UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.

17 Civ. 3960 (JMF)

STIPULATION AND ORDER

WHEREAS, on or about May 25, 2017, Plaintiff Charles Seife filed a complaint pursuant to the Freedom of Information Act ("FOIA") in the above-captioned matter (the "Complaint") seeking to compel Defendants Food and Drug Administration ("FDA") and the Department of Health and Human Services to disclose documents responsive to a FOIA request submitted by Plaintiff on December 6, 2016, and challenging Defendants' denial of Plaintiff's request for expedited processing of his FOIA request;

WHEREAS, on June 21, 2017, Plaintiff filed a motion for partial summary judgment challenging Defendants' denial of Plaintiff's request for expedited processing of his FOIA request, *see* ECF No. 16;

WHEREAS, on July 10, 2017, Plaintiff narrowed his FOIA request, *see* ECF No. 26-3, and subsequently agreed to certain further narrowing of his FOIA request as set forth below; and

WHEREAS, Plaintiff and Defendants (collectively the "Parties") participated in an in-person settlement conference before Magistrate Judge Ellis on July 14, 2017 and telephonic conferences on July 20, 21 and 24, 2017;

NOW, THEREFORE, IT IS HEREBY STIPULATED AND AGREED, by and between the Parties and their counsel, that:

1. On July 24, 2017, the FDA produced non-exempt portions[1] of "The Chronology prepared by Virginia Behr and submitted to the Scientific Dispute Resolution Board regarding eteplirsen ("Behr Chronology")," and "Email and memo from John Jenkins to Robert Califf, dated Sept. 14, 2016, sent at 5:36 PM, subject 'Memo.'"

2. Beginning on August 17, 2017, the FDA will make rolling bi-weekly productions of documents with production to be completed in accordance with the schedule set forth below.

3. On or before September 15, 2017, the FDA will produce all non-exempt portions of the narrative portion of the Clinical Study Report (CSR) related to Study 201.

4. On or before September 30, 2017, the FDA will produce:

a. Emails[2] from/to Robert Califf, Robert Temple, Margaret Hamburg, Janet Woodcock, or Richard Moscicki dated from 10/1/2014 to present that contain any of the following words: Sarepta; Eteplirsen; AVI-4658; Drisapersen; Kyndrisa; PRO051;

[1] Pursuant to the schedule set forth herein, the FDA will produce only records that have been redacted of all information or data that is exempt from disclosure under 5 U.S.C. § 552(b).

[2] FDA will produce attachments along with the parent emails. When there are multiple emails forming one chain, FDA will only produce the last complete chain, rather than the chain and the individual messages that comprise the chain.

GSK2402968; Exondys; and Dystrophin, except that the FDA will produce only a random sample of emails from members of the general public returned by these searches.[3]

b. Emails from 1/1/2015 to present from Robert Califf and/or Ellis Unger to editors or publishers of the *Annals of Neurology*.

c. Emails from 10/1/2014 to present mentioning possible or actual recusal by Richard Moscicki from any of his duties.

d. Emails to/from Richard Moscicki dated 10/1/14 to present that: (a) mention or are addressed to Ed Kaye, (b) mention or are addressed to a Sarepta employee, or (c) mention or are addressed to a BioMarin employee.

e. Emails dated 10/1/14 to the present between Sarepta and FDA or internal to FDA, for which Califf, Woodcock, or Mosicicki are the custodians, that relate to Study 201 or Study 202 and mention Exondys 51 or eteplirsen and (i) mention changes in study protocols, study endpoints, immunohistochemistry or IHC; or (ii) are to/from Robert Califf, Janet Woodcock, or Richard Moscicki.

f. The Tables/Figures/Graphs contained in Section 14 of the CSR related to Study 201 and the Appendices in Section 16 of this CSR with the exception of the Case Report Forms in Appendix 16.3.

5. On or before October 15, 2017, the FDA will produce all non-exempt portions of the narrative portion of the CSR related to Study 202.

[3] Once Plaintiff has had the opportunity to review the sampling of emails from the public, the Parties will discuss whether Plaintiff maintains his request for communications from members of the general public that are otherwise responsive to his FOIA request and, if so, will determine a production schedule for such documents.

6. On or before October 27, 2017, the FDA will produce:

a. Study 201/202 Protocols and protocol amendments;

b. Statistical analysis Plan and Plan Amendment regarding Study 201/202.

c. Emails from/to Robert Califf or Janet Woodcock dated 1/1/09 to 9/30/14 that are to/from any Sarepta employee that contain any of the following words: Sarepta; Eteplirsen; AVI-4658; Drisapersen; Kyndrisa; PRO051; GSK2402968; Exondys; and Dystrophin.

d. Emails from/to Richard Moscicki dated 4/21/13 to 9/31/14 that are to/from any Sarepta employee that contain any of the following words: Sarepta; Eteplirsen; AVI-4658; Drisapersen; Kyndrisa; PRO051; GSK2402968; Exondys; and Dystrophin.

e. Emails from/to Richard Moscicki dated 4/21/13 to 9/31/14 that: (a) mention or are addressed to Ed Kaye, (b) mention or are addressed to a Sarepta employee, or (c) mention or are addressed to a BioMarin employee.

f. Emails dated 4/21/13 to 9/31/14 that mention possible or actual recusal by Richard Moscicki from any of his duties.

7. On or before November 30, 2017, the FDA will produce the Tables/Figures/Graphs contained in Section 14 of the CSR related to Study 202 and the

Appendices in Section 16 of the CSR with the exception of the Case Report Forms in Appendix 16.3.[4]

8. On or before December 11, 2017, the FDA will produce:

a. Emails from/to Robert Califf, Robert Temple, Margaret Hamburg, or Janet Woodcock dated 1/1/09 to 9/30/14 that contain any of the following words: Sarepta; Eteplirsen; AVI-4658; Drisapersen; Kyndrisa; PRO051; GSK2402968; Exondys; and Dystrophin, except that the FDA will produce only a sampling of emails from the public returned by these searches.

b. Emails from/to Richard Moscicki dated 4/21/13 to 9/31/14 that contain any of the following words: Sarepta; Eteplirsen; AVI-4658; Drisapersen; Kyndrisa; PRO051; GSK2402968; Exondys; and Dystrophin, except that the FDA will produce only a sampling of emails from the public returned by these searches.

c. Emails dated 1/1/09 to 9/30/14 between Sarepta and FDA or internal to FDA that relate to Study 201 or Study 202 and mention Exondys 51 or eteplirsen and (i) mention changes in study protocols, study endpoints, immunohistochemistry or IHC; or (ii) are to/from Robert Califf or Janet Woodcock.

d. Emails dated 4/21/13 to 9/30/14 between Sarepta and FDA or internal to FDA that relate to Study 201 or Study 202 and mention Exondys 51 or eteplirsen

[4] After the FDA completes its production of documents pursuant to the schedule set forth herein, the Parties will discuss whether Plaintiff wants production of the Case Study Reports for Study 201 and Study 202 and, if so, determine a schedule for such production.

and (i) mention changes in study protocols, study endpoints, immunohistochemistry or IHC; and (ii) are to/from Richard Moscicki.

e. Any non-email documents responsive to any of the categories described above, including other electronic documents and hard copy documents but excluding the Case Study Report Forms for Study 201 and Study 202.

9. In the event FDA is unable to complete its production on the dates outlined above or other disputes arise between the Parties, the Parties will in good faith attempt to reach agreement and either the Parties will jointly advise the Court of any modification of this Stipulation or either Party may present the disputed issue to Magistrate Judge Ellis for resolution.

10. In order to resolve this case without further litigation, FDA has agreed to process Plaintiff's FOIA request on an expedited basis, consistent with 21 C.F.R. § 20.44(a), which provides that, besides expediting a FOIA request when the requester demonstrates compelling need, FDA can exercise its discretion to expedite requests "in other cases as determined by the agency." FDA expressly denies that Plaintiff has met the requirements for demonstrating a compelling need as required by 21 C.F.R. § 20.44. FDA's processing of this FOIA request on an expedited basis has no precedential effect with regard to future FOIA requests.

11. Upon entry of this Stipulation and Order, but no later than July 31, 2017, Plaintiff will voluntary withdraw his motion for partial summary judgment challenging Defendants' denial of Plaintiff's request for expedited processing of his FOIA request, ECF No. 16.

Dated: July 26, 2017
New York, NY

Media Freedom Information Access Clinic

By: _____

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SO ORDERED:

Jesse M. Furman
United States District Judge

July 27, 2017

The Clerk of Court is directed to close this case. All motions are moot. All conferences are cancelled. The Court retains jurisdiction to enforce the terms of this Stipulation and Order and to adjudicate any disputes in connection with it.