

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

_____)	
Charles Seife)	
)	
<i>Plaintiff,</i>)	
)	
v.)	
)	
Food and Drug Administration and)	
Department of Health and Human)	
Services)	
)	
<i>Defendants</i>)	
and)	
)	
SAREPTA THERAPEUTICS,)	
)	
<i>Proposed Defendant-Intervenor.</i>)	Case No. 1:17-cv-3960 (JMF)
_____)	

ANSWER TO COMPLAINT

Defendant-Intervenor Sarepta Therapeutics, Inc. ("Sarepta") hereby answers plaintiff's Complaint in the following numbered paragraphs, which correspond to the Complaint's numbered paragraphs.

1. Sarepta admits that this is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. §§ 552, et seq., brought by Charles Seife ("Plaintiff"). Sarepta is without knowledge sufficient to respond to the remainder of Paragraph 1.

2. This paragraph characterizes the purpose and motivation for this action, and Sarepta is without knowledge sufficient to respond.

3. Sarepta admits it manufactures and sells eteplirsen in the United States under the trade name "Exondys 51." Sarepta admits that this drug is the only disease-modifying treatment approved for Duchenne Muscular Dystrophy ("Duchenne") in the United States. Sarepta denies

that it sells directly to those that take Exondys 51, or that those to whom Sarepta does sell all pay "\$300,000 per year or more."

4. This paragraph ascribes certain actions to unspecified "families" and certain beliefs to unnamed "officials." Sarepta is without knowledge sufficient to admit or deny whether such actions were taken or such beliefs are held.

5. Sarepta admits that a study of Exondys 51 showed positive results. Sarepta also admits the FDA review team recommended further research into the drug's effectiveness. Sarepta denies all other characterizations or statements in the paragraph.

6. The course of the FDA's consideration of Exondys 51 is the subject of public documents that speak for themselves. Sarepta is without knowledge sufficient to respond to the various characterizations in the remainder of the paragraph.

7. The course of the FDA's consideration of Exondys 51 is the subject of public documents that speak for themselves. Sarepta is without knowledge sufficient to respond to the various characterizations in the remainder of the paragraph.

8. This paragraph contains Plaintiff's characterization of his FOIA Request. The Court is respectfully referred to the Request itself for a complete and accurate statement of its contents. Sarepta is without knowledge sufficient to admit or deny the remainder of the paragraph, except insofar as the paragraph states legal conclusions or inflammatory characterizations to which no response is required.

9. This paragraph characterizes the purpose and motivation for this action, and calls for various legal conclusions. Sarepta is without knowledge sufficient to respond.

10. Sarepta is without knowledge sufficient to admit or deny.

11. Admit.

12. Admit.

13. This paragraph contains plaintiff's statement of the jurisdictional basis for this action, to which no response is required.

14. This paragraph contains plaintiff's statement of the venue for this action, to which no response is required.

15. This paragraph contains statements of law to which no answer is required, but to the extent a response is deemed required, denied.

16. This paragraph contains statements of law to which no answer is required, but to the extent a response is deemed required, denied.

17. Admit that Study 201 sought to measure, among other things, dystrophin levels. Admit that dystrophin levels are correlated to neuromuscular health. Admit that the six-minute walk test was a primary outcome measure. The remainder of the paragraph contain characterizations to which no response is required.

18. Admit that Study 201 was a single-center, double-blinded, randomized-controlled trial conducted in twelve patients with Duchenne, four of whom initially received a placebo. Sarepta is without knowledge sufficient to respond to the remainder of the paragraph.

19. Admit that after twenty-four weeks, the four patients initially given placebos received eteplirsen. Admit that after twenty-eight weeks, the patients began an open-label phase referred to as Study 202. Sarepta is without knowledge sufficient to respond to the allegations about what "all investigators -- and all patients" knew. The remainder of the paragraph refers to various public documents that speak for themselves. Sarepta is without knowledge sufficient to respond to the various characterizations in the remainder of the paragraph.

20. The paragraph asserts without citation various characterizations of testing results and analysis. To the extent such assertions are based on published findings, those findings speak for themselves. To the extent they are not based on published findings, they are denied. Sarepta is without knowledge sufficient to respond to the various characterizations in the remainder of the paragraph.

21. The paragraph asserts without citation various characterization of testing results and analysis. To the extent such assertions are based on published findings, those findings speak for themselves. To the extent they are not based on published findings, they are denied. Sarepta is without knowledge sufficient to respond to the various characterizations in the remainder of the paragraph.

22. Admit that Sarepta conducted a study referred to as Study 301. Admit that Study 301 was an open-label trial with thirteen patients, and that all thirteen patients received the drug. The remainder of the paragraph asserts without citation various characterization of testing results and analysis. To the extent such assertions are based on published findings, those findings speak for themselves. To the extent they are not based on published findings, they are denied. Sarepta is without knowledge sufficient to respond to the various characterizations and unattributed quotations in the remainder of the paragraph.

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

24. Sarepta is without knowledge sufficient to admit or deny.

25. Paragraph 25 describes and characterizes public meetings and media reports that are recorded in public documents which are the best evidence of the events described. Sarepta is

without knowledge sufficient to respond to the various characterizations in the remainder of the paragraph.

26. Paragraph 26 describes public meetings that are recorded in public documents which are the best evidence of the events described. Sarepta is without knowledge sufficient to respond to the remainder of the paragraph.

27. Paragraph 27 describes a publicly available document that is the best evidence of its contents. Sarepta is without knowledge sufficient to respond to the remainder of the paragraph.

28. Sarepta is without knowledge sufficient to admit or deny the statements in this paragraph.

29. Sarepta is without knowledge sufficient to admit or deny the statements in this paragraph.

30. Sarepta is without knowledge sufficient to admit or deny the statements in this paragraph.

31. Sarepta is without knowledge sufficient to admit or deny the statements in this paragraph.

32. Paragraph 32 describes a publicly available document that is the best evidence of its contents. Sarepta is without knowledge sufficient to respond to the remainder of the paragraph.

33. Paragraph 33 describes a publicly available document that is the best evidence of its contents. Sarepta is without knowledge sufficient to respond to the remainder of the paragraph.

34. Sarepta admits the FDA granted Exondys 51 approval on September 19, 2016.

35. Sarepta is without knowledge sufficient to admit or deny the statements in this paragraph.

36. Sarepta is without knowledge sufficient to admit or deny the statements in this paragraph.

37. Paragraph 37 describes a publicly available document that is the best evidence of its contents. Sarepta is without knowledge sufficient to respond to the remainder of the paragraph.

38. Paragraph 38 contains conclusions of law to which no answer is required, but to the extent a response is deemed required, denied.

39. Sarepta is without knowledge sufficient to respond to the statements in this paragraph. The remainder of this paragraph contains conclusions of law to which no answer is required.

40. Sarepta is without knowledge sufficient to admit or deny.

41. This paragraph contains legal conclusions to which no response is required, to the extent a response is deemed required, denied. This paragraph also states that Plaintiff "noted" various assertions regarding Sarepta, the market for Exondis 51, and "seventy percent of neurologists." Sarepta is without knowledge sufficient to admit or deny whether Plaintiff made such assertions.

42. Sarepta is without knowledge sufficient to admit or deny.

43. Sarepta is without knowledge sufficient to admit or deny.

44. Sarepta is without knowledge sufficient to admit or deny.

45. Sarepta is without knowledge sufficient to admit or deny.

46. Paragraph 46 describes a publicly available document that is the best evidence of its contents. Sarepta is without knowledge sufficient to respond to the remainder of the paragraph.

47. Paragraph 47 describes a publicly available document that is the best evidence of its contents. Sarepta is without knowledge sufficient to respond to the remainder of the paragraph.

48. Paragraph 48 describes a publicly available document that is the best evidence of its contents. Sarepta is without knowledge sufficient to respond to the remainder of the paragraph.

49. Paragraph 49 describes the contents of Plaintiff's administrative appeal, a document that is the best evidence of its contents.

50. Paragraph 50 describes the contents of Plaintiff's administrative appeal, a document that is the best evidence of its contents.

51. The paragraph states legal conclusions regarding the standards for expedited processing of FOIA requests, to which no response is required. The paragraph further contains uncited characterizations of the terms of "public debate" and the views of unnamed "commentators" that are too vague to permit a meaningful response, and so are denied.

52. The paragraph states legal conclusions regarding the standards for expedited processing of FOIA requests, to which no response is required.

53. Sarepta is without knowledge sufficient to admit or deny, except insofar as the paragraph states legal conclusions, to which no response is required. The paragraph also characterizes the contents of public media reports that are themselves the best evidence of their contents.

54. Sarepta is without knowledge sufficient to admit or deny.

55. Sarepta is without knowledge sufficient to admit or deny.

56. Sarepta is without knowledge sufficient to admit or deny.

57. Sarepta is without knowledge sufficient to admit or deny.

58. Sarepta is without knowledge sufficient to admit or deny.

59. Sarepta is without knowledge sufficient to admit or deny. To the extent this paragraph characterizes the contents of a document, Sarepta respectfully refers the Court to the document itself for a full and accurate statement of its contents.

60. Sarepta is without knowledge sufficient to admit or deny. To the extent this paragraph characterizes the contents of a document, Sarepta respectfully refers the Court to the document itself for a full and accurate statement of its contents.

61. Sarepta is without knowledge sufficient to admit or deny. To the extent this paragraph characterizes the contents of a document, Sarepta respectfully refers the Court to the document itself for a full and accurate statement of its contents.

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66. Sarepta is without knowledge sufficient to admit or deny. To the extent this paragraph characterizes the contents of a document, Sarepta respectfully refers the Court to the document itself for a full and accurate statement of its contents.

67. Sarepta is without knowledge sufficient to admit or deny. To the extent this paragraph characterizes the contents of a document, Sarepta respectfully refers the Court to the document itself for a full and accurate statement of its contents.

68. Sarepta is without knowledge sufficient to admit or deny. To the extent this paragraph characterizes the contents of a document, Sarepta respectfully refers the Court to the document itself for a full and accurate statement of its contents.

69. This paragraph contains legal conclusions to which no response is required, and to the extent a response is deemed required, these conclusions are denied.

70. This paragraph contains legal conclusions to which no response is required, and to the extent a response is deemed required, these conclusions are denied.

71. This paragraph characterizes the contents of a document. Sarepta respectfully refers the Court to the document itself for a full and accurate statement of its contents.

72. This paragraph characterizes the contents of a document. Sarepta respectfully refers the Court to the document itself for a full and accurate statement of its contents.

73. Sarepta incorporates its responses to the foregoing paragraphs.

74. This paragraph states legal conclusions to which no response is required.

75. Sarepta incorporates its responses to the foregoing paragraphs.

76. This paragraph states legal conclusions to which no response is required.
77. Sarepta incorporates its responses to the foregoing paragraphs.
78. This paragraph states legal conclusions to which no response is required.
79. Sarepta incorporates its responses to the foregoing paragraphs.
80. This paragraph states legal conclusions to which no response is required.

The remaining paragraphs set forth plaintiff's prayer for relief to which no answer is required. Sarepta hereby denies all allegations of the Complaint not otherwise specifically answered above to which a response is required.

SAREPTA'S AFFIRMATIVE DEFENSES

1. The information Plaintiff requests, insofar as it is confidential business information of Sarepta, is exempt from disclosure under 5 U.S.C. § 552(b) (4) and therefore prohibited from disclosure by 18 U.S.C. § 1905.

2. Sarepta reserves the right to assert additional defenses that become available or apparent during the course of this litigation and reserves the right to amend this answer to assert such defenses.

WHEREFORE, having fully answered, Sarepta respectfully requests that this Court enter judgment for Sarepta and against Plaintiff; and grant such other and further relief as may be just and proper.

Dated: September 15, 2017

Respectfully Submitted,

/s/ Daniel R. Bernstein

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