UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FUNCTIONAL GOVERNMENT INITIATIVE 6218 Georgia Avenue, N.W. Suite 1-1235 Washington, D.C. 20011, Plaintiff, v. U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES 200 Independence Avenue, S.W. Washington, D.C. 20201; NATIONAL INSTITUTES OF HEALTH 10 Center Drive Bethesda, MD 20892; and NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES 5601 Fishers Lane, MSC 9806 Bethesda, MD 20892-9806, Defendants.	)	Civil Case No. 22-cv-1704

COMPLAINT

1. Plaintiff, Functional Government Initiative ("FGI"), brings this action against the United States Department of Health and Human Services ("HHS"), National Institutes of Health ("NIH"), and the National Institute of Allergy and Infectious Diseases ("NIAID") pursuant to the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, requesting declaratory and injunctive relief to compel Defendants' compliance with FOIA.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this FOIA matter pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. §§ 1331, 2201, and 2202.

3. Venue in this Court is provided for by 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

PARTIES TO THE ACTION

4. Plaintiff, FGI, is an unincorporated association of individuals dedicated to improving the American public's access to information about the officials, decisions, actions, and priorities of their government. *See* D.C. Code § 29-1102(5).

5. FGI accomplishes its mission though investigative research, analysis, and dissemination of the information it obtains. The records FGI obtains under the FOIA are vital to accomplishing its mission.

6. Defendant, HHS, is an executive department and therefore an "agency" within the meaning of and subject to FOIA as provided for by §§ 5 U.S.C. § 551(1) and § 552(f)(1).

7. Defendant, the National Institutes of Health ("NIH"), is an operating division within HHS and an "agency" within the meaning of and subject to FOIA as provided for by §§ 5 U.S.C. § 551(1) and § 552(f)(1).

8. Defendant, the National Institute of Allergy and Infectious Diseases ("NIAID") is one of the collection of institutes and centers within NIH and an "agency" within the meaning of and subject to FOIA as provided for by 5 U.S.C. §§ 551(1) and 552(f)(1).

9. As discussed below, on February 19, 2022, FGI submitted FOIA requests to each of the Defendants regarding actions taken by the federal government in the distribution of monoclonal antibodies ("mAb"). The FOIAs are identical in all material respects except that,

in attempt to aid Defendants in their search, FGI identified specific parties within the offices of each Defendant whose records should be among those searched.

10. The release of the documents requested by FGI from HHS, NIH, and NIAID is in the public interest because it will provide American citizens with insight into their government's decision making for the distribution of mAb, which is critical to an understanding of the government's response to the COVID-19 pandemic. The American public is entitled to know what considerations factored into the government's distribution of mAb and whether mAb were provided in a manner best designed to protect public health, were guided by science, and were without political interference. The release of the documents requested by FGI will advance the public's knowledge on all of these issues which, to date, have not been fully ventilated.

A. STATEMENT OF FACTS PERTINENT TO FGI's FOIA TO DEFENDANT HHS

11. On February 19, 2021, FGI submitted a FOIA request to HHS for information pertaining to the distribution of mAb in response to the outbreak of COVID-19 as follows:

FGI requests all records from February 1, 2021, to the date the agency conducts the search between the list of HHS officials listed below and those identified in items 1-6 about the ability of mAb providers to order MAbs directly:

1. Other officials within HHS;

2. Officials within other federal entities (e.g., federal departments, other agencies, or services);

3. Officials at the White House, specifically including White House COVID Coordinator, Jeff Zients and any of his deputies;

4. Employees of mAbs manufacturers (and any of their subsidies or affiliated companies),

including but not limited to Regeneron Pharmaceuticals, Inc.; Eli Lily and Company; GlaxoSmithKline plc; Vir Biotechnology, Inc.; Pfizer, Inc.; and Merck & Co., Inc.;

5. Employees of AmerisourceBergen, Corp; and

6. People representing medical advisory boards, councils, associations, or similar professional medical organizations.

In addition, please provide the following:

7. All records of officials' communications referencing the development and implementation of the processes for determining the amount of mAbs to be distributed to each state or territory that had requested them.

A copy of FGI's FOIA request to HHS is attached as Exhibit 1.

12. In an attempt to aid HHS in its records search, FGI identified specific parties within HHS whose records should be among those reviewed for responsive information. *Id*.

13. FGI submitted its February 19, 2022, FOIA request via HHS's online FOIA Public Access Link (s*ee* HHS FOIA Submission Site-Home) and moments later HHS generated an email from noreply@ains.com assigning FGI's FOIA as Case Number 2022-00437-OS and generated a second email that identified the status of FGI's request as "Received".

14. HHS's FOIA regulations provide that:

> We acknowledge all FOIA requests in writing within 10 working days after receipt by the appropriate office. The acknowledgement letter or email informs you of your request tracking number, provides contact information, and informs you of any complexity we are aware of in processing that may lengthen the time required to reach a final decision on the release of the records. In addition, the acknowledgement letter or email or a subsequent communication may also seek additional information to clarify your request.
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> 45 C.F.R. § 5.29 (a).

15. HHS's emails did not identify a specific FOIA officer FGI could contact, inform FGI of any complexity that may lengthen the time required for HHS to reach a final decision, nor seek additional information about FGI's request.

16. FGI has checked the status of its request regularly on HHS's FOIA website: https://requests.publiclink.hhs.gov. As of June 13, 2022, the status of FGI's request is shown as "Assigned for Processing".

17. Additionally, on May 9, 2022, and May 17, 2022, FGI emailed HHS at FOIAREQUEST@HHS.gov seeking updates on the status of its FOIA request and an estimate as to when HHS would produce records. FGI has received no response to these email inquiries.

18. As of today, HHS has not provided FGI with a determination of whether it will comply with FGI's request and has not indicated whether it has begun an actual search for responsive documents, nor has it produced responsive documents, communicated to FGI the scope of the documents it intends to produce and withhold, along with the reasons for such withholding, or informed FGI of its ability to appeal any adverse portion of its determination.

19. As of today, FGI's FOIA request to HHS has been pending for considerably longer than the statutory period within which HHS is required to complete its search. 5 U.S.C. § 552(a)(6)(A)-(B).

20. Because HHS has failed to provide FGI with a determination within the applicable statutory time limits, FGI is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552 (a)(6)(C)(i).

21. Absent the filing of this lawsuit, FGI will not obtain the records to which it is entitled under FOIA.

22. Accordingly, FGI may now pursue relief in this Court to compel release of responsive, non-exempt records improperly withheld by HHS. *See* 5 U.S.C. § 552 (a)(4)(B).

B. STATEMENT OF FACTS PERTINENT TO FGI's FOIA TO DEFENDANT NIH

23. On February 19, 2021, FGI submitted a FOIA request to NIH pertaining to the distribution of mAb in response to the COVID-19 pandemic.

24. FGI's request asks for records related to mAb, including internal communications, communications with other federal agencies, communications with the White House COVID Coordinator and any of his deputies, employees of specified companies involved in manufacturing and distributing mAb, and communications with representatives of medical advisory boards or similar organizations and records related to distribution of mAb to states or territories that requested them.

    A copy of FGI's FOIA request to NIH is attached as Exhibit 2.

25. The same day, FGI received an automated response from NIH designating FGI's FOIA as Request #57920.

26. FGI's FOIA request to NIH seeking information about the distribution of mAb is identical in all material respects to the request FGI submitted to HHS except that, in attempt to aid NIH in its search, FGI identified specific parties within NIH whose records should be among those searched.

27. On April 20, 2022, an NIH FOIA officer emailed FGI seeking clarification of its FOIA request. The request for clarification was made after the time for NIH to have responded to FGI's FOIA had expired. *See* 5 U.S.C. § 502 (a)(6)(A)(ii)(I).

28. FGI responded to the points raised in the NIH's FOIA Officer's email on May 9, 2022, and agreed to assist NIH by narrowing the scope of the FOIA request and providing specific terms for NIH to use in completing its search.

29. NIH did not respond to FGI's email, nor has it provided FGI with any further information about its FOIA request.

30. As of today, FGI's FOIA request has been pending well beyond the statutory period for NIH to have made a determination. 5 U.S.C. § 552(a)(6)(A)-(B).

31. Because NIH has failed to provide FGI with a determination within the applicable statutory time limits, FGI is deemed to have exhausted its administrative remedies under FOIA. 5 U.S.C. § 552 (a)(6)(C)(i).

32. Absent the filing of this lawsuit, FGI will not obtain the records to which it is entitled under FOIA.

33. FGI may now pursue relief in this Court to compel release of records improperly withheld by HHS. *See* 5 U.S.C. § 552 (a)(4)(B).

C. STATEMENT OF FACTS PERTINENT TO FGI's FOIA TO DEFENDANT NIAID

34. On February 19, 2021, FGI submitted a FOIA request to NIAID pertaining to the distribution of mAb in response to the outbreak of COVID-19. FGI's request asks for records related to mAb, including internal communications, communications with other federal agencies, communications with the White House COVID Coordinator and any of his deputies, employees of specified companies involved in manufacturing and distributing mAb, and representatives of medical advisory boards or similar organizations and records related to distribution of mAb to states or territories that requested them.

A copy of FGI's FOIA request to NIAID is attached as Exhibit 3.

35. FGI's FOIA request to NIAID is identical in all material respects to the requests FGI submitted to HHS and NIH in seeking information about the distribution of mAb, except that, in attempt to aid NIAID in its search, FGI identified specific parties within NIAID whose records should be among those searched.

36. On February 19, 2022, FGI received an automated email response from the NIAID FOIA officer acknowledging receipt of FGI's FOIA, Request #57921.

37. Between February 22, 2022, and March 9, 2022, FGI worked with the FOIA officer to satisfy three emails from the officer asking FGI for additional information or to narrow its request to help NIAID in completing its records search.

38. On March 24, 2022, FGI received a letter from NIAID, however, the letter did not provide any substantive determinations or information about the status of NIAID's search, rather the letter again acknowledged receipt of FGI's FOIA and identified a contact for follow-up within the FOIA Office.

39. Having received had no substantive communication from the FOIA officer since March 9, 2022, FGI requested an update on the status of NIAID's search on May 9, 2022.

40. To FGI's surprise, by email dated May 10, 2022, the FOIA officer stated that "Your requests are currently under review. The current estimate is 6 months." The email did not expressly indicate that a search was underway or explain why the agency required approximately 9 months from the date of submission to complete its "review" of FGI's request. FGI has heard nothing further from NIAID about its FOIA request.

41. As of today, FGI's FOIA request has been pending well beyond the statutory period for NIH to have made a determination. 5 U.S.C. § 552(a)(6)(A)-(B).

42. NIAID has not provided FGI with a determination of whether it will comply with FGI's request, nor has it produced responsive documents, communicated to FGI the scope of the documents it intends to produce and withhold, along with the reasons for such withholding, or informed FGI of its ability to appeal any adverse portion of its determination.

43. Because NIAID has failed to provide FGI with a determination within the applicable statutory time limits, FGI is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552 (a)(6)(C)(i).

44. Absent the filing of this lawsuit, FGI will not obtain the records to which it is entitled under FOIA.

45. Accordingly, FGI may now pursue relief in this Court to compel the release of records improperly withheld by NIAID. *See* 5 U.S.C. § 552 (a)(4)(B).

COUNT I
Wrongful Withholding of Non-Exempt Responsive Records By Defendant HHS
In Violation of FOIA, 5 U.S.C. § 552

46. FGI restates and incorporates by reference all the preceding paragraphs.

47. FGI properly requested records within the possession, custody, and control of HHS.

48. Because HHS is an "agency" subject to FOIA, it must release all non-exempt records and provide legitimate reasons for withholding any records.

49. By failing to produce all responsive, non-exempt records, HHS is wrongfully withholding agency records subject to release under FOIA.

50. Additionally, by failing to segregate exempt information in otherwise non-exempt records responsive to FGI's FOIA request, HHS is wrongfully withholding agency records subject to release under FOIA.

51. Because HHS has failed to provide a determination within the applicable statutory time limits in response to FGI's FOIA request, FGI is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552 (a)(6)(C)(i).

52. Accordingly, FGI is entitled to declaratory and injunctive relief requiring HHS to promptly produce all non-exempt records responsive to its FOIA request and provide indexes justifying the withholding of any responsive records under a claim of exemption.

COUNT II
Wrongful Withholding of Non-Exempt Responsive Records By Defendant NIH
In Violation of FOIA, 5 U.S.C. § 552

53. FGI restates and incorporates by reference all the preceding paragraphs.

54. FGI properly requested records within the possession, custody, and control of NIH.

55. Because NIH is an "agency" subject to FOIA, it must release all non-exempt records and provide legitimate reasons for withholding any records.

56. By failing to produce all responsive, non-exempt records, NIH is wrongfully withholding agency records subject to release under FOIA.

57. Additionally, by failing to segregate exempt information in otherwise non-exempt records responsive to FGI's FOIA request, NIH is wrongfully withholding agency records subject to release under FOIA.

58. Because NIH has failed to provide a determination within the applicable statutory time limits in response to FGI's FOIA request, FGI is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552 (a)(6)(C)(i).

59. Accordingly, FGI is entitled to declaratory and injunctive relief requiring NIH to promptly produce all non-exempt records responsive to its FOIA request and provide indexes justifying the withholding of any responsive records under a claim of exemption.

COUNT III
Wrongful Withholding of Non-Exempt Responsive Records by Defendant NIAID
In Violation of FOIA, 5 U.S.C. § 552

60. FGI restates and incorporates by reference all the preceding paragraphs.

61. FGI properly requested records within the possession, custody, and control of NIAID.

62. Because NIAID is an "agency" subject to FOIA, it must release all non-exempt records and provide legitimate reasons for withholding any records.

63. By failing to produce all responsive, non-exempt records, NIAID is wrongfully withholding agency records subject to release under FOIA.

64. Additionally, by failing to segregate exempt information in otherwise non-exempt records responsive to FGI's FOIA request, NIAID is wrongfully withholding agency records subject to release under FOIA.

65. Because NIAID has failed to provide a determination within the applicable statutory time limits in response to FGI's FOIA, FGI is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552 (a)(6)(C)(i).

66. Accordingly, FGI is entitled to declaratory and injunctive relief requiring NIAID to promptly produce all non-exempt records responsive to its FOIA request and provide indexes justifying the withholding of any responsive records under a claim of exemption.

REQUESTED RELIEF

FGI respectfully requests this Court:

(1) Take and maintain jurisdiction over this case until HHS, NIH, and NIAID comply with the requirements of FOIA and the orders of this Court.

(2) Order HHS, NIH, and NIAID to produce all non-exempt records responsive to FGI's FOIA

requests, and indexes justifying the withholding all or part of any responsive records under claim of exemption.

(3) Order HHS, NIH, and NIAID to produce all non-exempt records within ten days or such other time as the Court deems appropriate, ,

(4) Enjoin HHS, NIH, and NIAID from continuing to withhold all non-exempt responsive records.

(5) Award the reasonable attorney's fees and other litigation costs reasonably incurred in this action, as provided for by 5 U.S.C. § 552(a)(4)(E).

(6) Grant FGI such other relief as this Court deems to be necessary and proper.

Dated: June 14, 2022

Respectfully submitted,

FUNCTIONAL GOVERNMENT INITITIATIVE
By Counsel:

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