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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE, Plaintiff, FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	1:17-cv-3960 (JMF)

DEFENDANTS' ANSWER TO THE COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF AND AFFIRMATIVE DEFENSES

Defendants the Food and Drug Administration ("FDA") and the Department of Health and Human Services ("HHS") (collectively, "Defendants"), by their attorney, Joon H. Kim, Acting United States Attorney for the Southern District of New York, hereby answer Plaintiff Charles Seife's Complaint for Injunctive and Declaratory Relief, upon information and belief, as follows:

INTRODUCTION[1]

1. The allegations contained in paragraph 1 constitute Plaintiff's characterization of his claims to which no response is required. To the extent that this Court deems a response necessary, Defendants admit that Plaintiff submitted a FOIA request to Defendants.

2. Defendants are without sufficient information to form a belief as to the truth of the allegations contained in the first sentence of paragraph 2, and therefore deny them. The allegations contained in the second sentence of paragraph 2 constitute Plaintiff's characterization of his claims in this action, to which no response is required, and of his FOIA request, which speaks for itself and is the best evidence of its contents. To the extent that this Court deems a response necessary, Defendants admit that FDA approved Exondys 51 (eteplirsen) Injection, 50 mg per mL, for the treatment of Duchenne muscular dystrophy ("DMD") in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping, a rare form of muscular dystrophy. The remaining allegations of paragraph 2 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny such allegations.

3. The allegations of paragraph 3 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit that FDA approved eteplirsen for Duchene muscular dystrophy in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping, but deny that eteplirsen is the only therapy approved for patients with a mutation of the DMD gene amenable to exon 51 skipping. Defendants are without sufficient information to form a belief as to the truth of the remaining allegations of paragraph 3, and therefore deny them.

[1] Defendants have included the headings listed in the complaint simply to assist in reading the pleadings and does not admit the accuracy of those headings.

4. The allegations of paragraph 4 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants deny that eteplirsen is the only therapy approved for patients with a mutation of the DMD gene amenable to exon 51 skipping. Defendants are without sufficient information to form a belief as to the truth of the remaining allegations of paragraph 4, and therefore deny them.

5. The allegations of paragraph 5 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants are without sufficient information to form a belief as to the truth of the allegation in paragraph 5 that "the promise of Exondys 51 tugged at the public heartstrings," and therefore deny it. The remaining allegations of paragraph 5 purport to characterize the contents of Sarepta's New Drug Application ("NDA") for eteplirsen, NDA No. 206488Orig1s000, and the findings by the FDA review team, which are included in FDA's approval package for the drug; those documents speak for themselves and are the best evidence of their contents. To the extent that Plaintiff's characterizations of those documents differ from their contents, Defendants deny such allegations.

6. The allegations of paragraph 6 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit that the Advisory Committee voted on certain questions presented about NDA No. 206488Orig1s000 at a meeting convened on April 25, 2016 to consider that NDA, that the Advisory Committee voted against approval for the same, that the FDA review team also did not recommend approval, and that the Advisory Committee votes are not binding on FDA. The allegations of paragraph 6 purport to describe the proceedings and

results of the April 25, 2016, Advisory Committee meeting regarding NDA No. 206488Orig1s000, the official transcript of which speaks for itself is the best evidence of its proceedings and contents. To the extent that Plaintiff's characterizations of the April 25, 2016, Advisory Committee meeting differ from its proceedings and contents as reflected in the transcript, Defendants deny such allegations. The allegations of paragraph 6 also purport to describe the FDA review team's deliberations, which are included in FDA's approval package for NDA No. 206488Orig1s000, which approval package speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the approval package differ from its contents, Defendants deny such allegations. Defendants are without sufficient information to form a belief as to the truth of the remaining allegations of paragraph 6, and therefore deny them.

7. The allegations of paragraph 7 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit that Dr. Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research ("CDER"), issued a memorandum dated July 14, 2016, explaining her findings and decision regarding NDA No. 206488Orig1s000 ("Woodcock Memo"), which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the Woodcock Memo differ from its contents, Defendants deny such allegations. Defendants further admit that certain FDA staff members disagreed with Dr. Woodcock's decision, that the dispute was appealed to the Scientific Dispute Process Review Board within the FDA Office of Chief Scientist, and that the dispute was ultimately resolved by the FDA Commissioner, Dr. Robert Califf, who issued a memorandum, dated September 16, 2016, explaining his findings and decision on the dispute ("Commissioner's Decision Memo"),

which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the Commissioner's Decision Memo differ from its contents, Defendants deny such allegations. Defendants further admit that a review team leader involved in the approval of eteplirsen resigned from FDA, but Defendants are without sufficient information to form a belief as to the reason(s) for such resignation and on that basis deny the allegations.

8. The allegations in the first sentence of paragraph 8 regarding the categories of information sought purport to characterize Plaintiff's FOIA request, which speaks for itself and is the best evidence of its contents. To the extent Plaintiff's characterizations differ from the contents of the FOIA request, Defendants deny such allegations. The remaining allegations of paragraph 8 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny such allegations.

9. The allegations in the first sentence of paragraph 9 regarding Plaintiff's request for expedited processing constitute Plaintiff's characterization of the relief sought in this action, to which no response is required. To the extent that this Court deems a response necessary, Defendants deny that Plaintiff is entitled to any relief. The remaining allegations of Paragraph 9 further set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny such allegations.

PARTIES

10. Defendants are without sufficient information to form a belief as to the truth of the allegations of paragraph 10, and therefore deny them.

11. In response to the allegations of paragraph 11, Defendants admit that FDA is a component of HHS, that FDA's mission is set forth in 21 U.S.C. § 393, that FDA, *inter alia*, regulates the safety, efficacy, and security of drugs and pharmaceuticals for human use, and that

FDA is an agency of the United States within the meaning of 5 U.S.C. § 552(f)(1). Defendants deny the remaining allegations of paragraph 11.

12. In response to the allegations of paragraph 12, Defendants admit that HHS is a Department within the Executive Branch of the United States, that its 11 operating divisions have responsibility for administering a wide variety of health and human services, and that HHS is an agency of the United States within the meaning of 5 U.S.C. § 552(f)(1).

JURISDICTION AND VENUE

13. Paragraph 13 contains Plaintiff's legal conclusion regarding jurisdiction, to which no response is required, except that Defendants deny that this Court has subject matter jurisdiction over this matter pursuant to 5 U.S.C. § 701 *et seq.*

14. Paragraph 14 contains Plaintiff's legal conclusion regarding venue, to which no response is required.

FACTS

15. The allegations of paragraph 15 are irrelevant to the resolution of the claims set forth in the complaint, and therefore no response is required. Furthermore, the allegations of paragraph 15 purport to state the requirements of 21 C.F.R. § 314.500 and 21 U.S.C. § 356(c), which are conclusions of law to which no response is required. To the extent that this Court deems a response necessary, Defendants respectfully refer the Court to 21 U.S.C. § 356(c) and 21 C.F.R. § 314.500 for a true and complete statement of their contents. Defendants deny the remaining allegations of paragraph 15.

16. The allegations of paragraph 16 are irrelevant to the resolution of the claims set forth in the complaint, and therefore no response is required. Furthermore, the allegations of paragraph 16 purport to state the requirements of 21 U.S.C. § 356(c)(1)(A), which are

conclusions of law to which no response is required. To the extent that this Court deems a response necessary, Defendants respectfully refer the Court to 21 U.S.C. § 356(c)(1)(A) for a true and complete statement of its contents. Defendants are also without sufficient information to form a belief as to the truth of the allegations in the last sentence of paragraph 16, and therefore deny them.

17. The allegations of paragraph 17 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit only that the primary endpoint of Study 201 was dystrophin production and that a clinical outcome measure, the 6-minute walk test (6MWT), was also assessed. To the extent paragraph 17 purports to characterize the methods and goals of Study 201, the study speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of Study 201 differ from its contents, Defendants deny such allegations. Defendants also are without sufficient information to form a belief as to the truth of the allegation that scientists agree that dystrophin levels is correlated to neuromuscular health, and therefore deny it.

18. The allegations of paragraph 18 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants aver that the allegations of paragraph 18 purport to characterize Study 201, and that the study speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of Study 201 differ from its contents, Defendants deny such allegations. Defendants are also without sufficient information to form a belief as to the truth of the allegation that Study 201 was the smallest pivotal study in modern FDA history, and therefore deny it.

19. The allegations of paragraph 19 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit only that FDA's approval of eteplirsen involved in part Study 201/202. To the extent paragraph 19 purports to characterize Study 201/202, the study speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of Study 201/202 differ from its contents, Defendants deny such allegations. The allegations of paragraph 19 also appear to refer to certain statements made by Dr. Luciana Borio, FDA Acting Chief Scientist and Chair of the Agency Scientific Dispute Process Review Board, as part of a memorandum dated August 8, 2016 ("SDR Board Memo"), regarding Sarepta's communications about its clinical trial results. The SDR Board Memo speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the SDR Board Memo differ from its contents, Defendants deny such allegations.

20. The allegations of paragraph 20 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants are without sufficient information to form a belief as to the truth of the allegation in the first sentence of paragraph 20, and therefore deny it. The remaining allegations of paragraph 20 purport to characterize the results of Study 201/202, which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of Study 201/202 differ from its contents, Defendants deny such allegations.

21. The allegations of paragraph 21 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, the allegations of paragraph 21 purport to characterize the methodology of Study 201/202, which speaks for itself and is the best evidence of its contents. To the extent that

Plaintiff's characterizations of Study 201/202 differ from its contents, Defendants deny such allegations.

22. The allegations of paragraph 22 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit only that Serepta submitted Study 301 as part of NDA No. 206488Orig1s000. To the extent that this Court deems a response necessary, the allegations of paragraph 22 purport to characterize the methodologies and results of Study 301, which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of Study 301 differ from its contents, Defendants deny such allegations. The allegations of paragraph 22 also appear to refer to certain statements made by Dr. Ellis Unger in a letter dated July 18, 2016 that Dr. Unger submitted to the Office of Scientific Integrity within the FDA Office of the Chief Scientist ("Unger Appeal Letter"), which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the Unger Appeal Letter differ from its contents, Defendants deny such allegations.

FDA Approval

23. In response to the allegations of paragraph 23, Defendants admit that Sarepta submitted a New Drug Application for eteplirsen on June 26, 2015, NDA No. 206488Orig1s000, and that the proposed indication for eteplirsen was treatment of Duchene muscular dystrophy in patients with a mutation of the DMD gene amenable to exon 51 skipping.

24. The allegations of paragraph 24 irrelevant to the resolution of the claims set forth in the complaint, and therefore no response is required. To the extent that this Court deems a response necessary, Defendants are without sufficient information to form a belief as to the truth of the allegations in the paragraph 24, and therefore deny them.

25. The allegations of paragraph 25 irrelevant to the resolution of the claims set forth in the complaint, and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit that FDA convened an Advisory Committee to consider eteplirsen on April 25, 2016, and that the meeting had been the subject of discussion in the media. The remaining allegations of paragraph 25 purport to describe the proceedings and results of the April 25, 2016, Advisory Committee meeting, the official transcript of which is the best evidence of its proceedings and contents. To the extent that Plaintiff's characterizations of the Advisory Committee meeting differ from its proceedings and contents as reflected in the transcript, Defendants deny such allegations. Furthermore, the last sentence of paragraph 25 purports to describe media reports about the audience's reaction during the meeting, to which no response is needed because such purported media reports are the best evidence of their contents.

26. The allegations of paragraph 26 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit only that Dr. Ronald Farkas, a review team leader, has resigned from the FDA and Defendants are without sufficient information to form a belief as to the reason(s) for such resignation. The allegations of paragraph 26 also appear to refer to certain statements allegedly made by Dr. Farkas during the April 25, 2016, Advisory Committee meeting, the official transcript of which is the best evidence of its contents. To the extent that Plaintiff's characterizations of the meeting differ from its contents, Defendants deny such allegations.

27. The allegations of paragraph 27 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit (as previously stated in paragraph 7) that Dr. Woodcock

issued the Woodcock Memo, explaining her findings and decision regarding NDA No. 206488Orig1s000, which memorandum speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the Woodcock Memo differ from its contents, Defendants deny such allegations. In addition, Defendants are without sufficient information to form a belief as to the truth of the allegation in the last sentence of paragraph 27, and therefore deny it.

28. The allegations of paragraph 28 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants are without sufficient information to form a belief as to the truth of the allegation in the first sentence of paragraph 28 and therefore deny it. Defendants also deny the allegation in the second sentence of paragraph 28.

29. The allegations of paragraph 29 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants are without sufficient information to form a belief as to the truth of the allegations in paragraph 29 and therefore deny them.

30. The allegations of paragraph 30 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit only that Dr. Ellis Unger disagreed with and appealed Dr. Woodcock's decision with respect to eteplirsen. To the extent the allegations of paragraph 30 purport to characterize the contents of the Unger Appeal Letter, which Dr. Unger submitted to the Office of Scientific Integrity within the FDA Office of the Chief Scientist, that document speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's

characterizations of the Unger Appeal Letter differ from its contents, Defendants deny such allegations.

31. The allegations of paragraph 31 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit only that the Scientific Dispute Process Review Board within the FDA Office of Chief Scientist considered Dr. Unger's appeal and that the Board's findings were documented in the SDR Board Memo, which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the SDR Board Memo differ from its contents, Defendants deny such allegations.

32. The allegations of paragraph 32 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit only that Dr. Luciana Borio conveyed her views on the dispute between Drs. Unger and Woodcock to the FDA Commissioner, Dr. Califf, as part of the SDR Board Memo, which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the SDR Board Memo differ from its contents, Defendants deny such allegations.

33. The allegations of paragraph 33 are irrelevant to the resolution of the claims set forth in the complaint and therefore no response is required. To the extent that this Court deems a response necessary, Defendants admit only that (as described in paragraph 7) Dr. Califf issued a memorandum, dated September 16, 2016 (not August 8, 2016, as Plaintiff alleges), the Commissioner's Decision Memo, explaining his findings and decision on the dispute between Drs. Woodcock and Unger regarding eteplirsen. The Commissioner's Decision Memo speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations

of the Commissioner's Decision Memo differ from its contents, Defendants deny such allegations.

34. Defendants admit the allegations of paragraph 34.

Seife's FOIA Request

35. Defendants are without sufficient information to form a belief as to the truth of the allegations in paragraph 35, and therefore deny them.

36. Defendants are without sufficient information to form a belief as to the truth of the allegations in paragraph 36, and therefore deny them.

37. Defendants admit that Plaintiff submitted a FOIA request by letter dated December 5, 2016 ("Plaintiff's December 5, 2016 FOIA request letter"), which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of Plaintiff's December 5, 2016 FOIA request letter differ from its contents, Defendants deny such allegations.

38. The allegations of paragraph 38 set forth legal conclusions to which no response is required. To the extent this that Court deems a response necessary, Defendants deny the allegations of paragraph 38.

39. In response to the allegations of paragraph 39, Defendants admit only that, as part of Plaintiff's December 5, 2016, FOIA request letter, Plaintiff requested expedited processing of his FOIA request. To the extent the allegations of paragraph 39 purports to state the requirements of 5 U.S.C. § 552(a)(6)(E), those allegations are conclusions of law to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of paragraph 39.

40. The allegations of paragraph 40 purport to describe the contents of Plaintiff's December 5, 2016, FOIA request letter; the document speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of Plaintiff's December 5, 2016 FOIA request letter differ from its contents, Defendants deny such allegations. In addition, the allegations of paragraph 40 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of paragraph 40.

41. The allegations of paragraph 41 purport to describe the contents of Plaintiff's December 5, 2016, FOIA request letter, which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of Plaintiff's December 5, 2016 FOIA request letter differ from its contents, Defendants deny such allegations. In addition, Defendants are without sufficient information to form a belief as to the truth of the allegations in paragraph 41, and therefore deny them.

42. The allegations of paragraph 42 purport to describe the contents of Plaintiff's December 5, 2016, FOIA request letter, which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of Plaintiff's December 5, 2016 FOIA request letter differ from its contents, Defendants deny such allegations. In addition, the remaining allegations of paragraph 42 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of paragraph 42.

FDA's Response

43. The allegations of paragraph 43 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of paragraph 43.

44. In response to the allegations of paragraph 44, Defendants admit that on December 20, 2016, Cortelyou Kenney ("Ms. Kenney") contacted the Division of Information Disclosure Policy ("DIDP") within CDER and spoke with a staff member who informed Ms. Kenney that, according to FDA's records, an acknowledgement letter in response to Plaintiff's December 14, 2016, FOIA request had been issued on December 14, 2016. As for the remaining allegations of paragraph 44, Defendants are without sufficient knowledge to admit or deny such allegations, and therefore deny them.

45. In response to the allegations of paragraph 45, Defendants admit that another staff member within DIDP spoke with Plaintiff on December 21, 2016, regarding his FOIA request. Defendants further admit that FDA denied Plaintiff's request for expedited processing by letter, dated December 21, 2016, ("December 21, 2016 letter"). To the extent that paragraph 45 purports to describe the contents of the December 21, 2016 letter, the document speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the December 21, 2016 letter differ from its contents, Defendants deny such allegations. Defendants deny the remaining allegations of paragraph 45.

46. In response to the allegations of paragraph 46, Defendants admit that Plaintiff appealed, by letter dated February 6, 2017, ("February 6, 2017, appeal letter"), FDA's denial of his request for expedited processing and alleged constructive denial of the substance of his FOIA request. To the extent that paragraph 46 purports to describe the contents of the February 6,

2017, appeal letter, the document speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of February 6, 2017, appeal letter differ from its contents, Defendants deny such allegations. Defendants deny that the February 6, 2017, appeal letter demonstrated substantial public interest or supported the need for expedition.

47. In response to the allegations of paragraph 47 Defendants admit only that Dr. Aaron Kesselheim sent Catherine Teti, Deputy Agency Chief FOIA Officer, a letter dated January 31, 2017, regarding Plaintiff's FOIA request ("Kesselheim letter"), which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the Kesselheim letter differ from its contents, Defendants deny such allegations. In addition, the allegations of paragraph 47 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of paragraph 47.

48. The allegations of paragraph 48 purport to describe the contents of the Kesselheim letter, which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the Kesselheim letter differ from its contents, Defendants deny such allegations. Furthermore, the allegations of paragraph 48 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of paragraph 48.

49. The allegations of paragraph 49 purports to describe the contents of Plaintiff's February 6, 2017, appeal letter, which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of Plaintiff's February 6, 2017, appeal letter differ from its contents, Defendants deny such allegations. Furthermore, the allegations of paragraph

49 set forth legal conclusions to which no response is required. To the extent this that Court deems a response necessary, Defendants deny the allegations of paragraph 49.

50. The allegations of paragraph 50 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of paragraph 50.

51. The allegations of paragraph 51 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of paragraph 51.

52. Defendants are without sufficient information to form a belief as to the allegations of paragraph 52 regarding the European Medicines Agency approval process, and therefore deny them. The remaining allegations of paragraph 52 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of paragraph 52.

53. The allegations of the first sentence of paragraph 53 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of the first sentence of paragraph 53. Defendants are without sufficient information to form a belief as to the truth of the allegations regarding Serepta, and therefore deny them. Defendants deny the remaining allegations in paragraph 53.

54. In response to the allegations of the first and second sentences of paragraph 54, Defendants admit that the Freedom of Information/Privacy Acts Division within the HHS Office of the Assistant Secretary for Public Affairs ("HHS Freedom of Information/Privacy Acts Division") acknowledged Plaintiff's appeal by letter dated February 8, 2017, and that Catherine Teti, HHS Deputy Agency Chief FOIA Officer, ultimately denied the appeal on April 25, 2017.

To the extent that the allegations of paragraph 54 purport to describe the contents of the February 8, 2017, letter, the document speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the February 8, 2017, letter differ from its contents, Defendants deny such allegations. The allegations in the last sentence of paragraph 54 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny such allegations.

55. The allegations of paragraph 55 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of paragraph 55.

56. Defendants admit the allegations of paragraph 56.

57. In response to the allegations of paragraph 57, Defendants admit only that Brandon Lancey ("Mr. Lancey"), a staff member within the HHS Freedom of Information/Privacy Acts Division, spoke to Ms. Kenney on March 17, 2017, and deny the remaining allegations of paragraph 57.

58. In response to the allegations of paragraph 58, Defendants deny the allegation that Mr. Lancey had the authority to make a final determination on Plaintiff's appeal, but admit that Catherine Teti, HHS Deputy Agency Chief FOIA Officer, did not reach a final determination regarding Plaintiff's appeal on March 17, 2017.

59. In response to the allegations of paragraph 59, Defendants admit that Mr. Lancey received an email from Ms. Kenney on March 21, 2017, which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the email differ from its contents, Defendants deny such allegations.

60. In response to the allegations of paragraph 60, Defendants admit that Mr. Lancey responded to Ms. Kenney by email on March 29, 2017, at 10:44 am, which email speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the email differ from its contents, Defendants deny such allegations.

61. In response to the allegations of paragraph 61, Defendants admit that Mr. Lancey received an email response from Ms. Kenney on March 29, 2017, at 1:40pm, which email speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the email differ from its contents, Defendants deny such allegations.

62. In response to the allegations of paragraph 62, Defendants admit that Mr. Lancey replied to Ms. Kenney by email on March 29, 2017, at 3:52 PM, which email speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the email differ from its contents, Defendants deny such allegations.

63. In response to the allegations of paragraph 63, Defendants admit that Ms. Kenney sent Mr. Lancey an email on April 3, 2017, which email speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the email differ from its contents, Defendants deny such allegations.

64. In response to the allegations of paragraph 64, Defendants admit that Mr. Lancey responded to Ms. Kenney by email on April 5, 2017, at 3:09 pm, which email speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the email differ from its contents, Defendants deny such allegations.

65. In response to the allegations of paragraph 65, Defendants admit that Ms. Kenney sent Mr. Lancey a response by an email on April 5, 2017, at 3:29 pm, which email speaks for

itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the email differ from its contents, Defendants deny such allegations.

66. In response to the allegations of paragraph 66, Defendants admit that Ms. Kenney sent Mr. Lancey an email on April 17, 2017, which email speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the email differ from its contents, Defendants deny such allegations.

67. In response to the allegations of paragraph 67, Defendants admit that Mr. Lancey responded to Ms. Kenney by email on April 17, 2017, which email speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the email differ from its contents, Defendants deny such allegations.

68. In response to the allegations of paragraph 68, Defendants admit that Mr. Lancey transmitted to Plaintiff, by email on April 25, 2017, a letter, also dated April 25, 2017, setting forth the final decision by Catherine Teti, HHS Deputy Agency Chief FOIA Officer, to deny Plaintiff's appeal ("April 25, 2017, denial letter"). To the extent that the allegations of paragraph 68 purport to describe the contents of the April 25, 2017, denial letter, the letter speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the April 25, 2017, denial letter differ from its contents, Defendants deny such allegations.

69. The allegations of paragraph 69 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of paragraph 69.

70. The allegations of the first sentence of paragraph 70 set forth legal conclusions to which no response is required. To the extent that this Court deems a response necessary, Defendants deny the allegations of the first sentence paragraph 70. Defendants are without

sufficient information to form a belief as to the truth of the allegations contained in the second sentence of paragraph 70 regarding Plaintiff's approach to investigative journalism, and therefore deny them. Defendants deny the remaining allegations in paragraph 70.

71. The allegations of paragraph 71 purport to describe the contents of that the April 25, 2017, denial letter, which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the April 25, 2017, denial letter differ from its contents, Defendants deny such allegations.

72. The allegations of paragraph 72 purport to describe the contents of that the April 25, 2017, denial letter, which speaks for itself and is the best evidence of its contents. To the extent that Plaintiff's characterizations of the April 25, 2017, denial letter differ from its contents, Defendants deny such allegations.

FIRST CAUSE OF ACTION
(Failure to expedite Plaintiff's FOIA request)

73. Defendants set forth their responses to paragraphs 1 through 72 as if fully set forth herein.

74. Defendants deny the allegations of paragraph 74.

SECOND CAUSE OF ACTION
(Failure to disclose records)

75. Defendants set forth their responses to paragraphs 1 through 74 as if fully set forth herein.

76. Defendants deny the allegations of paragraph 76.

THIRD CAUSE OF ACTION
(Failure to grant waiver of fees)

77. Defendants set forth their responses to paragraphs 1 through 76 as if fully set forth herein.

78. Defendants deny the allegations of paragraph 78.

FOURTH CAUSE OF ACTION
(Failure to grant limitation of fees)

79. Defendants set forth their responses to paragraphs 1 through 78 as if fully set forth herein.

80. Defendants deny the allegations of paragraph 80.

RELIEF REQUESTED

The remainder of the complaint consists of Plaintiff's Request for Relief, to which no response is required. To the extent that a response is required, Defendants deny the allegations in the Relief Requested section of the complaint, and deny that Plaintiff is entitled to any of the relief requested in subparts (a) through (g), or to any relief whatsoever from Defendants.

AFFIRMATIVE AND OTHER DEFENSES

Any allegations not specifically admitted, denied, or otherwise responded to are hereby denied. In further response to the complaint, Defendants aver as follows:

FIRST DEFENSE

Plaintiff's complaint fails to state a claim upon which relief may be granted.

SECOND DEFENSE

Plaintiff has failed to exhaust its administrative remedies.

THIRD D.pEFENSE

Plaintiff is not entitled to expedited processing of the FOIA request.

FOURTH DEFENSE

Defendants are exercising due diligence in processing the FOIA request, and exceptional circumstances exist that necessitate additional time for Defendants to process the FOIA request. *See* 5 U.S.C. § 552(a)(6)(C).

FIFTH DEFENSE

The Court are without subject matter jurisdiction over Plaintiff's requests for relief that exceed the relief authorized by the FOIA, 5 U.S.C. § 552. Pursuant to the FOIA, jurisdiction is limited to the district courts' authority to "enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." 5 U.S.C. § 552(a)(4)(B).

SIXTH DEFENSE

Some or all of the documents requested in the FOIA request are exempt from disclosure. *See* 5 U.S.C. § 552(b).

SEVENTH DEFENSE

Plaintiff is not entitled to a waiver of fees or a limitation of fees.

THEREFORE, Defendants demand judgment dismissing the complaint and granting such other and further relief as this Court deems proper, including costs and disbursements.

Dated: July 5, 2017

Respectfully submitted,

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