

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

KNOWLEDGE ECOLOGY)
INTERNATIONAL)
1621 Connecticut Ave NW Suite 500)
Washington, DC 20009)
))
Plaintiff,)
))
v.)
))
U.S. DEPARTMENT OF HEALTH)
AND HUMAN SERVICES)
200 Independence Ave SW)
Washington, DC 20201)
))
and)
))
U.S. DEPARTMENT OF THE ARMY)
114 Army Pentagon)
Washington, DC 20310)
))
Defendants.)

Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Knowledge Ecology International (KEI) brings this action under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, against the United States Department of Health and Human Services (HHS) and the United States Department of the Army (the “Army” or the “U.S. Army”) seeking the expedited release of COVID-19 contracts awarding hundreds of millions to two billion taxpayers’ dollars to fund COVID-19 research and development or to advance purchase hundreds of millions of doses of COVID-19 vaccine candidates. As grounds therefore, Plaintiff alleges as follows:

JURISDICTION AND VENUE

1. Jurisdiction over this action is conferred by 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.
2. Venue is properly vested in this district under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

PARTIES

3. Plaintiff KEI is a nonprofit organization that works on issues pertaining to access to affordable medicines, access to knowledge and related intellectual property concerns. KEI is located in the District of Columbia and submitted the FOIA requests at issue.

4. Defendant HHS is an agency of the United States government within the meaning of 5 U.S.C. § 552(f)(1). Upon information and belief, HHS has possession, custody, and control over the records sought from HHS. It is headquartered in the District of Columbia.

5. Defendant the U.S. Army is an agency of the United States government within the meaning of 5 U.S.C. § 552(f)(1). Upon information and belief, the Army has possession, custody, and control over the records sought from the Army. It is headquartered in the District of Columbia.

STATEMENT OF FACTS

I. THE HHS FOIA REQUESTS

Request 2020-00968-FOIA-OS, COVID-19 Research and Development Contracts

6. On April 9, 2020, KEI submitted a FOIA request to HHS seeking all contracts “included in Biomedical Advanced Research and Development Authority (BARDA)’s Novel Coronavirus Medical Countermeasure Portfolio.”

7. The request outlines why KEI is entitled to expedited processing and a full waiver of all fees associated with processing the request.

8. By email dated April 15, 2020, HHS acknowledged the request and labeled it Request No. 2020-00968-FOIA-OS.

9. On April 17, 2020, an HHS FOIA officer sent KEI an email asking if the request could be “narrowed, in an effort to speed fulfillment of the request [.]”

10. By email dated April 17, 2020, KEI responded that its “priority” was three contracts funding the development of COVID-19 vaccines, and three contracts pertaining to COVID-19 therapeutics:

- a. The BARDA-Janssen/Johnson & Johnson contract for the development of a COVID-19 vaccine (the “Janssen vaccine contract”);
- b. The BARDA-Sanofi contract for the development of a COVID-19 vaccine;
- c. The BARDA-Moderna contract for the development of a COVID-19 vaccine;
- d. The BARDA-Genentech/Roche contract for the development of a COVID-19 treatment;
- e. The BARDA-Janssen/Johnson & Johnson contract for the development of a COVID-19 treatment (the “Janssen treatment contract”); and
- f. The BARDA-Regeneron contract for the development of a COVID-19 treatment.

11. On June 23, 2020, after KEI reminded HHS that KEI’s request for expedited processing was outstanding and that HHS was required (per the statutory deadline) to make a determination on KEI’s request for expedited processing within 10 days, HHS sent KEI a letter stating that it was granting KEI’s request for expedited processing, as “[t]he subject matter of

your request demonstrates that there is an ‘urgency to inform the public concerning actual or alleged Federal activity.’”

12. On June 24, 2020, HHS provided KEI with a final response letter concerning Request No. 2020-00968-FOIA-OS. The letter states that HHS located 512 pages of responsive records, and that of those records, 122 pages were withheld in their entirety under Exemption 4 of the FOIA; 173 pages were released in their entirety; and 217 pages were released with portions redacted, pursuant to Exemptions 4 and 6 of the FOIA.

13. On June 25 and June 26, 2020, HHS provided the following records to KEI: the Genentech, Janssen treatment and Regeneron contracts, amendments to those contracts related to COVID-19, the full Moderna contract, and amendments to the Sanofi contract and the Janssen vaccine contract, but not the original agreements.

14. The records provided by HHS to KEI improperly redact information under Exemption 4 of the FOIA.

15. Exemption 4 allows agencies to withhold “trade secrets and commercial financial information obtained from a person [that is] privileged or confidential.” 5 U.S.C. § 552(b)(4).

16. Information is “confidential” under Exemption 4 of the FOIA if it “is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy.” *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019).

17. While the Supreme Court has not resolved whether information must always be submitted to the government under an assurance of privacy to be confidential under Exemption 4, it is always a relevant factor “to determining whether financial information that is shared with the government is ‘confidential’ pursuant to the FOIA's Exemption 4.” *See Stotter v. U.S. Agency for Int’l Dev.*, No. 14-CV-2156 (KBJ), 2020 WL 5878033, at *5 (D.D.C. Oct. 3, 2020).

18. As a result of the FOIA Improvement Act of 2016, in order to withhold information under Exemption 4, agencies must not only show that the technical criteria for Exemption 4 are satisfied but also “must explain how disclosing, in whole or in part, the specific information withheld under Exemption 4 would harm an interest protected by this exemption, such as by causing genuine harm to [the submitter's] economic or business interests . . . thereby dissuading others from submitting similar information to the government[.]” *Ctr. for Investigative Reporting v. U.S. Customs & Border Prot.*, 436 F. Supp. 3d 90, 113 (D.D.C. 2019)(internal citations and quotation marks omitted).

19. The June 24, 2020 final response letter does not state that the information redacted under Exemption 4 was provided to HHS under an assurance of privacy or that disclosure would harm an interest protected by Exemption 4.

20. Information is not protected under Exemption 4 if it is in the public domain or is not customarily treated as confidential by its owner.

21. The information redacted under Exemption 4 in the responsive records includes the total award under the contracts—information that can be located at FPDS.gov, the website for Federal Procurement Data System - Next Generation, an online database of government contracts maintained by the United States government. Total dollar amounts for the contracts have also been disclosed by the contractors and HHS in press releases announcing the agreements.

22. Information redacted in the responsive records under Exemption 4 also includes information not customarily treated as confidential by its owner, such as the cost-sharing arrangement between the United States government and Regeneron Pharmaceuticals in HHS-Regeneron contracts, including the one at issue in this FOIA request.

23. Information redacted under Exemption 4 in the responsive records includes information that Moderna is contractually obligated to publicly disclose, in all press releases describing the scope of work under the contract (which entails development of the National Institutes of Health-Moderna vaccine candidate mRNA-1273 to FDA approval and “Domestic Manufacturing scale out”): the total and proportionate share of the development costs financed by the U.S. government.

24. In addition, the records provided by HHS in response to Request No. 2020-00968-FOIA-OS do not include two responsive records—HHSO100201700018C, a contract between HHS and Janssen, as originally executed, and HHSO100201600005I, a contract between HHS and Protein Sciences Corporation, as originally executed.

25. Upon information and belief, the entire texts of HHSO100201700018C and HHSO100201600005I as originally executed are not trade secrets or confidential information shielded by Exemption 4.

26. On September 1, 2020, KEI appealed the improper redactions under Exemption 4 of the FOIA and the unjustified withholding of two responsive contracts.

27. As of the date of this Complaint, HHS has not issued a final determination regarding the appeal.

28. KEI has exhausted all administrative remedies regarding Request No. 2020-00968-FOIA-OS.

May 12, 2020 Request—Phlow Corporation Contract

29. On May 12, 2020, KEI submitted a FOIA request to HHS seeking:

Contract No. 75A50120C00092, the four-year contract between the Biomedical Advanced Research and Development Authority (BARDA) and Phlow Corporation of Richmond, VA, to manufacture pharmaceutical ingredients and generic medicines needed to treat COVID-19.

30. The request outlines why KEI is entitled to a full waiver of fees and expedited processing regarding this request.

31. Upon information and belief, as of the date of this Complaint, HHS has not acknowledged the May 12, 2020 FOIA request seeking records related to the Phlow Corporation contract.

32. KEI has constructively exhausted all administrative remedies regarding this request.

FOIA Request No. 2020-01451-FOIA-OS—Novavax Contract

33. On July 8, 2020, KEI submitted a FOIA request to HHS seeking a copy of the \$1.6 billion contract between HHS, DOD, and Novavax concerning Novavax's research and development and manufacture of Novavax's COVID-19 vaccine candidate.

34. The request outlines why KEI is entitled to expedited processing and a full fee waiver.

35. HHS acknowledged the request and labeled it Request No. 2020-01451-FOIA-OS.

36. By email dated July 16, 2020, HHS provided KEI with a letter stating that HHS granted KEI's request for expedited processing.

37. As of the date of this Complaint, HHS has not provided a final determination regarding the request, responsive records, or a determination regarding KEI's request for a full waiver of fees.

38. KEI has constructively exhausted all administrative remedies regarding FOIA Request No. 2020-01451-FOIA-OS.

July 27, 2020 Request—Three COVID-19 R&D Contracts

39. On July 27, 2020, KEI submitted a FOIA request to HHS seeking the following contracts executed by HHS to fund COVID-19 research and development (R&D):

75A50120F33006, a contract between HHS and CIADM at Emergent Biosolutions to develop a plasmid treatment for COVID-19; “W15QKN1691002, a contract with SAb Biotherapeutics, Inc., <https://medicalcountermeasures.gov/newsroom/2020/sab-185/>”; and the contract between HHS and Grifols Shared Services North America, Inc. to develop a plasma-based antibody against COVID-19.

40. The request outlines why KEI is entitled to expedited processing and a full waiver of fees.

41. Upon information and belief, as of the date of this Complaint, HHS has not acknowledged the request.

42. KEI has constructively exhausted all administrative remedies with respect to this request.

July 28, 2020 Request—Moderna Contract Extension

43. On July 28, 2020, KEI submitted a FOIA request to HHS seeking:

Contract No. 75A50120C00034 (P00003), an amendment to a contract between Biomedical Advanced Research and Development Authority (BARDA) and Modernatx, Inc. (Moderna), in which BARDA is obligating an additional \$471,596,459 to the development of Moderna’s investigational COVID-19 vaccine candidate.

44. The request outlines why KEI is entitled to expedited processing and a full waiver of fees.

45. Upon information and belief, as of the date of this Complaint, HHS has not acknowledged the request.

46. KEI has constructively exhausted all administrative remedies with respect to this request.

FOIA Request No. 2020-01589-FOIA-OS—Pfizer Contract

47. On July 28, 2020 KEI submitted a FOIA request to HHS seeking:

the contract between [] Biomedical Advanced Research and Development Authority (BARDA), the Department of Defense, and Pfizer, ‘for large-scale production and nationwide delivery of 100 million doses of a COVID-19 vaccine in the United States following the vaccine’s successful manufacture and approval.’

48. The request provides a link to an HHS press release announcing the agreement.

49. The request outlines why KEI is entitled to expedited processing a full waiver of fees associated with processing the request.

50. On August 3, 2020, HHS acknowledged the request and labeled it Request No. 2020-01589-FOIA-OS.

51. On August 7, 2020, HHS provided KEI with a letter seeking clarification regarding the request, stating that the request does not reasonably describe the records sought because HHS needed a “contract number[] to initiate a search.” The letter advises KEI to search for the contract number at FPDS.gov.

52. By email dated August 7, 2020, KEI informed HHS that the FOIA does not require a requester to provide a contract number for the request to reasonably describe the records sought, and that the contract number is not listed at FPDS.gov. The email copied and pasted the text of an HHS web page describing the Pfizer contract.

53. By email dated August 11, 2020, HHS stated that it will “take [the] request off of ‘hold’ and will continue to process [KEI’s] request using the information provided.”

54. The request was perfected as originally submitted on July 28, 2020 because it reasonably describes the records sought.

55. As of the date of this Complaint, HHS has not provided KEI with a determination concerning KEI's request for a fee waiver or its request for expedited processing, nor has HHS provided a final determination regarding the request or responsive records.

56. KEI has constructively exhausted all administrative remedies with regard to Request No. 2020-01589-FOIA-OS.

II. THE U.S. ARMY REQUESTS

July 8, 2020 FOIA Request—JPEO-CBRN Novavax Contract

57. On July 8, 2020, KEI submitted a FOIA request to the United States Army/the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRN) seeking:

the agreement between Novavax, the Biomedical Advanced Research and Development Authority (BARDA), and the U.S. Department of Defense (DoD)/the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense regarding the demonstration project for the manufacture of Novavax's NVX-CoV2373 vaccine[.]

58. The request outlines why KEI is entitled to expedited processing and a full waiver of fees.

59. Upon information and belief, as of the date of this Complaint, the Army/JPEO-CBRN has not acknowledged the request.

60. KEI has constructively exhausted all administrative remedies with regard to this request.

July 28, 2020 FOIA Request—JPEO-CBRN Pfizer Contract

61. On July 28, 2020 KEI submitted a FOIA request to the Army/JPEO-CBRN seeking:

the contract between Biomedical Advanced Research and Development Authority (BARDA), the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, and Pfizer, ‘for large-scale production and nationwide delivery of 100 million doses of a COVID-19 vaccine in the United States following the vaccine’s successful manufacture and approval.’

62. The request outlines why KEI is entitled to expedited processing and a full waiver of fees.

63. Upon information and belief, as of the date of this Complaint, the Army/JPEO-CBRN has not acknowledged the request.

64. KEI has constructively exhausted all administrative remedies with regard to this request.

Request No. FA-20-0033—The Moderna Procurement Contract

65. On August 13, 2020, KEI submitted a FOIA request to the U.S. Army Contracting Command seeking:

the contract between the Department of Defense (DOD), US U.S. Army Contracting Command, Aberdeen Proving Ground, Maryland and Moderna TX, Inc. The agreement is W911QY-20-C-0100, and is ‘a \$1,525,000,000 firm-fixed-price contract for 100 million filled drug production doses of a SARS-CoV-2 mRNA-1273 vaccine.’

66. The request outlines why KEI is entitled to expedited processing and a full waiver of fees.

67. On August 17, 2020, the Army Contracting Command acknowledged the request and labeled it Request No. FA-20-0033.

68. As of the date of this Complaint, the Army has not provided a determination regarding KEI's request for a fee waiver and its request for expedited processing, nor has it provided responsive records or a final determination for Request No. FA-20-0033.

CLAIMS FOR RELIEF

COUNT I

(Wrongful Withholding and Redacting of Information in Responsive Records, HHS)

69. KEI realleges the foregoing paragraphs as if stated herein.

70. HHS improperly invoked Exemption 4 of the FOIA to redact information and withhold entire pages of information from records responsive to Request No. 2020-00968.

71. HHS's improper invocation of Exemption 4 to redact and withhold information responsive to Request No. 2020-00968-FOIA-OS violates the FOIA.

COUNT II

(Failure to Produce Records, HHS)

72. KEI realleges the foregoing paragraphs as if stated herein.

73. KEI properly submitted FOIA Requests No. 2020-01451-FOIA-OS and 2020-01859-FOIA-OS to HHS.

74. Upon information and belief, each of the two requests seek information within the custody and control of HHS.

75. HHS has not provided a final response or responsive records for Requests No. 2020-01451-FOIA-OS and 2020-01859-FOIA-OS within the deadline established by the FOIA.

76. There is no legal basis for the HHS's failure to disclose the responsive records.

COUNT III

(Failure to Respond to Requests, HHS)

77. KEI realleges the foregoing paragraphs as if stated herein.

78. KEI properly submitted FOIA requests to HHS on May 12, 2020, July 27, 2020 and July 28, 2020.

79. Upon information and belief, each of the three requests seeks records within the custody and control of HHS.

80. Upon information and belief, HHS has not acknowledged the requests and as such, has not provided responsive records or a final determination within the statutory deadline.

81. There is no legal basis for HHS's failure to provide responsive records within the deadline established by the FOIA.

COUNT IV
(Failure to Produce Records, U.S. Army)

82. KEI realleges the foregoing paragraphs as if stated herein.

83. KEI properly submitted to the U.S. Army FOIA Request No. FA-20-0033 seeking records within the custody and control of the Army.

84. The Army failed to provide responsive records or a final determination regarding the request within the deadline established by the FOIA.

85. The Army has no legal basis for failing to provide responsive records within the deadline established by the FOIA.

COUNT V
(Failure to Respond to Requests, U.S. Army)

86. KEI realleges the foregoing paragraphs as if stated herein.

87. KEI properly submitted FOIA requests to the Army on July 8, 2020 and July 28, 2020.

88. Upon information and belief, the Army FOIA requests seek records within the custody and control of the Army.

89. Upon information and belief, the Army has not acknowledged the requests and as such, has not provided responsive records within the statutory deadline.

90. There is no legal basis for the Army failure to acknowledge the requests, provide responsive records or issue a final determination within the statutory deadline.

COUNT VI
(Failure to Expedite Release of Records, HHS)

91. KEI realleges the foregoing paragraphs as if stated herein.

92. KEI requested expedited processing of the HHS FOIA requests described in this Complaint.

93. KEI is entitled to expedited processing of the HHS FOIA requests.

94. HHS either granted expedited processing and failed to provide an expedited response to the requests or it failed to acknowledge and respond to the requests for expedited processing within the statutory deadline, in violation of the FOIA.

COUNT VII
(Failure to Expedite Release of Records, U.S. Army)

95. KEI realleges the foregoing paragraphs as if stated herein.

96. KEI requested expedited processing for each of the U.S. Army FOIA requests described in this Complaint.

97. KEI is entitled to expedited processing of the U.S. Army FOIA requests.

98. The U.S. Army failed to respond to the requests for expedited processing within the statutory deadline, in violation of the FOIA.

REQUESTED RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

A. Declare that the failure of HHS and the Army to provide KEI with timely and full responses to KEI's FOIA requests described above is in violation of the FOIA;

B. Declare that HHS's redactions and withholding of records under Exemption 4 are in violation of the FOIA;

C. Order HHS and the Army to produce, within 20 days of the Court's order and at no cost, all non-exempt responsive records and *Vaughn* indexes of any responsive records withheld under a claim of exemption;

C. Enjoin the HHS and the Army from continuing to withhold responsive records;

D. Award KEI its reasonable costs, litigation expenses, and attorneys' fees incurred in prosecuting this civil action under the FOIA, 5 U.S.C. § 552(a)(4)(E); and

E. Grant such other relief as the Court deems just and proper.

Dated: October 16, 2020

/s/ Lynne Bernabei

Lynne Bernabei (D.C. Bar No. 938936)
Bernabei & Kabat, PLLC
1400 16th Street NW Ste 500
Washington, DC 20036
(202) 745-1942
bernabei@bernabeipllc.com

/s/ Kathryn Ardizzone

Kathryn Ardizzone (D.C. Bar No. 1631208)¹
Knowledge Ecology International
1621 Connecticut Ave NW, Suite 500
Washington, DC 20009
(202) 332-2670
kathryn.ardizzone@keionline.org
Counsel for Plaintiff

¹ *Pro hac vice* admission and admission to the Bar of the United States District Court for the District of Columbia pending.