Exhibit 1

FUNCTIONAL GOVERNMENT INITIATIVE

February 19, 2022

Submitted online at requests.publiclink.hhs.gov

FOIA Officer/Director
Freedom of Information and Privacy Acts Division
U.S. Department of Health and Human Services
Hubert H. Humphrey Bldg., Suite 729H
200 Independence Avenue, SW
Washington, DC 20201

Dear Freedom of Information Officer:

The Functional Government Initiative (FGI) submits this request for records under the Freedom of Information Act, 5 U.S.C. § 552, as amended, (FOIA) and the relevant implementing regulations of the Department of Health and Human Services (HHS). FGI, which is a non-partisan organization, engages in research, investigation, and education to promote transparency in government and support values that help to build a solid infrastructure for a bright American future.

Your prompt response pursuant to the requirements of FOIA, 5 U.S.C. § 522(a)(6)(A), is appreciated.

BACKGROUND

In February 2021, HHS and the Office of the Assistant Secretary of Preparedness and Response implemented a distribution process for monoclonal antibody therapeutics for use in the treatment of COVID-19 (mAbs) hereby mAb providers were able to order mAbs directly from the manufacturer (typically, by using the services of the medical distribution company AmerisourceBergen).[1]

On September 13, 2021, HHS implemented a new distribution process whereby mAb providers were no longer able to order mAbs directly. Rather, the agency required states and territories were required to submit weekly orders for mAbs to the agency. The agency would then determine the amount of mAbs to be distributed to each state and territory.

REQUESTED RECORDS

[1]See https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/FAQs-mAB.aspx. See also https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/Update-13Sept21.aspx

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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 mAb 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.

For the above criteria, please include search for records held in the offices and by the people listed below. Some names are listed, but we do not know of any consolidated source to see the current and former staff in these positions. Specifically, we are requesting records held by any presidentially appointed and Senate-confirmed (PAS) officials, any schedule C appointees, and any non-career SES appointees in the offices, even if not listed, and anyone serving in an acting capacity and anyone who left the offices but formerly worked in any of these positions during the time range of this request.

- Office of the Secretary
  - Xaiver Bacerra, Secretary
  - Andrea Palm, Deputy Secretary
  - Sean McCluskie, Chief of Staff
  - Anne Reid, Deputy Chief of Staff
  - Dawn O'Connell, Senior Counselor, COVID Response
  - Sarah Despres, Counselor for Public Health and Science
  - Kathryn Alvarez, Deputy Chief of Staff, COVID Response
  - Perrie Briskin, Senior Advisor to the Chief of Staff
  - David Kessler, Chief Science Officer, COVID Response
  - Esmeralda Orozco, Special Assistant for Scheduling
  - AJ Pearlman, Chief of Staff, COVID Response

    - Lizeth Zardeneta, Executive Assistant and Briefing Book Coordinator
    - Any other schedule C or non-career SES appointees who worked in the office
- Office of the Assistant Secretary for Preparedness and Response (ASPR)
    - Dawn O'Connell, Assistant Secretary for Preparedness and Response
    - Nikki Bratcher-Bowman, Principal Deputy Assistant Secretary for Preparedness and Response
    - Sabrina Bousbar, Special Assistant, COVID - Preparedness and Response
    - Any other schedule C or non-career SES appointees in the office
- Office of the Assistant Secretary for Legislation (ASL)
    - Melanie Egorin, Assistant Secretary for Legislation
    - Steven Hild, Deputy Assistant Secretary for Legislation
    - Lauren Jee, Deputy Assistant Secretary for Mandatory Health Programs
    - Anne Tatem, Deputy Director Discretionary Health
    - Leslie Zelenko, Senior Advisor and Congressional Liaison
    - Any other schedule C or non-career SES appointees in the office
- Office of Intergovernmental and External Affairs (IEA)
    - Marvin Figueroa, Director
    - Yvanna Cancela, Principal Deputy Director
    - Any other schedule C or non-career SES appointees in the office

The term "all records" in this request refers to, but is not limited to all documents, letters, correspondence, emails including attachments, schedules and calendar entries, electronic meeting invitations and replies, facsimiles, memoranda, text messages, notes from meetings and telephone calls, minutes of meetings, agendas of meetings, comments, files, presentations, consultations, drawings, diagrams, graphs, charts, assessments, evaluations, telephone records and logs, virtual meeting logs such as those produced by Microsoft Teams, papers (published or unpublished), reports, studies, photographs and other images, databases, data, maps, and/or all other responsive records in draft or final form that fall within the definition of "agency records" subject to FOIA.

We ask that you please provide all records in an electronic format and, to the extent practicable, in native file format or, if not practicable, with full metadata for all fields. FOIA provides that "an agency shall provide the record in any form or format requested by the person if the record is readily reproducible by the agency in that form or format."[2]

Please provide records in either of the following formats:

1. Load-ready format with an index in .csv file or Excel spreadsheet, or
2. In .pdf format without any portfolios or embedded files and not in a single batched.pdf file.

[2] 5 U.S.C. § 552(a)(3)(B)

If you should seek to withhold or redact any responsive records, we request that you do the following:

1. Identify each such record with specificity, including date, author, recipient, and parties copied,
2. Explain in full the basis for withholding responsive material,
3. Provide all segregable portions of the records for which you claim a specific exemption[3], and
4. Correlate any redactions with specific exemptions under FOIA.

If you or your office have destroyed or determine to withhold any records that could be reasonably construed to be responsive to this request, we ask that you indicate this fact and the reasons therefore in your response.

Agencies are prohibited from denying requests for information under FOIA unless the agency reasonably believes release of the information will harm an interest that is protected by the exemption.[4]

Should you decide to invoke a FOIA exemption, including any subsection (c) exclusions, please include sufficient information for us to assess the basis for the exemption, including any interests that would be harmed by release. Please include a detailed list with the following:

1. Basic factual material about each withheld record, including the originator, date, length, general subject matter, and location of each item, and
2. Complete justifications for each withheld record, including the specific exemptions under which the record or portion thereof, was withheld and a full explanation of how each exemption applies to the withheld material. Such statements will be helpful in deciding whether to appeal an adverse determination. Your written justification may help to avoid litigation.

If you determine that portions of the records requested are exempt from disclosure, we request that you segregate the exempt portions and send the non-exempt portions to my email address below within the statutory time limit.[5]

FGI is willing to receive records on a rolling basis pursuant to an agreed upon schedule.

In order to facilitate our request most efficiently, we request that the FOIA office use the agency's email management system to search and process this request.

[3] See 5 U.S.C. § 552(b)
[4] FOIA Improvement Act of 2016 (Public Law No. 114-185), 5 U.S.C. § 552(a)(8)(A)
[5] 5 U.S.C. § 552(b)

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REQUEST FOR FEE WAIVER

Pursuant to 5 U.S.C. § 552 and 45 CFR § 5.54(b), we request a waiver of fees that HHS would otherwise charge for searching and producing the records described above, because this request satisfies both fee waiver requirements. FOIA provides for fee waivers when:

1. "Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government"; and
2. Disclosure "is not primarily in the commercial interest of the requester."[6]

1. THE REQUEST IS IN THE PUBLIC INTEREST

Pursuant to the statute, a federal agency first must consider whether a disclosure of the requested records is in the public interest by addressing:

A. Whether the requested records concern "the operations or activities of the government,"
B. Whether the disclosure is "likely to contribute significantly" to an understanding of government operations or activities, and
C. Whether the disclosure will contribute to the understanding by a broad audience of persons interested in the subject.

As shown below, FGI meets each of these factors.

A. The requested records concern the operations and activities of the Federal government.

This request seeks important records about the actions of HHS in developing processes for the allocation of life-saving medicines to millions of Americans during a global pandemic. There can be little doubt that HHS possesses such records. Additionally, these records will shed light on the coordination of activities by HHS with other federal agencies, the White House, and private entities as part of an effort to address a global pandemic. The Department of Justice Freedom of Information Act Guide acknowledges that "in most cases records possessed by a federal agency will meet this threshold."[7] The threshold is met here not only because those records responsive to the request are possessed by HHS staff but also because the records concern the department's work as part of the federal government.

[6] 5 U.S.C. § 552(a)(4)(A)(iii)
[7] https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/fees-feewaivers.pdf

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B. Disclosure is "likely to contribute significantly" to an understanding of government operations or activities.

Disclosure of the requested records is not only "likely to contribute" but also is certain to contribute to public understanding of these matters. The requested information will provide an understanding of the development and implementation of strategies for the allocation of a limited supply of new, lifesaving medicines to the American public. FGI is not requesting these records merely for their intrinsic informational value. As noted in the preceding section, the department's activities impacted other agencies, private companies, state and territorial governments, and, ultimately, the health of the American public. To FGI's knowledge, these recently created records have not been previously assembled, assessed, and disseminated, and FGI is capable of accomplishing this important work. The records obtained through FGI's efforts will contribute significantly to an understanding of whether government activities undertaken for the stated purpose of advancing public health were accomplished in an objectively fair and legal way. This understanding is vital to our democratic system and will be significantly advanced by a timely and full response to FGI's request.

Thus, FGI meets this factor.

C. Disclosure of the requested records will contribute to the understanding by a reasonably broad audience.

In determining whether disclosure of requested information will contribute significantly to public understanding, a guiding consideration is whether the requester will disseminate the information to a reasonably broad audience of persons interested in the subject.[8] FGI need not show how it intends to distribute the information, because "nothing in FOIA, the [agency] regulation, or our case law require[s] such pointless specificity."[9] It is sufficient for FGI to show how it distributes information to the public generally.[10]

FGI is a non-partisan organization that informs, educates, and counsels the public about government operations. A key component in being able in to fulfill this mission is access to information about the activities and decisions of senior government officials. Once the information is obtained, FGI has robust mechanisms in place, including its website, social media channels, and other similar platforms, to share information with the general public and interested organizations. FGI intends to use its channels to publish the information from these requested records, along with expert analysis. FGI also has a broad network of reporters, bloggers, and media publications with interest in its content and with durable

[8] *Carney v U.S. Dept. of Justice*, 19 F.3d 807 (2nd Cir. 1994)
[9] *Judicial Watch*, 326 F.3d at 1314.
[10] Id.

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relationships with the organization. FGI intends to use these far-reaching media outlets to publicize information obtained from this request.

Through these means, FGI's dissemination of the information will:

1. Ensure that the information requested contributes significantly to the public's understanding of the government's operations or activities,
2. Ensure that the information enhances the public's understanding to a greater degree than currently exists,
3. Demonstrate that FGI possesses the expertise to explain the requested information to the public,
4. Demonstrate that FGI possesses the ability to make the requested information accessible to the general public, and
5. Demonstrate that the news media recognizes FGI as a reliable source in the relevant field.

Moreover, the public does not currently have an ability to easily evaluate the requested records. We are unaware of these records having been released to date.

Thus, FGI meets this factor.

2. OBTAINING THE REQUESTED RECORDS IS OF NO COMMERCIAL INTEREST TO FGI.

Disclosure is in no way connected with any commercial interest of the requestors. FGI is a non-partisan organization. FGI has no commercial interest and will realize no commercial benefit from the release of the requested records.

CONCLUSION

For all the foregoing reasons, FGI qualifies for a full fee waiver. We anticipate that HHS will immediately grant this fee waiver request and disclose the requested records in compliance with FOIA.

Thank you for your prompt attention to this request. If you have any questions, please contact me. All records and any related correspondence should be sent to my attention to the email address below.

Sincerely,

Chris Stanley

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