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)

December 23, 2019

REPLY 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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The issue before this Court is not and has never been whether Sarepta's controversial and extraordinarily expensive drug "should have been approved by [the] FDA." FDA Opp. 1, ECF No. 157. Rather, it is whether the Freedom of Information Act ("FOIA"), as amended in 2016 (the "2016 Amendments"), permits the FDA to withhold from the public Sarepta's clinical trial data—data needed to assess whether the FDA followed its statutory mandates and to inform doctors, patients, and researchers about health matters of immense public interest. Science journalist Charles Seife has demonstrated that it was not lawful to withhold the clinical trial data in December 2016, and it did not become lawful when the Supreme Court reinterpreted Exemption 4 in *Food Marketing Institute v. Argus Leader* ("*FMI*), 139 S. Ct. 2356 (2019), which necessitated supplemental briefing in this case.

As Seife has shown, after the 2016 FOIA Amendments defendants must establish both that the withheld data qualifies as "confidential" "commercial or financial" information under Exemption 4, and that releasing the data will cause a "foreseeable harm" to the interest protected by Exemption 4. Seife Br. 9-11, ECF No. 148. Defendants dispute this basic point and suggest the Supreme Court in *FMI* "rejected" Seife's understanding of the FDA's burden under the 2016 Amendments. FDA Opp. 1, 14. But the Amendments were not before the Court in *FMI* and are not even cited in passing anywhere in that opinion. While it is true that neither Seife's reading of the 2016 Amendments nor his understanding of the new test for Exemption 4 that *FMI* left for lower courts to work out has yet "been adopted by a single court," Sarepta Opp. 1-2, ECF No. 154, that is only because *FMI* was just decided on June 24, 2019. Since then, only two courts have issued opinions on the 2016 Amendments' effect on Exemption 4, and they are contradictory and unpublished. Other cases addressing agency burdens under the new test for Exemption 4 and the 2016 Amendments remain pending.

Given the novel issues these cases present, this Court should issue a published opinion providing guidance and rejecting defendants' overbroad arguments about agencies' authority to keep

secret information essential for the public to know what its government is up to. While Sarepta accuses Seife of "invent[ing] law out of whole cloth," Sarepta Opp. 25, his sound interpretation of both the 2016 Amendments and *FMI*'s new test for Exemption 4 is entirely consistent with FOIA jurisprudence, including what little Exemption 4 precedent survives. It also rests on *FMI*'s instruction to "stop" where the statutory text "yields a clear answer," *FMI*, 139 S. Ct. at 2354 (collecting cases), a portion of the *FMI* decision that defendants wish away in favor of out of context snippets from legislative history and regulations that do violence to the text, structure, and purpose of FOIA.

I. The Foreseeable Harm Standard Was Not Addressed In *FMI* And Applies Fully To Exemption 4 Cases

A. The Burden To Withhold Under The 2016 Amendments Was Not Resolved by *FMI*; It Was Not Even Addressed

FMI did not and could not "reject[]" the foreseeable harm test proposed by Seife. FDA Opp. 1, 14. The 2016 Amendments are not retroactive and apply only to requests made after June 30, 2016. *See* FOIA Improvement Act of 2016, Pub. L. No. 114-185, § 6, 130 Stat. 538 (2016). *FMI* involved a 2011 FOIA request. *See* J.A. at 37-38, *FMI*, 139 S. Ct. 2356 (2019) (No. 18-481), 2018 WL 7915640 (U.S.), at *37-38. So the application of the 2016 Amendments to information otherwise within Exemption 4 was never before the Court under Article III's "case and controversy" requirement.

Moreover, *FMI* resolved only the meaning of the word "confidential" in Exemption 4. *See* 139 S. Ct. at 2366; 5 U.S.C. § 552(b)(4).[1] The meanings of the terms "reasonably," "foreseeable harm,"

[1] The petition for certiorari made clear the issue in dispute solely "concerns the meaning of 'confidential' in FOIA Exemption 4." *Seife v. FDA*, 2019 WL 1382724, at *1 (S.D.N.Y. Mar. 27, 2019) (Furman, J.) (citing Pet. for Cert. at i, No. 18-481 (U.S. Oct. 11, 2018), *cert. granted*, 139 S. Ct. 915 (2019)). Importantly, the Supreme Court's new definition of "confidential" focuses entirely on how the owner (and potentially the government) treat the information, not on the effect of disclosure. The Court rejected the position, advocated in a dissenting opinion, that harm resulting from disclosure is

and the "interest" used in the 2016 Amendments, Seife Br. 12-17, were not before the Court and were not addressed. The Court need not take Seife's word for it: *Center for Investigative Reporting v. Dep't of Labor* ("*CFIR*") just recognized that "the Supreme Court did not address the validity of the foreseeable harm standard" in *FMI* and held that "the foreseeable harm standard applies" to Exemption 4. 2019 WL 6716352, at *7 (N.D. Cal. Dec. 10, 2019).

B. The 2016 Amendments Raise The Bar For Withholding And Require The Agency To Reasonably Foresee A Particular Harm

Defendants argue that since the 2016 Amendments do not "alter the scope" of any exemption, they need only show the information at issue is "confidential" under *FMI*. FDA Opp. 9-13. That simply is not so. As this Court has already recognized, the 2016 Amendments do impose an additional statutory obligation to withhold information, even when it falls within an exemption. *See NRDC v. EPA*, 2019 WL 3338266, at *1 (S.D.N.Y. July 25, 2019) (Furman, J.); *see also* Seife Br. 10-12. Nor is this obligation limited to Exemption 5 as defendants contend. FDA Opp. 9-12. The 2016 Amendments clearly state: "[a]n agency shall (i) withhold information under [FOIA] only if: (I) the agency reasonably foresees that disclosure would harm an interest protected by an exemption . . . or; (II) disclosure is prohibited by law." 5 U.S.C. § 552(a)(8)(A)(i). Disclosure of the data at issue is not prohibited by law (*see infra* Part I.E), so the burden to reasonably foresee a particular harm fully applies.

To the extent relevant, the FDA's discussion of Exemption 5 further confirms that defendants have failed to meet their evidentiary burden. In *NRDC,* the EPA argued that "[r]elease of the withheld information would discourage open and frank discussion" and "have a chilling effect on the Agency's decision-making processes." *NRDC*, 2019 WL 3338266, at *1. The Court found this to do no more

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relevant to whether information is "confidential" under Exemption 4. *Compare FMI*, 139 S. Ct. at 2366 *with id.* at 2368 (Breyer, J., concurring in part and dissenting in part).

than establish that the information fell within Exemption 5 and failed to "sufficiently 'explain how a *particular* Exemption 5 withholding would harm the agency's deliberative process.'" *Id.* (citation omitted) Notably, the EPA's insufficient declaration in *NRDC* was more robust than the declaration FDA belatedly submits here, which argues in a single sentence that "it is reasonably foreseeable that FDA's public disclosure of the confidential commercial information to plaintiff would harm the confidential nature of that information because the information would no longer be private." Sager Decl. ¶ 8, ECF No. 159.

Neither the FDA nor Sarepta adequately explains how releasing the withheld information would cause particular "harm."[2] And while the EPA was given a second chance in *NRDC* to issue a new affidavit, the FDA's offhand request to do so here should be rejected. FDA Opp. 15, n.9. Defendants have already been afforded the opportunity to brief the effect of the foreseeable harm standard, yet they have failed to articulate any meaningful harm that would flow from release, despite thirty-one unused pages of briefing space to do so, the Court's August 2 order,[3] the *NRDC* opinion, Seife's supplemental filing, and conversation among counsel about the relevance here of the 2016 Amendments. *See* Seife Br. 15 & n.8. Given the extraordinary costs and risk of a drug patients continue

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[2] Nor do defendants meaningfully address the plain text obligation of "the agency" itself to "reasonably foresee" the harm to withhold information, 5 U.S.C. § 552(a)(8)(A)(i); Seife Br. 13-15. The FDA complains that doing so would result in "burdens and delay" and is "not supported by any FOIA case law or the legislative history of the 2016 [a]mendments." FDA Opp. 15-16 n.10. But as then Judge Kavanaugh recognized in *CREW*, when agencies made a similar complaint about the requirement to comply with strict FOIA-processing deadlines: "Congress made that decision. If the Executive Branch does not like it or disagrees with Congress's judgment, it may so inform Congress and seek new legislation." *Citizens for Responsibility & Ethics in Washington v. Fed. Election Comm'n* ("*CREW*"), 711 F.3d 180, 189-90 (D.C. Cir. 2013)..

[3] The Court ordered the parties' "'supplemental' motion papers [to] incorporate any and all arguments from their prior briefing that remain relevant" such that "the parties' 'supplemental' motions should stand on their own and should not incorporate by reference arguments made in the earlier briefing." ECF 137 at 2.

to take, Seife Br. 31-32, this Court should not further delay disclosure of the data at issue. *See CFIR*, 2019 WL 6716352, at *7 (not affording defendants opportunity to supplement record after failing to show foreseeable harm).

C. Because FOIA Must Be Read As A Whole, The Interest Protected By The 2016 Amendments Is Plainly Not An Interest In "Confidentiality"

Defendants incorrectly argue that the "interest" protected by Exemption 4 is solely one of "confidentiality" by zooming in on that word alone. FDA Opp. 13. But *FMI* reminds us that a "proper starting point [for statutory interpretation] lies in a careful examination of the ordinary meaning and structure of *the law itself*." 139 S. Ct. at 2364 (emphasis added) (citation omitted). When it comes to interpreting the highly complex and interlocking provisions of FOIA, the entire exemption and the 2016 amendments must be "harmoniz[ed]"—rather than focusing on a single word in isolation. Seife Br. 12-17; *see also CREW*, 711 F.3d at 188-90; *see also Chrysler Corp. v. Brown*, 441 U.S. 281, 291-93 (1979) (analyzing FOIA's subparts and "language, logic, [and] history").

In harmonizing Exemption 4 with the 2016 Amendments, it is clear defendants' interpretation of "interest" in the 2016 Amendments as solely protecting "confidentiality" violates blackletter rules of statutory construction. Equating "interest" with "confidentiality," means any loss of confidentiality, no matter how immaterial, would be sufficient to qualify as a "foreseeable harm" because "[d]isclosure would necessarily destroy the private nature of the information." FDA Opp. 13. This interpretation effectively reads the word "harm" out of the 2016 Amendments—any information otherwise within Exemption 4 would qualify. Defendants' reading therefore violates the "cardinal rule of statutory interpretation that no provision should be construed to be entirely redundant." *Nielsen v. Preap*, 139 S. Ct. 954, 969 (2019) (citation omitted); *see also Williams v. Taylor*, 529 U.S. 362, 404 (2000). Defendants offer no alternative explanation of harm and fail to explain how "harm" from loss of confidentiality under their interpretation should be measured or quantified.

In contrast, Seife takes a textually grounded approach to interpreting the 2016 Amendments that harmonizes the distinct provisions of FOIA and makes them work together. Seife Br. 12-13. The "interest" protected by Exemption 4 is the economic value of intangible property protected by Exemption 4, which itself is made up of confidential "commercial or financial" information and "trade secrets." *Id.* at 15-17. The "harm" to that "interest" is measured by the tangible and material diminution in value of the information to its owner that would result from its disclosure. *Id.* This reading of the 2016 Amendments as applied to Exemption 4 is entirely compatible with *FMI*. It fully accepts that information falls within the exemption if it is "customarily kept private or at least closely held," *FMI*, 139 S. Ct. at 2363, and requires a foreseeable harm defined and weighed by comparing the current value of the information against the value of the information after a FOIA disclosure.

D. The Public Interest In Disclosure Should Properly Be Considered

The text, structure, and purpose of the 2016 Amendments all support the conclusion that some threshold level of "harm" must be demonstrated to the "interest protected" by Exemption 4. If any *de minimis* amount of harm sufficed for withholding, it would "produce absurd results" and the 2016 Amendments would impose no limitation at all. *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 324 n.2 (1988) (Scalia, J., concurring in part). To determine what amount of "harm" is required to justify withholding, it follows that the private "harm" to a protected "interest" must be evaluated in light of the public's "interest" in disclosure. Granted, the public interest under FOIA is not limitless—"[t]he only valid public interest in the FOIA context is one that serves FOIA's core purpose of shedding light on an agency's performance of its statutory duties." *Rosenberg v. DOD*, 342 F. Supp. 3d 62, 91 (D.D.C. 2018) (quoting *Smith v. Dep't of Labor*, 798 F. Supp. 2d 274, 285 (D.D.C. 2011)). It is this public interest against which the "harm" to an "interest protected by an exemption" must be weighed.

The FDA argues that *FMI* forecloses any such evaluation of interests, FDA Opp. 16-17, but

FOIA's text, structure, and purpose, FOIA jurisprudence, and *FMI* itself all support this approach. *FMI* instructs that "when Congress enacted FOIA it sought a 'workable balance' between disclosure and other governmental interests." 139 S. Ct. at 2366. The Supreme Court described this "workable balance" in its first Exemption 4 case, *Chrysler,* where it explained that courts applying Exemption 4 must "balance the *opposing interests* . . . [and] [s]uccess lies in providing a workable formula which encompasses, balances, and protects *all* interests, yet places emphasis on the *fullest responsible disclosure*." *Chrysler*, 441 U.S. at 292 n.12 (emphasis added).

Pre-*FMI* cases establish that the validity of the interest in knowing what the "government is up to," is the interest protected by FOIA. The FDA accuses Seife of "misleadingly quot[ing] the D.C. Circuit's decision in *Public Health Citizen Research Group v. FDA*, 185 F.3d 898, 903 (D.C. Cir. 1999)," but notes *Public Citizen* "remains valid after [*FMI*]." FDA Opp. 17. Seife's reading is a correct and careful reading that distinguishes between the different "interests" protected by FOIA. While the majority in *Public Citizen* did eschew "a consequentialist approach to the public interest in disclosure," this was in the context of rejecting "collateral benefits" in health and safety "to bolster the case for disclosure by claiming an additional public benefit." *Public Citizen*, 185 F.3d 904. Nevertheless, the majority noted the public interest in shedding light on "what the [ ] government is up to," since "the basic purpose of [FOIA] [is] to open agency action to the light of public scrutiny." *Id.*

Judge Garland underscored in his concurrence that "my colleagues recognize…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." *Id.* at 909 (Garland, J., concurring). Judge Garland also relies on a canonical FOIA case that is still good law: *Dep't of Justice v. Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 773 (1989), in which "there was no question but that a balancing test was required with respect to Exemption 7(C)" and the question was only "what

interests could be weighed in the balance." *Public Citizen*, 185 F.3d at 909 (Garland, J., concurring). In *Reporters Committee*, the Court held that "information about private citizens that is accumulated in various governmental files but that reveals little or nothing about an agency's own conduct" should not be disclosed. 489 U.S. at 773. But that is not the case here, where evidence strongly suggests that disclosure could reveal agency malfeasance. Seife Br. 29-34.

This same approach to the public interest is reflected in a holding later affirmed by defendants' most important case, *Critical Mass Energy Project v. Nuclear Regulatory Commission.* On remand from the D.C. Circuit, the district court endorsed weighing the public interest in disclosure in Exemption 4 cases, holding "[t]he determination mandated by the court of appeals requires 'balanc[ing] the individual litigant's [i.e., the request[e]r's] need for information against the government's need to obtain the information in the future,' . . . and 'the extent to which the government's ability to obtain [the] information would be impaired . . . against the *public interest in disclosure.*'" 731 F. Supp. 554, 555-56 (D.D.C. 1990) (emphasis added) (citations omitted), *aff'd after reh'g en banc,* 975 F.2d 871 (D.C. Cir. 1992). In assessing whether an "interest" protected by an exemption is foreseeably harmed, courts should properly consider the extent to which FOIA's core interest in disclosure would be affected.[4]

E. Defendants Do Not Escape The 2016 Amendments Using The Trade Secrets Act Or FDA Regulations

Defendants argue that the 2016 Amendments are inapposite under Exemption 4 because such

[4] The FDA argues that the Court should "disregard" plaintiff's evidence of the public interest as not based on personal knowledge. FDA Opp. 19, n. 13. Seife is an experienced math and science journalist and has previously used FOIA requests to document instances of research misconduct. Seife Decl. ¶¶ 4-7, ECF 149. Seife is drawing on this background in reviewing the evidence and in reaching conclusions that the withheld information would shed light on the agency's performance of its duties. *Id.* ¶¶ 116-66. The Ninth Circuit cases, referenced in Seife's brief, Seife Br. 28, speak for themselves, but are unnecessary for him to prevail.

information is "exempt from disclosure under a law outside the four corners of FOIA," specifically the Trade Secrets Act or FDA regulations. FDA Opp. 9-10; Sarepta Opp. 19-20. These theories should be flatly rejected as contrary to the text, structure, and purpose of FOIA.

First, the Supreme Court itself has viewed Exemption 4 as a discretionary exemption, contradicting the premise of defendants' theory that other laws make its application mandatory. In *Chrysler*, an Exemption 4 case, Justice Rehnquist writing for a unanimous Court described FOIA as "exclusively a disclosure statute" that prohibits only the improper "'withholding [of] agency records'" and does "not limit an agency's discretion to disclose information." 441 U.S. at 292, 294. As Judge Posner noted in *General Electric Company v. U.S. Nuclear Regulatory Commission*, 750 F.2d 1394, 1401-02 (7th Cir. 1984), *Chrysler* strongly suggests that "the Trade Secrets Act has no independent force in cases where the Freedom of Information Act is involved." *See also McDonell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182, 1194, 1204 (D.C. Cir. 2004) (Garland, J., dissenting) (collecting cases and also questioning if Trade Secret Act is co-extensive with Exemption 4). Again, the Court in *FMI* noted the government's representation that "it 'will not disclose' the contested data unless compelled to do so"—a representation that implies disclosure is discretionary and would make no sense if the Trade Secrets Act independently barred disclosure. *FMI*, 139 S. Ct. at 2362.[5]

Second, defendants' reading of the "prohibited by law" phrase as encompassing random statutes discussed in the legislative history and agency regulations does profound violence to the structure and text of FOIA and should be categorically rejected. Defendants' reading would treat agency regulations

[5] While certain lower courts in other circuits have suggested that Exemption 4 is mandatory, Sarepta Opp. 19-20 (collecting cases), the Second Circuit has never adopted this view and has implied that Exemption 4 is *permissive*, *see Nadler v. FDIC*, 92 F.3d 93, 97 (2d Cir. 1996) (declining to reach the issue); *Bloomberg, LP. v. Bd. of Governors of the Fed. Reserve Sys.*, 601 F.3d 143, 147 (2d Cir. 2010) (Exemption 4 "*allows* a federal agency . . . to refuse disclosure") (emphasis added), cases both defendants fail to cite.

or a statute mentioned in legislative history as authorizing withholding—effectively treating the "prohibited by law" provision as it were a new exemption in the withholding subsection of FOIA. In contrast, a reading of the phrase "prohibited by law" as an exception to the need to show a foreseeable harm that applies only to FOIA's mandatory exemptions (of which Exemption 4 is not one) would limit withholding to narrow circumstances and comport with the longstanding rule that "in the interpretation of statutes, . . . proviso[s] [are] construed strictly." *United States v. Dickson*, 40 U.S. 141, 165 (1841).[6] By casting the "prohibited by law" provision as a "super-exemption," defendants' reading would also swallow Exemption 3, which expressly prohibits disclosure where required by certain statutes under certain circumstances. Defendants' reading thus ignore *FMI*'s clear instruction to "stop" where the text "yields a clear answer." 139 S. Ct. at 2364. Seife's reading of the mandatory exemptions is the grammatically correct reading of FOIA that does not "alter FOIA's plain terms on the strength only of arguments from legislative history" as *FMI* forbade and as defendants ask this Court to do. *Id.*

Finally, even if defendants were correct that the Trade Secret Act rendered portions of Exemption 4 mandatory, this case does not deal with those portions because it involves commercial information, not trade secrets. *See* ECF No. 65.[7] The Seventh Circuit has confirmed this crucial

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[6] This Court need not define "prohibited by law" since defining "law" raises questions that have stumped jurists for millennia. Leading legal scholar Hart stated that "[p]lainly the best course is to defer giving any answer'" as "nothing concise enough to be recognized as a definition could provide a satisfactory answer." H.L.A. Hart, *The Concept of Law* 1, 5, 16 (Oxford Univ. Press 1961). That said, should the Court be inclined to adopt a definition, "disclosure is prohibited by law" in the 2016 Amendments should be read to refer only to FOIA's mandatory exemptions, including Exemption 3. Sarepta itself argues for this interpretation, though it incorrectly categorizes Exemption 4 and portions of Exemption 6 as mandatory. Sarepta. Opp. 20 ("Classified information, information protected from disclosure by the Trade Secrets Act, information protected by the Privacy Act [namely portions of information covered by Exemption 6], and information protected by Exemption 3 are all information whose disclosure is prohibited by law.") Only Exemption 4 is before this Court..

[7] The Verni Declaration attempts to assert for the first time that the clinical trial data at issue is a "trade secret," Verni Decl. ¶ 7, ECF 143, but Sarepta has agreed that the data is commercial information.

distinction under FOIA, concluding: "[I]t is hard to believe that Congress wanted" FOIA requesters "to stub their toes on a rather obscure criminal statute . . . designed to protect that narrower category of trade secrets . . . whose disclosure could be devastating . . . and not just harmful." *General Electric Co.*, 750 F.2d at 1401-02. Moreover, criminal statutes like the Trade Secrets Act must be strictly construed and not expanded beyond their terms even if the two terms are "of kindred character[] with those which are enumerated." *United States v. Wiltberger*, 18 U.S. 76, 96 (1820) (Marshall, C.J.).

II. Even If The 2016 Amendments Do Not Apply, Defendants Do Not Meet The New *FMI* Standard For Withholding

As Seife has demonstrated, defendants have not even met their burden to demonstrate the information qualifies as "confidential" under Exemption 4. Seife Br. 34-43. In *FMI*, the Supreme Court held that information "customarily kept private, or at least closely held, by the person imparting it" is to be considered "confidential" under Exemption 4. 139 S. Ct. at 2363. Defendants argue that Exemption 4 encompasses any information submitted to an agency that is not actually public. They contend that Sarepta's declaration—stating that Sarepta considers the information at issue confidential and has never publicly released it—satisfies their burden. Sarepta Opp. 10-11. This interpretation of *FMI* seeks to "*expand* Exemption 4 beyond what its terms permit"—something *FMI* declares just as impermissible as attempting to "arbitrarily *constrict* it." 139 S. Ct. at 2366.

FMI never equates the test for Exemption 4 confidentiality with the test of whether *identical information* is already public. This latter test, urged by defendants, has long been recognized by courts—including in this case—as an affirmative defense to a request under Exemption 4. *See Inner City*

Sarepta Supp. MSJ Br. 12-13, ECF 140. Trade secrets are covered by a different line of FOIA doctrine, and a change in the entire theory of the case at this hour would work severe prejudice to Seife, who has relied on the representation the parties entered into since March 22, 2018. ECF 65.

Press/Cmty. on the Move v. Bd. of Governors of Fed. Reserve Sys., 463 F.3d 239, 244-45 (2d Cir. 2006); *Seife*, 2019 WL 1382724, at *2-3; *Niagara Mohawk Power Corp. v. U.S. Dep't of Energy,* 169 F.3d 16, 19 (D.C. Cir. 1999). The Supreme Court could have adopted this test in *FMI*, but did not do so because it essentially flips from an agency FOIA's statutory burden to prove an exemption properly applies. *See* 5 U.S.C. § 552(a)(4)(B); *U.S. Dep't of State v. Ray*, 502 U.S. 164, 173 (1991). The "already public" test places the burden of proving information is public on the requester when used as an affirmative defense because otherwise the opponent of disclosure would have to "undertake an exhaustive, potentially limitless search" to "identify all of the public sources in which the information contained in its documents is not reproduced." *Inner City Press*, 463 F.3d at 244-45. Defendants' approach would shift a similar burden to the FOIA requester whenever an information submitter provides a sworn statement that information is private. Overcoming this burden would be all but impossible in most cases, given the information asymmetries preventing the requester from knowing what is behind the redactions. *See* Seife Br. 13-14 (collecting cases). The Supreme Court in *DOJ v. Landano*, 508 U.S. 165 (1993), identified problems with creating standards such as this. "[T]hough rebuttable in theory" defendants' proposed standard "is in practice all but irrebuttable" because "the requester—who has no knowledge about the particular source or the information being withheld—very rarely will be in a position to offer persuasive evidence." *Landano*, 508 U.S. at 176-77.

The problem with requiring proof that *identical information* is public is amplified in cases where there is a potential for government embarrassment. It requires the court and the FOIA requester to take defendants at their word when there are strong incentives for selective, or inaccurate, disclosure. *See* Seife Br. 13-14. According to Sarepta, unexplained redactions should be permitted to defeat even the accurate deductions of the FOIA requester about the contents of withheld information. Sarepta Opp. 14. The requester and the court must take a submitter's assertion of confidentiality as all but

dispositive. This approach, once again, contradicts FOIA, which places on the courts a statutory duty to conduct *de novo* review of withholding decisions, § 552(a)(4)(B), in order to "ensure that the agency's assertions are reliable." *Jones v. FBI*, 41 F.3d 238, 242-43 (6th Cir. 1994). FOIA does not permit the type of dispositive deference defendants demand.[8]

Finally, defendants' reading also contradicts the Supreme Court's longstanding mandate that FOIA exemptions be narrowly construed, *see Milner v. Dep't of Navy*, 562 U.S. 562, 571-72 (2011) (collecting cases), and cannot be squared with *FMI*, which provides illustrative standards for secrecy, *FMI*, 139 S. Ct. at 2363, including that information is "known only to a limited few," *id.*, a standard Sarepta surely fails. Seife Br. 37-41.

The substantial problems created by defendants' approach are avoided by a common sense reading of *FMI*. Seife's application of the phrase "customarily kept private or at least closely held" is consistent with FOIA's purpose and grounded in *FMI*'s guidance that the holder not share information "freely." 139 S. Ct. at 2363; Seife Br. 36-37. Given this workable alternative, the Court should decline to follow the pessimistic logic of *American Small Business League v. DOD*, 2019 WL 6255353, at *3-5 (N.D. Cal. Nov. 24, 2019), which allows "defendants [to] merely invoke the magic words—'customarily and actually kept confidential'—to prevail," even while recognizing this outcome is "'at odds with' FOIA's purpose." These "magic words" can be read more narrowly. Seife Br. 35 &

[8] Non-conclusory declarations presented in "good faith" that provide the court and the requester "as much information as possible" can permit meaningful adversarial review. *See Halpern v. FBI*, 181 F.3d 279, 290 (2d Cir. 1999). But the declarations here are insufficient. *Seife*, 2019 WL 1382724 at *2. The latest round of briefing confirms this. Sherwood admits in her third declaration that half of the table at FDACDER0006538 was erroneously redacted. Sherwood was forced to include a version of the table without the erroneous redaction in Exhibit A of her third declaration. Sherwood Decl. ¶ 4. Seife is *not* using information post-dating the last round of summary judgment briefing; there is no moving target as defendants argue. *See* FDA Opp. 7.

n.18; *see also FMI*, 139 S. Ct. at 2365 (discussing *Critical Mass* descriptively, not prescriptively).

Sarepta has customarily shared its information with others (*i.e.*, the EMA and information-sharing coalitions) in a manner that is not "closely held" or restricted to "a limited few," 139 S. Ct. at 2363, even if NDAs were used, Seife Br. 36-41.[9] Seife does not argue that the information cannot be confidential "so long as Sarepta gave it to *anyone* else," Sarepta Opp. 5, but rather that this Court should look at industry standards for data-sharing and see how the *company itself* does (or does not) comply with them, Seife Br. 36-37.

Seife's approach is also consistent with a federal court decision on this same issue that post-dates his supplemental brief. *CFIR* observed that when information of the *same type* has been shared publicly, representations that it is confidential come into doubt. *See CFIR*, 2019 WL 6716352 at *6. This is true even if the released information is *not identical* to the information at issue. *Id. CFIR* is also consistent with the holding of *Critical Mass*, which held information to be confidential "*if it is of a kind* that would *customarily* not be released to the public by the person from whom it was obtained." *Critical Mass Energy Project v. NRC*, 975 F.2d 871, 879-80 (D.C. Cir. 1992) (en banc) (emphasis added).[10] As

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[9] Seife does not rely on the "waiver" doctrine as Sarepta contends. Sarepta Opp. 5-6. Under that controversial doctrine, FOIA information released by a court under a protective order becomes public because FOIA authorizes disclosure to "any person," *i.e.*, the public. *Compare Am. Small Bus. League*, 2019 WL 6255353, at *5 & n.4 (citing *Maricopa Audubon Soc'y v. U.S. Forest Serv.*, 108 F.3d 1082, 1088 (9th Cir. 1997)) (litigation confidentiality order not permitted because disclosure to one is disclosure to all)) *with Allnet Commc'n Servs., Inc. v. F.C.C.*, 800 F. Supp. 984, 988-89 (D.D.C. 1992) (litigation confidentiality order permitted). Of course, limited release under a protective order is a distinct from whether the *information submitter itself* has "customarily and actually kept [the information] private" "in the ordinary course of business." *Am. Small Bus. League*, 2019 WL 6255353, at *5.

[10] Sarepta distorts the holding and the relevance of *Critical Mass*. The information there was not deemed confidential because industry members had NDAs amongst themselves. Rather, it was because they submitted a joint report as a coalition to a government agency and there were concerns that a failure to provide confidentiality would chill *voluntary* submissions in the future. *See Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 644 F. Supp. 344, 347 (D.D.C. 1986); *see also Critical Mass Energy Project*,

CFIR observed, the data at issue in *FMI* "was not disclosed, or made 'publicly available in any way,'" while the information in *CFIR* had been made *partially* available to the public. 2019 WL 6716352 at *6. It was unimportant that not "all data points" were public; what mattered was that "the information disclosed was substantial enough to undermine the Government's claim of confidentiality and call into doubt the [intervenor-defendant's] supporting declaration." *Id.* Partial disclosure was enough to convince the court that "there is a significant possibility" some information was not confidential. *Id.*

This Court should draw the same conclusion from Sarepta's disclosures of information sought by Seife. The extent to which Sarepta has made much of the requested information publicly available is well documented throughout this case. *See* Seife Br. 23-24, 37-41. Sarepta claims that the 135-page report produced by the EMA Committee for Medicinal Products for Human Use is not all-encompassing enough to jeopardize confidentiality, Sarepta Opp. 16, but this argument misses the point. Neither the EMA report nor Sarepta's other disclosures need to reveal *all* the information sought for its claim of confidentiality to be defeated. It is enough that Sarepta's public disclosures are "substanti[ve]" and "call into doubt" the company's claim of confidentiality. *CFIR*, 2019 WL 6716352 at *6. Sarepta's disclosures to the EMA easily meet this test. Sarepta concedes that the EMA report includes "summary charts" for Studies 201 and 202. Sarepta. Opp. Br. 16. These charts alone, like the published summary data in *CFIR*, raise sufficient doubts to defeat Sarepta's claim of confidentiality.

CONCLUSION

For the foregoing reasons, this Court should deny defendants' motions for summary judgment and grant Seife's cross-motion for summary judgment.

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731 F. Supp. at 556-57. Here, Sarepta's information was *not* voluntarily submitted, *see* Seife Br. 35 n.18, and there is no concern about impairing submission of mandatory clinical trial data.

Dated: December 23, 2019

Respectfully submitted,

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