UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE and PETER LURIE,

Plaintiffs,

v.

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.

Civil Action No. 18-cv-11462
ECF Case

COMPLAINT

December 7, 2018

INTRODUCTION

Plaintiffs, Charles Seife and Peter Lurie, by their undersigned attorneys, allege:

1. This action under the Administrative Procedure Act challenges an agency rule that purports to relieve medical researchers of their express statutory obligation to report basic results information for certain clinical trials involving human subjects. It further seeks to compel the defendant agencies to post public notices that are mandated by law but which have been unlawfully withheld and/or unreasonably delayed.

2. Clinical trial data regarding medications, medical devices, and medical treatments provide a crucial resource for clinicians, patients, researchers, policymakers, and the general public. Comprehensive reporting of this data serves to promote the integrity of clinical research, improves the quality of decisions made by clinicians and policymakers, reduces bias in scientific

literature, and informs patients, clinicians, and regulators about intervention safety and effectiveness.

3. Recognizing the importance of public access to clinical trial data, Congress in 2007 required researchers conducting certain trials for approved drugs or devices to report the results of their trials to defendant agencies. If a drug or device being studied is not approved at the time of a trial's completion, but is subsequently approved, Congress required the basic results information to be reported no later than 30 days after approval.

4. Congress further required defendants to make the information reported to them available to the public by means of a registry and results data bank accessible through the internet. To comply with that statutory obligation, defendants created and maintain the public website ClinicalTrials.gov.

5. Congress simultaneously required defendants to publish specific, statutorily prescribed public notices on ClinicalTrials.gov whenever a researcher (1) fails to submit required clinical trial information, (2) submits false or misleading information, and/or (3) fails to submit primary or secondary outcome data, the main categories of data on which a trial focuses. Congress also required defendants to disclose any penalties they impose for violations of the reporting requirements and to disclose whether the responsible party corrected the violation.

6. To ensure public access to these mandatory compliance notices, Congress required defendants to provide a mechanism by which the public could easily search ClinicalTrials.gov for noncompliance notices.

7. In September 2016, or nine years after Congress imposed these requirements, defendants promulgated a final rule that contravenes the clear statutory disclosure mandates. The final rule purports to relieve parties responsible for clinical trials completed before January

18, 2017, from disclosing the basic trial results for studies of drugs or devices that were unapproved as of the trial's primary completion date, but which were subsequently approved.

8. Moreover, there has been, and continues to be, widespread and well-documented failure by responsible parties to comply with their statutory reporting obligations over the last eleven years. Defendants have nevertheless failed to post even a single statutorily required notice of noncompliance on ClinicalTrials.gov, and they have failed to create a mechanism by which the public can search for instances of noncompliance.

9. Defendants' promulgation of a rule inconsistent with the statutory public disclosure mandate, as well as the failure to issue notices of noncompliance, deprives plaintiffs and other members of the public of the data necessary to ensure transparency in research, promote better decision-making by clinicians and policymakers, eliminate bias in the medical literature, and inform patients, clinicians, and regulators about medical product safety and effectiveness.

10. By this action, plaintiffs seek an order (1) striking down those portions of defendants' final rule purporting to relieve responsible parties of their statutory obligation to report basic results for pre-final rule clinical trials for unapproved drugs or devices that were subsequently approved; and (2) compelling defendants to issue noncompliance notices for any clinical trial where the responsible party has failed to satisfy its statutory reporting obligations and to make those notices easily searchable on ClinicalTrials.gov.

PARTIES

11. Plaintiff Charles Seife is a Professor of Journalism at New York University who resides in New York, New York and reports regularly on clinical trials and the FDA. He has published numerous articles about the FDA, including an exposé on drugs that won approval

based on fraudulent trials. His reporting on the FDA has appeared in diverse outlets from *ProPublica* and *Slate* to *Scientific American*. He is currently conducting research on clinical trials and uses ClinicalTrials.gov in his research.

12. Plaintiff Peter Lurie is a family physician and the President of the Center for Science in the Public Interest. Until August 2017, he served as the Associate Commissioner for Public Health Strategy and Analysis at the Food and Drug Administration, where he led the agency's Transparency Initiative and worked on issues including food and drug safety, expanded access to investigational drugs, and prescription drug abuse. Prior to that, he was the Deputy Director of Public Citizen's Health Research Group, where he contributed to the organization's *Worst Pills, Best Pills* consumer guide to medications.

13. Defendant U.S. Department of Health and Human Services ("HHS") is an agency established within the executive branch of the U.S. government and is an agency within the meaning of 5 U.S.C. § 551(1).

14. Defendant Alex M. Azar II is the Secretary of Health and Human Services. He is sued in his official capacity, in which he is responsible for HHS's compliance with the Food and Drug Administration Amendments Act of 2007 ("FDAAA").

15. Defendant National Institutes of Health ("NIH") is an agency established within the executive branch of the U.S. government and is an agency within the meaning of 5 U.S.C. § 551(1).

16. Defendant Dr. Francis S. Collins is the Director of NIH. He is sued in his official capacity, in which he is responsible for NIH's compliance with FDAAA.

17. Defendant U.S. Food and Drug Administration ("FDA") is an agency established within the executive branch of the U.S. government and is an agency within the meaning of 5 U.S.C. § 551(1).

18. Defendant Dr. Scott Gottlieb is the Commissioner of Food and Drugs. He is sued in that capacity, in which he is responsible for FDA's compliance with FDAAA.

JURISDICTION AND VENUE

19. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

20. Venue is proper under 28 U.S.C § 1391(e)(1) because at least one plaintiff resides in this district and no real property is involved in the action.

FACTUAL ALLEGATIONS

A. Importance of Public Access to Clinical Trial Information

21. Public registration and reporting of clinical trial information provides significant benefits to researchers, regulators, policymakers, and the public at large.

22. Access to clinical trial data promotes good research practices; avoids unnecessary duplication of research; improves the credibility of research results by allowing independent scrutiny; and enables new knowledge to be generated from meta-analyses or systematic reviews of data. *See, e.g.*, Collaboration for Research Integrity and Transparency, *Promoting Transparency in Clinical Research: Why and How* 8–11 (2017).[1]

23. Registration and reporting of clinical trial data must also be comprehensive to avoid biasing systematic reviews and meta-analyses, which are widely used to inform the standard of clinical care. *Id.* at 14. Such systematic reviews and meta-analyses are also important to improving medical care for subpopulations. *Id.* at 14–15.

[1] https://law.yale.edu/system/files/area/center/crit/crit_white_paper_november_2017_best_promoting_transparency_in_clinical_research_why_and_how.pdf.

24. Registration and reporting of clinical trial data help clinicians, patients, and those who pay for medical treatments to accurately assess the value of medicines and make informed treatment decisions. *Id.* at 16–17.

25. Defendants NIH and HHS have both acknowledged these benefits, writing:

> [A]ccess to more complete information about clinical trials has both scientific and other public health benefits. The scientific benefits relate to the prevention of incomplete and biased reporting of individual trials, and the provision of information about a more complete and unbiased set of trials; the resulting set of data about clinical trials can form a more robust basis for current medical decision making and future research planning. In addition, *ClinicalTrials.gov* provides an overview of the clinical trials enterprise, facilitating quality improvement in study focus, design, and reporting.

Clinical Trials Registration and Results Information Submission, 81 Fed. Reg. 64,981, 64,985 (Sept. 21, 2016).

26. Dr. Rebecca Williams, then Assistant Director of ClinicalTrials.gov, now Director, recently underscored that public reporting of clinical trial data "increase[s] trust in [the] clinical research enterprise." Melissa Fassbender, *NIH: 'If we don't report our results we will repeat mistakes,'* Outsourcing-Pharma.com (May 16, 2018).[2]

27. Dr. Jodi Black, Deputy Director of the Office of Extramural Research at NIH, has also stressed the importance of agency action to spur the public reporting of clinical trial data, saying, "sharing results should not be optional." *Id.*

28. Clinical trial data can be invaluable for researchers looking to continue the work and research of others, as well as doctors, patients, and families of patients who are seeking the most reliable treatments.

[2] https://www.outsourcing-pharma.com/Article/2018/05/16/NIH-discusses-the-public-benefits-of-access-to-clinical-trial-information.

B. Statutory and Regulatory Background

29. In 1997, Congress enacted the Food and Drug Administration Modernization Act, which required HHS and NIH to create a data bank of information on clinical trials related to drugs for serious or life-threatening diseases and to disseminate the data bank to a wide audience. Pub. L. No. 105-155, § 113, 111 Stat. 2296, 2310–12 (codified at 42 U.S.C. § 282(i)).

30. Defendant NIH subsequently created ClinicalTrials.gov to comply with defendants' obligation under the Food and Drug Administration Modernization Act to disseminate clinical trial information, and the website was made available to the public on February 29, 2000.

31. Seven years later, Congress enacted the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110–85, 121 Stat. 823 ("FDAAA").

32. FDAAA requires the Secretary of HHS, acting through the Director of NIH, to expand the clinical trials data bank "[t]o enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials." 42 U.S.C. § 282(j)(2)(A)(i).

33. Under FDAAA, "responsible parties" for "applicable clinical trials" must register those trials with the Director of NIH, and, for many applicable clinical trials, report results information. *Id.* § 282(j)(2)(A), (C); *id.* § 282(j)(3); *see* 42 C.F.R. § 11.42.

FDAAA's Registration Requirements

34. In general, FDAAA requires responsible parties to register all applicable clinical trials with the Director of NIH and submit "descriptive information," "recruitment information," "location and contact information," and "administrative data" no later than twenty-one days after the first patient is enrolled. 42 U.S.C. § 282(j)(2)(A)(ii), (C).

35. FDAAA defines "responsible party" as the sponsor of a trial, meaning the person or party who initiates the trial. *Id.* § 282(j)(1)(A)(ix). The sponsor can designate a qualified principal investigator to be the responsible party, *id.* § 282(j)(1)(A)(ix)(II), but for each trial, there may be only one responsible party, 42 C.F.R. § 11.4(c).

36. FDAAA defines "applicable clinical trials," as trials that (1) were initiated on or after September 27, 2007, or that were ongoing as of December 26, 2007, and (2) meet the following criteria, set forth in 42 U.S.C. § 282(j)(1)(A)(ii)–(iii):

a. "a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes)";

b. "a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act"; or

c. "a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act."

FDAAA's Results Reporting Requirements

37. Responsible parties must also submit results data for many applicable clinical trials. *See* 42 U.S.C. § 282(j)(3).

38. FDAAA mandates the submission of "basic results" information for applicable clinical trials for FDA-regulated drugs and devices.[3]

39. "Basic results" information consists of (1) demographic and baseline characteristics of patient samples; (2) primary and secondary outcomes; (3) a point of contact;

[3] *I.e.*, "for each applicable clinical trial for a drug that is approved under section 355 of Title 21 or licensed under section 262 of . . . [T]itle [42] or a device that is cleared under section 360(k) of Title 21 or approved under section 360e or 360j(m) of Title 21." 42 U.S.C. § 282(j)(3)(C).

and (4) whether there exists an agreement restricting the principal investigator from discussing or publishing the results of a trial. *Id.*

40. Congress required the Secretary of HHS to further expand the results reporting requirements by September 27, 2010 (*i.e.*, within three years of FDAAA's enactment) by issuing regulations. *Id.* § 282(j)(3)(D)(i). These regulations must (1) establish whether responsible parties for clinical trials for *unapproved* devices and drugs must also submit basic results information, *id.* § 282(j)(3)(D)(ii)(II); and (2) require, in addition to basic results information, the submission of "expanded results information," including:

a. "[a] summary of the clinical trial and its results that is written in non-technical, understandable language for patients, if the Secretary determines that such types of summary can be included without being misleading or promotional";

b. "[a] summary of the clinical trial and its results that is technical in nature, if the Secretary determines that such types of summary can be included without being misleading or promotional";

c. "[t]he full protocol or such information on the protocol for the trial as may be necessary to help to evaluate the results of the trial"; and

d. "[s]uch other categories [of information] as the Secretary determines appropriate."

Id. § 282(j)(3)(D)(i)–(iii).

41. In general, FDAAA requires responsible parties to submit both basic and expanded results information to the Director of NIH not later than one year after the earlier of (1) the estimated completion date of the trial or (2) the actual date of completion. *Id.* § 282(j)(3)(D)(iv), (E)(i). FDAAA also provides for "delayed submission" of results information for certain applicable clinical trials and for "extensions" under certain circumstances. *Id.* § 282(j)(3)(E)(iii)–(vi).

FDAAA Requires Results Reporting for Trials for Drugs or Devices Approved After a Trial's Completion Date

42. Congress explicitly addressed responsible parties' results reporting obligations for clinical trials for drugs or devices approved after a trial's completion date. FDAAA provides:

> With respect to an applicable clinical trial that is completed before the [drug or device is approved, licensed, or cleared], the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) not later than 30 days after the drug or device is [approved, licensed, or cleared].

Id. § 282(j)(3)(E)(iv).

FDAAA Requires Defendants to Provide Public Notices of Noncompliance

43. FDAAA requires the clinical trials registry and results databank to be "made publicly available through the Internet." *Id.* § 282(j)(2)(A)(i), (3)(B)(ii).

44. Congress required defendants to issue public notices of violations of FDAAA's results reporting requirements in the data bank entry of any clinical trial for which the responsible party fails to comply with FDAAA's results reporting requirements. These notices must state that the party is not in compliance and in what way they are not in compliance, the specific penalties imposed, and whether the responsible party has corrected the information. *Id.* § 282(j)(5)(E)(i)–(ii).

45. For failure to submit required clinical information, submission of false or misleading information, and failure to submit primary and secondary outcomes, Congress prescribed the specific language that is required to be posted on ClinicalTrials.gov:

> **(iii) Failure to submit statement**
>
> The notice under clause (i) for a violation described in clause (i)(I)(aa) shall include the following statement: "The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.".

> **(iv) Submission of false information statement**
>
> The notice under clause (i) for a violation described in clause (i)(I)(bb) shall include the following statement: "The entry for this clinical trial was found to be false or misleading and therefore not in compliance with the law.".
>
> **(v) Non-submission of [primary and secondary outcomes] statement**
>
> The notice under clause (ii) for a violation described in clause (ii) shall include the following statement: "The entry for this clinical trial did not contain information on the primary and secondary outcomes at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.".

Id. § 282(j)(5)(E)(iii)–(v).

46. Congress further mandated that "[t]he Director of NIH shall provide that the public may easily search the registry and results data bank for entries that include notices required under this subparagraph." *Id.* § 282(j)(5)(E)(vi).

Defendants Promulgate Final Rule Implementing FDAAA's Results Reporting Requirements

47. In September 2016—six years after the statutory deadline, *see id.* § 282(j)(3)(D)(i)—defendants NIH and HHS promulgated a final rule implementing FDAAA's registration and reporting requirements. Clinical Trials Registration and Results Information Submission, 81 Fed. Reg. 64,981 (Sept. 21, 2016) (codified at 42 C.F.R. § 11) (the "FDAAA Final Rule" or "Final Rule").

48. The Final Rule took effect on January 18, 2017. *Id.*

49. Consistent with Congress's directive in FDAAA, the Final Rule expanded FDAAA's results reporting information to include applicable clinical trials for unapproved products that have a primary completion date on or after January 18, 2017. 42 C.F.R. § 11.42.

50. Defendants also expanded the scope of the results information that responsible parties must submit to include, for example, statistical analyses for each outcome measure and adverse event information (meaning any unfavorable medical incident a patient experienced during the course of the trial). *See id.* § 11.48. The additional results information required by the FDAAA Final Rule must, in general, be submitted within one year after the earlier of (1) the estimated completion date of the trial or (2) the actual date of completion. 42 U.S.C. § 282(j)(3)(D)(iv), (E)(i); 42 C.F.R. §§ 11.10(b)(17) (defining primary completion date), 11.44 (establishing deadlines).

51. Under the final rule, NIH must post registration and results information not later than thirty calendar days after the date of submission. 42 C.F.R. §§ 11.35, 11.52.

Defendants' Final Rule Purports to Relieve Responsible Parties for Certain Clinical Trials from Their Reporting Obligations Under FDAAA

52. Clinical trials may be conducted either for: (1) drugs or devices that have already been approved, licensed, or cleared by the trial's primary completion date; or (2) drugs or devices that have not yet been approved, licensed, or cleared as of the trial's primary completion date.

53. The Final Rule purports to relieve responsible parties for pre-Final Rule clinical trials for drugs or devices approved after a trial's primary completion date from their obligation to report basic results information.

54. The Final Rule provision laying out responsible parties' reporting obligations is codified at 42 C.F.R. § 11.42.

55. That provision specifies only that responsible parties for applicable clinical trials for which the studied product is not approved, licensed, or cleared by the FDA and for which the

primary completion date is *on or after* January 18, 2017, must report basic results information. 42 C.F.R. § 11.42(b).[4]

56. The Final Rule does not require basic results information ever to be reported for applicable clinical trials with a primary completion date *before* January 18, 2017, if the drug or device was not approved until after the primary completion date (hereinafter, "pre-Rule, pre-approval trials").[5] *See id.* In other words, the Final Rule purports to exempt from basic results reporting requirements any applicable clinical trial with a primary completion date before January 18, 2017, for a product not approved as of that primary completion date, regardless of whether and when the product is later approved.

57. The Final Rule's preamble makes plain that the Final Rule does not require responsible parties to report basic results information for pre-Rule, pre-approval trials:

> [W]hether results information submission is required for an applicable clinical trial of an unapproved, unlicensed, or uncleared product depends on whether the primary completion date for that trial falls before or after the effective date of the regulations. If it falls before the effective date, then no results information is required to be submitted for that applicable clinical trial, regardless of whether the product studied in that clinical trial is later approved, licensed, or cleared.

Clinical Trials Registration and Results Information Submission, 81 Fed. Reg. 64,981, 65,120 (Sept. 21, 2016) (codified at 42 C.F.R. § 11.2 *et seq.*).

[4] The primary completion date is "[t]he date on which the last participant in a clinical study was examined or received an intervention to collect final data for the primary outcome measure." *Glossary of Common Site Terms*, ClinicalTrials.gov (Nov. 2018), https://clinicaltrials.gov/ct2/about-studies/glossary.

[5] In this case, pre-approval means that the primary completion date of the clinical trial preceded the date that the drug or device was subsequently approved, cleared, or licensed. This definition excludes drugs or devices that have not yet been approved, cleared, or licensed.

58. On information and belief, employees of defendant agencies have confirmed to researchers and members of the public that the Final Rule does not require responsible parties for pre-rule, pre-approval trials to report basic results information.

59. The statute itself, however, requires the submission of results data for these applicable clinical trials no later than 30 days after the drug or device is approved, licensed, or cleared. 42 U.S.C. § 282(j)(3)(E)(iv); *see supra* ¶ 42.

D. Despite Widespread Noncompliance with FDAAA's Reporting Requirements, Defendants Have Posted No Statutorily Required Notices of Noncompliance

Defendants' Knowledge or Constructive Knowledge of Noncompliance with FDAAA Reporting Requirements

60. Defendants collectively have the ability to identify many, if not all, applicable clinical trials for which results reporting is required under FDAAA before and after the effective date of the FDAAA Final Rule.

61. Congress itself defined "applicable clinical drugs trials" and "applicable clinical device trials" in FDAAA and specified that those applicable clinical trials for approved drugs or devices must submit results to ClinicalTrials.gov. 42 U.S.C. § 282(j)(1)(A)(i)–(iii), (3)(C).

62. FDAAA requires applications or submissions to defendant FDA for drug and device approvals to certify whether "all applicable requirements of this subsection [42 U.S.C. § 282(j)] have been met." *See* 42 U.S.C. § 282(j)(5)(B).

63. On January 21, 2009, defendant FDA issued final guidance and a certification form (FDA 3674) implementing the statutory requirement. Final Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff: Certifications to Accompany Drug, Biologic Product, and Device Applications/Submissions, 74 Fed. Reg. 3,615 (Jan. 21, 2009). Sponsors of clinical trials must submit this certification form to FDA alongside

various applications or submissions that are themselves mandatory, such as an application for a new drug approval. A true and correct copy of "Certification Form FDA 3674 (revision Nov. 2008)" is attached as Exhibit A.

64. Defendant FDA thus had actual or constructive knowledge even before the FDAAA Final Rule was promulgated that clinical trials referenced in applications or submissions where the sponsor certified the FDAAA requirements applied were applicable clinical trials.

65. Following promulgation of the FDAAA Final Rule, defendants have knowledge of whether a trial qualifies as an applicable clinical trial that is subject to compliance with FDAAA's results reporting requirements. The Final Rule further specifies what constitutes an "applicable clinical trial" and defines with particularity what information must be submitted. *See* 42 C.F.R. § 11.22 (defining "applicable clinical trial"); *id.* § 11.28 (specifying information that must be submitted for clinical trial registration). Since promulgating the FDAAA Final Rule, defendant NIH has updated the data submission fields for ClinicalTrials.gov so that it can easily identify applicable clinical trials. *See ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies*, ClinicalTrials.gov (June 27, 2018).[6]

66. Non-binding, draft guidance issued by defendant Food and Drug Administration in September 2018 confirms defendants' knowledge or constructive knowledge of noncompliance. *See* U.S. Food & Drug Admin., *Civil Monetary Penalties Relating to the ClinicalTrials.gov Data Bank: Guidance for FDA Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to FDA*, U.S. Dep't of Health & Hum. Servs. 4 (Sept. 2018).[7] As is stated in the guidance, FDA has multiple ways of identifying noncompliance, including its Bioresearch Monitoring Program as well as complaints received by the agency.

[6] https://prsinfo.clinicaltrials.gov/definitions.html.
[7] https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM607698.pdf.

67. Additionally, defendant FDA has access to "non-public information, including, but not limited to, information submitted to the ClinicalTrials.gov data bank and to FDA" that may be used to identify noncompliance. *Id.*

Public Investigation and Reporting of Widespread Noncompliance with FDAAA's Registration and Results Reporting Requirements.

68. Notwithstanding FDAAA's registration and reporting requirements, including those that took effect immediately upon the statute's enactment in 2007, there has been, and remains, public knowledge of widespread noncompliance by responsible parties since the statute took effect.

69. For example, between 2012 and 2014, 32.8% of applicable clinical trials were registered late, and 57% of those trials were registered more than a year late. Deborah A. Zarin et al., *Update on Trial Registration 11 Years After the ICMJE Policy Was Established*, 376 New Eng. J. Med. 383 (2017).[8]

70. A study of trials that occurred between 2008 and 2013 found that only 13.4% of responsible parties reported their results as required by 42 U.S.C. § 402(j)(3)(C) within a year of finishing the trial. Monique Anderson et al., *Compliance with Results Reporting at ClinicalTrials.gov*, 372 New Eng. J. Med. 1031 (2015).[9]

71. As of 2013, only 37.7% of trial results had ever been reported and posted. Hiroki Saito & Christopher Gill, *How Frequently Do the Results from Completed US Clinical Trials Enter the Public Domain? — A Statistical Analysis of the ClinicalTrials.gov Database*, 9:7 PLOS (2014).[10]

[8] https://www.nejm.org/doi/full/10.1056/nejmsr1601330.
[9] https://www.nejm.org/doi/full/10.1056/NEJMsa1409364.
[10] https://doi.org/10.1371/journal.pone.0101826.

72. Defendants could also have determined before the FDAAA Final Rule took effect whether other trials not identified by sponsors as covered by the reporting requirements were, in fact, covered. Non-governmental researchers have been able to determine whether pre-FDAAA Final Rule trials were applicable clinical trials using only publicly available data. *See, e.g.*, Monique L. Anderson et al., *Compliance with Results Reporting at ClinicalTrials.gov*, 372 New Eng. J. Med. 1031 (2015)[11]; Andrew P. Prayle et al., *Compliance with Mandatory Reporting of Clinical Trial Results on ClinicalTrials.gov: Cross Sectional Study*, 2012 BMJ 344.[12] Given defendants' access to non-public data, they could have identified applicable clinical trials even in cases where the non-governmental researchers' analyses may have misclassified a particular clinical trial.

73. Examples of noncompliance abound. On information and belief, results are missing from numerous pivotal trials. Pivotal trials refer to the key trials on which defendants base their regulatory decision to approve a new drug or biologic. Those trials are always completed before a drug or biologic is approved, and they are the most significant evidence of a drug's safety and efficacy. Examples of pivotal pre-Rule, pre-approval trials for which results should have been reported years ago but for which no results information appears on ClinicalTrials.gov include:

a. **"Oritavancin Versus IV Vancomycin for the Treatment of Patients With Acute Bacterial Skin and Skin Structure Infection (SOLO I)."** *See A Multicenter, Double-Blind, Randomized Study to Evaluate the Efficacy and Safety of Single-Dose IV Oritavancin Versus IV Vancomycin for the Treatment of Patients With Acute Bacterial Skin and Skin Structure Infection (SOLO I)*, ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/results/NCT01252719 (primary completion date October 2012) (last updated November 14, 2012).

[11] https://www.nejm.org/doi/full/10.1056/NEJMsa1409364.
[12] https://www.bmj.com/content/344/bmj.d7373.

b. **"Oritavancin Versus IV Vancomycin for the Treatment of Patients With Acute Bacterial Skin and Skin Structure Infection (SOLO II)."** *See A Multicenter, Double-Blind, Randomized Study to Evaluate the Efficacy and Safety of Single-Dose IV Oritavancin Versus IV Vancomycin for the Treatment of Patients With Acute Bacterial Skin and Skin Structure Infection (SOLO II)*, ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/results/NCT01252732 (primary completion date June 2013) (last updated June 26, 2013).

c. **"Study of TAS-102 in Patients With Metastatic Colorectal Cancer Refractory to Standard Chemotherapies (RECOURSE)."** *See Randomized, Double-blind, Phase 3 Study of TAS-102 Plus Best Supportive Care (BSC) Versus Placebo Plus BSC in Patients With Metastatic Colorectal Cancer Refractory to Standard Chemotherapies*, ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/results/NCT01607957 (primary completion date January 2014) (last updated October 6, 2017).

74. Similarly, on information and belief, results information for the following applicable clinical trials in pediatric populations of approved drugs and biologics should have been submitted within a year of the trials' primary completion dates—*i.e.* years ago, but no results information appears in ClinicalTrials.gov:

a. **"Primary Prevention of Hypertension in Obese Adolescents."** *See Primary Prevention of Hypertension in Obese Adolescents*, ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/study/NCT00288158 (primary completion date January 2011) (last updated September 14, 2017).

b. **"Efficacy and Safety of Decitabine as Epigenetic Priming With Induction Chemotherapy in Pediatric Acute Myelogenous Leukemia (AML) Subjects."** *See A Randomized, Open Label, Multicenter Study to Evaluate the Efficacy and Safety of Decitabine as Epigenetic Priming With Induction Chemotherapy in Pediatric Acute Myelogenous Leukemia (AML) Subjects*, ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/study/NCT01177540 (primary completion date August 2013) (last updated October 22, 2013).

75. On information and belief, two of the pediatric trials for which results have not been reported are studies required by the FDA to be completed by the manufacturer under the Pediatric Research Equity Act, 21 U.S.C. § 355c, which requires manufacturers to conduct

studies in pediatric populations for new drug and biologic applications submitted on or after September 27, 2007, regarding the safety and effectiveness of the product in pediatric populations, and appropriate dosing and administration:

a. **"Safety and Efficacy Study of Ceftaroline Versus a Comparator in Pediatric Subjects With Community Acquired Bacterial Pneumonia (CABP)."** *See A Multicenter, Randomized, Observer-Blinded, Active-Controlled Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of Ceftaroline Versus Ceftriaxone in Pediatric Subjects With Community-acquired Bacterial Pneumonia Requiring Hospitalization,* ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/results/NCT01530763 (primary completion date August 2014) (last updated January 13, 2015).

b. **"Safety and Efficacy Study of Ceftaroline Versus a Comparator in Pediatric Subjects With Complicated Skin Infections."** *See A Multicenter, Randomized, Observer-Blinded, Active-Controlled Study to Evaluate the Safety, Tolerability, Efficacy, and Pharmacokinetics of Ceftaroline Versus Comparator in Pediatric Subjects With Acute Bacterial Skin and Skin Structure Infections,* ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/results/NCT01400867 (primary completion date May 2014) (last updated January 13, 2015).

76. On information and belief, other examples of trials in pediatric populations for which results information is long overdue include the thirteen trials identified in Exhibit B.

77. Noncompliance is not limited to pivotal and pediatric trials. On information and belief, results information for the following applicable clinical trials should have been reported within a year of the studies' primary completion date—*i.e.* years ago—but no results information has ever been posted on ClinicalTrials.gov:

a. "**CRLX101 in Combination With Bevacizumab for Metastatic Renal Cell Carcinoma (mRCC) Versus Standard of Care (SOC)."** *See A Randomized, Phase 2 Study to Assess the Safety and Efficacy of CRLX101 in Combination With Bevacizumab in Patients With Metastatic Renal Cell Carcinoma (RCC) Versus Standard of Care (SOC) (Investigator's Choice),* ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/results/NCT02187302 (primary completion date July 2016) (last updated April 20, 2017).

b. **"To Determine The Efficacy and Safety of GDC-0449 in Patients With Basal Cell Nevus Syndrome (BCNS) (GDC-0449)."** *See A Randomized, Phase II Multicenter Trial Evaluating the Efficacy and Safety of a Systemic Hedgehog Pathway Antagonist (GDC-0449) in Patients With Basal Cell Nevus Syndrome (BCNS),* ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/results/NCT00957229 (primary completion date January 2014) (last updated June 6, 2016).

c. **"Trial Comparing the Effects of Intermittent Vismodegib vs. PDT in Patients With Multiple Basal Cell Carcinomas."** *See A Phase II Randomized, Open Label Trial Comparing the Effects of Intermittent Vismodegib Versus PDT on the Maintenance of Benefit Following 7 Months of Continuous Vismodegib Treatment in Patients With Multiple Basal Cell Carcinomas,* ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/results/NCT01556009 (primary completion date December 2015) (last updated January 14, 2016).

78. On information and belief, other trials for drugs or biologics approved between 2012 and 2015 for which results information is long overdue include the eight trials identified in Exhibit C.

79. Many responsible parties continue to miss their reporting deadlines even after the Final Rule, which expanded responsible parties' reporting obligations.

80. AllTrials, in conjunction with the Evidence-Based Medicine DataLab at the University of Oxford, has begun publicly documenting noncompliance with FDAAA. *See FDAAA Trials Tracker*, AllTrials (last visited Dec. 6, 2018).[13]

81. According to AllTrials, "major trial sponsors completed 25,927 eligible trials and ha[d not] published results for 11,714 of them" between January 2006 and November 2016. *Launch of New TrialsTracker*, AllTrials (Nov. 3, 2016).[14] That amounts to 45.2% of trials. *Id.*

82. Additionally, AllTrials reports that only 60.8% of applicable clinical trials with completion dates *on or after* the FDAAA Final Rule effective date, January 18, 2017, have

[13] http://fdaaa.trialstracker.net.
[14] http://www.alltrials.net/news/trialstracker.

publicly reported results on ClinicalTrials.gov. *FDAAA Trials Tracker* (last visited Dec. 6, 2018).[15] Notably, this number only includes trials that were initially registered on ClinicalTrials.gov. *Id.* If trials that were never registered in the first place were included, the share of clinical trials for which reported information is available would be even smaller.

83. Plaintiffs have identified examples of noncompliant trials, which should have reported results information under the FDAAA Final Rule but failed to do so, in Exhibit D.

84. A recent survey of academic institutions required to submit clinical trials to ClinicalTrials.gov showed that many of these institutions were unprepared to meet the ClinicalTrial.gov registration and reporting requirements, suggesting that many academic clinical trials may be out of compliance.[16] The lack of statutorily required notices will make these trials difficult to identify.

Defendants Have Issued No Public Notices of Noncompliance and Have Not Provided for Easy Searching of Those Notices

85. On information and belief, defendants have never posted a single public notice of noncompliance on ClinicalTrials.gov, as required by 42 U.S.C. § 282(j)(5)(E)(i)–(v), notwithstanding the widespread, ongoing noncompliance with FDAAA's registration and reporting requirements documented above.

86. There are currently no public notices on ClinicalTrials.gov for any of the clinical trials that are not in compliance with the reporting requirements of FDAAA, as required by 42 U.S.C. § 282(j)(5)(E)(i)–(v).

87. Searching the ClinicalTrials.gov database for the language of the required notices of noncompliance specified in 42 U.S.C. § 282(j)(5)(E)(i)–(v) returns no results. Exs. E–G.

[15] http://fdaaa.trialstracker.net/.

[16] Evan Mayo-Wilson et al., *Clinical Trial Registration and Reporting: A Survey of Academic Organizations in the United States*, 16 BMC Med. 60 (2018).

88. Site-specific searches limited to ClinicalTrials.gov on Google.com for the language of the required notices of noncompliance specified in 42 U.S.C. § 282(j)(5)(E)(iii)-(v) similarly show that no notices are posted on ClinicalTrials.gov. Exs. H–J.

89. An inspection of the ClinicalTrials.gov entries for the clinical trials identified in paragraphs 73, 74, 75, and 77 above that have failed to submit results information reveals no public notices of noncompliance. *See supra* ¶¶ 73, 74, 75, and 77 and accompanying citations.

90. None of the search features on ClinicalTrials.gov, including the Advanced Search features, allow for the public to "easily search the registry and results data bank for entries that include [public notices]." 42 U.S.C. § 282(j)(5)(E)(vi). Ex. K; *Advanced Search*, ClinicalTrials.gov (last visited Dec. 5, 2018).[17]

CAUSES OF ACTION

FIRST CLAIM
Violation of APA—Unlawful Statutory Interpretation

91. Plaintiffs repeat, reallege, and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

92. The Administrative Procedure Act ("APA") provides that a reviewing court shall hold unlawful and set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C)

93. In purporting to relieve certain responsible parties of their statutory obligation under 42 U.S.C. § 282(j)(3)(E)(iv) to report basic clinical trial results for pre-Rule, pre-approval trials, the Final Rule is arbitrary, capricious, an abuse of discretion, or otherwise not in

[17] https://clinicaltrials.gov/ct2/search/advanced.

accordance with law, and is in excess of defendants' statutory jurisdiction, authority, or limitations, within the meaning of 5 U.S.C. § 706(2)(A) and (C).

94. Plaintiffs Seife and Lurie are adversely affected and aggrieved by defendants' final agency action.

95. Plaintiffs Seife and Lurie are entitled to the results information for pre-Rule, pre-approval trials. 42 U.S.C. § 282(j)(3)(E)(iv); 42 U.S.C. § 282(j)(3)(C).

96. As noted above, Congress expanded the public registry and results databank in FDAAA "[t]o enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials," 42 U.S.C. § 282(j)(2)(A)(i), and "[t]o provide more complete results information and to enhance patient access to and understanding of the results of clinical trials," *id.* § 282(j)(3)(D)(i).

97. On ClinicalTrials.gov itself, defendant agencies have made clear that FDAAA's registration and reporting requirements are intended to serve the general public, patients, the research community, clinicians, users of medical literature, journal editors, agencies providing grant funding for clinical trials, the research community, institutional review boards,[18] ethicists, and policy makers. *Why Should I Register and Submit Results?*, ClinicalTrials.gov.[19]

98. Defendant agencies' failure to require responsible parties for pre-Rule, pre-approval trials to report basic results information, *see* 42 C.F.R. § 11.42, denies plaintiffs Seife and Lurie information to which they are entitled by law.

99. Without the basic results information for pre-Rule, pre-approval trials, Seife and Lurie have been significantly hampered in their efforts to characterize the integrity of the clinical

[18] Institutional review boards (IRBs) ensure that research methods, including clinical trials, comply with appropriate ethical requirements. To be effective, IRBs need to evaluate whether a research protocol is appropriate; full registration and reporting of results on ClinicalTrials.gov can aid that evaluation.

[19] https://clinicaltrials.gov/ct2/manage-recs/background (last visited Dec. 5, 2018).

trial research enterprise and complete their research related to pharmaceutical and medical device evidence development and dissemination.

SECOND CLAIM
Violation of APA – Agency Action Unlawfully Withheld and/or Unreasonably Delayed

100. Plaintiffs repeat, reallege, and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

101. Defendants have a non-discretionary obligation to issue and post public notices of noncompliance for applicable clinical trials that do not register and report as required by FDAAA and the FDAAA Final Rule. 42 U.S.C. § 282(j)(5)(E)(i)–(v).

102. Defendants have a non-discretionary obligation to create a public search function for notices of noncompliance on ClinicalTrials.gov. 42 U.S.C. § 282(j)(5)(E)(vi).

103. Defendants' failure to issue and post public notices of noncompliance for clinical trials, and their failure to create a search function for notices of noncompliance on ClinicalTrials.gov, constitutes agency action unlawfully withheld and/or unreasonably delayed, in violation of 5 U.S.C. § 706(1).

104. Defendants are on notice that responsible parties for certain applicable clinical trials which initiated on or after January 18, 2017, should have reported, but have not reported, results information for those trials.

105. Defendants have issued no notices of noncompliance, agency enforcement action, or whether responsible parties have corrected the results reporting deficiency.

106. Plaintiffs Seife and Lurie are entitled to notices of noncompliance, 42 U.S.C. § 282(j)(5)(E)(i)–(v); and access to a mechanism to "easily search the registry and results data bank for entries that include notices" of noncompliance, 42 U.S.C. § 282(j)(5)(E)(vi).

107. Defendant agencies' failure to make available the notices of noncompliance, as to both pre-Rule and post-Rule, pre-approval trials and other covered applicable clinical trials, and as required by 42 U.S.C. § 282(j)(5)(E), denies plaintiffs Seife and Lurie information to which they are entitled by law.

108. Defendant agencies' failure to make available a public search function required by 42 U.S.C. § 282(j)(5)(E) denies plaintiffs Seife and Lurie information to which they are entitled by law by preventing them from searching for notices of noncompliance, particularly with respect to statutorily required notices of noncompliance for which FDAAA does not mandate specific language.[20]

109. Together, these actions deprive Seife and Lurie, as well as other researchers and advocates, of the data necessary to ensure transparency in research, promote better decision-making by clinicians and policymakers, eliminate bias in the medical literature, and to make patients, clinicians, and regulators aware of medical product safety and effectiveness.

110. Plaintiff Seife is a journalist and researcher who studies, writes about, and educates the public on the integrity of the clinical trial research enterprise and issues related to pharmaceutical and medical device regulation.[21]

111. Plaintiff Seife has spent and will continue to spend time attempting to identify trials that are out of compliance, the reason why those trials are out of compliance, whether defendant agencies have taken any action to correct the noncompliance, and whether the responsible party has corrected the information.

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[20] For example, NIH must post notices detailing any penalties imposed and whether the responsible party has corrected the information in ClinicalTrials.gov, but FDAAA does not mandate any specific language for these notices. 42 U.S.C. § 282(j)(5)(E)(i)(II)–(III).

[21] E.g., Charles Seife, *Research Misconduct Identified by the US Food and Drug Administration: Out of Sight, Out of Mind, Out of the Peer-Reviewed Literature*, 175 JAMA Internal Med. 567 (2015); Charles Seife, *Are Your Medications Safe?*, Slate (Feb. 9, 2015, 11:16 AM), https://slate.com/technology/2015/02/fda-inspections-fraud-fabrication-and-scientific-misconduct-are-hidden-from-the-public-and-doctors.html.

112. Without the statutorily required notices and search function, Seife must continue to expend substantial time and resources to attempt to identify noncompliant trials. First, he must manually conduct a series of advanced searches on ClinicalTrials.gov to identify potentially applicable clinical trials for which results are not reported by, for example, filtering trials by completion date, interventional status, the location of the study, and other relevant variables. Then, he must analyze each potentially applicable clinical trial one-by-one to determine the probability that the trial is not in compliance by analyzing, among other things, whether the responsible party was granted an extension or submitted results which are not yet posted.

113. Seife and his research assistants spent more than 100 research hours to manually sort through ClinicalTrials.gov data in conjunction with his 2015 paper on clinical trial research misconduct.[22] The lack of statutorily required notices and a search function increased the amount of time and work required for this research.

114. Seife has concrete plans to extend his research by investigating the extent to which drug and device approval applications contain all the relevant clinical trials for the drug or device. To complete this project, he will need to search ClinicalTrials.gov trial-by-trial.

115. Because of the lack of statutorily required notices and search function, Seife created a program to search ClinicalTrials.gov for noncompliant trials in conjunction with his research. Seife spent approximately 100 hours to create the code.

116. Seife intends to use his program to search through the ClinicalTrials.gov data bank, but changes to the website made by defendant NIH have rendered the program unusable. Plaintiff Seife will need to expend additional time and other resources to modify the program to fix the functionality for his future research.

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[22] Charles Seife, *Research Misconduct Identified by the US Food and Drug Administration: Out of Sight, Out of Mind, Out of the Peer-Reviewed Literature*, 175 JAMA Internal Med. 567 (2015).

117. Seife's need to fix the program would be obviated if defendants complied with their statutory obligations to post noncompliance notices and create a search function on ClinicalTrials.gov. Seife would use the ClinicalTrials.gov search function, if it were available, instead of his own program to conduct his research.

118. Similarly, plaintiff Lurie is a doctor and researcher who studies, writes about, and educates the public on transparency issues involving clinical trial research, such as the publication and reporting of postmarketing requirement studies, including those contained in the ClinicalTrials.gov data bank.[23]

119. Lurie similarly has spent time in the course of his research attempting to identify trials that have failed to publish results.[24]

120. Plaintiffs Seife and Lurie are injured by defendants' failure to post notices of penalties imposed for responsible parties' failure to comply with FDAAA's reporting requirements mandated by 42 U.S.C. § 282(j)(5)(E)(i)(II). Without these notices, Seife and Lurie are unable to ascertain whether a responsible party has properly registered said clinical trial and reported results as required by law; analyze that information to inform their efforts to characterize the integrity of the clinical research enterprise; and make the public, patients, clinicians, and regulators aware of all research that offers insight into medical product safety and effectiveness.

121. Plaintiffs Seife and Lurie are injured by defendants' failure to post notices indicating whether a responsible party has corrected any error in its reporting of clinical trial

[23] E.g., Marisa L. Cruz, Jing Xu, Mwango Kashoki & Peter Lurie, *Publication and Reporting of the Results of Postmarket Studies for Drugs Required by the U.S. Food and Drug Administration, 2009 to 2013*, 177 JAMA Internal Med. 1207 (2017); *Video and Transcript*, *FDA Transparency and Oversight*, *Panel on Correcting Misinformation*, C-SPAN (Jan. 16, 2018), https://www.c-span.org/video/?439824-102/fda-transparency-oversight-panel-correcting-misinformation.

[24] *See, e.g.*, Cruz et al., *supra* note 23.

information required by 42 U.S.C. § 282(j)(5)(E)(i)(III). Without these notices, Seife and Lurie are unable to rely on this information in their efforts to characterize the integrity of the clinical research enterprise, and to make the public, patients, clinicians, and regulators aware of all research that offers insight into medical product safety and effectiveness.

122. Plaintiffs Seife and Lurie are injured by defendants' failure to post failure-to-submit notices required by 42 U.S.C. § 282(j)(5)(E)(iii). Without these notices, Seife and Lurie are unable to ascertain whether a responsible party has properly reported clinical trial results as required by law; analyze this information in their efforts to characterize the integrity of the clinical research enterprise; and make the public, patients, clinicians, and regulators aware of all research that offers insight into medical product safety and effectiveness.

123. Plaintiffs Seife and Lurie are injured by defendants' failure to post submission-of-false-information notices required by 42 U.S.C. § 282(j)(5)(E)(iv). Without these notices, Seife and Lurie are unable to rely on the accuracy of clinical trial information in their efforts to characterize the integrity of the clinical research enterprise, and to make the public, patients, clinicians, and regulators aware of all research that offers insight into medical product safety and effectiveness.

124. Plaintiffs Seife and Lurie are injured by defendants' failure to post non-submission-of-primary-and-secondary-outcomes notices required by 42 U.S.C. § 282(j)(5)(E)(ii), (v). Without these notices, Seife and Lurie are unable to ascertain whether a responsible party has properly reported results as required by law; analyze that information to inform their efforts to characterize the integrity of the clinical research enterprise; and make the public, patients, clinicians, and regulators aware of all research that offers insight into medical product safety and effectiveness.

125. Plaintiffs Seife and Lurie are injured by defendants' failure to provide a search field for notices of noncompliance required by 42 U.S.C. § 282(j)(5)(E). Without this search capability, Seife and Lurie are unable to ascertain whether a responsible party has properly registered its clinical trial and reported results as required by law; analyze that information to inform their efforts to characterize the integrity of the clinical research enterprise; and make the public, patients, clinicians, and regulators aware of all research that offers insight into medical product safety and effectiveness.

126. As a result, plaintiffs Seife and Lurie are unable to track the progress of clinical trials, the overall compliance rates with FDAAA's reporting requirements, and defendants' enforcement efforts, or to convey that information to the broader public.

127. Instead, to ascertain even some of the information that would otherwise be provided by FDAAA's required notices, plaintiff Seife must and plaintiff Lurie would have to expend time and resources attempting to compile the information through other, significantly less efficient means. Even then, neither Seife nor Lurie could fully reverse engineer the information that would be provided by FDAAA's statutory notices.

THIRD CLAIM
Violation of APA – Agency Action Contrary to Law

128. Plaintiffs repeat, reallege, and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

129. Defendants' failure to comply with the Public Health Service Act, 42 U.S.C. § 282(j)(5)(E)—*i.e.*, their failure to issue and post public notices of noncompliance for applicable clinical trials that do not register and report, and to create a search field for such notices, as required by FDAAA and the FDAAA Final Rule—is agency action contrary to law in violation of the APA, 5 U.S.C. § 706(2)(A), (C).

130. Seife and Lurie are adversely affected and aggrieved by defendants' failure to create the search function required by FDAAA as they must or would have to expend time and resources searching ClinicalTrials.gov for individual notices of noncompliance.

RELIEF REQUESTED

WHEREFORE, plaintiffs respectfully request this Court to:

A. Declare that defendants' Final Rule violates the Public Health Service Act by purporting to relieve responsible parties for pre-Rule, pre-approval trials of their statutory obligation under 42 U.S.C. § 282(j)(3)(E)(iv) to report basic results;

B. Set aside the Final Rule, insofar as it purports to relieve responsible parties of the mandatory obligation to report basic clinical trial results set forth in 42 U.S.C. § 282(j)(3)(E)(iv) for pre-Rule, pre-approval trials;

C. Declare that defendants' failure to issue and post on ClinicalTrials.gov public notices of noncompliance for applicable clinical trials that do not register and report as required FDAAA and the FDAAA Final Rule are agency action contrary to law, unlawfully withheld and/or unreasonably delayed;

D. Enjoin defendants to comply with the substantive provisions of FDAAA that require them to issue and post public notices of noncompliance on ClinicalTrials.gov;

E. Enjoin defendants to comply with the substantive requirements of FDAAA by creating a search function for notices of noncompliance on ClinicalTrials.gov;

F. Award plaintiffs their costs and reasonable attorneys' fees under 28 U.S.C. § 2412; and

G. Grant such other and further relief as the Court deems just and proper.

Dated: December 7, 2018

Respectfully submitted,

MEDIA FREEDOM & INFORMATION ACCESS CLINIC

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[25] This complaint has been prepared in part by a clinic associated with the Abrams Institute for Freedom of Expression and the Information Society Project at Yale Law School, but does not purport to present the school's institutional views, if any.