UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE, Plaintiff, v. FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Civil Action No. 1:17-cv-3960

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

Plaintiff Charles Seife, by and through his undersigned attorneys, alleges as follows:

INTRODUCTION

1. This lawsuit challenges the denial of expedited processing of a December 2016 request under the Freedom of Information of Act (FOIA), 5 U.S.C. § 552, submitted by plaintiff Charles Seife to defendants Food and Drug Administration (FDA) and Department of Health and Human Services (HHS). It further challenges the constructive denial of Seife's FOIA request by defendants' failure to disclose any of the records requested.

2. Seife is a journalist who regularly reports on the FDA. Through this action, he seeks disclosure of information relating to the FDA's recent approval of a new chemical compound called eteplirsen for the treatment of a rare form of muscular dystrophy—an approval so controversial it "ignited a civil war" at the FDA and received widespread attention from patient groups, doctors, drug companies, members of Congress, the press and the public. The controversy is ongoing, and a compelling need exists for prompt public disclosure of the information requested by Seife.

3. Sarepta Therapeutics ("Sarepta") is now manufacturing and selling eteplirsen in the United States under the trade name "Exondys 51." This drug is the only disease-modifying treatment approved for Duchenne Muscular Dystrophy ("Duchenne") in the United States, a neuromuscular disorder that causes progressive muscle degeneration in young boys, as well as death from respiratory or cardiac failure. Sarepta charges $300,000 per year or more to those taking Exondys 51.

4. Because eteplirsen is the only treatment for Duchenne that supposedly provides more than palliative care, families are going to extraordinary lengths to come up with the funds needed to pay for the drug. Some are believed to be mortgaging their homes and suffering irreparable personal and financial harm to obtain the drug, even though certain FDA officials believe Exondys 51 may be no more than an "elegant placebo."

5. The promise of Exondys 51 tugged at the public's heartstrings after investigators initially reported that the first small-scale, placebo-controlled study showed positive results. But when Sarepta later submitted its approval package, the FDA review team concluded that this initial trial was so flawed that further research into the drug's effectiveness was needed.

6. After the review team's conclusion became public, FDA reviewers received thousands of emails from patient groups and the public, including graphic hate mail. Shouting matches broke out at the Advisory Committee meeting where the independent experts tasked with examining the efficacy of the drug publicly voted against approval. While Advisory Committee votes are non-binding, the FDA's internal review team concurred and decided to reject the drug.

7. In an extraordinary action, the head of the FDA's Center for Drug Evaluation and Research (CDER) unilaterally approved the drug despite its rejection by the review team, and the

review team's lead scientist resigned from the agency. The dispute then escalated to the FDA Commissioner, who sided with the head of CDER, but at the same time called for the retraction of the published clinical study due to its serious flaws.

8. In connection with his reporting on this continuing controversy, Seife seeks six discrete and easily searchable categories of information related to the approval of eteplirsen. This information is needed to answer urgent questions about the efficacy of Exondys 51 and the validity of the approval process. It will shed light on the hotly debated issue of whether the FDA approved an entirely ineffective drug based on faulty clinical trials and undue industry influence, or whether an effective drug is being unjustly excluded from reimbursement in many prescription drug plans.

9. Through this action, Seife seeks an order requiring defendants to expedite the processing of his FOIA request based upon the ongoing public controversy surrounding the approval of eteplirsen and the irreparable harm to both Seife and the public caused by defendants' failure to disclose information that could fundamentally alter the way the controversial drug is perceived, prescribed, and insured. The information Seife seeks is also relevant to a current debate over the evidentiary standards that should be applied when a drug manufacturer seeks accelerated approval of a new chemical, the drafting of new regulations for drug approval required by the recently enacted 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016), and Sarepta's pending application for approval of eteplirsen by regulators in Europe.

PARTIES

10. Plaintiff Charles Seife is a Professor of Journalism at New York University who resides in New York, New York and reports regularly on 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*.

11. Defendant U.S. Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services. The FDA is responsible for regulating the safety, efficacy, and security of drugs and other pharmaceutical products intended for human use. The FDA is also responsible for providing the public with accurate scientific information regarding drugs and other products. The FDA is an agency of the United States within the meaning of 5 U.S.C. § 552(f)(1).

12. Defendant U.S. Department of Health and Human Services (HHS) is an agency within the Executive Branch of the United States government. HHS is responsible for managing a wide variety of health and welfare programs, both directly and through its components. HHS is an agency of the United States within the meaning of 5 U.S.C. § 552(f)(1).

JURISDICTION AND VENUE

13. This Court has subject-matter jurisdiction over this action and personal jurisdiction over the defendants pursuant to 5 U.S.C. §§ 552(a)(4)(B) and 552(a)(6)(E)(iii). This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. §§ 701-06.

14. Venue is proper in this district under 5 U.S.C. § 552(a)(4)(B).

FACTS

Clinical Trials

15. FDA regulations provide an accelerated approval pathway for drugs that treat an unmet medical need. To qualify for accelerated approval, a drug must treat a "serious or life threatening disease[]" and must provide "meaningful" benefit over existing therapies. 21 C.F.R.

314.500; *see* 21 U.S.C. § 356(c). New cancer drugs routinely receive accelerated approval, for example.

16. There are two means by which a drug manufacturer can obtain accelerated approval for a qualifying drug: by directly demonstrating that the drug provides "clinical benefit," or by indirectly demonstrating a clinical benefit by using a "surrogate endpoint." *See* 21 U.S.C. § 356(c)(1)(A). A "surrogate endpoint" is a marker that "is reasonably likely . . . to predict clinical benefit." *Id.* An example of a surrogate marker is cholesterol level as a stand in for cardiac health.

17. The first human trial of eteplirsen, Study 201, sought to measure, among other things, the surrogate endpoint of "dystrophin" levels, which scientists agree is correlated to neuromuscular health. The clinical endpoint measured in the test was a six-minute walk.

18. Because the variation of Duchenne that eteplirsen treats is so rare, Study 201 was the smallest pivotal study in modern FDA history. It was a single-center, double-blinded, randomized-controlled trial conducted in twelve patients with Duchenne, four of whom received a placebo.

19. After twenty-four weeks, investigators took the four patients initially given placebos and put them on a regime of eteplirsen; after forty-eight weeks, they extended the study to an open-label phase (Study 202) where all investigators—and all patients—were aware that the patients were receiving the study drug. At various times, Sarepta announced that the ongoing trial was meeting with great success, though the FDA would later say that "Sarepta's misleading communications led to unrealistic expectations and hope for DMD patients and their families."

20. The positive results of Study 201/202 claimed by Sarepta galvanized the Duchenne community but were later called into question. The lab readings showing a large

increase in dystrophin were erroneous, and further analysis showed that patients tended to have dystrophin levels less than 1 percent of normal, far below those expected to result in any clinical benefit. Participants in the study who received the drug also failed to show any improvement on the clinical endpoint, the six-minute walk test.

21. In addition to lab errors, there were several methodological changes to Study 201/202's protocol and to the study endpoints while the study was underway. These changes further called into question the study's integrity.

22. Sarepta conducted an additional study, Study 301. Study 301 was an open-label trial with thirteen patients. All thirteen patients received the drug. Participants showed no improvement in the six-minute walk test, and over the course of the forty-eight week study, participants had an average increase in dystrophin of only 0.3 percent. As one FDA official explained, if "10 inches of snow on a sidewalk . . . needed to be cleared" these results would be the equivalent of "1/32nd of an inch" being removed.

FDA Approval

23. On June 26, 2015, Sarepta submitted a New Drug Application for eteplirsen for the treatment of Duchenne muscular dystrophy.

24. Pressure to approve the drug ran high after the company, patient groups, doctors, and 109 members of Congress lobbied the FDA. Many believed eteplirsen represented a cure due to the faulty results reported for Study 201/202.

25. On April 25, 2016, the FDA convened an Advisory Committee to consider eteplirsen. The emotionally-charged hearing lasted over eleven hours and featured fifty-one speakers, all but one of whom spoke in favor of approval. The Committee then voted seven-to-three (with three abstentions) that Study 201/202 did not provide substantial evidence that Exondys 51 was effective for the treatment of Duchenne. Two of the three members who voted

that Study 201/202 supported the effectiveness of eteplirsen were patient representatives. The Committee then voted seven-to-six that eteplirsen did not meet the statutory standard for accelerated approval. Media reports noted that audience members broke into angry shouts after the final vote.

26. The FDA clinical team reviewing eteplirsen unanimously recommended against approval and the team leader, Dr. Ronald Farkas, expressed "strong doubts" about the accuracy of the clinical trials. Shortly before that recommendation was overruled, Dr. Farkas resigned from the FDA.

27. Less than three months after the contentious Advisory Committee meeting, on July 14, 2016, the head of the FDA's Center for Drug Evaluation and Research, Dr. Janet Woodcock, unilaterally issued a decisional memorandum granting eteplirsen accelerated approval. According to the FDA's Acting Chief Scientist, Dr. Luciana Boria, this could be the first time in FDA history that a Center Director had overruled a review team based on the assessment of a drug's efficacy.

28. Rumors abounded that Dr. Woodcock had succumbed to external influence when she overruled the review team and advisory committee in 2016. Dr. Woodcock admitted at the time that she was concerned about the survival of Sarepta if eteplirsen was not approved.

29. According to the director of the CDER Office of Drug Evaluation, Dr. Ellis Unger, Dr. Woodcock made clear to the review team in May 2016 that she intended to approve eteplirsen, even before she had read the final review memoranda. Indeed, she issued her approval memorandum before the review team's final analysis, recommending against approval, was drafted by Dr. Unger.

30. On July 18, 2016, Dr. Unger appealed Dr. Woodcock's decision to approve the drug on the grounds that the level of dystrophin production in trial participants receiving eteplirsen was not large enough to be "reasonably likely" to predict a clinical benefit, as required for accelerated approval. Dr. Unger also highlighted the unknown risks of the drug as well as the known risks associated with the injection ports used to administer it, which posed a risk of infection due to the immuno-suppressants patients take.

31. The FDA convened a panel to review the appeal. The panel found that Dr. Unger had "never received any unconflicted review of his scientific arguments or the underlying evidence." It concluded that the Commissioner should conduct his own review of the science or convene a panel of outside experts to do so.

32. The head of the panel, the Acting Chief Scientist of the FDA, Dr. Luciana Borio, wrote separately to the FDA Commissioner to support Dr. Unger's view of the science.

33. On August 8, 2016, the FDA commissioner, Dr. Robert Califf, issued a memorandum conceding that flaws in the design and implementation of the clinical trials "made it impossible to use much of the resulting trial data as reliable evidence in regulatory decision-making, including for reasonable extrapolation to clinical care." He also called for the retraction of the published scientific article on results of the original trial, Study 201/202, because it was misleading. Nonetheless, Dr. Califf deferred to Dr. Woodcock's decision, citing her years of clinical experience.

34. On September 19, 2016, the FDA granted Exondys 51 accelerated approval.

Seife's FOIA Request

35. Seife became interested in the controversy surrounding the approval of Exondys 51 and conducted a careful investigation. Seife interviewed a number of sources, who described

particular categories of information he should request from the FDA and explained the importance of disclosure of the information.

36. Through this investigation Seife was able to identify information relevant to his reporting, including information relevant to understanding the influence exerted by industry members over Dr. Woodcock and her deputy Dr. Richard Moscicki, who had previously worked with the CEO of Sarepta and did not recuse himself from the approval process. In addition, Seife wanted information concerning the non-scientific motivations to approve the drug and the validity of the science used by Sarepta.

37. On December 5, 2016, Seife filed a FOIA request, requesting expedited processing and attaching several hundred pages of material documenting his right to expedited processing. His request narrowly sought the following specific records:

- The Chronology prepared by Virginia Behr and submitted to the Scientific Dispute Resolution Board regarding eteplirsen ("Behr Chronology").
- Any e-mails, memos, or other correspondences dated from 1/1/2005 to the present which contains one or more of the following words:

  a "Sarepta"; or
  b. "Eteplirsen"; or
  c. "AVI-4658"; or
  d. "Drisapersen"; or
  e. "Kyndrisa"; or
  f. "PRO051"; or
  g. "GSK2402968"; or
  h. "DMD"; or
  i. "Duchenne"; or
  j. "Dystrophy"; or
  k "Exondys"; or
  l. "Dystrophin."

  And is:

  m. To or from Robert Califf; or
  n. To or from Margaret Hamburg; or
  o. To or from Janet Woodcock; or
  p. To or from Richard Moscicki; or

q. To or from Robert Temple.

- Any e-mails, memos, or other correspondences from Robert Califf and/or Ellis Unger to editors or publishers of the *Annals of Neurology*.

- Any documents dated from 1/1/2010 onwards mentioning possible or actual recusal by Richard Moscicki from any of his duties.

- Any e-mails, memos, or other correspondences to or from Richard Moscicki dated from 1/1/2010 onward that:

  a. Mentions or is addressed to Ed Kaye; or
  b. Mentions or is addressed to a Sarepta employee; or
  c. Mentions or is addressed to a BioMarin employee; or
  d. Mentions Genzyme.

- The following data regarding Study 201/202:

  a. Clinical Study Reports;
  b. Protocols and protocol amendments;
  c. Statistical Analysis Plans and plan amendments; and
  d. Documents of regulatory communications.

A true and correct copy of Seife's December 5, 2016, FOIA request (excluding attachments) is annexed as Exhibit A.

38. The information sought by Seife was (and remains) relevant to ongoing controversies concerning the efficacy of eteplirsen, the FDA's drug approval process, the FDA's implementation of new statutory standards, and a still-pending review of eteplirsen in Europe. It was and remains relevant to families' decisions to mortgage their homes or undergo other financial burdens to purchase Exondys 51.

39. Given the existing controversies and the need to timely report on them, Seife requested expedited processing under 5 U.S.C. § 552(a)(6)(E). Under this statutory provision, an agency is required to provide a FOIA response within 10 days when the requestor is "a person primarily engaged in disseminating information" and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." *Id.* § 552(a)(6)(E)(i), (v).

40. Seife sought expedited processing, among other reasons, on the grounds that he is a journalist and the approval of Exondys 51 was a "breaking news story." His FOIA request cited a critical amount of media attention from *Forbes*, *The New York Times*, *STAT News*, *The Washington Post*, and many other news outlets concerning the approval of Exondys 51.

41. In addition, Seife noted that the enormous costs of the drug—ranging from $300,000 to $500,000, depending on the weight of the child—rendered his reporting on the drug highly newsworthy. The drug cost is crushing for families of young boys with Duchenne. According to Sarepta's CEO, only 250 boys had applied to use Exondys 51 out of the thousands eligible. Meanwhile, seventy percent of neurologists believe the drug is effective and are willing to prescribe it, indicating that more families may purchase the drug the longer it remains on the market.

42. In addition to expedited processing, Seife sought a public-interest fee waiver because disclosure of the information he seeks is in the public interest within the meaning of 5 U.S.C. § 552(a)(4)(A)(ii)(II). He also requested a fee waiver because he does not have a commercial interest in disclosure.

The FDA's Response

43. Defendants did not respond to Seife's FOIA request within 10 days as required by the FOIA provision governing expedited processing. 5 U.S.C. § 552(a)(6)(E).

44. On December 20, 2016, an attorney for Seife, Cortelyou Kenney, contacted the FDA and spoke with the specialist assigned to Seife's request. The specialist was unaware that Seife had requested expedited processing and stated that an acknowledgement letter had been mailed on December 14, 2016. Seife did not receive a hard copy of the letter until January.

45. The next day, December 21, 2016, Seife called the FDA and spoke to a supervisor, who confirmed that the FDA had received the request but had not yet decided

whether to grant expedited processing. Later that day, Seife and Kenney received a form letter by email denying Seife's request for expedited processing and advising him of his right to appeal within ninety days. Also included in the email was an acknowledgement of Seife's request. A true and correct copy of the FDA's December 21, 2016, denial of expedited processing is annexed as Exhibit B.

46. On February 6, 2017, Seife appealed the denial of expedited processing and the constructive denial of his FOIA request, submitting several hundred additional pages of documentation demonstrating the substantial public interest and supporting the need for expedition. A true and correct copy of Seife's February 6, 2017 administrative appeal (excluding attachments) is annexed as Exhibit C.

47. While Seife's appeal was pending, Dr. Aaron Kesselheim, a member of the Advisory Committee that had voted against Exondys 51's approval, wrote to HHS to urge disclosure of the records sought by Seife. Dr. Kesselheim stressed that expedited approval was both proper and necessary because some families may be shouldering out of pocket the substantial cost of a potentially useless drug by mortgaging their homes and undergoing enormous personal trauma to obtain the drug.

48. Kesselheim detailed the need for prompt disclosure:

> If the information Professor Seife seeks is released and reveals that the FDA approval process was flawed or sheds new light that undercuts the perceived efficacy of the drug in treating muscular dystrophy, far fewer physicians would prescribe the product and families would be relieved of these risks. By contrast, the information sought may further support the validity of the FDA's approval of eteplirsen and help families and their advocates convince insurance companies to cover the drug. Both outcomes would also be of enormous interest to the American public as important news about the lives of thousands of boys with a rare disease and their brave personal narratives, and about the decision making of the national drug regulator.

49. Seife's appeal contained additional reasons for expedited processing. For one, the lowered scientific standards used in approving Exondys 51 make prompt release of the requested records of importance to the public. Disclosure of the facts surrounding approval of Exondys 51 may improve the implementation of the 21st Century Cures Act, a law enacted in December 2016 that requires the FDA to issue new regulations for the use of "patient testimonials" in the drug approval process. An increased reliance on "patient testimonials" in the drug approval process cuts against the current rigorous standards requiring a drug's manufacturer to provide substantial evidence of safety and efficacy derived from adequate and well-controlled studies. Investigative journalism demonstrating how the use of patient testimonials influenced FDA officials in the case of Exondys 51 can help to properly shape the new regulations to best serve the public interest.

50. Seife's appeal also demonstrated the relevance of timely reporting on the review process for Exondys 51 to public debate over administrative changes at the FDA under the Trump Administration. The designated new FDA Commissioner has suggested changing the accelerated approval pathway, and Exondys 51 has become the lens though which the accelerated approval process is viewed. The relevance of the requested information to the current evaluation of incoming officials also warrants expedited processing.

51. Expedited processing is also needed given the ongoing debate about the drug approval process, driven largely by industry representatives who complain that the FDA process is too slow and are fighting for faster approvals. Exondys 51 is at the center of an ongoing debate about whether its approval essentially signaled the FDA's removal of any need to establish clinical efficacy, or to the contrary demonstrates that the FDA approval process is functioning as it should. Commentators from all perspectives recognize that the approval of

Exondys 51 will color the FDA's approach to new drug applications, further supporting the need for timely disclosure of the FDA records at issue.

52. Timely release of the information requested by Seife is also important given the process for approving Exondys 51 currently underway before the European Medicines Agency (EMA). The EMA accepted Sarepta's application for approval on December 21, 2016, and the standard review period is 210 days. Approval by the EMA would itself be immensely important to the public, and may be affected by timely disclosure of the information at issue.

53. Prompt disclosure is also needed to inform investors. Sarepta's solvency apparently depends on the success of Exondys 51. Since the drug's approval, financial advisors have picked the company as a stock to watch in 2017, further underscoring the significant news value of the requested information. Indeed, in the wake of disclosure of the flaws in Study 201/202, Sarepta's stock dropped precipitously and shareholder suits alleging fraud soon followed. Seife's request would inform the public whether Sarepta fudged the results of Study 201/202 and also whether it unduly influenced the FDA.

54. Notwithstanding the multiple grounds demonstrating the public importance of prompt disclosure, defendants have refused to expedite processing of Seife's request. On February 8, 2017, HHS's Division of Information initially responded to Seife's appeal by indicating that "unusual circumstances" required it to consult "with another office or agency that [had] substantial interest in the determination of the appeal." Pursuant to 5 U.S.C. § 552(a)(6)(B)(i), defendants were thus permitted 30 days to respond to Seife's appeal, instead of the ordinary 20 days to respond to an appeal from the denial of expedited processing.

55. HHS did not respond to the appeal within 30 days as required by law.

56. On March 15, 2017, Kenney contacted HHS by phone and left a voice message inquiring after the status of Seife's appeal.

57. On March 17, 2017, an HHS official named Brandon Lancey returned Kenney's call. It was apparent from the call that HHS had not consulted another office or agency and had done nothing with Seife's appeal. Lancey stated he had a backlog of 170 appeals to review, but said he would "bump" Seife's appeal to the front of the queue and would try to reach a determination by the end of the day.

58. Lancey did not reach a determination that day.

59. Having heard nothing from Lancey, four days later, on March 21, 2017, Kenney sent Lancey an email asking him to email a decision on Seife's appeal as soon as one was made.

60. More than a week later, on March 29, 2017, Lancey informed Kenney by email that he was in the process of writing up a response to the appeal and would have it completed "soon." However, he would then need to forward the response to the Office of the General Counsel for review and finally to the Deputy Chief FOIA Officer for "final sign-off."

61. Kenney replied immediately to ask Lancey for an estimated date of completion, noting the matter was time-sensitive and the FDA was "already past its statutory deadline."

62. Lancey responded the same day, telling Kenney that his goal was to send his recommendation to the Office of the General Counsel "by the end of the week" (which would have been March 31). He added that he would "see what [he] [could] do to help move it along."

63. On April 3, 2017, Kenney emailed Lancey again and asked if he had completed his recommendation and if he had a timeline for a response to the appeal.

64. On April 5, 2017, Lancey responded that he had submitted his recommendation to the Office of General Counsel for its consultation. He promised to follow up with them to see where they were in their review.

65. Kenney immediately responded that Seife remained "eager" for the response.

66. Having heard nothing further, on April 17, 2017, Kenney emailed Lancey again stating that Seife was "extremely anxious to have the information." She again asked if he could provide a date by which a decision would be provided.

67. Lancey responded the same day, telling Kenney that "the Office of the General Counsel had informed [Lancey] that they hope[d] to finish their review by Wednesday [April 19, 2017.]"

68. On April 25, 2017, Seife received an email from Lancey denying the appeal. The letter stated that expedited processing was denied because HHS saw no "urgency to inform the American public." The letter observed that Seife made his FOIA request two and a half months after Exondys 51 was approved, that there had been a "steady decline" in the number of news stories written about the approval over that time, and that over 2000 documents related to Exondys 51 were available on the FDA website. A true and correct copy of HHS's April 25, 2017, denial letter is annexed as Exhibit D.

69. None of defendants' assertions justify the denial of expedited processing as mandated by law. The information requested by Seife is key to several ongoing public debates—about a specific drug and about the regulatory processes for new drug approvals.

70. Nor has Seife waived his right to an expedited response. Seife's careful approach to investigative journalism, which led him to interview confidential sources to determine the

specific information he should target before he made his FOIA request, confirms the ongoing importance of the story rather than refutes it.

71. The denial letter also asserted that the FDA had not constructively denied Seife's FOIA request, claiming the FDA was excused from responding within the 20-day statutory deadline by "exceptional circumstances." Specifically, the letter cited the fact that in Fiscal Year 2016, the FDA received more requests than any year since 2007, had received 28 percent more requests the first quarter of 2017 than two years previously, and 40 percent of these requests were marked as "complex." It also asserted that FDA had reduced its backlog by 14 percent over the last two years, and that the number of complex requests processed by the FDA has increased.

72. The denial letter did not give any estimated date for a response to Seife's FOIA request.

FIRST CAUSE OF ACTION

(VIOLATION OF FOIA FOR FAILURE TO EXPEDITE PLAINTIFF'S REQUEST)

73. Plaintiff repeats, realleges, and incorporates the allegations in the foregoing paragraphs as though fully set forth herein.

74. Defendants' failure to expedite the processing of plaintiff's request and appeal violates FOIA, 5 U.S.C. § 552(a)(6)(E), and defendants' corresponding regulations.

SECOND CAUSE OF ACTION

(VIOLATION OF FOIA FOR FAILURE TO DISCLOSE RECORDS)

75. Plaintiff repeats, realleges, and incorporates the allegations in the foregoing paragraphs as though fully set forth herein.

76. Defendants' wrongful withholding of records, or portions thereof, requested by plaintiff violates FOIA, 5 U.S.C. § 552(a)(3)(A) and 5 U.S.C. § 552(a)(6)(A), and defendants' corresponding regulations.

THIRD CAUSE OF ACTION

(VIOLATION OF FOIA FOR FAILURE TO GRANT WAIVER OF FEES)

77. Plaintiff repeats, realleges, and incorporates the allegations in the foregoing paragraphs as though fully set forth herein.

78. Defendants' failure to grant plaintiffs a waiver of fees violates FOIA, 5 U.S.C. § 552(a)(4)(A)(iii), and defendants' corresponding regulations.

FOURTH CAUSE OF ACTION

(VIOLATION OF FOIA FOR FAILURE TO GRANT LIMITATION OF FEES)

79. Plaintiff repeats, realleges, and incorporates the allegations in the foregoing paragraphs as though fully set forth herein.

80. Defendants' failure to grant a limitation of fees violates FOIA, 5 U.S.C. § 552(a)(4)(A)(ii)(II), and defendants' corresponding regulations.

RELIEF REQUESTED

WHEREFORE, plaintiff respectfully prays that this Court:

a. expedite consideration of this Complaint pursuant to 28 U.S.C. § 1657;

b. declare that defendants improperly failed to grant expedited consideration to plaintiff's FOIA request and order them to conduct an immediate, complete and thorough search for all responsive records;

c. order defendants immediately and expeditiously to provide to plaintiff copies of the requested records in their native electronic format or other electronic format, as requested;

d. enjoin defendants from unlawfully withholding the records requested by plaintiff, or portions thereof;

e. enjoin defendants from assessing any fees against plaintiff in relation to the processing of the FOIA requests;

f. award to plaintiff the costs of this proceeding, including reasonable attorneys' fees, pursuant to 5 U.S.C. § 552(a)(4)(E); and

g. grant such other and further relief as the Court deems just and proper.

Dated: May 25, 2017
New York, NY

Respectfully submitted,

MEDIA FREEDOM & INFORMATION
ACCESS CLINIC

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