EXHIBIT B

FRIER LEVITT
ATTORNEYS AT LAW

Nicole M. DeWitt, Esq.
direct: 973. 852.8389
ndewitt@frierlevitt.com

October 30, 2019

U.S. Department of Health and Human Services, Deputy Agency Chief FOI Officer
Office of the Assistant Secretary for Public Affairs
Room 729H, 200 Independence Avenue SW.
Washington, D.C. 20201

SENT VIA U.S. MAIL & ELECTRONIC MAIL (FOIARequest@PSC.hhs.gov, Kim.Hutchinson@hhs.gov, Michael.Marquis@hhs.gov)

Re: Appeal of Determination FDA FOIA Request 2016-1341

On behalf of the Goldwater Institute ("Goldwater Institute") and pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, the Goldwater Institute hereby appeals the Food and Drug Administration's ("FDA") failure to make a determination on the Goldwater Institute's FOIA request, as is required by law.

Factual Background

On February 8, 2016, the Goldwater Institute submitted a FOIA request ("Request"), including a request for the waiver of all fees pursuant to 5 U.S.C. § 522(a)(4)(A)(iii), to the FDA. A copy of the Request is attached as "Exhibit 1".

The Request sought copies of all expanded access submissions and protocols that were allowed to proceed from ten (10) specified organizations and institutions, including those from providers rendering medical services or investigators as defined in 21 C.F.R. § 56.102(h). The Request also sought all single patient protocols, single patient emergency protocols, and intermediate size protocols from these approved expanded access submissions. Specifically, the Request sought the following:

> *Copies of all expanded access submissions and protocols that were allowed to proceed by the following list of requesting organizations, institutions, investigators or treating physicians at those organizations and institutions, including all single patient protocols, single patient emergency protocols, and intermediate size protocols for F12, FY13, FY14 and FY 15:*
>
> - *Memorial Sloan Kettering (MSK) Cancer Center, New York City, New York*
> - *University of Texas M.D. Anderson Cancer Center, Houston, Texas*
> - *Mayo Clinic, Rochester, Minnesota*
> - *Dana-Farber/Brigham and Women's Cancer Center, Boston, Massachusetts*
> - *Johns Hopkins Hospital, Baltimore Maryland*
> - *University of Washington Medical Center, Seattle, Washington*
> - *Massachusetts General Hospital, Boston, Massachusetts*

- *UCSF Medical Center, San Francisco, California*
- *UCLA Medical Center, Los Angeles, California*
- *Stanford Hospital and Clinics, Stanford, California*

If this information is available by the name of the requesting organization, institution, investigator, or treating physician in list format, we request that list. If no records exist identifying the requesting organization, institution, investigator, or treating physician in list format, then we request any other records indicating the name or identity of the requesting organization, institution, investigator or treating physician.

The Request included a request for a fee waiver because the Goldwater Institute is a nonprofit public policy organization that is seeking this information to contribute to the public's understanding of the FDA's expanded access submission approval process. Accordingly, none of the responsive records will be used for commercial purposes.

By letter dated February 19, 2016, the FDA confirmed receipt of the Request but made no determination regarding the documents the FDA intends to produce or withhold ("Response"). In that Response, the FDA did not indicate an estimated completion date or any "unusual circumstances" that would justify the continued withholding of the requested records or that would extend the date by which the FDA must make a determination on a request pursuant to 5 U.S.C. § 552(a)(6)(B)(i). A copy of the Response is attached as "Exhibit 2".

Thereafter, on or about June 22, 2016, approximately **four months** after receipt of the Request by the FDA, the Goldwater Institute was advised that the Request was number 40 in queue, which would require an additional six to eight months before the Request would be processed. The Goldwater Institute received this information via the designated contact at the FDA for the Request, Lotoya Lewis. At this time, the Goldwater Institute had not received any substantive communications from the FDA in response to the Request, such as the requested documents or information related to the scope of the documents the FDA intended to produce and withhold. A copy of internal e-mail correspondence related to the Request status is attached as "Exhibit 3".

On or about February 28, 2018, approximately **two years** after receipt of the Request by the FDA, the Goldwater Institute still had not received any substantive communications from the FDA in response to the Request, such as the requested documents or information related to the scope of the documents the FDA intended to produce and withhold. The Goldwater Institute inquired about the status of the Request via e-mail to Claire B. Stansbury and Paula Rohde at the FDA. On February 28, 2018, Ms. Rohde stated via e-mail "I asked CDER to provide an update. They should be contacting the requester in the next couple days." Please let me know on Monday, if your office has not heard from them." A copy of the February 28, 2018 e-mail correspondence with Ms. Stansbury and Ms. Rohde is attached as "Exhibit 4".

On February 28, 2018, the Goldwater Institute received e-mail correspondence from Eli Landy, Esq, Lead Regulatory Counsel at the Food and Drug Administration Center for Drug Evaluation and Research, with the status of the Request. Specifically, Mr. Landy stated:

> I understand that you have requested a status update about the status of your request and the estimated response time frame for your request. Currently, your request is 186 out of 541. Please be advised that the FDA processes requests on a first in, first out basis. Based on the breadth of this request and the complexity of the requests ahead of it in the queue, we estimate that it may take **18-24 months** to process this request.

This status update completely disregarded the previous two years in which the Request was in queue and the statutory deadline of twenty days to respond to a FOIA request absent unusual circumstances. *See* 5 U.S.C. § 552(a)(6)(B)(i). Moreover, despite Mr. Landy's assertion that FOIA requests are processed on a "first-in, first-out" basis, the status of the Request did not move up in line for processing from the 40th spot in June 2016 but, instead, moved down 146 spots to the number 186 of 541. Jonathan Riches, Director of National Litigation and General Counsel of the Goldwater Institute, notified the FDA of the Request's two-year decline in the processing queue via e-mail on February 28, 2018 stating in pertinent part that:

> This Request has been pending for **two years**. The statutory deadline for FOIA responses is **20 days**. Your agency has already greatly exceeded the timeframe for a response with neither a proper explanation ("too busy" is not one) or a waiver from us.
>
> As a factual matter, your assertion that our request is "186 out of 541" directly contravenes what your agency has previously represented. In June 2016, Latoya Lewis, a records processor at your agency, informed us that we were "40th in line". I find it inconceivable that in the course of two years, we have not only moved up in position, but somehow fallen 126 positions. Particularly if, as you assert, the agency has a policy of "first-in, first-out."

In addition to putting the FDA on notice of the unreasonable delay in providing any substantive information related to the Request, Mr. Riches also advised the FDA of Goldwater Institute's position with respect to limiting the scope of the Request on a short-term basis, despite disputing the assertion of the FDA for first time, two years after receipt, that the Request was complex. Specifically, Mr. Riches offered the following:

> In the interest of resolving this without litigation, if your agency is able to respond within 30 days, we will narrow out request to just the number of approved emergency access applications by the institutions referenced in our letter for FY15. We would expect the remaining documents to be promptly furnished thereafter.

The FDA did not reply *at all* to the e-mail dated February 28, 2018 from the Goldwater Institute. A copy of the February 28, 2018, March 13, 2018 and March 14, 2018 e-mail correspondence with Mr. Riches and Mr. Landy is attached as "Exhibit 5".

On March 13, 2018, the Goldwater Institute inquired about the status of the Request a third time in an e-mail to Mr. Landy of the FDA. On March 14, 2018, Mr. Landy replied stating that "[t]he request is currently 184 out of 578 of the CDER's queue. Please note that Latoya Lewis doesn't work in CDER but rather works in a different center, and consequently her response did not concern the CDER's queue." The e-mail dated March 14, 2018 did not indicate what queue Ms. Lewis' response, indicating that the Request was "40th in queue", referred to or the results of processing the Request in this queue, to the extent that there was, in fact, a different queue. The e-mail dated March 14, 2018 did not acknowledge the Goldwater Institute's dispute of the complexity of the Request or the offer to limit the scope of the Request if said documents were provided within thirty days. On March 14, 2018, the Goldwater Institute made a final inquiry via e-mail to Mr. Landy at the FDA seeking confirmation that this was the agency's final position regarding the Request and stating that "[i]f you are able to provide the records in a more timely manner, we are available to discuss." The FDA never responded to this e-mail. See Exhibit 5.

As of the date of this appeal, 1,360 days after the Goldwater Institute submitted the Request, no further communication from the FDA has been received, no determination has been made with respect to the Request, and no responsive records have been produced.

Argument

Under the FOIA, an agency is required to make a "determination" with regard to a public records request within twenty business days of its receipt. 5 U.S.C. § 552(a)(6)(A)(i). To satisfy this requirement, the agency "must at least: (i) gather and review the documents; (ii) determine and communicate the scope of the documents it intends to produce and withhold, and the reasons for withholding any documents; and (iii) inform the requester that it can appeal whatever portion of the 'determination' is adverse." *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 188 (D.C. Cir. 2013).

The FOIA allows an agency to extend the date by which it may make a determination by no more than "ten working days" in "unusual circumstances." 5 U.S.C. § 552(a)(6)(B)(i). Further "unusual circumstances" do not allow an agency to unduly delay release of records as "unusual circumstances" apply "only to the extent reasonably necessary to the proper processing of the particular requests." 5 U.S.C. § 552(a)(6)(B)(iii). Further, to the extent an agency cannot process a FOIA request within the statutory timeframe set forth in 5 U.S.C. § 552(a)(6)(A)(i), the agency must provide the requester "the opportunity to arrange with the agency an alternative time frame for processing the request or a modified request." 5 U.S.C. § 552(a)(6)(B)(ii).

Here, the Goldwater Institute submitted the Request on February 8, 2016. The FDA confirmed, by letter dated February 19, 2016, receipt of the Request. In this case, the FDA has failed to make a "determination" concerning the Goldwater Institute's Request within twenty business days, or even thirty business days, assuming *arguendo*, that the requests involve "unusual circumstances" as defined by the FOIA, which it does not. The agency received the Request, and acknowledged receiving the request three years and eight months ago. Because the FDA has failed to make a determination on the request, it has clearly violated FOIA's twenty-day statutory deadline. *See* 5 U.S.C. § 552(a)(6)(A)(i); *id.* § 552(a)(6)(B)(i); *id.* § 552(a)(6)(B)(iii)(III).

Indeed, an estimated completion date of 42 to 48 months, **approximately four years**, from receipt of the Request in February 2016, in which the FDA has failed to provide any substantive information whatsoever about the processing of the Request is not a delay "reasonably necessary to the proper processing of the particular requests." 5 U.S.C. § 552(a)(6)(B)(iii). The FDA has indicated that the Request has been pending in more than one queue, while it is unclear exactly which queue based on the lack of information provided by the FDA during the past three years. During this time, the FDA has not communicated the scope of the documents it intends to produce or withhold, communicated any reasons for the withholding of any documents, or produced any documents in response to the Request. The FDA has not responded to the Goldwater Institute's offer to modify the scope of the request or set an alternative timeframe for processing of the request. Thus, the agency is in violation of its statutory duties under FOIA. *See* 5 U.S.C. § 552(a)(6)(A)(i); *id.* § 552(a)(6)(B)(i); *id.* § 552(a)(6)(B)(iii)(III); *id.* 5 U.S.C. § 552(a)(6)(B)(iii).

Pursuant to the Department of Health and Human Services Regulations, upon receipt of a FOIA request, the FDA must advise the requester, either in the initial acknowledgement of receipt or in subsequent

communications, of "potential complicating factors … and, when appropriate, we will offer requesters an opportunity to narrow or modify their request so that it can be placed in the simple processing track." 45 C.F.R. § 5.24(e). Here, the FDA has not provided any information related to the estimated amount of work, such as the "number of records requested, the number of pages involved in processing the request, and the need for consultation or referrals." *Id.* In addition, a FOIA request with processing time of approximately four years would certainly be appropriate for modification to allow for processing on the simple queue. However, despite Goldwater Institute's offer to modify the Request, the FDA has not responded to the Goldwater Institute or otherwise provided the Goldwater Institute with an opportunity to narrow or modify the Request so that it can be placed in the simple processing queue. In addition, a request must be processed "in the order received, on a first-in, first-out basis, absent approval for expedited processing based upon a compelling need." *Id.* Here, the Request was number 40 in queue in June 2016, but then 186 in queue in February 2018. The Request's status in the queue indicates that the processing was not conducted on a "first-in, first-out basis" despite the obligation of the agency to do so under the regulations. Based on the foregoing, the FDA has repeatedly failed to comply with the Department of Department of Health and Human Services Freedom of Information Regulations with respect to processing of the Request as set forth in 45 C.F.R. § 5.24(e).

In addition, a fee waiver is appropriate in this case under 5 U.S.C. § 552(a)(4)(A)(ii), as well as by FDA regulations at 21 C.F.R. § 20.46 and Department of Health and Human Services' regulations at 45 C.F.R. § 5.54. First, the subject matter of the requested records obviously concerns the operations of government, as the FDA sets reviews and monitors expanded access submissions for investigational drugs. *See* 21 C.F.R. 312 Subpart I. Second, the disclosure of the requested records is likely to contribute to an understanding of federal government operations and activities that is not already public knowledge because the Goldwater Institute is a public policy organization that has been engaged in research and analysis on issues pertaining to government transparency and health care, including the FDA expanded access approval process. Third, disclosure of the requested records will contribute to an understanding of expanded access submissions and approval by the public at large, as evidenced by public comments on the expanded access program and right-to-try laws by Goldwater Institute personnel, national reporting on the matter, and published articles and policy reports by the Goldwater Institute.[1] Fourth, the contribution to the public understanding of federal government operations will be significant as the requested information relates to increased access to investigational drugs, a subject of nationwide importance reviewed by the Government Accountability Office and Congress[2], and the Goldwater Institute is a leading researcher and policy analyst on expanded access in the

[1] *See, e.g.,* Christina Corieri, "Everyone Deserve the Right to Try: Empowering the Terminally Ill to Take Control of their Treatment," *Goldwater Institute*, February 11, 2014, https://goldwaterinstitute.org/wp-content/uploads/cms_page_media/2015/1/29/Right%20To%20Try.pdf; "A National Right to Life A Proposal to help terminal patients past the FDA blockade." *Wall Street Journal,* February 26, 2017, https://www.wsj.com/articles/a-national-right-to-life-1488145977; Alison Rodriguez and Mary Caffrey, "Weighing the Merits of Right-to-Try Laws and FDA's Expanded Access Program," *American Journal of Managed Care,* February 28, 2018, https://www.ajmc.com/journals/evidence-based-oncology/2018/patient-centered-oncology-care-2017/weighing-the-merits-of-righttotry-laws-and-fdas-expanded-access-program;
Michael Mezher, "FDA to Launch Expanded Access Pilot 'Project Facilitate' by End of May," *Regulatory Affairs Professionals Society,* May 16, 2019, https://www.raps.org/news-and-articles/news-articles/2019/5/fda-to-launch-expanded-access-pilot-project-facil.

[2] *See, e.g.,* GAO, "Investigational New Drugs: FDA Has Taken Steps to Improve the Expanded Access Program but Should Further Clarify How Adverse Events Data Are Used, GAO-17-564 (Washington, D.C.: July 11,

United States. In addition to the Request furthering the public interest, the Request does not further any commercial interest under 21 C.F.R. § 20.46(c) as the Goldwater Institute is a nonprofit organization under 501(c)(3) of the federal tax code and the Request does not relate to any business, trade or profit of the Goldwater Institute.

Finally, the Goldwater Institute understands that because the FDA has failed to make a determination on the requested records within the statutory deadline, an administrative appeal is not required in this case in order to exhaust remedies prior to filing an action to compel the requested records in federal district court. 5 U.S.C. § 552(a)(6)(C)(i) ("Any person making a request to any agency for records under paragraph (1), (2), or (3) of this subsection shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions of this paragraph."); *see also Citizens for Responsibility & Ethics in Wash.,* 711 F.3d at 182 (finding that if an agency fails to comply with the determination time limit, the requester is viewed as having "fulfilled the exhaustion requirement."). This appeal is submitted as a courtesy to provide the FDA a final opportunity to provide responsive records as is required by law prior to the Goldwater Institute seeking an order to compel production in federal district court. 5 U.S.C. § 552(a)(6)(B)(i).

Conclusion

By failing to provide a determination with respect to the Goldwater Institute's Request within the statutory deadline, the FDA is in violation of its obligations under federal law.

Based on the foregoing, the Goldwater Institute requests that this appeal be granted and that all responsive records pertaining to the Goldwater Institute's FOIA request dated February 8, 2016 be released without delay.

The Goldwater Institute further requests that a fee waiver be granted pursuant to 5 U.S.C. § 552(a)(4)(A)(ii) and 21 C.F.R. § 20.46.

Should you have any questions regarding this appeal, please do not hesitate to contact me at 973-852-8389 or ndewitt@frierlevitt.com.

I look forward to your determination with respect to this appeal within twenty business days. 5 U.S.C. § 552(a)(6)(A)(ii).

Very truly yours,

FRIER & LEVITT

/s/ Nicole DeWitt

Nicole M. DeWitt, Esq.

2017); GAO, "Investigational Drugs FDA and Drug Manufacturers Have Ongoing Efforts to Facilitate Access for Some Patients," GAO-19-630 (Washington, D.C.: September 2019).

Exhibit 1

GOLDWATER
INSTITUTE

February 8, 2016

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Freedom of Information Act Request for records

On behalf of the Scharf-Norton Center for Constitutional Litigation at the Goldwater Institute (the "**Goldwater Institute**") and pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, this correspondence is a request for records, regardless of format, medium or physical characteristics.

Specifically, we seek the following documents and records:

Copies of all expanded access submissions and protocols that were allowed to proceed by the following list of requesting organizations, institutions, investigators or treating physicians at those organizations and institutions, including all single patient protocols, single patient emergency protocols, and intermediate size protocols for FY 12, FY 13, FY 14, and FY15:

- *Memorial Sloan Kettering (MSK) Cancer Center, New York City, New York*
- *University of Texas M.D. Anderson Cancer Center, Houston, Texas*
- *Mayo Clinic, Rochester, Minnesota*
- *Dana-Farber Brigham and Women's Cancer Center, Boston, Massachusetts*
- *Johns Hopkins Hospital, Baltimore, Maryland*
- *University of Washington Medical Center, Seattle, Washington*
- *Massachusetts General Hospital, Boston, Massachusetts*
- *UCSF Medical Center, San Francisco, California*
- *UCLA Medical Center, Los Angeles, California*
- *Stanford Hospital and Clinics, Stanford, California*

If this information is available by the name of the requesting organization, institution, investigator, or treating physician in list format, we request that list. If no records exist identifying the requesting organization, institution, investigator, or treating physician in list format, then we request any other records indicating the name or identity of the requesting organization, institution, investigator or treating physician.

Electronic production of records and information is acceptable. If the records are produced electronically, please include all associated metadata. If you refer me to a website containing responsive records, please specify the precise web address where they may be found.

Please note that the Goldwater Institute is a not-for-profit 501(c)(3) organization. As such, no responsive records will be used for a commercial purpose. Therefore, we respectfully request a

waiver of all fees associated with the production of responsive records pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) which reads as follows:

"Documents shall be furnished without any charge or at a charge reduced below the fees established under clause (ii) if disclosure of the 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 is not primarily in the commercial interest of the requester."

The Goldwater Institute conducts research and analysis on issues pertaining to government transparency and health care, among others. The Goldwater Institute is currently engaged in research and analysis pertaining to the FDA drug approval process. This information will be used to aid in that research and analysis and is expected to contribute to the public's understanding of the drug approval process in the United States.

Should our request for a waiver be denied, we are willing to pay fees for this request up to one hundred dollars ($100.00). If you estimate that fees will exceed this amount, please inform me first.

I request your response within the statutory timeframe of twenty (20) business days. If you are unable to complete the request within that time, please contact me with your progress and expected completion date.

Please mail responsive records to the mailed address above or e-mail address below.

If you deny access to any of the above public records, please provide forthwith a written statement of the express grounds for the denial, citing the law or regulation under which access is denied.

If you have any questions about this request or foresee any problems in fully releasing the requested records please contact me as soon as possible. I can be reached at 602-462-5000 or jriches@goldwaterinstitute.org.

Thank you for your prompt attention to this request.

Sincerely,

Jon Riches
Director of National Litigation and General Counsel

Exhibit 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

GOLDWATER INSTITUTE
JON RICHES
500 EAST COLORADO RD
PHOENIX AZ 85004 USA

02/19/2016

In Reply refer to:

2016-1341

Your reference:

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

MEMORIAL SLOAN KETTERING CANCER CTR, NEW YORK, NY; MAYO CLINIC, ROCHESTER, NY; JOHNS HOPKINS HOSPITAL, BALTIMORE, MD, ETC - ACCESS SUBMISSIONS AND PROTOCOLS FY12 TO FY15

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact the undersigned to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

If you have any questions about your request, please call Claire B. Stansbury, Information Technician, at (301) 796-8979 or write to us at:

Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the reference number above which will help us to answer your questions more quickly.

Sincerely,

Claire B. Stansbury
Information Technician

Exhibit 3

From: Naomi Lopez-Bauman <nlopez-bauman@goldwaterinstitute.org>
Sent: Wednesday, June 22, 2016 11:18 AM
To: Jonathan Riches <jriches@goldwaterinstitute.org>
Cc: Christina Sandefur <csandefur@goldwaterinstitute.org>
Subject: FDA FOIA update

The FOIA request asking for the number of compassionate use applications from the nation's leading hospitals is about 40th in line right now. That could mean about 6 to 8 more months before it reaches the top of the queue for processing.

FDA contact: Lotoya Lewis, 301-796-3651

FOIA request: 2016-1341

Naomi Lopez Bauman
Director of Healthcare Policy
Goldwater Institute | www.GoldwaterInstitute.org | 602.462.5000

"The Goldwater Institute is simply in the liberty business, and there's no institution in the country that performs that business better." – George Will

Exhibit 4

Jonathan Riches

From: Rohde, Paula <Paula.Rohde@fda.hhs.gov>
Sent: Wednesday, February 28, 2018 1:13 PM
To: Kelly Day; Stansbury, Claire B
Cc: Jonathan Riches
Subject: RE: Freedom of Information Act Request 2016-1341

I asked CDER to provide an update. They should be contacting the requester in the next couple of days. Please let me know on Monday, if your office has not heard from them.

From: Kelly Day [mailto:Kday@goldwaterinstitute.org]
Sent: Wednesday, February 28, 2018 2:39 PM
To: Stansbury, Claire B <Claire.Stansbury@fda.hhs.gov>
Cc: Rohde, Paula <Paula.Rohde@fda.hhs.gov>; Jonathan Riches <jriches@goldwaterinstitute.org>
Subject: Freedom of Information Act Request 2016-1341

Please see attached re the Freedom of Information Act Request 2016-1341.

Kelly Day
Legal Assistant | Office Administrator
Goldwater Institute
kday@goldwaterinstitute.org | **602.633.8972**
www.GoldwaterInstitute.org

Ask me about the American Freedom Network – our pro bono program for lawyers who care about liberty!

"The Goldwater Institute is simply in the liberty business, and there's no institution in the country that performs that business better." – George Will

GOLDWATER INSTITUTE

February 28, 2018

Food and Drug Administration
Division of Freedom of Information
Attn: Claire Stansbury
5630 Fishers Lane, Room 1035
Rockville, MD 20857
Claire.Stansbury@fda.hhs.gov

Re: Freedom of Information Act Request 2016-1341

On February 8, 2016, the Goldwater Institute ("Institute") submitted the attached Freedom of Information Act (FOIA), 5 U.S.C. § 552, request to your office.

Your office acknowledged receipt on February 19, 2016.

This request remains unfilled and no responsive records have been provided to the Institute.

As you know, under the FOIA there is a statutory deadline of twenty (20) business days to respond to public records requests. This request has now been "pending" for 739 days.

Please promptly provide the records requested. If you deny access to any of the above public records, please provide a written statement of the express grounds for the denial, citing the law or regulation under which access is denied.

Please note that if the requested records are not promptly furnished, or if there is continued delay on this request, or our organization will file an action for injunctive and other appropriate relief in federal district court.

If you have any questions about this request or foresee any problems in fully releasing the requested records as soon as practicable, please contact me at (602) 462-5000 or jriches@goldwaterinstitute.org.

Thank you for your prompt attention to this matter.

Sincerely,

Jon Riches
General Counsel
Scharf-Norton Center for Constitutional Litigation
at the Goldwater Institute

cc: Paula Rohde, Paula.Rohde@fda.hhs.gov

GOLDWATER
INSTITUTE

February 8, 2016

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Freedom of Information Act Request for records

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- *University of Texas M.D. Anderson Cancer Center, Houston, Texas*
- *Mayo Clinic, Rochester, Minnesota*
- *Dana-Farber Brigham and Women's Cancer Center, Boston, Massachusetts*
- *Johns Hopkins Hospital, Baltimore, Maryland*
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- *Massachusetts General Hospital, Boston, Massachusetts*
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- *UCLA Medical Center, Los Angeles, California*
- *Stanford Hospital and Clinics, Stanford, California*

If this information is available by the name of the requesting organization, institution, investigator, or treating physician in list format, we request that list. If no records exist identifying the requesting organization, institution, investigator, or treating physician in list format, then we request any other records indicating the name or identity of the requesting organization, institution, investigator or treating physician.

Electronic production of records and information is acceptable. If the records are produced electronically, please include all associated metadata. If you refer me to a website containing responsive records, please specify the precise web address where they may be found.

Please note that the Goldwater Institute is a not-for-profit 501(c)(3) organization. As such, no responsive records will be used for a commercial purpose. Therefore, we respectfully request a

waiver of all fees associated with the production of responsive records pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) which reads as follows:

"Documents shall be furnished without any charge or at a charge reduced below the fees established under clause (ii) if disclosure of the 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 is not primarily in the commercial interest of the requester."

The Goldwater Institute conducts research and analysis on issues pertaining to government transparency and health care, among others. The Goldwater Institute is currently engaged in research and analysis pertaining to the FDA drug approval process. This information will be used to aid in that research and analysis and is expected to contribute to the public's understanding of the drug approval process in the United States.

Should our request for a waiver be denied, we are willing to pay fees for this request up to one hundred dollars ($100.00). If you estimate that fees will exceed this amount, please inform me first.

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Please mail responsive records to the mailed address above or e-mail address below.

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Thank you for your prompt attention to this request.

Sincerely,

Jon Riches
Director of National Litigation and General Counsel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

GOLDWATER INSTITUTE
JON RICHES
500 EAST COLORADO RD
PHOENIX AZ 85004 USA

02/19/2016

In Reply refer to:

2016-1341

Your reference:

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

MEMORIAL SLOAN KETTERING CANCER CTR, NEW YORK, NY; MAYO CLINIC, ROCHESTER, NY; JOHNS HOPKINS HOSPITAL, BALTIMORE, MD, ETC - ACCESS SUBMISSIONS AND PROTOCOLS FY12 TO FY15

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact the undersigned to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

If you have any questions about your request, please call Claire B. Stansbury, Information Technician, at (301) 796-8979 or write to us at:

Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the reference number above which will help us to answer your questions more quickly.

Sincerely,

Claire B. Stansbury
Information Technician

Exhibit 5

Jonathan Riches

From: Jonathan Riches
Sent: Wednesday, March 14, 2018 9:11 AM
To: Landy, Eli
Subject: Re: FDA FOIA No. 2016-1341

Eli,

Unfortunately, a four-year response timeframe is not acceptable under any circumstances, and particularly not acceptable when the statutory *requirement* is 20 days.

Please let me know if this is the FDA's final response, and we will seek to compel production. If you are able to provide the records in a more timely manner, we are available to discuss.

Regards,

Jon Riches
Director of National Litigation & General Counsel
Goldwater Institute | www.GoldwaterInstitute.org | 602.462.5000

"The Goldwater Institute is simply in the liberty business, and there's no institution in the country that performs that business better." – George Will

From: "Landy, Eli" <Eli.Landy@fda.hhs.gov>
Date: Wednesday, March 14, 2018 at 8:37 AM
To: Jonathan Riches <jriches@goldwaterinstitute.org>
Subject: RE: FDA FOIA No. 2016-1341

Mr. Riches,

This request is currently 184 out of 578 in CDER's queue. Please note that Latoye Lewis doesn't work in CDER but rather works in a different Center, and consequently her response did not concern CDER's queue.

Eli Landy
Lead Regulatory Counsel
Food and Drug Administration
Center for Drug Evaluation and Research
10001 New Hampshire Avenue
HILL-3120
Silver Spring, MD 20993-0002
301-796-2697

From: Jonathan Riches [mailto:jriches@goldwaterinstitute.org]
Sent: Tuesday, March 13, 2018 11:39 AM
To: Landy, Eli <Eli.Landy@fda.hhs.gov>
Cc: Kelly Day <Kday@goldwaterinstitute.org>
Subject: Re: FDA FOIA No. 2016-1341

Eli,

What is the status of this request?

Regards,

Jon Riches
Director of National Litigation & General Counsel
Goldwater Institute | www.GoldwaterInstitute.org | 602.462.5000

"The Goldwater Institute is simply in the liberty business, and there's no institution in the country that performs that business better." – George Will

From: Jonathan Riches <jriches@goldwaterinstitute.org>
Date: Wednesday, February 28, 2018 at 4:24 PM
To: "Eli.Landy@fda.hhs.gov" <Eli.Landy@fda.hhs.gov>
Cc: Kelly Day <Kday@goldwaterinstitute.org>
Subject: RE: FDA FOIA No. 2016-1341

Mr. Landy,

Unfortunately, your response to our inquiry, attached here, is unsatisfactory.

This request has been pending for over **two years**. The statutory deadline for FOIA responses is **20 days**. Your agency has already greatly exceeded the timeframe for a response with neither a proper explanation ("too busy" is not one), nor a waiver from us.

As a factual matter, your assertion that our request is "186 out of 541" directly contravenes what your agency has previously represented. In June 2016, Lotoya Lewis, a records processor at your agency, informed us that we were "40th in line." I find it inconceivable that in the course of two years, we have not only not moved up in position, but somehow fallen 126 positions. Particularly if, as you assert, the policy of the agency is "first-in, first-out."

From the date of this e-mail, we will provide the agency 30 days to provide a written response to our records request. If a response is not received in that time period, we will file a complaint in U.S. District Court to compel production of the records requested.

Despite your assertion, our records request is straightforward and noncomplex. The information we seek should be readily available.

In the interest of resolving this without litigation, if your agency is able to respond within 30 day, we will narrow our request to just the number of approved emergency access applications by the institutions referenced in our letter for FY15. We would expect the remaining records to be promptly furnished thereafter.

I am available to discuss this matter with you at your convenience.

Best,

Jon Riches
Director of National Litigation & General Counsel
Goldwater Institute | www.GoldwaterInstitute.org

"The Goldwater Institute is simply in the liberty business, and there's no institution in the country that performs that business better." – George Will

From: Landy, Eli [mailto:Eli.Landy@fda.hhs.gov]
Sent: Wednesday, February 28, 2018 1:11 PM
To: Kelly Day <Kday@goldwaterinstitute.org>
Subject: FDA FOIA No. 2016-1341

Good afternoon Ms. Day,

I understand that you have requested a status update and estimated response time frame for your request. Currently, your request is 186 out of 541. Please be advised that the FDA processes requests on a first-in, first-out basis. Based on the breadth of this request and the complexity of the requests ahead of it in the queue, we estimate it may take 18-24 months to process this request.

Eli Landy
Lead Regulatory Counsel
Food and Drug Administration
Center for Drug Evaluation and Research
10001 New Hampshire Avenue
HILL-3120
Silver Spring, MD 20993-0002
301-796-2697