IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BLOOMBERG L.P.,
731 Lexington Ave
New York, NY 10022

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,
Office of the Chief Counsel
White Oak Bldg. 1
10903 New Hampshire Avenue,
Silver Spring, MD 20993

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Office of the General Counsel
200 Independence Ave., SW, Room 713-F
Washington, D.C. 20201

Defendants.

COMPLAINT

1. Plaintiff BLOOMBERG L.P. brings this suit to force Defendants FOOD AND DRUG ADMINISTRATION and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES to produce records regarding accelerated approval drugs.

PARTIES

2. Plaintiff BLOOMBERG L.P. is the owner and operator of Bloomberg News. Bloomberg's newsroom of more than 2,700 journalists and analysts delivers thousands of stories a day, producing context that is featured across multiple platforms, including digital, TV, radio, streaming video, print, and live events. BLOOMBERG L.P. is the FOIA requester in this case.

3. Defendant FOOD AND DRUG ADMINISTRATION is a federal agency, and a component of U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and subject to the Freedom of Information Act, 5 U.S.C. § 552.

4. Defendant U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES is a federal agency and subject to the Freedom of Information Act, 5 U.S.C. § 552.

JURISDICTION AND VENUE

5. This case is brought under 5 U.S.C. § 552(a)(4)(B) and presents a federal question conferring jurisdiction on this Court. *See* 28 U.S.C. § 1331.

6. Venue is proper under 5 U.S.C. § 552(a)(4)(B).

JUNE 30, 2023 FOIA REQUEST TO FDA (EXONDYS)

7. On June 30, 2023, Plaintiff submitted a FOIA request to FDA for the following records:

> 1. Annual reports, annual status updates of postmarketing commitments/requirements (PMC/PMR), PMC/PMR-related submissions, PMC/PMR schedule milestones, annual report review forms, and summary reviews referencing the accelerated approval of Exondys 51 (Eteplirsen). This should include, but not be limited to, reports referencing Exondys 51 study PMR 3095-1, 3095-2, 3095-3, and PMR 3095-4.
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> 2. Access to and copies of emails, memos, letters, talking points, and meeting minutes referencing the FDA's interactions with Sarepta Therapeutics Inc about Exondys 51's postmarketing requirements/commitments, confirmatory trials, and proposed clinical trial protocols. Please search records in the Center for Drug Evaluation and Research between July 1, 2016 and June 30, 2023. Emails can exclude attachments and emails referencing news articles, but we reserve rights to request up to 50 attachments later.

8. A true and correct copy of the FOIA request, along with subsequent correspondence, is attached as Exhibit 1.

9. On June 30, 2023, FDA acknowledged receipt of the FOIA request and assigned confirmation number FDA23094075 to the matter. *Id*.

10. On July 5, 2023, FDA stated it "may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA," adding that related requests "may take up to 18 to 24 months to process." *Id*.

11. The parties conferred over several phone calls to discuss several FOIA requests submitted by Plaintiff.

12. On August 17, 2023, FDA informed Plaintiff that documents related to ongoing clinical trials are exempt from disclosure under FOIA Exemptions b(4) and b(5), but the documents would be releasable with redactions "once the PMR is released." FDA stated that Plaintiff's FOIA requests would take "months if not years to process."

13. A true and correct copy of the correspondence is attached as Exhibit 2.

14. As of the date of this filing, FDA has not issued a determination or produced any records responsive to the FOIA request.

JUNE 30, 2023 FOIA REQUEST TO FDA (AMONDYS)

15. On June 30, 2023, Plaintiff submitted a FOIA request to FDA for the following records:

> 1. Annual reports, annual status updates of postmarketing commitments/requirements (PMC/PMR), PMC/PMR-related submissions, PMC/PMR schedule milestones, annual report review forms, and summary reviews referencing the accelerated approval of AMONDYS 45 and VYONDYS 53. This should include, but not be limited to, reports referencing AMONDYS 45 study PMR 4005-1, PMR 4005-2, PMR 4005-3, PMR 4005-4, PMR 4005-6, PMR 4005-7, PMR 4005-8, PMR 4005-9, PMR 4005-10 and PMR 4005-11; Vyondys 53 study PMR 3690-1, PMR 3690-2, PMR 3690-3, PMR 3690-4 , PMR 3690-5 ,PMR 3690-6, and PMR 3690-7.
>
> 2. Access to and copies of emails, memos, letters, talking points, and meeting minutes referencing the FDA's interactions with Sarepta Therapeutics Inc about AMONDYS 45 and VYONDYS 53's postmarketing requirements/commitments, confirmatory trials, and proposed clinical trial protocols. Please search records in the Center for Drug Evaluation and Research between December 19, 2018 and June 30, 2023. Emails can

> exclude attachments and emails referencing news articles but we reserve rights to request up to 50 attachments later.

16. A true and correct copy of the FOIA request, along with subsequent correspondence, is attached as Exhibit 3.

17. On June 30, 2023, FDA acknowledged receipt of the FOIA request and assigned confirmation number FDA23094076 to the matter. *Id*.

18. On July 5, 2023, FDA stated it "may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA," adding that related requests "may take up to 18 to 24 months to process." *Id*.

19. The parties conferred over several phone calls to discuss several FOIA requests submitted by Plaintiff.

20. On August 17, 2023, FDA informed Plaintiff that documents related to ongoing clinical trials are exempt from disclosure under FOIA Exemptions b(4) and b(5), but the documents would be releasable with redactions "once the PMR is released." FDA stated that Plaintiff's FOIA requests would take "months if not years to process." Ex 2.

21. As of the date of this filing, FDA has not issued a determination or produced any records responsive to the FOIA request.

JUNE 30, 2023 FOIA REQUEST TO FDA (CLOLAR)

22. On June 30, 2023, Plaintiff submitted a FOIA request to FDA for the following records:

> 1. The FDA's 'Summary Review' for the full approval of CLOLAR (clofarabine). Per the Food and Drug Administration Amendments Act, action packages for original BLAs or NDAs are required to be posted within 30 calendar days of the third Freedom of Information Act request for the action package. A summary review (Summary Basis of Regulatory Action) is required to be posted within 48 hours of approval unless redaction is required. Please see page one: https://www.fda.gov/media/82426/download

> 2. Annual reports, annual status updates of postmarketing commitments/requirements (PMC/PMR), PMC/PMR-related submissions, PMC/PMR schedule milestones, annual report review forms, and summary reviews referencing the accelerated approval of CLOLAR (clofarabine), including, but not limited to, reports referencing Clolar study CLO-216, PMR 253-1, PMR 253-2, and the final report dated October 27, 2021
>
> 3. Access to and copies of emails and meeting minutes referencing postmarketing requirements/commitments, confirmatory trials, proposed clinical trial protocols, and labeling discussions for the drug Clolar from Genzyme and/or Sanofi-Aventis. Please include any emails or memos referencing Clolar study CLO-216, PMR 253-1, and PMR 253-2. Please search records in the Center for Drug Evaluation and Research between December 28, 2004 and June 30, 2023. Emails can exclude attachments and emails referencing news articles but we reserve rights to request up to 50 attachments later.

23. A true and correct copy of the FOIA request, along with subsequent correspondence, is attached as Exhibit 4.

24. On June 30, 2023, FDA acknowledged receipt of the FOIA request and assigned confirmation number FDA23094081 to the matter. *Id*.

25. On July 5, 2023, FDA stated it "may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA," adding that related requests "may take up to 18 to 24 months to process." *Id*.

26. The parties conferred over several phone calls to discuss several FOIA requests submitted by Plaintiff.

27. On August 17, 2023, FDA informed Plaintiff that documents related to ongoing clinical trials are exempt from disclosure under FOIA Exemptions b(4) and b(5), but the documents would be releasable with redactions "once the PMR is released." FDA stated that Plaintiff's FOIA requests would take "months if not years to process." Ex 2.

28. As of the date of this filing, FDA has not issued a determination or produced any records responsive to the FOIA request.

JUNE 30, 2023 FOIA REQUEST TO FDA (NORTHERA)

29. On June 30, 2023, Plaintiff submitted a FOIA request to FDA for the following records:

> 1. Annual reports, annual status updates of postmarketing commitments/requirements (PMC/PMR), PMC/PMR-related submissions, PMC/PMR schedule milestones, annual report review forms, and summary reviews referencing the accelerated approval of NORTHERA (droxidopa), including, but not limited to, any reports referencing PMR 2129-1 and PMR 2129-2.
>
> 2. Access to and copies of emails and meeting minutes referencing the FDA's interactions with Lundbeck about Northera's postmarketing requirements/commitments, confirmatory trials, and proposed clinical trial protocols. Please search records in the Center for Drug Evaluation and Research between February 18, 2014 and June 30, 2023. Emails can exclude attachments and
> emails solely referencing news articles but we reserve rights to request up to 20 attachments later.

30. A true and correct copy of the FOIA request, along with subsequent correspondence, is attached as Exhibit 5.

31. On June 30, 2023, FDA acknowledged receipt of the FOIA request and assigned confirmation number FDA23094083 to the matter. *Id*.

32. On July 5, 2023, FDA stated it "may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA," adding that related requests "may take up to 18 to 24 months to process." *Id*.

33. The parties conferred over several phone calls to discuss several FOIA requests submitted by Plaintiff.

34. On August 17, 2023, FDA informed Plaintiff that documents related to ongoing clinical trials are exempt from disclosure under FOIA Exemptions b(4) and b(5), but the documents would be releasable with redactions "once the PMR is released." FDA stated that Plaintiff's FOIA requests would take "months if not years to process." Ex 2.

35. FDA recommended that Plaintiff submit "one revised omnibus request" in place of this request, combined with six other FOIA requests submitted by Plaintiff. FDA also informed Plaintiff that the scope of the requests "must be significantly narrowed to prevent time/resources being allocated to information that is not the primary area of interest." Plaintiff has declined to do so. *Id*.

36. As of the date of this filing, FDA has not issued a determination or produced any records responsive to the FOIA request.

JUNE 30, 2023 FOIA REQUEST TO FDA (DELAYED ACCEPTANCE)

37. On June 30, 2023, Plaintiff submitted a FOIA request to FDA for the following records:

> Annual reports, annual status updates of postmarketing commitments/requirements (PMC/PMR), PMC/PMR-related submissions, PMC/PMR schedule milestones, annual report review forms, and summary reviews referencing the following accelerated approval drugs and indications listed as delayed as of the date of this request. Please search records in both the Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research between January 1, 2012 to June 30, 2023. For definitions of the reports and forms please see pages 3-5 https://www.fda.gov/media/90205/download.
> 1) Beleodaq (Belinostat), NDA/BLA Number: 206256
> 2) Folotyn (Pralatrexate), NDA/BLA Number: 22468
> 3) Galafold (Migalastat), NDA/BLA Number: 208623
> 4) Aliqopa (Copanlisib Hydrochloride), NDA/BLA Number: 209936
> 5) Vitrakvi (larotrectinib), NDA/BLA Number: 210861
> 6) Vitrakvi (larotrectinib), NDA/BLA Number: 211710
> 7) Opdivo (Nivolumab), NDA/BLA Number: 125554, S-34
> 8) Benznidazole, NDA/BLA Number: 209570
> 9) BEXSERO, Meningococcal Group B Vaccine, NDA/BLA Number:125546
> 10) Jemperli (dostarlimab-gxly), NDA/BLA Number 761174
> 11) Jemperli (dostarlimab-gxly), NDA/BLA Number: 761223
> 12) Arikayce (Amikacin), NDA/BLA Number: 207356
> 13) Balversa (erdafitinib), NDA/BLA Number: 212018
> 14) Sirturo (Bedaquiline), NDA/BLA Number: 204384
> 15) Sirturo (Bedaquiline), NDA/BLA Number: 204384, S-10
> 16) Sirturo (Bedaquiline), NDA/BLA Number: 204384, S-13
> 17) XPOVIO (selinexor), NDA/BLA Number: 212306
> 18) XPOVIO (selinexor), NDA/BLA Number: 212306, S-1

19) Retevmo (selpercatinib), NDA/BLA Number: 213246
20) Keytruda (pembrolizumab), NDA/BLA Number: 125514, S-42
21) Monjuvi (tafasitamab-cxix), NDA/BLA Number: 761163
22) Imbruvica (Ibrutinib), NDA/BLA Number: 205552
23) Imbruvica (Ibrutinib), NDA/BLA Number: 205552, S-16
24) Imbruvica (Ibrutinib), NDA/BLA Number: 210563
25) COPIKTRA (Duvelisib), NDA/BLA Number: 211155
26) Elaprase (Idursulfase), NDA/BLA Number: 125151, S-184

38. A true and correct copy of the FOIA request, along with subsequent correspondence, is attached as Exhibit 6.

39. On June 30, 2023, FDA acknowledged receipt of the FOIA request and assigned confirmation number FDA23094080 to the matter. *Id*.

40. On July 5, 2023, FDA stated it "may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA," adding that related requests "may take up to 18 to 24 months to process." *Id*.

41. The parties conferred over several phone calls to discuss several FOIA requests submitted by Plaintiff.

42. On August 17, 2023, FDA informed Plaintiff that documents related to ongoing clinical trials are exempt from disclosure under FOIA Exemptions b(4) and b(5), but the documents would be releasable with redactions "once the PMR is released." FDA stated that Plaintiff's FOIA requests would take "months if not years to process." Ex 2.

43. As of the date of this filing, FDA has not issued a determination or produced any records responsive to the FOIA request.

JULY 7, 2023 FOIA REQUEST TO FDA (BILLY DUNN)

44. On July 7, 2023, Plaintiffs submitted a FOIA/Privacy Act request to FDA for the following records:

> For the period of time between March 15, 2019 and March 15, 2023: Emails, memos or other electronic communications to or from the following (former) FDA official, Billy Dunn, billy.dunn@fda.hhs.gov, referencing

> any of the following terms: "Alzheimer's disease", "ALS", "duchenne muscular dystrophy", "accelerated approval", "confirmatory study", "confirmatory trial", "PMC", "PMR" "postmarketing", "aducanumab", "golodirsen", "VYONDYS", "casimersen", "Amondys", "eteplirsen", "tofersen", "QALSODY", "AMX0035", "lecanemab", "sodium phenylbutyrate", "omaveloxolone", "SKYCLARYS", "Leqembi", "Aduhelm," "Exondys", "Alzheimer's Association", "I AM ALS".
>
> Please limit your search to records withing the following offices: Office of Neuroscience, Center for Drug Evaluation; Office of the Director.
>
> Please search for records to or from the following FDA official and any email addresses associated with him: Billy Dunn, billy.dunn@fda.hhs.gov (Office of Neuroscience), or any other email addresses or other electronic addresses associated with Billy Dunn.
>
> Emails can exclude attachments and emails solely referencing news articles but we reserve rights to request up to 50 attachments later.

45. A true and correct copy of the FOIA request, along with subsequent correspondence, is attached as Exhibit 7.

46. FDA assigned control number 2023-5839 to the matter.

47. On July 10, 2023, FDA stated it "may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA," adding that related requests "may take up to 18 to 24 months to process." *Id*.

48. The parties conferred over several phone calls to discuss several FOIA requests submitted by Plaintiff.

49. On August 17, 2023, FDA informed Plaintiff that documents related to ongoing clinical trials are exempt from disclosure under FOIA Exemptions b(4) and b(5), but the documents would be releasable with redactions "once the PMR is released." FDA stated that Plaintiff's FOIA requests would take "months if not years to process." Ex 2.

50. FDA recommended that Plaintiff submit "one revised omnibus request" in place of this request, combined with six other FOIA requests submitted by Plaintiff. FDA also informed Plaintiff that the scope of the requests "must be significantly narrowed to prevent time/resources

being allocated to information that is not the primary area of interest." Plaintiff has declined to do so. *Id*.

51. As of the date of this filing, FDA has not issued a determination or produced any records responsive to the FOIA request.

COUNT I – FDA'S FOIA VIOLATION
JUNE 30, 2023 EXONDYS FOIA REQUEST

52. The above paragraphs are incorporated by reference.

53. Plaintiff's FOIA request seeks the disclosure of agency records and was properly made.

54. Defendant FDA is a federal agency subject to FOIA.

55. Included within the scope of the request are one or more records or portions of records that are not exempt under FOIA.

56. Defendant FDA has failed to conduct a reasonable search for records responsive to the request.

57. Defendant FDA has failed to issue a complete determination within the statutory deadline.

58. Defendant FDA has failed to produce all non-exempt records responsive to the request.

COUNT II – FDA'S FOIA VIOLATION
JUNE 30, 2023 AMONDYS VYONDYS FOIA REQUEST

59. The above paragraphs are incorporated by reference.

60. Plaintiff's FOIA request seeks the disclosure of agency records and was properly made.

61. Defendant FDA is a federal agency subject to FOIA.

62. Included within the scope of the request are one or more records or portions of records that are not exempt under FOIA.

63. Defendant FDA has failed to conduct a reasonable search for records responsive to the request.

64. Defendant FDA has failed to issue a complete determination within the statutory deadline.

65. Defendant FDA has failed to produce all non-exempt records responsive to the request.

COUNT III – FDA'S FOIA VIOLATION
JUNE 30, 2023 CLOLAR FOIA REQUEST

66. The above paragraphs are incorporated by reference.

67. Plaintiff's FOIA request seeks the disclosure of agency records and was properly made.

68. Defendant FDA is a federal agency subject to FOIA.

69. Included within the scope of the request are one or more records or portions of records that are not exempt under FOIA.

70. Defendant FDA has failed to conduct a reasonable search for records responsive to the request.

71. Defendant FDA has failed to issue a complete determination within the statutory deadline.

72. Defendant FDA has failed to produce all non-exempt records responsive to the request.

COUNT IV – FDA'S FOIA VIOLATION
JUNE 30, 2023 NORTHERA FOIA REQUEST

73. The above paragraphs are incorporated by reference.

74. Plaintiff's FOIA request seeks the disclosure of agency records and was properly made.

75. Defendant FDA is a federal agency subject to FOIA.

76. Included within the scope of the request are one or more records or portions of records that are not exempt under FOIA.

77. Defendant FDA has failed to conduct a reasonable search for records responsive to the request.

78. Defendant FDA has failed to issue a complete determination within the statutory deadline.

79. Defendant FDA has failed to produce all non-exempt records responsive to the request.

COUNT V – FDA'S FOIA VIOLATION
JUNE 30, 2023 DELAYED ACCEPTANCE FOIA REQUEST

80. The above paragraphs are incorporated by reference.

81. Plaintiff's FOIA request seeks the disclosure of agency records and was properly made.

82. Defendant FDA is a federal agency subject to FOIA.

83. Included within the scope of the request are one or more records or portions of records that are not exempt under FOIA.

84. Defendant FDA has failed to conduct a reasonable search for records responsive to the request.

85. Defendant FDA has failed to issue a complete determination within the statutory deadline.

86. Defendant FDA has failed to produce all non-exempt records responsive to the request.

COUNT VI – FDA'S FOIA VIOLATION
JULY 7, 2023 BILLY DUNN FOIA REQUEST

87. The above paragraphs are incorporated by reference.

88. Plaintiff's FOIA request seeks the disclosure of agency records and was properly made.

89. Defendant FDA is a federal agency subject to FOIA.

90. Included within the scope of the request are one or more records or portions of records that are not exempt under FOIA.

91. Defendant FDA has failed to conduct a reasonable search for records responsive to the request.

92. Defendant FDA has failed to issue a complete determination within the statutory deadline.

93. Defendant FDA has failed to produce all non-exempt records responsive to the request.

WHEREFORE, Plaintiff asks the Court to:

i. declare that Defendants have violated FOIA;

ii. order Defendants to conduct a reasonable search for records and to produce the requested records promptly;

iii. enjoin Defendants from withholding non-exempt public records under FOIA;

iv. award Plaintiff attorneys' fees and costs; and

v. award such other relief the Court considers appropriate.

Dated: March 22, 2024

RESPECTFULLY SUBMITTED,

/s/ Matthew V. Topic

Attorneys for Plaintiff,
BLOOMBERG L.P.

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