UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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CHARLES SEIFE and PETER LURIE,

Plaintiffs,

- against -

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, in his official capacity; NATIONAL INSTITUTES OF HEALTH; FRANCIS S. COLLINS, DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH, in his official capacity; U.S. FOOD AND DRUG ADMINISTRATION; and SCOTT GOTTLIEB, COMMISSIONER OF FOOD AND DRUGS, in his official capacity,

Defendants.

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MEMORANDUM AND ORDER

18 Civ. 11462 (NRB)

NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE

The U.S. Department of Health and Human Services ("HHS"), Secretary of Health and Human Services Alex M. Azar II, the National Institutes of Health ("NIH"), Director of NIH Francis S. Collins, the U.S. Food and Drug Administration (the "FDA"), and Commissioner of Food and Drugs Stephen M. Hahn[1] (collectively, "defendants") move to dismiss the complaint of Charles Seife and Peter Lurie (together, "plaintiffs"), or, in the alternative, for summary judgment. Plaintiffs cross-move for summary judgment. Defendants' motion to dismiss is granted in part and denied in

[1] Stephen M. Hahn, the current Commissioner of Food and Drugs, is automatically substituted for Scott Gottlieb, the former Commissioner of Food and Drugs, pursuant to Federal Rule of Civil Procedure 25(d). The Clerk of Court is respectfully directed to amend the case caption accordingly.

part. Defendants' motion for summary judgment is granted in part and denied in part. Plaintiffs' cross-motion for summary judgment is granted in part and denied in part.

I. BACKGROUND

A. Statutory Background

In 1997, Congress enacted the Food and Drug Administration Modernization Act ("FDAMA"). Among other things, FDAMA provided that "[t]he Secretary[2], acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions." 42 U.S.C. § 282(i)(1)(A). It also required the Secretary to "disseminate such information through information systems . . . available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers." Id. § 282(i)(2). Pursuant to these directives, HHS and NIH created ClinicalTrials.gov, an online clinical trial database made publicly accessible in 2000. Joint Stipulation ("Stip.") ¶ 1.

In 2004, Congress raised concerns about the safety and effectiveness of several FDA-approved products for which unfavorable clinical trial results had not been publicly disclosed. Pls.' 56.1 ¶ 7 (citing Declaration of Christopher

[2] All statutory references to "the Secretary" are to the Secretary of HHS unless specified otherwise.

Morten ("Morten Decl."), Ex. 5 at 66); see also H. Rep. 110-225 at 11-12 (2007). Congress observed that under FDAMA, "negative results may or may not be released by [clinical trial] sponsors," H. Rep 110-225 at 12, and it questioned whether, as a result, clinical trial sponsors were misleading the public about the safety and efficacy of their drugs and devices by publishing only favorable clinical trial results on ClinicalTrials.gov, see id. at 11-12. Congress also expressed misgivings about ClinicalTrials.gov hosting information for clinical trials relating to serious or life-threatening diseases and conditions only. See id. at 12.

To address these concerns, Congress enacted Section 801 of the Food and Drug Administration Amendments Act of 2007, codified as 42 U.S.C. § 282(j) (the "FDAAA"), which sought to "increase the availability of information to the public" and to "communicate the risks and benefits of drugs" in order to "help patients, providers, and researchers learn new information and make more informed healthcare decisions." H. Rep. 110-225 at 12.

To accomplish these goals, the FDAAA defined a broad set of "applicable clinical trials"[3] ("ACTs") for which "responsible

[3] An "applicable clinical trial" is "an applicable device clinical trial or an applicable drug clinical trial." 42 U.S.C. § 282(j)(1)(A)(i). These terms are defined expansively to include, among other things, "a prospective clinical study of health outcomes comparing an intervention with a device subject to [the FDA's approval requirements] against a control in human subjects," 42 U.S.C. § 282(j)(1)(A)(ii)(I), and "a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to [the FDA's approval requirements]."

parties"[4] must submit certain clinical trial registration information, see 42 U.S.C. § 282(j)(2)(A)(ii), and clinical trial results information, see, e.g., id. § 282(j)(3)(C), that HHS, acting through NIH, must include on ClinicalTrials.gov, id. § 282(j)(2)(A)(i). The FDAAA also established various enforcement mechanisms to ensure that responsible parties comply with their obligations under the statute. See, e.g., id. §§ 282(j)(5)(C)(ii), 282(j)(5)(E)(i).

1. Clinical Trial Registration Information

Under the FDAAA, responsible parties must submit certain registration information within 21 days after the first patient enrolls in an ACT. See 42 U.S.C. § 282(j)(2)(A)(ii). The registration information includes "descriptive information" (e.g., "a brief summary, intended for the lay public" and "the primary disease or condition being studied"), "recruitment information" (e.g., "eligibility criteria" and "whether the trial accepts healthy volunteers"), "location and contact information" (e.g., "the name of the sponsor" and "the responsible party"), and certain "administrative data." Id.

[4] A "responsible party" is "the sponsor of the clinical trial" or "the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirement under this subsection for the submission of clinical trial information." 42 U.S.C. § 282(j)(1)(A)(ix).

2. Clinical Trial Results Information

The FDAAA also mandates that responsible parties submit, and defendants include on ClinicalTrials.gov, clinical trial results information. See 42 U.S.C. § 282(j)(3)(B). In this regard, the FDAAA distinguishes between two types of results: Basic Results and Expanded Results. Compare id. § 282(j)(3)(C) (describing Basic Results) with id. § 282(j)(3)(D)(iii) (describing Expanded Results).

2.1 Basic and Expanded Results

Basic Results consist of four categories of information. See id. § 282(j)(3)(C). First, they include demographic and baseline characteristics of the ACT's patient sample, including the number of patients who dropped out or were excluded from the trial analysis. Id. § 282(j)(3)(C)(i). Second, they incorporate primary and secondary outcomes, including tests for the statistical significance of such outcomes. Id. § 282(j)(3)(C)(ii). NIH describes outcomes as "planned measurement[s] . . . used to determine the effect of an intervention/treatment on participants," and notes that primary outcomes are "the most important for evaluating the effect of an intervention/treatment." Morten Decl., Ex. 6 at 12. Third, Basic Results include a point of contact for scientific information about the ACT's results. 42 U.S.C. § 282(j)(3)(C)(iii). Fourth, Basic Results encompass whether there is an agreement between the sponsor and the principal

investigator that restricts the principal investigator's ability to discuss or publish the ACT's results after its completion. Id. § 282(j)(3)(C)(iv).

Expanded Results also consist of four categories of information. See id. § 282(j)(3)(D)(iii). They include a summary of the ACT and its results "that is written in non-technical, understandable language," as well as one "that is technical in nature," but, in either case, only "if the Secretary determines that such types of summary can be included without being misleading or promotional." Id. § 282(j)(3)(D)(iii)(I)-(II). They also encompass the ACT's protocol, and "[s]uch other categories as the Secretary determines appropriate." Id. § 282(j)(3)(D)(iii)(III)-(IV).

2.2 Requirements for Basic Results

The FDAAA requires HHS to include Basic Results for certain ACTs on ClinicalTrials.gov:

> [T]he Secretary shall include in [ClinicalTrials.gov] for each [ACT] for a drug that is approved under [21 U.S.C. § 355] or licensed under [42 U.S.C. § 262] or a device that is cleared under [21 U.S.C. § 360(k)] or approved under [21 U.S.C. §§ 360e or 360j(m)], the following elements: [Basic Results].

42 U.S.C. § 282(j)(3)(C). To enable HHS to do this, the FDAAA mandates that "the responsible party . . . submit to the Director of NIH for inclusion in [ClinicalTrials.gov] the clinical trial information described in subparagraph (C) [i.e., Basic Results]

not later than 1 year, or such other period as may be provided by regulation . . . after the earlier of" the ACT's estimated or actual completion date. Id. § 282(j)(3)(E)(i).

Consistent with ensuring public access to clinical trial results for FDA-approved products[5], the FDAAA addressed the situation where an ACT studied a product that was approved after, rather than before, the ACT's estimated or actual completion date:

> With respect to an [ACT] that is completed before the drug is initially approved under [21 U.S.C. § 355] or initially licensed under [42 U.S.C. § 262], or the device is initially cleared under [21 U.S.C. § 360(k)] or initially approved under [21 U.S.C. §§ 360e or 360j(m)], the responsible party shall submit to the Director of NIH for inclusion in [ClinicalTrials.gov] the clinical trial information described in subparagraphs (C) [i.e., Basic Results] and (D) [i.e., Expanded Results] not later than 30 days after the drug or device is approved under [21 U.S.C. § 355], licensed under [42 U.S.C. § 262], cleared under [21 U.S.C. § 360k], or approved under [21 U.S.C. §§ 360e or 360j(m)], as applicable.

42 U.S.C. § 282(j)(3)(E)(iv). Such ACTs are common because federal law generally requires that the FDA review the results of at least one, and sometimes two or more, ACTs before approving a product. See, e.g., 21 U.S.C. § 355(b)(1)(A) (requiring applications for approval of new drugs to include clinical trial results); id. § 360e(c)(1)(A) (requiring the same for premarket approval applications for Class III devices).

[5] The Court uses the phrases "FDA-approved products" and "approved products" to refer to drugs that are approved or licensed by the FDA and to devices that are approved or cleared by the FDA.

2.3 Requirements for Expanded Results

Whereas the FDAAA requires that ClinicalTrials.gov include Basic Results for any ACT of a product that is approved, it delegated authority to HHS to promulgate regulations governing the inclusion of Expanded Results. See 42 U.S.C. § 282(j)(3)(D)(i).

Under the FDAAA, the regulations that HHS promulgates must require ClinicalTrials.gov to include Expanded Results for each ACT of a product that is approved: "[t]he regulations under this subparagraph shall require the inclusion of the results information described in clause (iii) [i.e., Expanded Results] for . . . each [ACT] for a drug that is approved under [21 U.S.C. § 355] or licensed under [42 U.S.C. § 262]," and for "each [ACT] for a device that is cleared under [21 U.S.C. § 360(k)] or approved under [21 U.S.C. §§ 360e or 360j(m)]." Id. § 282(j)(3)(D)(ii)(I). By contrast, the FDAAA affords HHS discretion to decide whether the regulations it promulgates will require ClinicalTrials.gov to include Expanded Results for an ACT of a product that is not approved: "[t]he regulations under this subparagraph shall establish whether or not the results information described in clause (iii) [i.e., Expanded Results] shall be required for . . . an [ACT] for a drug that is not approved under [21 U.S.C. § 355] and not licensed under [42 U.S.C. § 262] (whether approval or licensure was sought or not)," and for "each [ACT] for a device that is not cleared under [21 U.S.C. § 360(k)] and not approved

under [21 U.S.C. §§ 360e or 360j(m)] (whether approval or licensure was sought or not)." Id. § 282(j)(3)(D)(ii)(II).

Congress set a deadline of September 27, 2010 for the Secretary to promulgate regulations pursuant to the FDAAA's delegation of rulemaking authority. Id. § 282(j)(3)(D)(i).

3. Violation Notices, Public Notices of Noncompliance, and a Search Function for Public Notices of Noncompliance

The FDAAA empowers HHS to issue a notice of noncompliance to a responsible party that fails to submit, or submits false or misleading, clinical trial information, including clinical trial results:

> If the Secretary determines that any clinical trial information was not submitted as required under [42 U.S.C. § 282(j)], or was submitted but is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such noncompliance by submitting the required revised clinical trial information not later than 30 days after such notification.

42 U.S.C. § 282(j)(5)(C)(ii) (the "FDA notice provision"). "If a violation . . . is not corrected within the 30-day period following notification under section 282(j)(5)(C) of Title 42 [i.e., the FDA notice provision], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected." 21 U.S.C. § 333(f)(3)(B). HHS delegated its authority to issue notices of

noncompliance under the FDA notice provision to the FDA. 77 Fed. Reg. 59,196 (Sept. 26, 2012). The FDA is yet to issue a noncompliance notice under the FDA notice provision. Stip. ¶ 3.

The FDAAA also provides that "[i]f the responsible party for an [ACT] fails to submit clinical trial information for such clinical trial . . . the Director of NIH shall include in the [ClinicalTrials.gov] entry for such clinical trial a notice" containing certain information. 42 U.S.C. § 282(j)(5)(E)(i) (the "NIH notice provision"). The notice must state "that the responsible party is not in compliance" by "failing to submit required clinical trial information" or by "submitting false or misleading clinical trial information," id. § 282(j)(5)(E)(i)(I), "the penalties imposed for the violation, if any," id. § 282(j)(5)(E)(i)(II), and "whether the responsible party has corrected the clinical trial information in [ClinicalTrials.gov]," id. § 282(j)(5)(E)(i)(III).

A separate provision also states that "[t]he Director of NIH shall provide that the public may easily search [ClinicalTrials.gov] for entries that include notices required under this subparagraph." Id. § 282(j)(5)(E)(vi) (the "notice search provision"). To date, NIH has neither posted a public notice of noncompliance nor created a search function for such notices on ClinicalTrials.gov. Stip. ¶¶ 4, 6.

B. The Final Rule

On September 21, 2016, almost ten years after Congress enacted the FDAAA and nearly six years after the FDAAA's September 27, 2010 deadline, HHS promulgated a regulation designed to implement the FDAAA, the effective date of which was January 18, 2017. Clinical Trials Registration and Results Information Submission, 81 Fed. Reg. 64,981 (Sept. 21, 2016) (the "Final Rule") (codified at 42 C.F.R. § 11 et seq.).

The Final Rule includes a section titled, "For which applicable clinical trials must clinical trial results information be submitted?":

> **(a) Applicable clinical trials for which the studied product is approved, licensed, or cleared by FDA.** Unless a waiver of the requirement to submit clinical trial results information is granted in accordance with § 11.54, clinical trial results information must be submitted for any applicable clinical trial for which the studied product is approved, licensed, or cleared by FDA for which submission of clinical trial registration information is required in accordance with the following:
>
> (1) If the primary completion date [of the ACT] is before January 18, 2017, the responsible party must submit [Basic Results and certain other data]; or
>
> (2) If the primary completion date [of the ACT] is on or after January 18, 2017, the responsible party must submit [Basic Results and a broader range of data than required under the previous paragraph].
>
> **(b) Applicable clinical trials for which the studied product is not approved, licensed, or cleared by FDA.** Unless a waiver of the requirement to submit clinical trial results information is granted in accordance with § 11.54, [Basic Results and other data] must be submitted for any applicable clinical trial with a primary completion date on or after January 18, 2017 for which

> clinical trial registration information is required to be submitted and for which the studied product is not approved, licensed, or cleared by FDA.

42 C.F.R. § 11.42 (boldface in original but other emphasis added). The emphasized portions of § 11.42 refer to the product's "marketing status." 81 Fed. Reg. at 65,120.

The preamble[6] to the Final Rule stated that "[f]or purposes of this final rule, the marketing status of a product will be determined based on its marketing status on the primary completion date [of the ACT]. Thus, if a drug product . . . or a device product is approved, licensed, or cleared for any use as of the primary completion date, we will consider that applicable clinical trial to be a trial of an approved, licensed, or cleared product. Similarly, if a drug product . . . or a device product is unapproved, unlicensed, or uncleared for any use as of the primary completion date, regardless of whether it is later approved, licensed, or cleared, we will consider that applicable clinical trial to be a trial of an unapproved, unlicensed, or uncleared product." Id. (emphasis added).

In other words, HHS interpreted the regulatory phrases "is approved, licensed, or cleared by FDA," 42 C.F.R. § 11.42(a), and "is not approved, licensed, or cleared by FDA," id. § 11.42(b), to

[6] "When issuing regulations, the Administrative Procedure Act requires agencies to 'incorporate in the rules adopted a concise general statement of their basis and purpose,' 5 U.S.C. § 553(c), a statement that is commonly known as the regulation's preamble." Halo v. Yale Health Plan, Dir. of Benefits & Records Yale Univ., 819 F.3d 42, 52 (2d Cir. 2016).

mean not whether the product is currently approved, licensed, or cleared, but instead whether the product was approved, licensed, or cleared on the date on which the ACT was completed.

The consequence of HHS's interpretation is that the responsible party for an ACT completed after the enactment of the FDAAA on September 27, 2007 but before the Final Rule's effective date of January 18, 2017 need not submit Basic Results if the ACT studied a product that was approved after the ACT's completion (hereinafter, "pre-Rule, pre-approval ACTs") because such an ACT falls under 42 C.F.R. § 11.42(b) instead of § 11.42(a). Thus, under HHS's interpretation, Basic Results for pre-Rule, pre-approval ACTs need not be disclosed regardless of whether those results indicate that an FDA-approved product that is used by possibly thousands of Americans is unsafe or ineffective.

The lawfulness of HHS's interpretation of § 11.42's regulatory language is the central dispute in this litigation.

C. Background on the Plaintiffs

1. Charles Seife

Charles Seife is an investigative journalist focusing on science and technology whose investigations have appeared in publications such as Scientific American and The New York Times. Declaration of Charles Seife ("Seife Decl.") ¶¶ 2-4. Many of Seife's investigations use clinical trial data to discern whether drug companies perform clinical trials that are adequate to prove

that drugs are safe and effective, whether those companies share the results of those trials timely, accurately, and fully, and whether the FDA adequately protects the public from ineffective or dangerous drugs. See id. ¶ 4 (listing six publications reporting on such investigations). Seife's research has revealed deficiencies in the evidence supporting the FDA's approval of various prescription drugs. See id. For example, Seife published an article in 2013 that used clinical trial data from ClinicalTrials.gov, court records, and FOIA requests to confirm that the FDA had allowed six drugs to remain on the market even though the clinical trials that were used to establish their safety and efficacy were found to be fraudulent. See id. ¶ 6.

Seife contends that HHS's interpretation of its Final Rule deprives him of access to Basic Results for pre-Rule, pre-approval ACTs of products the safety and efficacy of which he is researching. Id. ¶ 10-11. Seife has offered two examples in support of this contention.

First, Seife offers Study 202, an ACT of the drug eteplirsen. Eteplirsen is an FDA-approved drug that is marketed by Sarepta Therapeutics, Inc. ("Sarepta") for the treatment of a rare genetic disorder called Duchenne muscular dystrophy ("DMD"). Id. ¶ 11. Eteplirsen is the only FDA-approved treatment for DMD that is claimed to provide more than palliative care. Id. ¶ 14. Sarepta

charges between $300,000 and $500,000 per year for eteplirsen, and many prescription drug plans do not cover the drug. Id.

Sarepta sponsored the first clinical trials of eteplirsen, Studies 201 and 202, and Sarepta's initial public statements about them indicated positive results. Id. ¶ 12. However, after Sarepta submitted its new drug application for eteplirsen to the FDA in 2015, the FDA's review team at the Center for Drug Evaluation and Research ("CDER") deemed Studies 201 and 202 flawed in their design, insufficient to establish the drug's effectiveness, and recommended against approving the drug. Id. ¶ 12.

After DMD patient groups opposed the FDA review team's recommendation, Jane Woodcock, the head of CDER, unilaterally approved the drug. Id. ¶ 12-13. Dr. John Jenkins, the review team's lead scientist, wrote in a memo that Woodcock had "'frequent private conversations with the sponsor and the stakeholder community,'" and that her involvement in eteplirsen's approval "'far exceed[ed] her usual hands on approach.'" Id. ¶ 13 (quoting from a FOIA production from the FDA to Seife available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/SeifeProduction_2017_07_24.pdf (last accessed on Feb. 11, 2020)). The dispute escalated to the Commissioner of Food and Drugs, who although sided with Woodcock, nonetheless called for the retraction of the published Study 202 due to its flaws. Id. Jenkins later resigned from his position at the FDA. Id.

Seife began researching eteplirsen in 2016 in order to evaluate the scientific soundness of the FDA's decision to approve the drug. Id. ¶ 15. To do this, he needs the clinical data to assess whether eteplirsen is effective. Id. Study 202, however, which specifically studied eteplirsen's effectiveness, is a pre-Rule, pre-approval ACT. See id. ¶ 17. Study 202's results, which were not otherwise available, were accordingly absent from ClinicalTrials.gov. Id. ¶ 20. The FDA published Study 202's Basic Results on ClinicalTrials.gov on July 10, 2019, just one month after Seife had submitted a declaration regarding his eteplirsen research in support of his claim to standing in this case. See https://clinicaltrials.gov/ct2/show/results/NCT01540409?term=NCT01540409&rank-1&view=results (last accessed on Feb. 6, 2020).

Second, Seife offers NCT00865280, an ACT of the drug omadacycline. Paratek Pharmaceuticals, Inc. ("Paratek") markets omadacycline for the treatment of certain bacterial infections. Supplemental Declaration of Charles Seife ("Seife Suppl. Decl.") ¶ 11. In 2009, Paratek commenced NCT00865280, the purpose of which was to assess omadacycline's safety and efficacy. Id. ¶¶ 12-13. NCT00865280 was scheduled to be completed in 2010, and Paratek claimed that it had enrolled 790 patients. Id. ¶¶ 13, 17. NCT00865280 was never completed, however, and, in 2012, Paratek formally terminated it. Id. ¶ 17. Moreover, the termination notice that appeared on ClinicalTrials.gov noted that only 143

patients had enrolled in the study, not the 790 that Paratek had claimed had enrolled. Id.

The FDA approved omadacycline in 2018. Id. ¶ 15. As a pre-Rule, pre-approval ACT, Paratek is not required to disclose NCT00865280's results under HHS's interpretation of the Final Rule. Id. ¶ 15. Moreover, those results are not available on NCT00865280's entry on ClinicalTrials.gov, nor are they available elsewhere. Id. ¶¶ 16-17. The absence of this information prevents Seife from researching omadacycline's safety and effectiveness. Id. ¶ 17.

Seife also researches the extent to which product approval applications to the FDA disclose all the pertinent clinical trials for the product, the extent to which the FDA's approval of products is based at least in part on clinical trials that do not comply with statutory and regulatory requirements, and compliance with the FDAAA's reporting obligations. See Seife Decl. ¶¶ 31, 34. He attests that, in the absence of public notices of noncompliance or a search function for such notices, he cannot carry out this research because he is unable to discern which clinical trials fail to comport with the FDAAA. See id. ¶¶ 31-34.

2. Peter Lurie

Peter Lurie is a family physician, the President of a not-for-profit public health watchdog called the Center for Science in the Public Interest, and an adjunct faculty member at the John

Hopkins Bloomberg School of Public Health. Declaration of Jacob Lurie ("Lurie Decl.") ¶¶ 2, 5, 7. He worked at the FDA from 2009 through 2017, including as Associate Commissioner for Public Health Strategy and Analysis. Lurie Decl., Ex. 1 at 11-12. Before working for the FDA, Lurie was Deputy Director of Public Citizen's Health Research Group, where he published a study on publication bias and selective results reporting on ClinicalTrials.gov. Id. ¶ 4. He has also served as a researcher at multiple universities, including the University of Michigan and the University of California, San Francisco. Id. ¶¶ 4-5.

Lurie has published more than one hundred articles in medical journals, including articles about clinical trial design, research ethics, and drug efficacy and safety. Id. ¶ 8. Much of Lurie's research and many of his publications concern "the integrity of the clinical trial research enterprise." Id. ¶ 9. Specifically, Lurie evaluates "whether clinical trials are designed and administered correctly," and "whether clinical trial results are reported to the medical community and to the public promptly, completely, and accurately." Id. (enumerating twelve academic articles concerning those topics). Lurie's current research focuses on these topics. Id. ¶ 10.

Lurie contends that the absence of Basic Results for pre-Rule, pre-approval ACTs hampers his research into the integrity of the clinical trial research enterprise. Pls.' 56.1 ¶ 42.

Specifically, he "would have been able to make fuller, richer comparisons in a study . . . comparing result reporting on ClinicalTrials.gov to other online registries." Lurie Decl. ¶ 13. He also asserts that the absence of public notices of noncompliance and a search function for such notices impedes his research. Id. ¶ 43. Without the public notices, Lurie cannot discern whether clinical trial results have been reported promptly, completely, and accurately, and therefore hamstrings his research into the integrity of the clinical trial research enterprise. Id. ¶¶ 45-46, 48.

E. Procedural History

On December 7, 2018, plaintiffs filed a complaint against defendants asserting three causes of action. Plaintiffs' first cause of action, brought under the Administrative Procedure Act (the "APA"), 5 U.S.C. § 706(2)(a), contends that HHS's interpretation of the Final Rule is contrary to the unambiguous terms of the FDAAA and thus unlawful. Plaintiffs' second cause of action, also brought under the APA, 5 U.S.C. § 706(1), challenges NIH's failure to post public noncompliance notices under the NIH notice provision and to create a search function for such notices under the notice search provision as agency action unlawfully withheld. While the complaint asserted a third claim against

defendants, plaintiffs have since consented to its dismissal.[7] See Pls.' Mem. at 16. Before the Court are defendants' motion to dismiss under Federal Rule of Civil Procedure 12(b)(1), or, in the alternative, for summary judgment, and plaintiffs' cross-motion for summary judgment. The Court held oral argument on the parties' motions on February 11, 2020.

I. DISCUSSION

A. Standards of Review

Defendants move to dismiss the complaint for "lack of subject-matter jurisdiction." Fed. R. Civ. P. 12(b)(1). "[A] district court may properly dismiss a case for lack of subject matter jurisdiction under Rule 12(b)(1) if it 'lacks the statutory or constitutional power to adjudicate it.'" Aurecchione v. Schoolman Transp. Sys., Inc., 426 F.3d 635, 638 (2d Cir. 2005) (quoting Makarova v. United States, 201 F.3d 110, 113 (2d Cir. 2000)). "In resolving a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), a district court . . . may refer to evidence outside the pleadings." Makarova, 201 F.3d at 113.

When reviewing agency action under the APA, "[t]he reviewing court shall . . . hold unlawful and set aside agency action . . . found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

[7] The Court accordingly dismisses plaintiffs' third cause of action.

"Where, as here, 'a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal,' and 'the entire case on review is a question of law.'" Assn. of Proprietary Coll. v. Duncan, 107 F.Supp. 3d 332, 344 (S.D.N.Y. 2015) (internal alteration omitted) (quoting Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001)). "[W]hile the usual summary judgment standard under Federal Rule of Civil Procedure 56 does not apply in such cases, summary judgment nonetheless is 'generally appropriate'" because courts "address legal questions in deciding whether the agency acted arbitrarily, capriciously or in some other way that violates 5 U.S.C. § 706." Id. (internal footnote omitted) (quoting Noroozi v. Napolitano, 905 F.Supp. 2d 535, 541 (S.D.N.Y. 2012)).

B. Standing

Defendants argue that plaintiffs lack standing under Article III of the U.S. Constitution. The "judicial Power of the United States" is constitutionally limited to "Cases" and "Controversies." U.S. Const. art. III, § 2. Because "[s]tanding to sue is a doctrine rooted in the traditional understanding of a case or controversy," Spokeo, Inc. v. Robins, --- U.S. ---, 136 S. Ct. 1540, 1547 (2016), "[w]hether a claimant has standing is the threshold question in every federal case, determining the power of the Court to entertain the suit," Fair Hous. in Huntington Comm. Inc. v. Town of Huntington, 316 F.3d 357, 361 (2d Cir. 2003). "If

plaintiffs lack Article III standing, a court has no subject matter jurisdiction to hear their claim." Cent. States Se. & Sw. Areas Health & Welfare Fund v. Merck-Medco Managed Care, L.L.C., 433 F.3d 181, 198 (2d Cir. 2005).

The Supreme Court has "established that the 'irreducible constitutional minimum' of standing consists of three elements." Spokeo, 136 S. Ct. at 1547 (quoting Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992)). "The plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." Id. "The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing these elements." Id. Because "the standing inquiry requires careful judicial examination of . . . whether the particular plaintiff is entitled to an adjudication of the particular claims asserted," Allen v. Wright, 468 U.S. 737, 752 (1984), standing must be assessed as to each plaintiff and each "plaintiff must demonstrate standing separately for each form of relief sought," Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 185 (2000).

1. Injury-in-Fact

"To establish injury in fact, a plaintiff must show that he or she suffered an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not

conjectural or hypothetical." Spokeo, 136 S. Ct. at 1548 (internal quotation marks omitted). "For an injury to be 'particularized,' it 'must affect the plaintiff in a personal and individual way.'" Id. at 1548 (quoting Defs. of Wildlife, 504 U.S at 560 n.1). "A 'concrete' injury must be 'de facto'; that is, it must actually exist." Id.

The term "'[c]oncrete' is not, however, necessarily synonymous with 'tangible,'" and "intangible injuries" -- including the "inability to obtain information that Congress had decided to make public" -- "can nevertheless be concrete." Id. at 1549 (internal quotation marks omitted). Indeed, the Supreme Court has consistently held that "a plaintiff suffers an 'injury in fact' when the plaintiff fails to obtain information which must be publicly disclosed pursuant to a statute." Fed. Election Comm'n v. Akins, 524 U.S 11, 21 (1998) ("Akins"); see also Spokeo, Inc., 136 S. Ct. at 1549-50 (reaffirming this aspect of Akins); Public Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 449 (1989) (finding that the inability to obtain information subject to disclosure under the Federal Advisory Committee Act "constitute[d] a sufficiently distinct injury to provide standing"); Havens Realty Corp. v. Coleman, 455 U.S. 363, 373-374 (1982) (deeming the deprivation of information about housing availability required to be disclosed under the Fair Housing Act a "specific injury" that

"satisfied" the "Art. III requirement of injury in fact" (internal quotation marks omitted)).

Under these precedents, a plaintiff suffers a sufficiently concrete and particularized injury to confer Article III standing "when [1] she is denied access to information that, in the plaintiff's view, must be disclosed pursuant to a statute and [2] there is 'no reason to doubt' that the information would help the plaintiff within the meaning of the statute." McFarlane v. First Unum Life Ins. Co., 274 F.Supp. 3d 150, 161 (S.D.N.Y. 2017) (quoting Akins, 524 U.S. at 21) (collecting cases); see also, e.g., Friends of Animals v. Jewell, 828 F.3d 989, 992 (D.C. Cir. 2016) ("A plaintiff suffers sufficiently concrete and particularized informational injury where the plaintiff alleges that: (1) it has been deprived of information that, on its interpretation, a statute requires the government or a third party to disclose to it, and (2) it suffers, by being denied access to that information, the type of harm Congress sought to prevent by requiring disclosure." (citing Akins, 524 U.S. at 21-22)). Applying this standard, Seife has standing to bring plaintiffs' first and second causes of action, whereas Lurie has standing to bring only the second.

First, both plaintiffs have "espouse[d] a view of the law under which [defendants are] obligated to disclose certain information that [plaintiffs] ha[ve] a right to obtain." Am. Soc. for Prevention of Cruelty to Animals v. Feld Entm't, Inc., 659

F.3d 13, 23 (D.C. Cir. 2011); see also Akins, 524 U.S. at 21. Specifically, on plaintiffs' reading, 42 U.S.C. § 282(j)(3)(C) provides that, contrary to HHS's interpretation of its Final Rule, ClinicalTrials.gov must include Basic Results for pre-Rule, pre-approval ACTs. Moreover, under plaintiffs' readings of the NIH notice and notice search provisions, 42 U.S.C. §§ 282(j)(5)(E)(i) and (vi), NIH has absolute obligations to post public noncompliance notices and to create a search function for such notices.

Second, by being denied access to that information, Seife suffers the type of harm that Congress sought to eliminate by enacting the FDAAA. Congress enacted the FDAAA in order to "help patients, providers, and researchers learn new information and make more informed healthcare decisions" by "increas[ing] the availability of information to the public" and "communicat[ing] the risks and benefits of drugs." H. Rep 110-225 at 12. Yet, by denying Seife access to Basic Results for NCT00865280 -- a pre-Rule, pre-approval ACT -- defendants have stymied Seife's research into omadacycline's safety and effectiveness. Moreover, by not posting public noncompliance notices and implementing a search function to locate such notices, NIH has prevented Seife from researching the safety and effectiveness of approved products that relied on noncompliant ACTs in order to obtain FDA approval.

NIH's refusal to post public notices of noncompliance also harms Lurie in a way that Congress sought to prevent by enacting

the FDAAA. Lurie researches "the integrity of the clinical trial research enterprise," Lurie Decl. ¶¶ 13-14, which includes "whether clinical trials are designed and administered correctly" and "whether clinical trial results are reported to the medical community and to the public promptly, completely, and accurately," Lurie Decl. ¶ 9. While it does not appear that Congress enacted the FDAAA to address concerns about clinical trial design and administration, Congress plainly intended to enable the public to discern whether the results of clinical trials were reported completely and accurately, as Lurie attests he is prevented from doing. See 42 U.S.C. § 282(j)(5)(E)(i) (instructing NIH to post "[p]ublic notices" for clinical trials that "fail[ed] to submit" or "submit[ed] false or misleading" results).

However, the denial of Basic Results for pre-Rule, pre-approval ACTs does not injure Lurie in a way that Congress sought to prevent with the FDAAA. Lurie wants access to Basic Results for pre-Rule, pre-approval ACTs in order to "make fuller, richer comparisons in a study . . . comparing result reporting on ClinicalTrials.gov to reporting on other online registries." Lurie Decl. ¶ 13. But there is no indication that Congress enacted the FDAAA's results reporting requirements to enable researchers to compare results reporting on ClinicalTrials.gov to other registries, or, more generally, to research the clinical trial enterprise. The denial of Basic Results for pre-Rule, pre-approval

ACTs therefore fails to impose an informational injury-in-fact on Lurie. See Nader v. Fed. Election Comm'n, 725 F.3d 226, 230 (D.C. Cir. 2013) (finding no informational injury where plaintiff's alleged harm was not what Congress sought to prevent from its enactment of the Federal Election Campaign Act); see also Electronic Privacy Info. Ctr. v. Presidential Advisory Comm'n on Election Integrity, 878 F.3d 371, 378 (D.C. Cir. 2017) (same).

Accordingly, the Court finds that the denial of Basic Results for pre-Rule, pre-approval ACTs imposes an informational injury-in-fact only on Seife. By contrast, NIH's failure to post public notices of noncompliance and to provide a search function for such notices inflicts informational injuries-in-fact on both plaintiffs.

2. Traceability and Redressability

"The traceability requirement for Article III standing means that the plaintiff must 'demonstrate a causal nexus between the defendant's conduct and the injury.'" Rothstein v. UBS AG, 708 F.3d 82, 91 (2d Cir. 2013) (quoting Heldman v. Sobol, 962 F.2d 148, 156 (2d Cir. 1992)). Plainly, plaintiffs' informational injuries are traceable to HHS's decision not to include Basic Results for pre-Rule, pre-approval ACTs on ClinicalTrials.gov, as well as NIH's failure to post public noncompliance notices and supply a search function for such notices. Cf. Pub. Citizen Health Research Grp. v. Acosta, 363 F.Supp. 3d 1, 12 (D.D.C. 2018)

(deeming traceability "quite clear" where information was inaccessible due to OSHA's suspension of the rule requiring employers to submit it).

Meanwhile, redressability requires that it "be likely that a favorable judicial decision will prevent or redress the injury." Summers v. Earth Island Inst., 555 U.S. 488, 493 (2009). "All that is required is a showing that such relief be reasonably designed to improve the opportunities of a plaintiff not otherwise disabled to avoid the specific injury alleged." Huntington Branch, N.A.A.C.P. v. Town of Huntington, N.Y., 689 F.2d 391, 394 (2d Cir. 1982). A judicial decision vacating HHS's interpretation, directing defendants to include Basic Results for pre-Rule, pre-approval ACTs on ClinicalTrials.gov, and enjoining defendants to post public noncompliance notices and to create a search function for such notices, is reasonably designed to afford plaintiffs the information the denial of which constitutes their injuries in fact.

C. The Final Rule

Because Seife has standing to challenge the legality of HHS's interpretation of the Final Rule, the Court addresses the merits of that challenge.

Generally, where, as here, the Court reviews an agency's interpretation of its own regulation, it applies the multistep standard of review set forth in Kisor v. Wilke, --- U.S. ---, 139 S. Ct. 2400 (2019). Broadly described, that standard of review

requires courts to defer to agencies' reasonable interpretations of their genuinely ambiguous regulations so long as certain other conditions are satisfied. See id. at 2415-18. Such deference is referred to as "Auer deference," and is named after Auer v. Robbins, 519 U.S. 452 (1997), which applied it.

However, the Supreme Court has "cautioned that Auer deference is just a 'general rule'; it 'does not apply in all cases.'" Kisor, 139 S. Ct. at 2414 (quoting Christopher v. SmithKline Beecham Corp., 567 U.S. 142, 155 (2012)). One circumstance in which Auer deference is inappropriate is "when an agency interprets a rule that parrots the statutory text." Id. at 2417 n.5 (citing Gonzales v. Oregon, 546 U.S. 243, 257 (2006)). When a regulation parrots the statute, the agency's interpretation "cannot be considered an interpretation of the regulation" because "the underlying regulation does little more than restate the terms of the statute itself, and the agency "does not acquire special authority to interpret its own words" because those words "come[] from Congress, not the [agency]." Gonzales, 546 U.S. at 257.

The Final Rule parrots the FDAAA and therefore Auer deference does not apply to HHS's interpretation of it. Under the Final Rule, a responsible party must submit Basic Results for a pre-Rule ACT if "the studied product is approved, licensed, or cleared by FDA." See 42 C.F.R. § 11.42(a). The Final Rule, in turn, defines an "approved drug" as "a drug product that is approved for any use

under [21 U.S.C. § 355] or a biological product licensed for any use under [42 U.S.C. § 262]," and an "approved or cleared device" as "a device that is cleared for any use under [21 U.S.C. § 360(k)] or approved for any use under [21 U.S.C. §§ 360e or 360j(m)]." Id. § 11.10(a). The Final Rule's language is virtually identical to the FDAAA, which requires responsible parties to submit, and defendants to include on ClinicalTrials.gov, Basic Results "for each applicable clinical trial for a drug that is approved under [21 U.S.C. § 355] or licensed under [42 U.S.C. § 262] or a device that is cleared under [21 U.S.C. § 360(k)] or approved under [21 U.S.C. §§ 360e or 360j(m)]." 42 U.S.C. § 282(j)(3)(C). The Final Rule therefore "does little more than restate the terms of the statute itself," such that HHS's interpretation is of Congress' words, not its own. Gonzales, 546 U.S. at 257.

Because Auer deference does not apply to HHS's interpretation, the Court must determine "whether [HHS's interpretation], on its own terms, is a permissible interpretation of" the FDAAA. Id. at 258. The parties urge the Court to make this determination using the two-step inquiry of Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984). Under the first step of Chevron, "applying the ordinary tools of statutory construction, the court must determine 'whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for

the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" City of Arlington, Tex. v. F.C.C., 569 U.S. 290, 296 (2013) (quoting Chevron, 467 U.S. at 842-43). Under the second step, "'if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.'" Id. (quoting Chevron, 467 U.S. at 843).

But Chevron applies only if "'it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.'" Rotimi v. Gonzales, 473 F.3d 55, 57 (2d Cir. 2007) (quoting United States v. Mead Corp., 533 U.S. 218, 226-27 (2001)). While HHS's interpretation meets the first half of this test, see 42 U.S.C. § 282(j)(3)(D)(i) (providing that "the Secretary shall by regulation expand [ClinicalTrials.gov] as provided under this subparagraph"), neither party has offered any argument for why HHS's interpretation, which appears only in the preamble to the Final Rule, satisfies the second half, see Kingdomware Tech., Inc. v. United States, --- U.S. ---, 136 S. Ct. 1969, 1979 (2016) (expressing skepticism "that the preamble to the agency's rulemaking could be owed Chevron deference"); Saunders v. City of

New York, 594 F.Supp. 2d 346, 355 (S.D.N.Y. 2008) (declining to apply Chevron to an interpretation in a regulation's preamble).

If Chevron does not supply the appropriate standard of review, then the Court would assess the lawfulness of HHS's interpretation under the less deferential standard set forth in Skidmore v. Swift & Co., 323 U.S. 134 (1944). See Estate of Landers v. Leavitt, 545 F.3d 98, 107 (2d Cir. 2008) (citing Mead Corp., 533 U.S. at 221). HHS's interpretation would be "entitled to 'respect according to its persuasiveness,' as evidenced by 'the thoroughness evident in the agency's consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade.'" Id. at 107 (internal citations and alterations omitted) (quoting Mead Corp., 533 U.S. at 221, 228 (quoting Skidmore, 323 U.S. at 140)).

In any event, the Court need not decide whether Chevron or Skidmore applies to HHS's interpretation of the Final Rule. "Although the Chevron and Skidmore deference standards differ in application, they are similar in one respect: As with Chevron deference, [the Court] will defer to the agency's interpretation under the Skidmore standard only when the statutory language at issue is ambiguous." Catskill Mountains Chapter of Trout Unltd., Inc. v. Envtl. Prot. Agency, 846 F.3d 492, 509 (2d Cir. 2017) (collecting cases). And here the FDAAAA unambiguously requires

responsible parties to submit, and ClinicalTrials.gov to include, Basic Results for pre-Rule, pre-approval ACTs.

The Court begins with the text of the pertinent provision of the FDAAA, which states that "the Secretary shall include in [ClinicalTrials.gov] for each applicable clinical trial for a drug that is approved . . . or licensed or a device that is cleared . . . or approved . . ., the following elements: [Basic Results]." 42 U.S.C. § 282(j)(3)(C). The word "is" is the third person singular present tense of the verb "be." "Be," Oxford English Dictionary Online (January 2020).[8] Accordingly, "a drug that is approved . . . or licensed," or "a device that is cleared . . . or approved," is a drug or device that is presently approved, licensed, or cleared. Section 282(j)(3)(C) therefore obligates HHS to include Basic Results on ClinicalTrials.gov for each ACT that studied a product that is presently approved by the FDA. Pre-Rule, pre-approval ACTs are ACTs of such products. Hence, the plain language of § 282(j)(3)(C) requires HHS to include Basic Results for such ACTs on ClinicalTrials.gov.

Context reinforces this reading of § 282(j)(3)(C). Section 282(j)(3)(E)(iv) provides that "[w]ith respect to an applicable clinical trial that is completed before the drug is initially approved . . . or initially licensed . . . or the device is

[8] Defendants conceded at oral argument that the word "is" is a present tense conjugation of the verb "be."

initially cleared . . . or initially approved . . ., the responsible party shall submit to the Director of NIH for inclusion in [ClinicalTrials.gov] the clinical trial information described in subparagraphs (C) [i.e., Basic Results] and (D) not later than 30 days after" the product's approval. By requiring responsible parties to submit Basic Results for pre-approval ACTs to defendants "for inclusion in" ClinicalTrials.gov, § 282(j)(3)(E)(iv) confirms that defendants are required to include Basic Results for such ACTs in ClinicalTrials.gov.

Defendants resist this clear inference on the ground that § 282(j)(3)(E)(iv) merely prescribes the deadline for responsible parties to submit Basic Results for pre-approval ACTs should HHS require responsible parties to do so through rulemaking under § 282(j)(3)(D)(i), which provides that "the Secretary shall by regulation expand [ClinicalTrials.gov] as provided under this subparagraph." But § 282(j)(3)(E)(iv) does not just set the deadline for the submission of Basic Results for pre-approval ACTs. It also imposes the obligation to do so by directing that responsible parties "shall submit" Basic Results for pre-approval ACTs. Moreover, defendants' argument rests on the false premise that HHS has discretion to decide whether the regulations it issues under § 282(j)(3)(D)(i) will require the submission of Basic Results. HHS has no such discretion. Instead, HHS has discretion only as to "whether or not the results information described in

clause (iii) [i.e., Expanded Results[9]] shall be required for . . . an applicable drug clinical trial for a drug that is not approved . . . and not licensed . . . and . . . an applicable device clinical trial for a device that is not cleared . . . and not approved . . . ," 42 U.S.C. § 282(j)(3)(D)(ii)(II), which concerns neither Basic Results nor pre-approval ACTs, as a pre-approval ACT is not an ACT of a product that "is not" approved.

Defendants' argument under § 282(j)(3)(D)(iv)(III)(aa) is based on faulty reasoning and thus unavailing. That provision states that "the Secretary shall by regulation determine . . . in the case when the clinical trial information described in clause (iii) is required to be submitted for the applicable clinical trials described in clause (ii)(II), the date which such clinical trial information shall be required to be submitted, taking into account . . . the certification process under subparagraph (E)(iii) when approval, license, or clearance is sought." Section 282(j)(3)(D)(ii)(II), in turn, provides that "[t]he regulations under this subparagraph shall establish whether or not the results information described in clause (iii) shall be required for . . . an applicable drug clinical trial for a drug that is not approved

[9] Defendants contend that the phrase "the results information described in clause (iii)" encompasses Basic Results in addition to Expanded Results. The only results "described in" clause (iii), however, are Expanded Results. See 42 U.S.C. §§ 282(j)(3)(D)(iii)(I)-(IV). To be sure, § 282(j)(3)(D)(iii) references Basic Results when it mentions "the elements described in subparagraph (C)." Id. But that reference does not describe Basic Results, which is apparent from its identification of § 282(j)(3)(C) as the provision that does.

. . . and not licensed . . . and . . . an applicable device clinical trial for a device that is not cleared . . . and not approved . . . ." And § 282(j)(3)(E)(iii) permits a responsible party to submit a certification that § 282(j)(3)(E)(iv), which concerns an ACT "that is completed before the drug is initially approved," applies. Defendants reason from these provisions that an ACT described in clause (ii)(II) -- that is, an ACT of a product that "is not approved" -- is an ACT "that is completed before the drug is initially approved." They conclude from this that an ACT "that is completed before the drug is initially approved" must be an ACT of a product that "is not approved."

That conclusion is illogical. If an ACT of a product that "is not approved" qualifies as an ACT "that is completed before the drug is initially approved," it does not follow that the converse is true, i.e., that an ACT "that is completed before the drug is initially approved" is an ACT of a product that "is not approved." Quite the contrary, an ACT of a product that is approved, but where approval was obtained only after the ACT's completion, is also an ACT "that is completed before the drug is initially approved." In both cases, the ACT was completed prior to the product's initial approval.

Confronting these textual hurdles, defendants argue that the Court should not construe the FDAAA to require responsible parties to submit, and ClinicalTrials.gov to include, Basic Results for

pre-Rule, pre-approval ACTs because doing so would violate a canon of statutory construction that holds that statutes should not be construed to apply retroactively. See Wetzler v. F.D.I.C., 38 F.3d 69, 74 (2d Cir. 1994) (collecting cases). As an initial matter, "[o]nly if [the Court] conclude[s] that statutory language is ambiguous do[es] [it] resort to canons of construction," and the statutory language here is not ambiguous. United States v. Magassouba, 544 F.3d 387, 404 (2d Cir. 2008) (internal quotation marks omitted). Moreover, even if the Court could invoke the canon against retroactivity, the canon would have no bearing on the Court's interpretation because the Court does not construe the FDAAA to apply to conduct that predates its enactment, which is the type of retroactivity to which the canon applies. See, e.g., Fernandez-Vargas v. Gonzales, 548 U.S. 30, 31 (2006) (explaining that the canon against retroactivity applies when the interpretation "would have a retroactive consequence in the disfavored sense of affecting substantive rights, liabilities, or duties on the basis of conduct arising before [the statute's] enactment." (internal quotation marks and alterations omitted, but emphasis added)). Nor could the Court interpret the FDAAA to apply to conduct that predates its enactment because the statute unambiguously prohibits itself from being so applied. 42 U.S.C. § 282(j)(2)(C) (limiting the FDAAA's results reporting obligations

to an ACT "that is initiated after, or is ongoing on the date that is 90 days after, September 27, 2007").

Defendants' complaint about retroactivity is really that construing the FDAAA to require ClinicalTrials.gov to include Basic Results for pre-Rule, pre-approval ACTs would require responsible parties to submit Basic Results for nearly a decade of pre-approval ACTs for which HHS had not previously required them to do so. But responsible parties knew since the FDAAA's enactment in 2007 that the statute required them to submit Basic Results for each ACT of a product that is approved. It was only when HHS promulgated the Final Rule nearly ten years after the FDAAA's enactment and almost six years after the statutory deadline for doing so, and included in its preamble an interpretation of it that was contrary to the text of the FDAAA, that HHS definitively told responsible parties that they were not required to submit Basic Results for pre-Rule, pre-approval ACTs. Defendants therefore created the retroactivity concern about which they complain. That concern has no bearing here, however, because "[n]o matter how it is framed, the question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, whether the agency has stayed within the bounds of its statutory authority," and HHS has not. City of Arlington, Tex. v. F.C.C., 569 U.S. 290, 297 (2013) (emphasis in original).

Finally, the Court's interpretation coheres with the FDAAA's purpose. Congress enacted the FDAAA in order to "help patients, providers, and researchers learn new information and make more informed healthcare decisions" by "increas[ing] the availability of information to the public" and "communicat[ing] the risks and benefits of drugs." H. Rep. 110-225 at 12. Among other things, Congress was concerned that "negative results may or may not be released by sponsors" and that the public therefore could not assess the safety and efficacy of drugs and devices. Id. Plainly, requiring ClinicalTrials.gov to include Basic Results for pre-Rule, pre-approval ACTs ameliorates that concern and furthers those broader goals. Doing the opposite, by contrast, would exempt the responsible parties for every pre-approval ACT completed soon after September 27, 2007 and January 18, 2017 from disclosing negative results regardless of whether thousands of Americans use the product, which would be utterly contrary to the FDAAA's aims.

The Court accordingly finds that the FDAAA unambiguously requires responsible parties to submit, and defendants to include on ClinicalTrials.gov, Basic Results for pre-Rule, pre-approval ACTs. Consequently, the Court need not decide whether Chevron or Skidmore applies to HHS's interpretation of the Final Rule, which

must be, and therefore is, set aside as contrary to the FDAAA.[10] In light of this conclusion, the Court declines to consider Seife's alternative contention that HHS adopted its interpretation arbitrarily and capriciously, and plaintiffs' motion for summary judgment is granted as to their first cause of action to hold unlawful and set aside HHS's interpretation of the Final Rule.

D. Public Noncompliance Notices and a Search Function for Them

Plaintiffs' second cause of action challenges NIH's failure to post notices of noncompliance pursuant to the NIH notice provision, 42 U.S.C. § 282(j)(5)(E)(i), and to create a search function for such notices pursuant to the notice search provision, id. § 282(j)(5)(E)(vi), as "agency action unlawfully withheld or unreasonably delayed," 5 U.S.C. § 706(1). Defendants oppose this contention on the ground that § 701(a)(2) of the APA precludes judicial review of NIH's challenged inaction.

1. Section 701(a)(2) of the APA

"The APA embodies a 'basic presumption of judicial review.'" Lunney v. United States, 319 F.3d 550, 558 (2d Cir. 2003) (quoting Abbott Labs. v. Gardner, 387 U.S. 136, 140 (1967)). "This is just

[10] The Court need not vacate any portion of the Final Rule because its pertinent provision, 42 C.F.R. § 11.42, has the same meaning as the statutory language that it parrots. Thus, § 11.42's distinction between an ACT for which "the studied product is approved, licensed, or cleared by FDA," id. § 11.42(a), and an ACT for which "the studied product is not approved, licensed, or cleared by FDA," id. § 11.42(b), distinguishes between an ACT of a product that is currently approved and an ACT of a product that is not currently approved. As such, § 11.42 properly implements the unambiguous terms of the FDAAA.

a presumption, however, and under [5 U.S.C.] § 701(a)(2) agency action is not subject to judicial review 'to the extent that' such action 'is committed to agency discretion by law.'" Lincoln v. Vigil, 508 U.S. 182, 190-91 (1993) (internal quotation marks and citation omitted).

The Supreme Court "ha[s] read § 701(a)(2) to preclude judicial review of certain categories of administrative decisions that courts traditionally have regarded as 'committed to agency discretion.'" Id. at 191. One of those categories is "'an agency's decision not to prosecute or enforce, whether through civil or criminal process,'" because such decisions are "'generally committed to an agency's absolute discretion.'" Salazar v. King, 822 F.3d 61, 75 (2d Cir. 2016) (emphasis in original) (quoting Heckler v. Chaney, 470 U.S. 821, 831 (1985) ("Chaney")). Accordingly, "an agency's decision not to invoke an enforcement mechanism provided by statute is not typically subject to judicial review," N.Y. Pub. Interest Research Grp. v. Whitman, 321 F.3d 316, 331 (2d Cir. 2003) ("NYPIRG"), in which case "the opposite presumption applies," Salazar, 822 F.3d at 75. To rebut this "presumed immun[ity] from judicial review," Chaney, 470 U.S. at 832, a plaintiff must demonstrate that the substantive statute has provided "guidelines" for the agency to follow in the exercise of its discretion, Riverkeeper, Inc. v. Collins, 359 F.3d 156, 165 (2d Cir. 2004).

In NYPIRG, the Second Circuit considered whether § 701(a)(2) precluded judicial review of the EPA's decision not to invoke an enforcement mechanism in a provision of the Clean Air Act (the "CAA") that is structured similarly to the FDA notice provision. Under the CAA, "[w]henever the [EPA] makes a determination that a permitting authority is not adequately administering and enforcing a program, or portion thereof, in accordance with the requirements of this subchapter, the [EPA] shall provide notice to the State . . . ." 42 U.S.C. § 7661a(i)(1). NYPIRG had argued that because the EPA "shall" notify states of deficiencies in their permitting programs, the agency had no discretion whether to do so, and therefore the Second Circuit could review the agency's failure to issue a deficiency notice to New York. NYPIRG, 321 F.3d at 330.

In rejecting this argument, the Second Circuit explained that "the key phrase of [the statute] is the opening one, 'Whenever the [EPA] makes a determination[.]'" Id. "Because the determination is to occur whenever the EPA makes it, the determination is necessarily discretionary." Id. Thus, while the EPA is obligated to issue deficiency notices to states, that "nondiscretionary obligation only arises after a discretionary determination by the EPA." Id. at 331. Thus, because the EPA had not yet made such a determination for New York, and because its failure to do so was committed to its discretion and thus not subject to judicial review

under § 701(a)(2), so, too, was its failure to issue a deficiency notice to New York. See id.

The Second Circuit's reasoning in NYPIRG compels the conclusion that the FDA's failure to issue notices of noncompliance under the FDA notice provision is not subject to judicial review under § 701(a)(2). The FDA notice provision provides that "[i]f the Secretary determines that any clinical trial information was not submitted as required under [42 U.S.C. § 282(j)], or was submitted but is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such noncompliance by submitting the required revised clinical trial information not later than 30 days after such notification." 42 U.S.C. 282(j)(5)(C)(ii) (emphasis added). Similar to how the CAA provided that the EPA "shall provide notice to the State," the FDA notice provision states that FDA "shall notify the responsible party." However, just as the EPA's nondiscretionary obligation was conditioned on a prior discretionary determination by the agency, so, too, is the FDA's. Compare 42 U.S.C. § 7661a(i)(1) ("Whenever the [EPA] makes a determination that . . . .") with 42 U.S.C. § 282(j)(5)(C)(ii) ("If the Secretary determines that . . . ."). Accordingly, the FDA's failure to issue notices of noncompliance to violators under the FDA notice provision is unreviewable just as the EPA's failure to issue a deficiency notice to New York was unreviewable.

Plaintiffs do not contest this conclusion. Instead, they maintain that it is irrelevant to the reviewability of NIH's inaction under the NIH notice and notice search provisions, which is the inaction that their second cause of action challenges. Specifically, plaintiffs insist that NIH's failure to post public noncompliance notices under the NIH notice provision is reviewable because, unlike the FDA notice provision, the NIH notice provision does not condition NIH's nondiscretionary obligation to post notices on a prior discretionary determination by NIH.

But plaintiffs' argument ignores that notices issued under the NIH notice provision are required to include information that exists only after the FDA exercises its unreviewable discretion under the FDA notice provision. Notices issued under the NIH notice provision must state "the penalties imposed for the violation, if any," 42 U.S.C. § 282(j)(5)(E)(i)(II), and "whether the responsible party has corrected the clinical trial information in [ClinicalTrials.gov]," id. § 282(j)(5)(E)(i)(III). However, notice under the FDA notice provision is what "give[s] such party an opportunity to remedy such noncompliance by submitting the required revised clinical trial information not later than 30 days after such notification." Id. § 282(j)(5)(C)(ii). Moreover, the penalties imposed for a violation are undefined until after the FDA issues a notice under the FDA notice provision because violations "not corrected within the 30-day period following

notification under section 282(j)(5)(C)(ii) of title 42 [i.e., the FDA notice provision,] are subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period under the violation is corrected." 21 U.S.C. § 333(f)(3). Requiring NIH to post a noncompliance notice on ClinicalTrials.gov before the FDA has issued a notice to the violator under the FDA notice provision would therefore require NIH to publish nonexistent information, which would be nonsensical.[11]

Accordingly, while NIH's nondiscretionary obligation to post public noncompliance notices under the NIH notice provision does not require NIH to have made a prior discretionary determination, it does require the FDA to have made one pursuant to the FDA notice provision. As the FDA has not yet made such a determination, and as its decision not to do so is immune from judicial review under § 701(a)(2), judicial review also cannot be had of NIH's inaction

[11] Plaintiffs' argument that the obligations under the NIH and FDA notice provisions are mutually exclusive is also problematic because, in plaintiffs' words, it would "create[] two distinct monitoring regimes" in which the FDA and NIH are independently required to verify compliance for every ACT for which the FDAAA requires responsible parties to submit results. See Pls.' Mem. at 9-11. There is no indication that Congress intended such duplication. Plaintiffs' sole argument to the contrary is that 42 U.S.C. § 282(j)(5)(A) requires, in their words, NIH and the FDA to "separately verify submission of clinical trial information required under FDAAA." Pls.' Reply at 13. But that is an inaccurate description of that subparagraph. Section 282(j)(5)(A) concerns ACTs funded in part by a grant from HHS, FDA, NIH, or the Agency for Healthcare Research and Quality, and it requires that the agency verify the ACT's compliance with the FDAAA "before releasing any remaining funding for a grant or funding for a future grant" to the grantee. Accordingly, to the extent that more than one of those agencies verifies an ACT's compliance with the FDAAA pursuant to § 282(j)(5)(A), it is only because more than one of them is funding the ACT. The vastly more expansive conclusion that the FDAAA requires the FDA and NIH to evaluate independently every ACT for which responsible parties must submit results for compliance with the FDAAA does not follow.

under the NIH notice provision. Cf. NYPIRG, 321 F.3d at 330. NIH's failure to create a search function for such notices is similarly immune from judicial review because it requires a notice for which to search, which requires the FDA to have exercised its unreviewable discretion under the FDA notice provision.

Plaintiffs nevertheless assert that § 701(a)(2) applies only to decisions not to institute enforcement proceedings, and that failing to post a public notice of noncompliance is not such a decision. Section 701(a)(2)'s application is not so limited. Instead, it applies more broadly to "an agency's decision not to invoke an enforcement mechanism provided by statute," NYPIRG, 321 F.3d at 331, and plaintiffs cannot plausibly contend that public noncompliance notices are not mechanisms for enforcing compliance with the FDAAA, cf. Chaney, 470 U.S. at 824 (characterizing the FDA's failure "to affix warnings to the labels of [certain] drugs stating that they were unapproved and unsafe for human execution" and "to send statements to the drug manufacturers and prison administrators stating that the drugs should not be so used" as "enforcement actions"). Moreover, even if notices under the NIH notice provision were not enforcement mechanisms, NIH's obligation to post them would still be contingent on the FDA's exercise of its unreviewable discretion under the FDA notice provision, which the FDA has not yet exercised.

2. Hypothetical Abdication Exception to Section 701(a)(2)

Plaintiffs contend that, even if § 701(a)(2) precludes judicial review of NIH's inaction, the Court should still review that inaction on the ground that it falls within a "hypothetical" exception to § 701(a)(2). Riverkeeper, Inc., 359 F.3d at 166. "In a footnote, the [Supreme] Court [in Chaney] posited the possibility that [§] 701(a)(2)'s presumption against federal judicial jurisdiction . . . might be overcome on a showing that the agency in question 'has consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities.'" Id. at 165 (quoting Chaney, 470 U.S. at 833 n.4). "The Court noted that in such a situation, 'the statute conferring authority on the agency might indicate that such decisions were not 'committed to agency discretion.'" Id. at 165-66 (quoting Chaney, 470 U.S. at 833 n.4).

The Second Circuit observed in Riverkeeper that "[n]o party has directed us to, nor can we locate, a decision by a court of appeals that has found, in performing the Chaney analysis, a federal agency to have abdicated its statutory duties." Id. at 170 n.17. Plaintiffs have similarly failed to direct the Court to any such decision, nor could the Court find one. Moreover, the Court located only three district court decisions finding that an agency abdicated its statutory duties; in each case, however, the district court based its finding on an express policy of

nonenforcement, as required under Chaney. See Am. Acad. of Pediatrics v. Food & Drug Admin., 379 F.Supp. 3d 461, 493 (D. Md. 2019) (challenging the FDA's express policy, stated in a published guidance release, that it would not enforce the Family Smoking Prevention and Tobacco Control Act's premarket review provisions); WildEarth Guardians v. U.S. Dep't of Justice, 181 F.Supp. 3d 651, 665-66 (D. Ariz. 2015) (denying motion to dismiss where "[p]laintiffs allege[d] the DOJ ha[d] formally expressed a general policy of non-enforcement" in a 1999 DOJ memorandum known as "the McKittrick policy."); Whitaker v. Clementon Hous. Auth., 788 F.Supp. 226, 231 (D.N.J. 1992) (contesting HUD's decision not to initiate an enforcement action as stated in letters that HUD had sent to the plaintiff). Plaintiffs do not allege any express policy of nonenforcement. Pls.' Mem. at 38.

Plaintiffs instead argue that the Court should infer a policy of nonenforcement by NIH, which argument they base on the Second Circuit's consideration of a similar contention in Riverkeeper, Inc. See 359 F.3d at 167. But the Second Circuit in Riverkeeper considered that argument only hypothetically, and, even then, rejected it. See id. at 170 ("Thus, even if we were to assume that the Chaney Court established by way of footnote 4 federal court jurisdiction . . . we would have no jurisdiction to review the NRC's decision here." (emphasis added)). After all, the abdication exception to § 701(a)(2) about which the Supreme Court

hypothesized requires the "express[] adopt[ion] [of] a general policy" of nonenforcement, Chaney, 470 U.S. at 165, hence, finding abdication based on an implicit policy would be contrary to the exception, see, e.g., Salmon Spawning and Recovery All. v. U.S. Customs & Border Prot., 550 F.3d 1121, 1129 n.5 (Fed. Cir. 2008) (rejecting application of Chaney's abdication exception because "plaintiffs ha[d] not alleged that there was any express policy of non-enforcement" (emphasis in original)); People for the Ethical Treatment of Animals, Inc. v. U.S. Dep't of Agric., 7 F.Supp. 3d 1, 12-13 (D.D.C. 2013) (doing the same in the absence of "some kind of official, concrete statement of the agency's general enforcement policy") (collecting cases).

In any event, the Court need not wade further into Chaney's posited abdication exception. Perhaps appreciating the limits of reviewability under the APA, plaintiffs restrict their second cause of action to challenging NIH's, and only NIH's, inaction under the NIH notice and notice search provisions. See Pls.' Mem. at 32; Compl. ¶¶ 100-127 (challenging inaction under 42 U.S.C. § 282(j)(5)(E), which applies only to NIH). However, as discussed above, NIH's duties under those provisions arise only after the FDA has exercised its discretion under the FDA notice provision. Thus, as the FDA has not yet exercised that discretion, NIH does not have any "'statutory responsibilities'" under the NIH notice and notice search provisions for it to "'abdicat[e].'"

Riverkeeper, Inc., 359 F.3d at 165 (quoting Chaney, 470 U.S. at 833 n.4).

III. CONCLUSION

The central issue in this case is whether the FDAAA requires ClinicalTrials.gov to include certain clinical trial results, referred to statutorily as "Basic Results," for certain clinical trials, referred to statutorily as "applicable clinical trials," if the applicable clinical trial was completed before the Final Rule's effective date of January 18, 2017 and studied a product that the FDA approved after the applicable clinical trial's completion. The Court concludes that the FDAAA unambiguously does. Thus, HHS's contrary interpretation, which the agency announced in the preamble of the Final Rule, is unlawful and must be set aside.

Defendants' motion to dismiss plaintiffs' complaint for lack of jurisdiction is granted as to Lurie's assertion of plaintiffs' first cause of action, which asks the Court to set aside HHS's interpretation of the Final Rule as contrary to the FDAAA. Defendants' motion to dismiss is denied in all other respects. Defendants' motion for summary judgment is denied as to plaintiffs' first cause of action but granted as to plaintiffs' second cause of action, which challenges NIH's failures to post public noncompliance notices and to create a search function for such notices as agency action unlawfully withheld. Plaintiffs' cross-motion for summary judgment is granted as to their first cause of

action but denied as to their second cause of action. The Court sets aside HHS's interpretation of the Final Rule as contrary to the unambiguous terms of the FDAAA, and enjoins defendants to comply with those terms, which require responsible parties to submit, and ClinicalTrials.gov to include, Basic Results for pre-Rule, pre-approval ACTs. The Clerk of Court is respectfully directed to terminate any motions pending in this case and to close it.

SO ORDERED.

Dated: New York, New York
February 24, 2020

NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE