He identified several categories of information held by the FDA that would be relevant to understanding whether the FDA approved the drug according to statutory criteria for safety and efficacy, or whether it had pushed Exondys 51 through for other reasons, such as the improper influence allegedly exerted by Dr. Woodcock and her Deputy Director, Dr. Richard Moscicki. *Id.* ¶ 24. Seife also identified specific undisclosed information needed to assess the validity of the competing claims about the trial results reported in the CSRs for Study 201 and Study 202. *Id.* ¶ 42.

Seife then drafted a FOIA request for the information he needed and submitted it to the FDA in December 2016. *Id.* ¶ 26. The FDA denied his request for expedited processing and failed to

produce any documents for nearly six months. *Id.* Seife then filed this lawsuit on May 25, 2017. *Id.* ¶ 27; Compl., ECF No. 1. Seife promptly moved for summary judgment on his right to expedited processing. Mot. for Partial Summ. J., ECF No. 16. In response to that motion, on July 11, 2017, this Court: (1) ordered disclosure by July 24, 2017 of one internal document (the Jenkins memo); and (2) referred the parties to Magistrate Judge Ellis for settlement talks. *See* ECF Nos. 29 & 30. After those settlement talks, the FDA agreed to a production schedule, which the Court approved on July 27, 2017. Stipulation and Order, ECF No. 39. Thereafter, on September 15, 2017, Sarepta filed an unopposed motion to intervene, ECF No. 44, which the Court granted, ECF No. 47.

Defendants filed motions for summary judgment on April 6, 2018, defending the FDA's withholding of the information at issue as exempt from disclosure under FOIA's Exemption 4. ECF Nos. 69, 70, & 74. On May 29, 2018, Seife filed a cross-motion for summary judgment seeking an order to compel the FDA to release the requested information. ECF No. 85. While these motions were pending, the Supreme Court granted certiorari in a case involving FOIA's Exemption 4: *Food Marketing Institute v. Argus Leader Media.* On March 27, 2019, this Court issued an order finding defendants had erroneously withheld public information and requiring the FDA to review and revise its redactions. *Seife v. FDA*, No. 17-CV-3960, 2019 WL 1382724 (S.D.N.Y. Mar. 27, 2019) (Furman, J.). The Court then stayed resolution of the summary judgment motions pending the Supreme Court's decision in *FMI*. *Id. At* *1 n.1 (noting the instant case involves "a request governed by the statute as amended in 2016," though postponing a full ruling until after *FMI*).

The Supreme Court issued its opinion on June 24, 2019, clarifying the agency's burden to establish that information falls within the scope of Exemption 4's discretionary authority to deny public access. 139 S. Ct. 2356. Pursuant to this Court's March order, both parties proposed to submit supplemental briefing, and a schedule was set on August 2, 2019. ECF No. 137.

ARGUMENT

As described below, the FDA must make *two* independent statutorily-required showings to justify a refusal to disclose information. It has only attempted to make one of them, and fails even at that.

I. THE FDA MUST MEET TWO STATUTORY BURDENS TO WITHHOLD THE INFORMATION AT ISSUE

Both the purpose and plain language of FOIA create a "strong presumption in favor of disclosure." *U.S. Dep't of State v. Ray*, 502 U.S. 164, 173 (1991). FOIA provides nine "limited exemptions" to disclosure, but these specific exemptions "do not obscure the basic policy that disclosure, not secrecy, is the dominant objective of the Act." *Dep't of Air Force v. Rose*, 425 U.S. 352, 361 (1976). Consequently, the exemptions "must be narrowly construed" to preserve FOIA's core purpose. *Id.* If the FDA seeks to avoid FOIA's requirement of disclosure, it bears the burden of demonstrating that an exemption applies. *See Ray*, 502 U.S. at 173.

Under Exemption 4, the FDA may withhold "commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. § 552(b)(4). To qualify as "confidential" as defined in *FMI*, the FDA must demonstrate that the withheld information is "customarily and actually treated as private by its owner and provided to the government under an assurance of privacy." 139 S. Ct. at 2366.

Yet it is no longer enough that the FDA prove that commercial or financial information is confidential to withhold it under Exemption 4. In 2016, Congress raised the bar for withholding records even higher by passing the FOIA Improvement Act. Pub. L. No. 114-185, § 2, 130 Stat. 538 (codified as amended at 5 U.S.C. § 552 (2018)). Under this amendment, the FDA can no longer withhold information under any exemption unless "the agency" also shows that it "reasonably foresees

that disclosure would harm an interest protected by [that] exemption." 5 U.S.C. § 552(a)(8)(A)(i).[3] Termed the "'foreseeable harm' standard," *Rosenberg v. DOD.*, 342 F. Supp. 3d 62, 72 (D.D.C. 2018), this amendment requires that an agency now "release a record—*even if* it falls within a FOIA exemption—if releasing the record would not reasonably harm an exemption-protected interest," *id.* at 73 (emphasis added); *see also Judicial Watch, Inc. v. U.S. Dep't of Commerce*, 375 F. Supp. 3d 93, 100 (D.D.C. 2019) ("[E]ven if an exemption applies, an agency must release the document unless doing so would reasonably harm an exemption-protected interest.").

Although the Supreme Court did not—and indeed, could not—address the foreseeable harm standard in its *FMI* opinion, the standard applies to cases involving Exemption 4 that arise after the 2016 amendment became effective, like this one. The litigation that led to the Court's decision in *FMI* began in 2011, five years before the amendment took effect on June 30, 2016. §1, 130 Stat. at 538. Thus, the Court's statements in *FMI* shape the agency's Exemption 4 burden, but the opinion provides no guidance on the foreseeable harm analysis. And although the Court determined that Exemption 4 did not have a built-in harm analysis prior to the amendment, Congress unambiguously required agencies to demonstrate foreseeable harm when it amended FOIA.

Since the 2016 amendment applies here, this Court must determine if defendants have met two independent and equally dispositive burdens. Defendants must show that the records fall within Exemption 4 *and* that their release will foreseeably harm an interest protected by this exemption. When determining whether the agency has met these two burdens—as with any decision about whether an agency has "improperly withheld" a record—"the court shall determine the matter *de novo*."

[3] The statute excepts from the foreseeable harm standard cases in which "disclosure is prohibited by law," § 552(a)(8)(A)(i)(II), an exception that does not apply here.

5 U.S.C. § 552(a)(4)(B). Under the *de novo* standard, "[t]he agency's decision that the information is exempt from disclosure receives no deference." *Bloomberg, L.P. v. Bd. of Governors of the Fed. Reserve Sys.*, 601 F.3d 143, 147 (2d Cir. 2010) (citing *Reporters Comm.*, 489 U.S. at 755). And, in a motion for summary judgment under FOIA, the agency bears the burden to introduce evidence "sufficient to afford the FOIA requester a meaningful opportunity to contest, and the district court an adequate foundation to review, the soundness of the withholding." *New York Times Co. v. DOD*, 499 F. Supp. 2d 501, 509 (S.D.N.Y. 2007) (quoting *Campbell v. DOJ*, 164 F.3d 20, 31 (D.C. Cir. 1998)). Here, defendants fail to meet both of their burdens.

II. DEFENDANTS FAIL TO ESTABLISH THAT DISCLOSURE OF THE DISPUTED INFORMATION WILL FORSEEABLY HARM AN "INTEREST PROTECTED BY" EXEMPTION 4

A. The 2016 Amendments Impose a Significant New Burden on the FDA

Because this case involves a FOIA request made after the effective date of the 2016 amendments, it is governed by the new foreseeable harm standard.[4] This requires the FDA to demonstrate a high likelihood of harm to an interest protected by Exemption 4 sufficient to outweigh FOIA's core objective of informing the public about "what the government is up to."

1. The agency must provide independent and meaningful evidence that disclosure will cause reasonably foreseeable harm.

This Court's own jurisprudence recognizes that the "foreseeable harm" standard created by the 2016 amendments imposes "an *independent* and *meaningful* burden on agencies" beyond that required to meet an exemption. *NRDC*, 2019 WL 3338266, at *1 (emphasis added). Other federal district

[4] This Court has already noted the applicability of the 2016 amendments in this case. *Seife*, 2019 WL 1382724, at *1 n.1. *See also* Compl., Ex. 1, ECF No. 1 (FOIA request dated December 5, 2016); Pl.'s Mot. for Summ. J. 12, ECF No. 86 (citing 5 U.S.C. § 552(a)(8)(A)(i)); Pl.'s Reply Mem. 11, ECF No. 112 (same); Letter Notice of Grant of Cert. of FMI, n.1, ECF No. 128 (same).

courts have uniformly applied foreseeable harm as its own, additional requirement in cases arising after the amendments. *See*, *e.g.*, *Judicial Watch*, 375 F. Supp. 3d at 99-100; *Rosenberg*, 342 F. Supp. 3d at 77-79; *Ecological Rights Found. v. Fed. Emergency Mgmt. Agency*, No. 16-CV-05254-MEJ, 2017 WL 5972702, at *6 (N.D. Cal. Nov. 30, 2017).

To meet this "*independent* and *meaningful* burden," *NRDC*, 2019 WL 3338266, at *1 (emphasis added), the agency must introduce evidence that contains far more than mere perfunctory or "boiler plate" statements of harm. *See Judicial Watch*, 375 F. Supp. 3d at 100; *Rosenberg*, 342 F. Supp. 3d at 79. It must instead set forth detailed information that "explain[s] how a particular . . . withholding would harm" the interest protected by the exemption. *Rosenberg*, 342 F. Supp. 3d at 78 (citing *Ecological Rights Found.*, 2017 WL 5972702, at *1). This requires a robust evidentiary showing, and courts have readily denied summary judgment when agencies could not establish a specific harm that disclosure would cause. *See, e.g.*, *Judicial Watch*, 375 F. Supp. 3d at 101 (denying summary judgment where the agency "failed to satisfactorily show" that disclosure "would result in reasonably foreseeable harm"); *see also Rosenberg*, 342 F. Supp. 3d at 79; *Ecological Rights Found.*, 2017 WL 5972702, at *6.

2. The harm must be likely to result from disclosure and material or tangible.

Grammatically, the adverb "reasonably" controls the scope of "reasonably foreseeable" harm required by the 2016 amendments. Without "reasonably," an agency would be able to withhold information for any theoretically foreseeable harm, reasonable or not. Although undefined in FOIA, the plain meaning of "reasonably" is "to a fairly high degree, level, or standard."[5] "Foreseeable" is

[5] Macmillan's Online Dictionary, https://www.macmillandictionary.com/us/dictionary/american/reasonably (last visited Nov. 1, 2019). *See also* Merriam-Webster's Online Dictionary, https://www.merriam-webster.com/dictionary/reasonably (last visited Nov. 1, 2019) (providing a legal definition of "reasonable" as "of an appropriate degree or kind" or "applying reason or logic.").

defined as "the characteristic of an event making it one to be anticipated." *Foreseeable*, *Ballentine's Law Dictionary* (3d ed. 1969). And Black's Law defines "harm" as an "injury, loss, damage; material or tangible detriment." *Harm*, *Black's Law Dictionary* (11th ed. 2019). Thus, read together, "reasonably foreseeable harm" requires harm that is *likely* to result from disclosure and that is also "material" and "tangible." *Id.* Accordingly, in order to satisfy the "reasonably foreseeable harm" standard in this case, the FDA is required to show that some tangible and material harm to an interest protected by Exemption 4 is likely to result from disclosure of the withheld CSR information.

3. The agency must independently substantiate third-party claims of foreseeable harm.

The plain text of the 2016 amendments also means that "the agency" itself—as opposed to a third-party information submitter—be the entity to "reasonably foresee[]" a harm. § 552(a)(8)(A)(i). Accordingly, in the context of Exemption 4, the agency must demonstrate that this burden is satisfied and verify in some meaningful manner claims made by an information submitter. This approach gives meaning to the word "agency" and follows the "cardinal rule" of statutory interpretation to give meaning to every word in a statute, *Nielsen v. Preap*, 139 S. Ct. 954, 969 (2019) (quoting *Kungys v. United States*, 485 U.S. 759, 778 (1988) (Scalia, J.) (plurality opinion)), as well as the textualist approach taken in *FMI*, 139 S. Ct. at 2363-65.

The requirement that the agency itself bear the burden of establishing foreseeable harm also furthers FOIA's core purpose of "know[ing] what the[] government is up to." *Reporters Comm.*, 489 U.S. at 773 (internal quotation marks omitted). Due to inherent information asymmetries between the FOIA-requester and the government, the government can access, process, and understand information that the requester or third parties cannot. *See Vaughn v. Rosen*, 484 F.2d 820, 824-26 (D.C. Cir. 1973). Naturally, the federal records that the public requests may, as here, contain information

that agencies may want to hide. *See Jones v. FBI*, 41 F.3d 238, 242-43 (6th Cir. 1994). Thus, to provide for meaningful adversarial review, the agency should be required to make clear how it has verified and substantiated claims of foreseeable harm, and the court, where necessary, should exercise its power of *in camera* review in conducting the *de novo* review of withholdings that FOIA requires. § 552(a)(4)(B). This approach accords with existing Second Circuit caselaw that a failure to submit "reasonably detailed explanations of why material was withheld" "[a]bsent a sufficiently specific explanation" impairs "the adversary process envisioned in FOIA litigation." *Halpern v. FBI*, 181 F.3d 279, 295 (2d Cir. 1999).[6]

That said, this Court need not address the exact mechanics of how an agency must substantiate an information submitter's claim of foreseeable harm because the FDA has not even attempted to do so here.[7] *See* Sherwood 2d Decl., Exs. 1 & 3, ECF No. 144 (reintroducing the original evidence of Ian Estepan); *but see* FDA Notice of Mot. Summ. J., ECF No. 145 (stating motion's reliance on FDA's

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[6] The requirement that the agency independently substantiate claims of "foreseeable harm" is also similar to other agency law contexts involving health and safety or environmental regulations. For example, the Bureau of Land Management is required by the "General Conformity Rule" to review the emissions related to a project's potential effects, and, if the EPA can "reasonably foresee more than *de minimis* [emissions]," the EPA has to perform a more detailed analysis. *WildEarth Guardians v. U.S. Bureau of Land Mgmt.*, 322 F. Supp. 3d 1134, 1141 (D. Colo. 2018) (citing 40 C.F.R. §§ 51.851, 93.150–93.165). There, whenever the EPA foresees more than *de minimis* harm, its obligation to review independently is triggered. *Id.* Where it foresees harm, the EPA is required to conduct a detailed investigation. *See id.*

[7] As Seife demonstrated in previously objecting to the Estepan testimony, he lacks any particular knowledge or expertise to support most of his conclusions about foreseeable harm. *See* Obj. to Decl. of Ian Estepan and Mot. to Strike, ECF No. 94; *see also* Pl.'s Combined Reply Mem. of Law in Further Support of (1) Pl.'s Cross Mot. for Summ. J. and (2) Pl.'s Mot. to Strike, ECF No. 112. Mr. Estepan is a marketing professional and healthcare investor who nonetheless opines at length about highly technical and scientific matters, including the scientific and regulatory utility of certain types of data to competing scientists. Estepan Decl., ECF No. 72; Estepan 2d Decl., ECF No. 105. Seife objected to the Estepan Declarations in their entirety, and in particular ¶¶ 18, 22-28, 29-33, 34-39, 40-43, 44-60 of the Estepan Declaration, as well as the numerous conclusory and speculative statements throughout. *See* ECF No. 94, 7-20; ECF No. 112, 13-19. The Court determined that "many of [these] arguments . . . go to credibility rather than admissibility," and that it would "resolve [these] challenges to the particular paragraphs of the declarations when deciding the parties' motions for summary judgment." 2019 WL 1382724, at *2-4.

previous declarations from Nancy Sager and Howard Philips but not resubmitting them despite court order to do so). Neither Sarepta nor the FDA *once* mention in their supplemental briefs the question of foreseeable harm, despite being on notice that the 2016 amendments apply here.[8] Given their failure to satisfy this burden, neither the FDA nor Sarepta should have a free opportunity to introduce new evidence to meet their initial moving burden under Rule 56, which, in FOIA cases, is designed to give the requester a meaningful ability to respond.

B. The "Interest Protected by" Exemption 4 Is the Submitter's Intangible Property Interest

Under the 2016 amendments, defendants must also demonstrate that disclosing the withheld information would harm the "interest protected by" Exemption 4. § 552(a)(8)(A)(i). Exemption 4 permits the withholding of "trade secrets and commercial or financial information obtained from a person and privileged or confidential." § 552(b)(4). To determine the "interest protected by" Exemption 4, the court must undergo a "careful examination of the ordinary meaning and structure of the [exemption] itself." *FMI*, 139 S. Ct. at 2364. As the structure and meaning illustrate, the "interest protected by" Exemption 4 is best understood as an interest in intangible property—namely the economic value derived from trade secrets or commercial or financial information—and the harm to that interest is best measured as the diminution in value of that information that would result from its disclosure.

First, looking to the structure of Exemption 4, it protects multiple forms of intangible property—be they trade secrets (which are not at issue in this case)[9] or confidential "commercial or

[8] Counsel for Seife flagged both orally and in writing that foreseeable harm would be central to Seife's cross-motion for summary judgment in late July 2019 before finalizing the briefing schedule, and even voluntarily provided a brief authored by counsel advancing similar arguments. Kenney Decl. ¶¶ 12-13.

[9] The parties stipulated that the information at issue falls under the umbrella of commercial information, and does not involve trade secrets. *See* Joint Letter on Issues to Be Addressed in Cross Mots. for

financial" information. Under well-accepted canons of construction, the phrases "trade secrets" and "commercial or financial information" within the Exemption are not read in isolation. *See U.S. Nat. Bank of Oregon v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) ("Over and over we have stressed that [i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.") (internal quotation marks omitted); *see also Abuelhawa v. United States*, 556 U.S. 816, 819 (2009) (noting the "rule that[] . . . statutes are not read as a collection of isolated phrases"). It also is blackletter law that trade secrets and commercial information are forms of intangible property. *See Carpenter v. United States*, 484 U.S. 19, 26 (1987) ("Confidential business information has long been recognized as property."); *Speedry Chem. Prods., Inc. v. Carter's Ink Co.*, 306 F.2d 328, 330 (2d Cir. 1962) ("There is a 'property right' in trade secrets, which may be protected against those who acquire and use the knowledge thereof wrongfully.").

Second, the text of Exemption 4—specifically the phrase "commercial or financial information" at issue here—also supports the reading that the "interest" protected by Exemption 4 is fundamentally economic in nature. Since FOIA does not define "commercial," it must be interpreted looking to its "ordinary, contemporary, common meaning." *FMI*, 139 S. Ct. at 2362 (citation omitted). At the time FOIA was enacted, "commercial" was defined as "[o]f, relating to, or engaged in commerce; mercantile"; "[p]roduced in large quantities for industry"; and "[h]aving financial gain as an object." *Commercial*, Standard College Dictionary (1963); *see also Am. Airlines, Inc. v. Nat'l Mediation Bd.*, 588 F.2d

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Summ. J., ECF No. 65; Sarepta's Suppl. Mem. Summ. J. at 11, ECF No. 140; FDA's Suppl. Mem. Summ. J. at 8, ECF No. 146. Although Sarepta now suggests that it does consider the information as "trade secrets," Verni Decl. ¶ 7, ECF No. 143, it is bound by the earlier stipulation, and, in any event, precedent holds that clinical trial data does not qualify as trade secrets under Exemption 4. *See Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983)

863, 870-72 (2d Cir. 1978) ("'Commercial' surely means pertaining or relating to or dealing with commerce."). Applying this definition, in *New York Public Interest Research Group. v. EPA*, this Court concluded that Exemption 4 could not be invoked to justify withholding because the term "commercial" did not encompass information where defendants "failed to establish that the information ha[d] any intrinsic value." 249 F. Supp. 2d 327, 334 (S.D.N.Y. 2003). This interpretation accords with the above—that the interest protected by Exemption 4 relates to the intrinsic value of the withheld *information itself*.

Accordingly, to measure the "harm" to the commercial interest protected by Exemption 4, this Court should look to the loss of value of the intangible property to the property holder. Although there are multiple metrics to measure this loss in value, the most common is the depreciation of the intangible property itself. For example, the Second Circuit has stated that "[t]he amount of damages recoverable in an action for misappropriation of trade secrets may be measured either by the plaintiff's losses, or by the profits unjustly received by the defendant." *A.F.A. Tours, Inc. v. Whitchurch*, 937 F.2d 82, 87 (2d Cir. 1991) (citations omitted).

In sum, both the structure and ordinary meaning of Exemption 4 make clear that to withhold the requested information, defendants must demonstrate that disclosure would result in a reasonably foreseeable harm measured by a diminution in value of the information at issue to Sarepta. Defendants have not and cannot make this showing, as demonstrated below.

C. Defendants Fail to Show that Disclosure Would Inflict on Sarepta a Harm of the Type Exemption 4 Seeks to Prevent

Defendants must demonstrate that disclosure of the withheld information would cause some tangible and material harm to a property interest of Sarepta. Just as Sarepta's conclusory claims were insufficient to show a competitive harm under the *National Parks* standard in the last round of

summary judgment briefing, so too are they insufficient to show a reasonably foreseeable harm now. The harm from disclosure put forth by Sarepta can primarily be measured in four categories, and there is insufficient evidence of *any* harm to justify withholding.[10]

1. Study procedures.

Disclosure of Sarepta's study procedures would not cause a commercial harm to Sarepta by allowing competitors to "copy Sarepta's study design, or selectively modify it." 2d Sherwood Decl. Ex. 1 ¶ 23. In fact, Seife has made clear that he does not seek step-by-step clinical protocol details, Seife Decl. ¶ 50; rather, he seeks the narrative description of the tests conducted and their results presented in the CSRs, Seife Decl. ¶¶ 43, 63-64, 91. Even if Seife *were* seeking the protocols, Sarepta cannot point to a single court that has barred their disclosure, and for good reason: Courts that have considered the issue have concluded that such protocols do not fall within Exemption 4 and that a public interest in their release must be taken into account. *See, e.g.*, *Pub. Citizen Health Research Grp. v.*

[10] Sarepta's contention that disclosure would cause harm also rests on the argument that competitors could use the information to "bypass the years of expensive trial and error work that Sarepta undertook," 2d Sherwood Decl. Ex. 1 ¶ 25, or to develop a "historical external control set," *id.* ¶ 33. Estepan claims that publicizing Sarepta's study results would "grant Sarepta's competitors the benefit of having conducted a clinical study of [Exondys 51] without actually having done so." *Id.* ¶ 29. Additionally, he asserts that release of this information "will free Sarepta's competitors from a years-long process of building the necessary understanding to meaningfully study drugs of this kind." *Id.* ¶ 43.

However, the argument that Sarepta has spent time developing a drug falls far short of demonstrating that it will suffer a reasonably foreseeable harm as a result of disclosure. Indeed, even under the earlier competitive harm standard, the argument that CSR disclosure may cause harm by providing competitors with a "road map" has been rejected. *See Teich v. FDA*, 751 F. Supp. 243, 253 (D.D.C. 1990). In *Teich*, the court rejected the argument that disclosure of protocols and test results would cause harm by "facilitating its competitors' safety testing" and providing a "road map" to competitors, thus "taking advantage of the research funds and time" that the company had expended. *Id.* at 253. The court found it "inconceivable that disclosure of the protocols and results alone will facilitate a competitor's premarket approval application" because the competitor must submit "not only the protocols and test results, but the raw data supporting those results." *Id.* Sarepta's competitors are similarly required to submit their own safety and efficacy data to the FDA to win approval for any new drug application. 21 U.S.C. § 355.

FDA, 964 F. Supp. 413, 416 (D.D.C. 1997); Dkt. Entry #45, 1:96-CV-01650 (ordering protocols released).

Sarepta originally argued, albeit without any evidentiary support, that disclosure of its discussion of dystrophin in the narrative portion of the CSR would allow competitors to know exactly how Sarepta obtained this measurement. Sarepta's Corrected Summ. J. Mem. at 18, ECF No. 78. However, Sarepta has failed to explain what was unique or unknown to the industry about the techniques it used. Additionally, Sarepta has made no claim that disclosure of these narrative descriptions would cause Sarepta *itself* to suffer any commercial harm from loss of value of the information as opposed to third parties benefiting, which is required under the 2016 amendments.[11]

2. Study results.

Disclosure of Sarepta's study results is unlikely to benefit Sarepta's competitors because Seife seeks only de-identified data that cannot be used for commercial purposes and can only be used to further public health. *See* Seife Decl. ¶¶ 108, 117, 148, 150, 155; *see also* Lurie Decl. ¶ 25. Estepan, Sarepta's initial declarant from the last round of briefing, asserts that "de-identified patient-level study results . . . could be useful for purposes of powering a clinical trial" or be used as a "historical control set." 2d Sherwood Decl., Ex. 1 ¶¶ 29-33 (attaching Estepan declaration); 2d Sherwood Decl., Ex. 3 ¶ 34 (attaching second Estepan declaration). By "de-identified," Estepan refers to patient data lacking only names and patient identifying numbers. But Seife is requesting data lacking *all* patient demographic information. Lurie Decl. ¶¶ 30, 33. Estepan argues that competitors would be better able to "retrospectively" design its clinical trials, noting that "patient age is a critical factor," 2d

[11] Sarepta's other original example of useful information, concerning its dosing procedures (Bates FDACDER_SAR 00021640), is from a redaction that Seife has agreed to forgo requesting. Seife Decl. ¶ 49.

Sherwood Decl. Ex. 1 ¶ 28, but patient age would not be included in the information Seife requests. Dr. Lurie—a medical doctor and epidemiologist with thirty years of experience in public health and clinical trial design—states that de-identified data, lacking all patient demographic information, cannot be used by competitors as a historical control in "any meaningful way." Lurie Decl. ¶ 31. This is because, as Sarepta acknowledges, 2d Sherwood Decl. Ex. 1 ¶ 33, the FDA has imposed stringent guidelines for Duchenne trials, including the requirement that patients be compared to a demographically similar population. Lurie Decl. ¶¶ 32.

Even if competitors could conceivably use this data in some way, they could not use the information for their own drug approval. As Dr. Lurie explains, the competitors' drugs "are different compounds, with different pharmacological profiles and different absorption rates" that would require separate clinical trials. *Id.* ¶ 25. In addition, drug manufacturers are given a period of "data exclusivity" preventing others from relying on the same data for submission in their drug approval applications.[12] In this case, Exondys 51 is entitled to seven years of data exclusivity because it is an "orphan drug." 21 U.S.C. §§ 360bb, 360cc. Finally, any claim that Sarepta's competitors could benefit from disclosure by using Sarepta's data in its own studies rests on the assumption that Sarepta's research and drug approval proceeded without misconduct. If its study and approval processes were flawed, or if the drug is ineffective, competitors would not benefit from this data in the slightest.

[12] The FDA has two provisions governing new drug applications: 21 U.S.C. §§ 355(b)(1) and (b)(2). Section 355(b)(1) requires applicants 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). Section 355(b)(2) allows applicants to rely on other applicants' investigations, even where the applicant does not have a right or reference, provided that the applicant certifies that no valid patents cover the drugs for which the investigations were conducted. § 355(b)(2). Because there are patents on the drug, 21 U.S.C. § 355(b)(2) is inapposite.

Sarepta also asserts, without evidentiary basis, that it will be harmed as a result of disclosure because competitors could use the information in marketing campaigns. 2d Sherwood Decl. Ex. 1 ¶ 32. Specifically, Estepan states that competitors could use the data to claim that their products are superior, or to "characterize [Sarepta's data] in the most unfavorable light possible." *Id.* However, fear of speculative reputational harm that competitors' marketing campaigns could have is irrelevant to the question of whether disclosure would harm the interest protected by Exemption 4. Sarepta must show that disclosure would cause a diminution in value of the withheld information—which these marketing campaigns would not.

Additionally, since FOIA is meant to enlighten the public about possible government misconduct, *Nat'l Archives & Records Admin. v. Favish*, 541 U.S. 157, 171-72 (2004), the argument that these marketing campaigns would cause "reputational harm" is insufficient to justify withholding the information, *see Gen. Elec. Co. v. U.S. Nuclear Regulatory Comm'n*, 750 F.2d 1394, 1402 (7th Cir. 1984) (Posner, J.) (rejecting reputational harm as a cognizable form of competitive harm under *National Parks* because competitors would "no doubt be delighted" to learn unfavorable information about General Electric). Though decided under the *National Parks* standard, the Seventh Circuit correctly recognized that "the competitive harm that attends any embarrassing disclosure is not the sort of thing that triggers [E]xemption 4." *Id.* If there is reason to believe that competitors could benefit from the revelation that Exondys 51 is ineffective or was approved as a result of agency misconduct, that is all the more reason in favor of disclosure. The required showing of harm under the 2016 amendments is completely unrelated to any reputational harm that disclosure may or may not cause.[13]

[13] Further, if Sarepta believes that a competitor used its information in an improper manner or made false claims about its drug, Sarepta would more appropriately seek a remedy in, for example, defamation law.

3. Endpoints.

Disclosure of the clinical endpoints described in the CSRs would not result in any commercial harm to Sarepta, given that many of the endpoints disclosed by Sarepta were developed by its competitors or are standard measures used in the community of muscular dystrophy researchers. Lurie Decl. ¶¶ 8, 28; Seife Decl. ¶¶ 62-84 (citing academic articles and guidelines substantiating this claim). For example, Dr. Lurie explains that Sarepta's main clinical endpoint, the 6-minute walk test, is widely used in the field. Lurie Decl. ¶ 8.

4. Adverse events.

Defendants have in no way argued that the withheld information regarding adverse events (AE) associated with Exondys 51 would lose value as a result of disclosure. Release of this information would, however, provide critical insight into the safety and efficacy of Exondys 51. Researchers, doctors, and patients cannot know whether Sarepta's public assessment was correct—or if the Adverse Events that it declined to disclose are indeed related to the drug—without understanding each Adverse Event, and the means taken to determine if it was related to the drug. *See* Lurie Decl. ¶¶ 13-18.

In fact, by arguing that revealing this safety and efficacy data would allow competitors to avoid "trial and error" in their own clinical studies, such as "unsuccessful . . . dosing approaches," 2d Sherwood Decl. Ex. 1 ¶ 25, Sarepta seeks to withhold data so that its competitors conduct futile clinical trials that expose children to unnecessary risks. As Dr. Lurie notes, "exposing pediatric patients—children—to trials that may well be useless and that carry risk because they could be accompanied by AEs . . . is unethical and is a violation of the Declaration of Helsinki, an international accord that governs ethics in medical trials." Lurie Decl. ¶ 37. By seeking to withhold the information regarding Adverse Events, Sarepta is putting innocent patients at risk, without actually avoiding any cognizable commercial harm to itself.

5. Relevance of public information to economic value.

This Court has held that for Seife's public information argument to succeed under Exemption 4, the information must be "identical" to that in the public domain. *Seife*, 2019 WL 1382724, at *2 n.3 (internal citation omitted). The fact that the information is largely public is nonetheless relevant to the information's commercial value, and hence to the foreseeable harm analysis.

With regard to the disclosure of the withheld information of each of the above four categories, Sarepta has not shown it is likely to suffer a reasonably foreseeable commercial harm because the most commercially valuable information related to Exondys 51 has already been made public by Sarepta itself. Lurie Decl. ¶¶ 22-23; *see also* Seife Decl. ¶¶ 56-92 (describing public materials). As such, the release of the "withheld granular details" will not affect the commercial value of the information because these details have relatively small incremental value. Lurie Decl. ¶ 35.

A great deal of information relating to the efficacy of approved drugs such as Exondys 51 is made publicly available by operation of law through a government-mandated website called ClinicalTrials.gov and through disclosure of Advisory Committee materials. Mandatory public disclosures include information describing the trial, its primary purpose, and how patients are recruited, along with such details as the study design, primary and secondary outcome measures, start and end dates, target number of subjects, and other information. *See* 42 U.S.C. § 282(j)(2)(A)(ii). The Food and Drug Administration Amendments Act of 2007 requires public disclosure of the "[b]asic [r]esults" for certain clinical trials, which includes primary and secondary study outcomes, as well as demographic and baseline characteristics of patient samples. *Id.*; *see* § 282(j)(3)(C). For drugs that are approved, basic results must be reported thirty days after approval. § 282(j)(3)(E)(iv).

In addition, information that Sarepta submitted to the FDA Advisory Committee makes public much of what is now being withheld from its CSRs. For example, the specific methodologies

used to analyze dystrophin levels, conduct biopsies, prepare tissues, and assay exon-skipping have all been reported in the scientific literature in great detail. Seife Decl. ¶ 82. The same is true of information regarding Sarepta's dystrophin measures and results, lymphocyte counts, and exon-skipping. *Id.* Sarepta's dosing information has also been widely reported. *Id.* ¶ 92; Lurie Decl. ¶ 24-25. Furthermore, Sarepta has publicly conceded, in encouraging the FDA to adopt IHC as a standard for measuring dystrophin, that IHC is "a well-established method, having been used for over 20 years in the diagnosis of [Duchenne] and has been validated in [Duchenne] clinical trials." Seife Decl. ¶ 82; Kenney Decl., Ex. W, 17-18.

Sarepta has also made extensive disclosures related to safety information and Adverse Events through ClinicalTrials.gov and the FDA Advisory Committee review process. Specifically, summary tables of Adverse Events experienced by patients in both Study 201 and the dose-ranging study are available on ClinicalTrials.gov. Seife Decl. ¶ 90. In addition, Sarepta submitted detailed AE information in its mandatory Advisory Committee submissions, including "narrative descriptions of adverse events, a discussion of adverse event categories of particular interest, case reports by individual participant number for particular adverse events, a table of all adverse events in the 24 weeks of Study 201, and a table of all adverse events from all Exondys 51 trials, by dosing and number of patients exposed." *Id.*

D. Under the 2016 Amendments, the Important FOIA Interests Advanced by Releasing the Information at Issue Further Compel Disclosure

1. The text, structure, and history of the 2016 amendments require consideration of the impact of withholding information on the public's ability to monitor agency action.

As the Supreme Court repeatedly has instructed, "Congress intended FOIA to 'permit access to official information long shielded unnecessarily from public view.'" *Milner v. Dep't of Navy,* 562 U.S.

562, 565 (2011) (*quoting EPA v. Mink,* 410 U.S. 73, 80 (1973)). The core objective of FOIA is to keep the public "informed about 'what [its] government is up to'" by allowing access to "[o]fficial information that sheds light on an agency's performance." *Reporters Comm.*, 489 U.S. at 773 (internal quotation marks omitted). Just as FOIA's nine exemptions must be construed narrowly to give effect to this objective, *see, e.g.*, *Milner*, 562 U.S. at 565, its new foreseeable harm standard must be construed in a manner consistent with FOIA's transparency goal. The ordinary meaning, structure, and history of the 2016 amendments all confirm that the foreseeable harm standard requires an agency to demonstrate that the "harm" from releasing information is sufficiently significant to override FOIA's default presumption of disclosure.

The plain text of the 2016 amendments reinforces FOIA's mission to maximize disclosure. Under the 2016 amendments, an agency may now withhold records "*only if*" the conditions of the amendments are met, and those conditions require a particular finding of likely "harm" to "an interest protected by" the exemption being invoked.[14] § 552(a)(8)(A)(i). This new standard significantly narrows an agency's ability to withhold records under FOIA's discretionary exemptions, such as Exemption 4.[15] Congress made clear that this change was made to "strengthen the existing Freedom

[14] *FMI* declined to consider the harm caused to an information provider in applying Exemption 4 because the language of Exemption 4 is clear. The 2016 FOIA Improvement Act, however, requires agencies invoking Exemption 4 specifically to find a likely "harm" to "an interest protected by" that exemption. § 552(a)(8)(A)(i).

[15] Sarepta, once again, takes the position in a footnote that the Trade Secret Act is coextensive with Exemption 4, rendering it mandatory. Sarepta's Suppl. Br. at 11 n.5. The Second Circuit has not adopted that view, *see Nadler v. FDIC*, 92 F.3d 93, 97 (2d Cir. 1996) (declining to reach the issue), and in *FMI* the Solicitor General took the contrary position, urging that Exemption 4 is *permissive*, not mandatory, both at oral argument and in the United States' amicus brief. *See* Br. of United States as Amicus Curiae Suppl. Pet'r at 32; Tr. of Oral Arg. at 23. As Seife has previously noted, there are good policy reasons to treat commercial information differently than trade secrets. *See Gen. Elec. Co.* 750 F.2d at 1401-02; *see also Charles River Park "A" Inc. v. HUD*, 519 F.2d 935, 943 (D.C. Cir. 1975) (noting that the Trade Secrets Act "is a criminal statute and should be narrowly construed"); *United States v. Wiltberger*, 18 U.S. 76, 95-96 (1820) (Marshall, C.J.) (noting any crime not enumerated in the language of the statute cannot be criminalized by judicial fiat).

of Information Act," not to weaken it. 162 Cong. Rec. S1494, S1495 (statement of Sen. Leahy). The justification required to withhold information was increased to redress a "culture of government secrecy" that "has served to undermine FOIA's fundamental promise." 114 Cong. Rec. S1494, 1494, 1495 (Mar. 15, 2016) (statement of Sen. Grassley); *see also* 162 Cong. Rec. H3714, H3717 (June 13, 2016) (statement of Rep. Meadows) (noting the "most important reform" is strengthening the presumption of openness).

The 2016 amendments do not define the level of "harm" to an exemption-protected interest required to meet this new standard, but the proper application of FOIA, again, is apparent from "careful examination of the ordinary meaning and structure" of the statute itself. *FMI*, 139 S. Ct. at 2364. The ordinary meaning of "harm" in this context, as shown above, is a tangible and material harm to an interest protected by Exemption 4. *See* Section II A.2. The structure of the statute—imposing an obligation to show harm before any information can be withheld under a discretionary exemption—means the extent of tangible harm caused by disclosure must necessarily be assessed against the importance of the information to public understanding of what an agency is up to.

Simply put, under the 2016 amendments, not just any "harm [to] an interest protected by [Exemption 4]" can suffice, no matter how *de minimis*. § 552(a)(8)(A)(i). It is axiomatic that FOIA's provisions must not be construed or applied in a manner that "negate their own stated purposes," *King v. Burwell*, 135 S. Ct. 2480, 2493 (2015) (internal citation omitted), and that "a law will not be interpreted to produce absurd results," *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 324 n.2 (1988) (Scalia, J., concurring in part). To avoid just that, an Exemption 4 harm identified by an agency as justification for withholding information, must necessarily be assessed against the value of that information in shedding light on agency action. Information critical to knowing whether an agency is following mandated procedures and pursing its assigned mission cannot properly be withheld without some

equally significant harm of a type Congress sought to protect against. With this approach, FOIA's disclosure mandate, its exemptions, and the 2016 amendments are construed together in a manner that advances, rather than defeats, FOIA's objective.

This approach is consistent with the Supreme Court's continuous recognition that "disclosure, not secrecy, is the dominant objective of [FOIA]," and therefore FOIA's enumerated exemptions "must be narrowly construed" to fulfill FOIA's statutory purpose. *Rose*, 425 U.S. at 361; *see also DOJ v. Tax Analysts*, 492 U.S. 136, 151 (1989); *FBI v. Abramson*, 456 U.S. 615, 630 (1982). As the Supreme Court has explained:

> It is not an easy task to *balance the opposing interests* [under Exemption 4], but it is not an impossible one either. . . . Success lies in providing a workable formula which encompasses, balances, and protects all interests, yet places emphasis on the fullest responsible disclosure.

Chrysler Corp. v. Brown, 441 U.S. 290, 292 n.12 (1979) (quoting S. Rep. No. 813, 89th Cong., 1st Sess., at 3 (1965) (emphasis added)). Just this year, in *FMI*, the Supreme Court again reiterated that Exemption 4 withholdings are to strike a "workable balance" between FOIA's central purpose of disclosure and the privacy interests of submitters. *FMI*, 139 S. Ct. at 2363.

Similarly, lower courts have long agreed that to carry out Congress's intent in creating Exemption 4, agencies withholding information under that exemption must consider the impact of non-disclosure on FOIA's objective of shedding light on government activity. For example, in *Public Citizen Health Research Group v. FDA*, the D.C. Circuit agreed that "the public interest side of the balance" under Exemption 4 is whether "the information sought . . . would reveal what the[] government is up to." 185 F.3d at 903 (internal quotation marks omitted). In that case, Judge Garland wrote separately to underscore that an interest in "'[o]fficial information that sheds light on an agency's performance of its statutory duties falls squarely within that statutory purpose' and may be weighed

in the balance" in applying Exemption 4. *Id.* at 909 (Garland, J., concurring) (quoting *Reporters Comm.*, 489 U.S. at 773); *see also GC Micro Corp. v. Def. Logistics Agency*, 33 F.3d 1109, 1115 (9th Cir. 1994), *overruled on other grounds by Animal Legal Def. Fund v. FDA*, 836 F.3d 987 (9th Cir. 2016) (noting that trial judges applying Exemption 4 should "balance the strong public interest in favor of disclosure against the right of private businesses to protect sensitive information"); *Martin v. Lauer*, 686 F.2d 24, 33 (D.C. Cir. 1982) (deciding whether to release FOIA-exempt material "requires a considered balancing of the public's interest in disclosure of particular material and the interests in nondisclosure acknowledged by statutory exemptions"); *Teich*, 751 F. Supp. at 253 (holding that disclosure would reveal safety issues that outweigh the "negligible competitive harm"); *JCI Metal Prods. v. Dep't of the Navy*, No. 09-CV-2139, 2010 WL 2925436, at *7 (S.D. Cal. July 23, 2010) (noting that the "public interest [in disclosure] outweighs any confidentiality concerns [plaintiff] might have in its unit prices").[16]

In short, under the 2016 amendments, information otherwise within Exemption 4 may be withheld only where a foreseeable "harm" to the information provider is significant enough to overcome the public interest in knowing what an agency is up to. In evaluating defendants' assertions of harm to Sarepta, this Court can and should consider the overriding FOIA interest in disclosure of information that is vital to knowing whether the FDA acted consistent with its statutory duties in approving Exondys 51, an interest heightened by the allegations of scientific and ethical wrongdoing.

[16] The legislative record reflects that Congress also has long understood that agencies applying Exemption 4 "must balance the competitive interest of a business against the public's right to know vital health, safety, economic, and legal information," Staff of Subcomm. on Admin. Practice and Procedure, S. Comm. on the Judiciary, 96th Cong., Agency Implementation of the 1974 Amendments to the Freedom of Information Act: Report on Oversight Hearings 3 (Comm. Print 1980), and expected courts applying Exemption 4 to "invalidate as an abuse of discretion any regulation that prevent [sic] the release of information vital to the public interest," H.R. Rep. No. 95-1382, at 46 (1978). Indeed, "[t]he legislative history is replete with references to Congress' desire to loosen the agency's grip on the data underlying government decisionmaking." *Chrysler Corp.*, 441 U.S. 290 n.10 (citing applicable legislative history).

2. Disclosing the information at issue is vital to knowing whether the FDA adhered to its statutory mandates and acted properly in approving Exondys 51.

There can be no serious debate about the value of the withheld information to advancing FOIA's accountability objective. Access to the withheld information will shed light on: (a) whether the FDA followed statutory standards and proper procedures in approving Exondys 51; (b) whether the FDA fulfilled its statutory mandate to "promote the public health," 21 U.S.C. § 393(b)(1), by ensuring that "drugs are safe and effective," *id.* § 393(b)(2)(b); and (c) whether scientific or other misconduct was involved in approving Exondys 51, as some FDA officials have alleged. The fundamental FOIA-protected interest in understanding what transpired during the approval of Exondys 51 far outweighs any minimal harm to Sarepta that could possibly result from disclosure of the withheld materials.

(a) Disclosure will shed light on whether the FDA followed statutory standards and proper procedures in approving Exondys 51.

Disclosing the requested records would serve FOIA's core objective by shedding light on whether the FDA followed certain standards and procedures. For example, the records could confirm whether the FDA followed the proper evidentiary standard mandated by Congress in approving Exondys 51. In 1962, Congress amended the Food Drug and Cosmetic Act (FDCA) to require that the FDA apply the "substantial evidence" standard in approving any new drug. Drug Amendments of 1962, Pub. L. No. 87-781, § 102(d), 76 Stat. 780, 781 (codified at 21 U.S.C. § 355(d)). Multiple FDA officials alleged the agency's approval of Exondys 51 did not satisfy this standard. Kenney Decl. 90, Ex. I., 3 (explaining that Dr. John Jenkins, Director of the Office for New Drugs, objected that a "totality of evidence" standard was improperly used.).

At the time Exondys 51 was approved, accelerated drug approval also required that a surrogate endpoint be "reasonably likely" to predict clinical benefit. 21 U.S.C. § 356(c). Dr. Ellis Unger, Director of the Office of Drug Evaluation-I, contended that Exondys 51 also did not satisfy this standard. *See* Kenney Decl., Ex. F, 12-14. Based on his own statistical analysis of Sarepta's data, Dr. Unger found "no evidence that the increase in dystrophin is reasonably likely to predict clinical benefit." *Id.* at 20.

The withheld information would shed light on whether the FDA followed these established standards. Among the information removed from the CSRs were several records related to dystrophin production, which was one of the prime biomarkers Dr. Woodcock relied upon to substantiate Exondys 51's approval. Seife Decl. ¶ 83. Specifically, the FDA withheld more than a dozen summary results tables, listings of results by individual patients, and other measures regarding dystrophin production. *Id.* Dr. Woodcock treated dystrophin production as a "surrogate measure" of the efficacy of Exondys 51 that was "reasonably likely" to predict a clinical benefit from the drug. *Id.* ¶ 75. Because dystrophin production allegedly played such a significant role in Dr. Woodcock's decision to approve Exondys 51, the withheld information is essential to assessing whether the FDA complied with the "substantial evidence" requirement. *Id.* ¶ 126.

The FDA also redacted results and descriptions of clinical metrics, also known as endpoints, used to assess the efficacy of Exondys 51 in the CSRs for Studies 201 and 202. *Id.* ¶¶ 63-64. These included the results from two essential endpoints, the 6-Minute Walk Test (6MWT) and the North Star Ambulatory Assessment (NSAA), as well as all the detailed NSAA summary result tables. *Id.* ¶ 161. As discussed, Dr. Woodcock and Dr. Unger reached contradictory conclusions about Exondys 51's effect on dystrophin levels and its relationship to clinical benefits, but both relied on the withheld 6MWT and NSAA data. *Id.* This information too is needed to assess evaluating Dr. Unger's claim

that Dr. Woodcock and, by proxy, the FDA did not satisfy statutory standards in approving Exondys 51.

(b) Disclosure will shed light on whether the FDA is carrying out its statutory mandate to protect public health and ensure drug safety and efficacy.

Access to the withheld records would also shed light on whether the FDA upheld their obligation to "promote the public health," 21 U.S.C. § 393(b)(1), and ensure "drugs are safe and effective," *id.* § 393(b)(2)(b). The evidence strongly suggests that the FDA violated its duty to "promote the public health" and approved a drug that was not "safe and effective." *Id.*

For example, the FDA has redacted much of the CSR information related to dystrophin, Seife Decl. ¶ 83, even though Studies 201 and 202 treated patients' dystrophin protein levels as a designated "surrogate measure" of Exondys 51's efficacy. *Id.* ¶ 75. The FDA also withheld the Pediatric Quality of Life Inventory, which provides objective measures of the quality of life for patients with Duchenne and is critical for determining whether Exondys 51 is making patients with Duchenne feel better or worse. *Id.* ¶ 74. This data goes to the heart of Exondys 51's efficacy in combatting Duchenne. The public needs access to these records to assess the basis for the FDA's determination that Exondys 51 is effective.

The FDA allegedly also failed to consider the significant safety risks associated with the drug. There are at least seven documented safety risks associated with Exondys 51, all of which are significant and some are lethal: (1) infection and sepsis, *id.* ¶¶ 133-38; (2) cardiomyopathy, *id.* ¶¶ 139-42; (3) blood clots, *id.* ¶¶ 143-48; (4) autoimmune responses, *id.* ¶¶ 149-50; (5) kidney damage, *id.* ¶¶ 151-52; (6) balance disorder leading to fractures, *id.* ¶¶ 153-54; and (7) hypokalemia, *id.* ¶ 155. With regard to the first, because a surgically-attached injection port is needed to administer Exondys 51, "there would definitely be serious infections and possibly deaths if this drug is marketed, yet evidence

of efficacy is lacking." Kenney Decl., Ex. F, 22. According to Dr. Unger, the FDA's approval of Exondys 51 gave "false hope in exchange for hardship and risk." Seife Decl. ¶ 19; Kenney Decl., Ex. F, 22.

Disclosure of the withheld information will help the public assess whether the FDA is fulfilling its congressional mandate to ensure drug safety. Specifically, the public needs access to the extensively redacted Adverse Events sections of the CSRs and other information on negative health effects associated with Exondys 51. For example, the FDA redacted information on adverse kidney events in the CSR for Study 202 and the relevant tables on creatine and blood urea, which are biomarkers of kidney function, in Study 201. Seife Decl. ¶¶ 151-52. The FDA also completely redacted tables containing both patient-level and summary results for vitals and electrocardiogram results. The FDA redacted all of the hematology tables for Studies 201 and 202, which are critical for understanding the pervasiveness of infection in patients taking Exondys 51, as well as their autoimmune responses. *Id.* ¶¶ 137, 148. The FDA redacted all of the data on patients' hematology and coagulation, which measures how well the blood clots. *Id.* ¶ 148. And the FDA repeatedly redacted shift tables, which show how patients' laboratory values changed from the initial stage to post-dose, including their potassium levels—a direct indicator of hypokalemia. Without these records, the public cannot assess whether the FDA adequately considered these safety risks associated with taking Exondys 51. *Id.* ¶¶ 128-57; Lurie Decl. ¶¶ 13-18. These concerns speak directly to whether the FDA is upholding its statutory mission to ensure that drugs are not only effective but also safe.

(c) Disclosure will shed light on whether there was scientific or other misconduct involved in approving Exondys 51, as some FDA officials have alleged.

The withheld information concerns allegations of scientific and ethical misconduct. As discussed, multiple allegations call into question the validity of the scientific data and analysis that the

FDA relied upon to approve Exondys 51. The FDA team tasked with reviewing Exondys 51 uniformly recommended against its approval because it did not meet the accepted scientific standards for clinical efficacy. Seife Decl. ¶ 15, Kenney Decl. Ex. E. Still, Dr. Woodcock unilaterally approved Exondys 51—raising further red flags. Seife Decl. ¶ 15; Kenney Decl., Ex. E.

Dr. Ronald Farkas, a clinical team leader at the FDA (who left the agency after Exondys 51 was approved), expressed concerns that Sarepta's data had been misrepresented and doctored in various ways to make Exondys 51 seem more successful than it was. Kenney Decl., Ex. L; Seife Decl. ¶ 40. He warned that there "seem[ed] to be reason for concern of misrepresentation of the data, even beyond the fact that it isn't clear what band represents dystrophin in the patient samples." Kenney Decl., Ex. L, 2; Seife Decl. ¶ 158. Dr. Farkas noticed that Sarepta's Western blot images, which detect dystrophin protein production, were "heavily manipulated photographically," that Sarepta had "delete[d] edges of the band that were darker than the central part," and that the images did not match what Sarepta CEO Dr. Kaye had presented in an earlier presentation to the FDA. Kenney Decl., Ex. L, 8; Seife Decl. ¶ 40.

Releasing the withheld records will shed light on whether these allegations of scientific and ethical misconduct are substantiated. For example, Seife believes it is likely the FDA continues to withhold Western blot data from the final CSRs for Study 201 and Study 202. Seife Decl. ¶ 131. Although the FDA has released some of the Western blots, without the requested records, the public will be unable to accurately assess whether the FDA decided to approve Exondys 51 based on doctored data. The FDA also withheld or redacted much of the information regarding Sarepta's two identified main endpoints. *Id.* ¶ 165. Without this information, the public will be unable to assess whether Sarepta engaged in endpoint switching and, in turn, whether the FDA chose to approve a drug based on the pharmaceutical developer's cherrypicked results. *Id.* at ¶ 166.

All of the important issues concerning the FDA's conduct will be illuminated by disclosure of the withheld information. This is precisely the type of information that FOIA seeks to make available to the public, and defendants have made no showing of any Exemption 4 harm to Sarepta that can properly justify the FDA's refusal to disclose this important information.

III. DEFENDANTS FAIL EVEN TO ESTABLISH THAT THE WITHHELD INFORMATION IS "CONFIDENTIAL" WITHIN THE MEANING OF EXEMPTION 4

Beyond their failure to satisfy the 2016 amendments, defendants' motion fails to establish that the withheld information qualifies for withholding under Exemption 4 at all. In *FMI*, the Supreme Court clarified the term "confidential" in the context of Exemption 4, holding that information must be "customarily kept private" to be confidential. 139 S. Ct. at 2363.[17] The word "customarily" was not defined in *FMI* and it is thus a question of first impression for this Court. The Supreme Court did clarify, however, that information is not "customarily kept private" if the owner of the information is "shar[ing] it freely." *Id.*

At the outset it bears emphasis that the Supreme Court did *not* equate the question of whether the information is "customarily kept private" on the one hand with whether the information is already public, on the other—a standard that would have been easy enough for the Supreme Court to articulate considering it had already been adopted by many lower courts in construing Exemption 4. *See, e.g.*, *Seife*, No. 17-CV-3960, 2019 WL 1382724, at *2 (noting "Exemption 4 does not apply to confidential commercial information 'if identical information is otherwise in the public domain' and

[17] The Court did not determine if information would shed "its confidential character for purposes of Exemption 4 if it's communicated to the government without assurances that the government will keep it private." *FMI*, 139 S. Ct. at 2363. For the purposes of this case, Seife does not dispute there was an assurance of privacy given to Sarepta by the FDA, so this issue need not be decided here either.

'freely available' there") (quoting *Inner City Press/Comty. on the Move v. Bd. of Governors of the Fed. Reserve Sys.*, 463 F.3d 239, 244 (2d Cir. 2006)).

To give full meaning to the Supreme Court's new test, this Court must grapple with the question of what being "customarily kept private" means, and if information is revealed to some, but not to the general public, whether such information falls within Exemption 4. For the reasons articulated below, this Court should find that Sarepta did not "customarily" keep the information private given its widespread sharing both to regulators other than the FDA and to collaborators within the industry.

Sarepta makes two arguments that the information qualifies as "customarily kept private"—namely that this conclusion supposedly follows from certain stipulated facts in Seife's prior Rule 56.1 statement (an argument notably absent from the FDA's briefing) and that the company had its employees and collaborators sign NDAs and restricted the flow of information within the company. Sarepta Summ. J. Mem. at 12-18, ECF No. 140.[18] These arguments should be rejected because they elevate formalism over substance in a manner detrimental to the core purpose of FOIA. If accepted on the record here, withholding would be permitted any time an information submitter makes such statements regardless of whether there are countervailing facts that suggest the information *has* been shared. *See New York Pub. Interest Research Grp.*, 249 F. Supp. 2d at 335 (critiquing the test proposed by

[18] In addition to *FMI*, Sarepta relies heavily on the D.C. Circuit opinion *Critical Mass Energy Project v. Nuclear Regulatory Commission*, 975 F.2d 871 (D.C. Cir. 1992) (en banc) and its progeny to argue that information qualifies as "confidential" because Sarepta kept it closely held. "[N]o circuit court," including the Second Circuit, has "expressly adopted" the *Critical Mass* test and only a few courts have even "cited to *Critical Mass* with approval." *New York Pub. Interest Research Grp.,* 249 F. Supp. 2d at 335 (collecting cases); *Inner City Press/Community on the Move v. Board of Governors of Fed. Reserve Sys.*, 463 F.3d 239, 245 n.6 (2d. Cir. 2006) (declining to adopt *Critical Mass*). And the *Critical Mass* facts are easily distinguished from the facts here. Each of the cases cited by Sarepta involves submissions that qualify as voluntary; Sarepta's submissions were not; they were a condition of drug approval. *See* FDA Summ. J. Mem. at 7, n.6., ECF No. 75; *id.* at 3 (citing *Guideline for Industry: Structure and Content of Clinical Study Reports*); *see also* 21 U.S.C. § 355(b)(1).

Sarepta). Here, even accepting Sarepta's assertions,[19] the practical reality is that Sarepta has shared its information freely with European regulators knowing that information would be released, and information of this type is routinely shared within the Duchenne community and by scientific researchers—arguments Seife vociferously made in the last round of briefing regardless of individual Rule 56.1 statements taken out of context.[20]

Instead of looking to defendants' formalistic definition of "custom" that would effectively give an information submitter carte blanche to lock up information even when other facts indicate that the information has been freely shared, at least within certain spheres, this Court should borrow the manner in which the term "custom" is defined in a familiar context: contract law. It is blackletter law that when a contract is ambiguous, courts look to evidence of "custom" to determine how a contract should be read and that custom, in this context, is understood to be "a general practice" that is "definite, fixed, reasonable and exists for a long enough time to have been known by the parties." 21A Am. Jur. 2d *Custom and Usages* § 1. The concept of a "general practice" goes beyond just the

[19] The sufficiency of the non-disclosure agreements (NDAs) signed by its employees to show a commitment to confidentiality is questionable. Even under the *Critical Mass* standard, its NDAs are not likely sufficient to show the requisite dedication to confidentiality. *See Elec. Privacy Info. Ctr. v. DHS*, 117 F. Supp. 3d 46, 64 (D.D.C 2015) (holding that the presence of an NDA is not enough under the *Critical Mass* standard to immediately conclude that the information is confidential).

[20] Seife does not dispute the Rule 56.1 statements, nor does he seek to retract them. But his admissions hardly indicate a blanket stipulation that Sarepta has kept the requested information confidential at all times. Taking these "concessions" in isolation is highly misleading and ignores the substantial argument Seife advanced that the information had been made public in various forms, including to the EMA. *See* Seife Rule 56.1 Statement ¶¶ 28-30, 32, 66-67, 70-72, 78-79, 124, ECF No. 91. It is well-accepted in other contexts, for example, in the law of evidence, that statements should be taken as a whole, and that courts should not zoom in on random concessions and then view them as outcome determinative. *See Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 171-72 & n.14 (1988) (discussing the rule of completeness in evidence and the proposition "that when one party has made use of a portion of a document, such that misunderstanding or distortion can be averted only through presentation of another portion, the material required for completeness is *ipso facto* relevant" and noting the prejudicial nature of a "statement . . . taken out of context"). In addition, since the submission of the last round of briefing, further information has been made public, and Seife now submits evidence of this fact. Seife Decl. ¶¶ 102-07.

practices within the company and looks at the industry as a whole. *Id.* § 7; *see British Int'l Ins. Co. v. Seguros La Republica, S.A.*, 342 F.3d 78, 84 (2d Cir. 2003). Defendants themselves approve of this approach in the context of the "assurance" prong—and thus it is appropriate to extrapolate backward to this first prong. Sarepta Summ. J. Mem. at 24, ECF No. 140. This application of what is considered customary is more meaningful and allows defendants' practices to be evaluated in light of the practical elements of information-sharing instead of promises of confidentiality that may be empty.

A. Sarepta Widely Shared the Information at Issue

Sarepta has customarily shared the information it now seeks to withhold. It submitted an application for market authorization for Exondys 51 from the European Medicines Agency (EMA) with the knowledge that, regardless of the outcome, the EMA would publish the submitted data. The release of an assessment report from the EMA, which neither the FDA nor Sarepta mentions, significantly undermines Sarepta's claim that it has treated its information as private. Seife Decl. ¶ 106. The EMA has a publicly searchable registry—EU Clinical Trials Register—that serves the same purpose as ClinicalTrials.gov. *Id.* ¶ 61. Sarepta registered Studies 201 and 202 on the EMA registry and applied for market authorization for Exondys 51 in the EU in November 2016. *Id.* ¶¶ 61, 103. Even though the EMA refused to authorize Exondys 51, it published an assessment report on the drug by the Committee for Medicinal Products for Human Use (CHMP). *Id.* ¶¶ 104-05. Sarepta had "full knowledge" that the clinical data for Studies 201 and 202 it submitted to the EMA would be published regardless of whether Exondys 51 was approved. *Id.* ¶ 106.

As a result of the EMA report's publication, "[m]ost of the information that [Seife is] seeking within the CSRs for Studies 201 and 202" has already actually been made public. *Id.* For example, the report "includes individual patient western blot data from Study 301 (Table 6), a spaghetti plot of individual patient 6-minute walk test distance from Study 202 (Figure 9), and a spaghetti plot of

individual patient 6-minute walk test distance over four years (Exondys 51-treated cohort and primary external control cohort) (Figure 15)." *Id.* ¶ 106. Sarepta cannot claim that any of this information has been treated as confidential since it submitted the data knowing it would be made public.

Beyond the published EMA report, Sarepta has customarily shared the withheld information in scientific literature and through its submissions to the FDA. For example, the specific methodologies used to analyze dystrophin levels, conduct biopsies, prepare tissues, and assay exon-skipping have all been reported in scientific journals. *Id.* ¶ 82 n. 30. The same is true of information regarding Sarepta's dystrophin measures and results, lymphocyte counts, and exon-skipping. *Id.* Sarepta redacted critical information about adverse events even though it has allowed details about such events from Studies 201 and 202 to be published in scientific literature and made available through ClinicalTrials.gov. *Id.* ¶ 90. It also included information about adverse events in its submission to the FDA Advisory Committee. *Id.* This submission included narrative descriptions, "a table of all adverse events in the 24 weeks of Study 201, and a table of all adverse events from all Exondys 51 trials, by dosing and number of patients exposed." *Id.* However, in the material given to Seife, key information "regarding adverse events in the CSRs and Appendices was partially redacted, with one column completely redacted in many of the summary-level tables [. . .] as well as redactions in the CSR narrative descriptions." *Id.* ¶ 91. Regardless of Sarepta's current insistence that information concerning adverse events and safety issues surrounding Exondys 51 should be considered confidential, Sarepta has customarily shared that information in the past.

One notable example of redacted information that has been made available elsewhere is the results of the 6-minute Walk Test (6MWT). The 6MWT "is a commonly used test used to evaluate patients with Duchenne." Seife Decl. ¶ 68. It measures the distance patients can walk in six minutes. *Id.* Given the importance of the 6MWT in measuring the effectiveness of Exondys 51, Sarepta

included detailed information about the results in its briefing materials for the FDA Advisory Committee meeting. *Id.* ¶ 69. For example, a spaghetti plot "depicting individual 6MWT results over the course of four years for study participants as compared to historical control patients" was "made publicly available as part of Sarepta's briefing document." *Id.* ¶ 68; Kenney Decl., Ex Q, 66. And yet, the FDA chose to redact the spaghetti plot in the CSR made available to Seife. Seife Decl. ¶ 71. To highlight the futility of this redaction, the spaghetti plot of individual 6MWT results was also made publicly available in Sarepta's May 3, 2018 Securities and Exchange Commission (SEC) Form 8-K filing. *Id.* ¶ 72. Sarepta contends that the redacted spaghetti plots with "the results of the 6-minute walk test and pulmonary function tests . . . depict 'different data' from the publicly available spaghetti plots." *Id.* ¶ 94; Sherwood Decl. ¶¶ 7, 14, 17, 55, ECF No 104. While the redacted plots might appear different from the available plots, they present the same data based on tests performed on twelve trial participants over a period of time. Seife Decl. ¶ 94. Indeed, if the redacted plots actually did show different results, that would call into question the validity of Sarepta's data.

Finally, Sarepta asserts that individual study results by time point are confidential. Sherwood Decl. ¶¶ 6-7, 14, 15, 48 (discussing 6-Minute Walk Test (6MWT)), *id.* ¶¶ 6, 8, 15, 16, 26 (discussing North Star Ambulatory Assessment (NSAA) total score and NSAA components including the Timed 10-Meter Run and Rise Time), *id.* ¶¶ 27, 51 (discussing the Maximum Voluntary Isometric Contraction Test (MVICT) and Hand-Held Dynamometry). However, these results "can readily be discerned from the publicly-released plots." Seife Decl. ¶ 96. With the help of a "free online plot digitizer," one can take data from the public test results and the patient-level plots provided by the FDA and "obtain individual patient results for all of the measured time points through week 216 for the functional assessment tests cited as confidential in the Sherwood declaration." *Id.* ¶¶ 99-100.

In its submissions to the EMA, the FDA Advisory Committee, and scientific literature over the years, Sarepta has customarily made available the information it now claims is confidential. Sarepta customarily published key information regarding adverse events and test results that Seife now seeks. *FMI* requires that information be treated, by custom and actual practice, as private in order for Exemption 4 to apply. Sarepta does not satisfy this standard.

B. The Information Was Widely Shared Within the Industry

Sarepta's confidentiality is extremely limited due to the facts that the company shared information with its competitors through information coalitions, Seife Decl. ¶ 108-115, and that much of this information is already known within the industry, and indeed was not invented by Sarepta.

First, the company has obtained its natural history registries from the University Hospitals Leuven, Leuven Neuromuscular Reference Center, and the Fondazione Telethon Registry in Italy. *Id.* ¶ 109. Both of these share their "data with researcher and pharmaceutical companies through the Collaborative Trajectory Analysis Project (cTAP), a public-private partnership focused on clinical trial data sharing and scientific analysis regarding Duchenne." *Id.* Sarepta participated in many international workshops for the disease with "academic researchers, non-profit organizations, and industry." Seife Decl.¶ 115. While Sarepta claims it has an NDA with these participants, Verni Dec. ¶¶ 8-10, the NDA submitted into evidence lacks any signatures from its collaborators in this information-sharing coalition, *id.*, Attachment 2, 23. While presumably the data is used to *facilitate* collaboration and the advancement of knowledge, this hardly qualifies as "confidential" insofar as the interest protected by Exemption 4 is commercial in nature and the goal of sharing information is to promote development of additional drugs for Duchenne. The fact that the information was not publicly released through these coalitions is of no moment for the Exemption 4 inquiry, which focuses on whether the information is "customarily kept private," *FMI*, 139 S. Ct. at 2363, and not whether it is released to

the public. The point here is that such information is known within the industry and Sarepta presents no evidence to the contrary.

Second, that Sarepta has its collaborators sign NDAs and holds the information close within the company given the redactions at issue does not bear on the fact that it is industry practice to share data, including information that Sarepta has redacted. For example, Sarepta contends that its immunohistochemistry (IHC) method of quantifying dystrophin is confidential commercial information. However, when it encouraged the FDA to approve the IHC technique, Sarepta conceded that IHC is "a well-established method, having been used for over 20 years in the diagnosis of [Duchenne] and has been validated in [Duchenne] clinical trials." Seife Decl. ¶ 82; Kenney Decl., Ex. W, 18-19 (Comment on FDA Notice).

C. *In Camera* Review Is Needed to Check Sarepta's Repeated Inaccurate Assertions That the Withheld Information Is Confidential Because It Is Non-Public

Sarepta continues to assert that the information contained in its CSRs is non-public, Sarepta Summ. J. Mem. at 19-20 & n.7, ECF No. 140, despite this Court's holding to the contrary. The Court previously held that Seife had demonstrated that the original redactions and withholdings were riddled with errors. *Seife*, No. 17-CV-3960, 2019 WL 1382724, at *2 (noting "[i]t would be foolhardy to conclude" there were no problems in other portions of the documents and ordering both the FDA and Sarepta to re-review and re-release documents). Such a step is once again warranted.

While the legal inquiry to determine if information is "confidential" because it is "customarily kept private" is different from determining whether information is actually "public," *in camera* comparison of withheld information to public information is needed to ensure Sarepta's new claims that the information is non-public are indeed accurate. Seife's additional submissions call into question Sarepta's motives for withholding information despite the limited commercial harm it could

conceivably cause, and again demonstrates that much has been widely shared or fully released. In light of these showings, this Court should again use a sampling procedure to determine the accuracy of Sarepta's claims, and order re-release of any additional information that is public separate from the legal inquiry of whether it qualifies as "confidential." *See NRDC*, No. 17-CV-5928, 2019 WL 4142725, at *15.

Seife respectfully requests the Court examine pages he submits as attachments to the new Seife Declaration to examine on an apples-to-apples basis with information under seal from Sarepta.

CONCLUSION

For each and all the foregoing reasons, plaintiff Charles Seife respectfully requests this Court to deny defendants' motion for summary judgment, grant his cross motion for summary judgment, order disclosure of the withheld information, and enter such other and further relief as to the Court seem just and proper.

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Respectfully submitted,

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