EXHIBIT E

PART 1

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May 8, 2020

U.S. Department of Health and Human Services,
Deputy Agency Chief FOI Officer
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201

SENT VIA U.S. MAIL & ELECTRONIC MAIL (FOIARequest@hhs.gov)

Re: FDA FOIA Request No. 2016-1341 and Ref No. 2020-00010-A-PHS.
Request for Expedited Processing

To Whom It May Concern:

On behalf of the Goldwater Institute ("Goldwater Institute") and pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552(A)(6)(E)(i), the Goldwater Institute hereby requests expedited processing and demands a response to the request within ten (10) business days, 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:*
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> - *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.

After several futile attempts to obtain information or otherwise narrow the scope of the Request to obtain some of the responsive information during a three (3) year time period, Goldwater Institute was left with no choice but to file an administrative appeal. On or about October 30, 2019, Goldwater Institute submitted a FOIA appeal, for the FDA's failure to make a determination on the Goldwater Institute's FOIA request, submitted on February 8, 2016 ("Constructive Denial Appeal"). A copy of the Constructive Denial Appeal, detailing Goldwater Institute's numerous attempts to obtain information, is attached as "Exhibit 2". On or about November 5, 2019, the FDA acknowledged receipt of the administrative appeal ("Appeal Acknowledgement Letter"). A copy of the Appeal Acknowledgement Letter is attached as "Exhibit 3".

Thereafter, despite numerous e-mail requests for information regarding the processing of the Request and Constructive Denial Appeal in the months that followed ("Follow-up Correspondence"), no information was provided. A copy of the Follow-up Correspondence is attached as "Exhibit 4". Notably, in the Constructive Denial Appeal, the Goldwater Institute appealed the agency's failure to properly process the Request in accordance with its duties under applicable statutes and regulations by highlighting the FDA's failure to communicate the scope of the documents it intends to produce or withhold or otherwise respond to Goldwater Institute's offer to modify the scope of the request. *See* Exhibit 2 at 4 (citing 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); 45 C.F.R. § 5.24(e)). Despite Goldwater Institute's notice of the FDA's failure to appropriately process the request in the Constructive Denial Appeal, the deficiencies have not been cured in the past four (4) years that the Request has been pending. The Agency's delays in this regard are not "reasonably necessary to the proper processing of the particular requests." 5 U.S.C. § 552(a)(6)(B)(iii).

On April 15, 2020, Goldwater Institute received a response to the Constructive Denial Appeal from the Department of Health and Human Services ("HHS") remanding the Request back to the FDA for completion ("Appeal Response"). A copy of the Appeal Response is attached as "Exhibit 5".
The Appeal Response stated that "[b]ecause the actions necessary to complete your request are yet to be accomplished, I am remanding this request back to the FDA for completion." Exhibit 4 at 1. The Appeal Response further provided that the "FDA has placed your request in the complex processing queue and estimates that your request will be completed by November of 2020." *Id.* The Appeal Response did not provide any information about the scope of the documents the FDA intends to

produce or withhold or otherwise respond to Goldwater Institute's offer to modify the scope of the request. *See id.* As a result of the Appeal Response, the FDA's processing of the Request under the complex processing queue would not result in any information whatsoever until potentially upwards of **five years** after the initial submission in February 2016. Moreover, the Appeal Response acknowledged that the FDA may ultimately deny the Request, in which Goldwater Institute would submit yet another administrative appeal.

Meanwhile, the public's need for information related to the processing of expanded access requests have become critical while the nation and the world respond to the COVID-19 public health crisis. To date, more than 800,000 cases of COVID-19 have been reported in the United States, with 44,575 deaths.[1] Pharmaceutical companies are ceaselessly working with global health leaders and U.S. government agencies, including but not limited to the FDA, to successfully complete accelerated clinical trials for a vaccine and other therapies to combat the deadly disease.[2] On April 17, 2020, a partnership among public and private entities, also known as Accelerating COVID-19 Therapeutic Interventions and Vaccines ("ACTIV"), was announced to "develop a collaborative framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes and/or leveraging assets among all partners to rapidly respond to the COVID-19 and future pandemics."[3] Government agency participants include HHS and FDA, in addition to National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC") and the European Medicines Agency ("EMA").[4]

In these unprecedented times, in addition to daily press releases[5] and publication of numerous COVID-19 guidance documents[6], the FDA is taking several measures to allow patients access to potentially life-saving drugs and therapies through, in part, the Expanded Access program[7]. By way of example and not limitation, on April 3, 2020, the FDA announced a national effort to accelerate the development of, and access to, two investigational therapies, convalescent plasma and hyperimmune globulin, derived from human blood from individuals who have recovered from the virus.[8] In this press release, the FDA acknowledged the importance of the expanded access program to evaluate the

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[1] *Coronavirus: What You Need to Know*, NATIONAL GOVERNORS ASSOCIATION, https://www.nga.org/coronavirus/#current (last accessed April 22, 2020).

[2] *See, e.g. Gilead Sciences Update to the Company's Ongoing Response to COVID-19,* GILEAD SCIENCES, INC., https://www.gilead.com/purpose/advancing-global-health/covid-19 (last visited April 22, 2020); *see also HHS Accelerates Clinical Trials, Prepares for Manufacturing of COVID-19 Vaccines,* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://www.hhs.gov/about/news/2020/03/30/hhs-accelerates-clinical-trials-prepares-manufacturing-covid-19-vaccines.html (last visited April 22, 2020).

[3] *NIH to launch public-private partnership to speed COVID-19 vaccine and treatment options,* NATIONAL INSTITUTES OF HEALTH, https://www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-covid-19-vaccine-treatment-options (last visited on April 22, 2020).

[4] *Id.*

[5] *See, e.g. Coronavirus Disease 2019 (COVID-19),* U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19#new (last visited on April 23, 2020).

[6] *COVID-19 Related Guidance Documents for Industry, FDA Staff and Other Stakeholders,* U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders (last visited on April 23, 2020).

[7] *See, e.g. FDA Combating COVID-19 with Therapeutics,* U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/media/136832/download (last visited on April 23, 2020).

[8] *FDA News Release: Coronavirus (COVID-19) Update: FDA Coordinates National Effort to Develop Blood-Related Therapies for COVID-19,* U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-coordinates-national-effort-develop-blood-related-therapies-covid-19 (last visited on April 23, 2020).

efficacy of plasma therapies.[9] On April 13, 2020, the FDA published *Investigational COVID-19 Convalescent Plasma; Guidance for Industry* to provide nonbinding recommendations to health care providers and investigators on the administration and study of investigational convalescent plasma collected from individuals who have recovered from COVID-19.[10] Therein, the FDA provides that for "patients with serious or immediately life-threatening COVID-19 who are not eligible for or who are unable to participate in randomized clinical trials, access to this investigational product may be available through participation of acute care facilities in an investigational expanded access protocol under an IND that is already in place."[11] One expanded access protocol in place for the use of plasma to treat COVID-19 is through collaboration with the Mayo Clinic, one of the institutions Goldwater Institute is seeking information in its Request.[12]

As additional unapproved therapies become available, more potential options are available for patients through the FDA's Expanded Access Program to combat COVID-19. By way of example and not limitation, the FDA has allowed for the study of remdesivir through clinical trials and under a multi-patient expanded access program coordinated by Gilead.[13] At present, there are more than a thousand clinical trials reported in a rapidly evolving response to the disease.[14] As stated just yesterday by U.S. Senator Mike Enzi, R-Wyo., to the FDA Commissioner Stephen Hahn in the context of the FDA's treatment of unapproved drugs in the Emergency Use Authorization ("EUA") program, "FDA's role as the gatekeeper to the United States' prescription drug marketplace is rarely so visible as it is now. As such, it is imperative that the public have a clear understanding of how FDA will implement its congressionally-delegated responsibilities and steer qualified therapies through regulatory hurdles on the basis of strong scientific evidence."[15] Transparency into the operations of the FDA is critical now, more than ever before. Whether an unapproved therapeutic is made available to a patient with an immediately life-threatening disease or condition under close physician supervision in a hospital setting via an EUA or outside a hospital setting through a physician prescription under an Expanded Access Investigational New Drug ("IND") protocol, the public has a right to know how access is granted to these drugs by the FDA.

Legal Argument

Under FOIA, the FDA is required to grant a request for expedited processing if the requester "demonstrates a compelling need." 5 U.S.C. § 552(A)(6)(E)(i). The requester may demonstrate a "compelling need" by showing either (1) that the requester is a "person primarily engaged in disseminating information" and that an "urgency to inform the public concerning actual or alleged

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[9] *Id.*
[10] *Investigational COVID-19 Convalescent Plasma Guidance for Industry,* U.S. FOOD & DRUG ADMINISTRATION, *available at* https://www.fda.gov/media/136798/download (last visited on April 23, 2020).
[11] *Id.* at 3. *See also* Exhibit 1.
[12] *Id. at 3; see also COVID-19 Expanded Access Program Plasma Donors Needed for Treatment Protocol*, https://www.uscovidplasma.org/ (last accessed April 29, 2020).
[13] *See Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment*, U.S. FOOD & DRUG ADMINISTRATION, *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment (last visited on May 6, 2020).
[14] *See COVID-19 Search,* NIH U.S. NATIONAL LIBRARY OF MEDICINE, *available at* https://clinicaltrials.gov/ct2/results?cond=COVID-19 (last visited May 6, 2020).
[15] *See Enzi questions FDA on plan to implement emergency use of COVID-19 drugs,* U.S. SENATOR FOR WYOMING MIKE ENZI, May 5, 2020, *available at* https://www.enzi.senate.gov/public/index.cfm/news-releases?ID=2EED6725-8726-4586-8097-850013CF2344 (last visited May 6, 2020).

Federal Government activity" exists; or (2) "that a failure to obtain requested records on an expedited basis … could reasonably be expected to pose an imminent threat to the life or physical safety of an individual." 5 U.S.C. § 552(A)(6)(E)(v).

I. The Evidence Demonstrates That Goldwater Institute Is Primarily Engaged in Disseminating Information to the General Public and That an Urgency to Inform the Public About the FDA's Expanded Access Program Exists

Under the FDA's regulations, in order to demonstrate a compelling need for expedited process by a "person primarily engaged in disseminating information" and that an "urgency to inform the public concerning actual or alleged Federal Government activity" exists, the requestor must show that: (1) "[t]he requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;" (2) "[t]here is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information;" and (3) "[t]he request for records specifically concerns identifiable operations or activities of the Federal Government." 21 C.F.R. § 20.44(c).

First, the Goldwater Institute is primarily engaged in disseminating information to the general public and not to a narrow interest group. Goldwater Institute is Goldwater Institute is a public policy research and litigation organization that is dedicated to empowering all Americans to live freer, happier lives, with specific focus on education, free speech, healthcare, equal protection, property rights, occupational licensing, and constitutional limits.[16] Since its establishment in almost thirty-two years ago, the Goldwater Institute has published information and secured victories on a wide range of issue such as Arizona state tax reform, Indiana's adoption of open school enrollment, protection of free speech under the First Amendment and the right to earn a living.[17] As it relates to healthcare generally, the Goldwater Institute regularly publishes articles and comments on pertinent issue, including but not limited to the FDA expanded access approval process, affecting a wide range of patients and providers.[18] In addition, the Goldwater Institute regularly publishes articles of widespread applicability for various issues, from faced by the public in the face of the COVID-19 pandemic.[19]

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[16] *About the Goldwater Institute,* GOLDWATER INSTITUTE, *available at* https://goldwaterinstitute.org/about/ (last visited on May 7, 2020).
[17] *30 Milestones for 30 Years of Advancing Freedom,* GOLDWATER INSTITUTE, *available at* https://goldwaterinstitute.org/30years/ (last visited on May 7, 2020).
[18] *See, e.g. Trump Drug Pricing Plan Should Remove Barriers that Can Unleash Price Transparency and Competition,* May 11, 2018, IN DEFENSE OF LIBERTY THE LATEST NEWS FROM THE GOLDWATER INSTITUTE, *available at* https://indefenseofliberty.blog/2018/05/11/trump-drug-pricing-plan-should-remove-barriers-that-can-unleash-price-transparency-and-competition/ (last visited on May 7, 2020); *Why Doesn't the Surgeon General Seek FDA Reclassification of Naloxone to OTC?,* April 18, 2018, IN DEFENSE OF LIBERTY THE LATEST NEWS FROM THE GOLDWATER INSTITUTE, *available at* https://indefenseofliberty.blog/2018/04/18/why-doesnt-the-surgeon-general-seek-fda-reclassification-of-naloxone-to-otc/ (last visited on May 7, 2020); *Why Illinois Healthcare Consumers Should be Relieved,* August 28, 2018, IN DEFENSE OF LIBERTY THE LATEST NEWS FROM THE GOLDWATER INSTITUTE, *available at* https://indefenseofliberty.blog/2018/08/28/why-illinois-healthcare-consumers-should-be-relieved/ (last visited on May 7, 2020); *A More Direct Future for Primary Healthcare?,* August 28, 2018, IN DEFENSE OF LIBERTY THE LATEST NEWS FROM THE GOLDWATER INSTITUTE, *available at* https://indefenseofliberty.blog/2019/08/28/a-more-direct-future-for-primary-healthcare/ (last visited on May 7, 2020); *New Report: This "Failed Public Policy" is Blocking Better Healthcare,* February 28, 2020, IN DEFENSE OF LIBERTY THE LATEST NEWS FROM THE GOLDWATER INSTITUTE, *available at* https://indefenseofliberty.blog/2020/02/28/new-report-this-failed-public-policy-is-blocking-better-healthcare/ (last visited on May 7, 2020).
[19] *See, e.g. Coronavirus Creates a Slippery Slope for Elections,* April 7, 2020, IN DEFENSE OF LIBERTY THE LATEST NEWS FROM THE GOLDWATER INSTITUTE, *available at* https://indefenseofliberty.blog/2020/04/07/coronavirus-creates-a-slippery-slope-for-elections/ (last

Second, there is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly. Information about the processing of expanded access submissions by the FDA is critical for patients, providers and other stakeholders to make optimal use of the program for therapies that are currently, and potentially available in the next year. Patients with COVID-19 experience symptoms within 2 – 14 days, manifesting with serious and life-threatening conditions requiring hospitalization for some patients.[20] With forecasting of state and national cumulative death rates being done by the week and thousands of new cases being reported each day, patients simply do not have the luxury of time to wait for access to an unapproved drug through the expanded access program.[21] This information will inform the public regarding the expanded access program while patients consider their options for treatment with unapproved therapeutics to fight the virus.[22]

Third, the request for records specifically concerns identifiable operations or activities of the Federal Government. The FDA's role in review of expanded access submissions, in which it either grants or denies patient access to a drug, is one of the core functions of the FDA. As part of this decision, the FDA must determine the following: (1) that the patient (or patients) to be treated has a serious or life-threatening disease or condition; (2) that there is no comparable or satisfactory therapy to diagnose, monitor, or treat the disease or condition; (3) that the patients cannot get the medical product under another investigational medical product study or protocol; (4) that the possible benefits

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visited on May 7, 2020); *Coronavirus: The Medicaid Expansion Heats Up Again,* April 8, 2020, IN DEFENSE OF LIBERTY THE LATEST NEWS FROM THE GOLDWATER INSTITUTE, *available at* https://indefenseofliberty.blog/2020/04/08/coronavirus-the-medicaid-expansion-debate-heats-up-again/ (last visited on May 7, 2020); *This Reform Should Top Every State Legislature's Economic Recovery Agenda,* April 15, 2020, IN DEFENSE OF LIBERTY THE LATEST NEWS FROM THE GOLDWATER INSTITUTE, *available at* https://indefenseofliberty.blog/2020/04/15/this-reform-should-top-every-state-legislatures-economic-recovery-agenda/ (last visited on May 7, 2020); *How to Increase the Number of Healthcare Workers When We Need Them Most,* April 16, 2020, IN DEFENSE OF LIBERTY THE LATEST NEWS FROM THE GOLDWATER INSTITUTE, *available at* https://indefenseofliberty.blog/2020/04/16/how-to-increase-the-number-of-healthcare-workers-when-we-need-them-most/ (last visited on May 7, 2020).

[20] *See, e.g., Symptoms of Coronavirus,* CENTERS FOR DISEASE CONTROL AND PREVENTION, *available at* https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html (last visited on May 7, 2020).

[21] *See, e.g., Cases in the U.S.,* CENTERS FOR DISEASE CONTROL AND PREVENTION, *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html (last visited on May 7, 2020); *Interpretation of Cumulative Death Forecasts,* CENTERS FOR DISEASE CONTROL AND PREVENTION, *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/forecasting-us.html (last visited on May 7, 2020). *See also,* Naomi Lopez Bauman, *A Glimmer of Hope in the Treatment of Coronavirus?,* GOLDWATER INSTITUTE, *available at* https://indefenseofliberty.blog/2020/04/14/a-glimmer-of-hope-in-the-treatment-of-coronavirus/ (last visited on May 7, 2020)("There has been much discussion about the importance of only allowing COVID-19 treatments outside of clinical trials if broad data collection is in place. . . It is understandable that there is a strong desire for more data both for patient safety and for more certainty around treatments. But the big trade-off is time—making the perfect data the enemy of a treatment delivered in time. At a time when lives hang in the balance, it doesn't make sense that a desire for more or more perfect data stand in the way of what a doctor thinks is best for their patient.).

[22] *See, e.g.,* Christina Sandefur, *What Role Should the Government Play in Patients' Access to Coronavirus Treatments?,* GOLDWATER INSTITUTE, *available at* https://indefenseofliberty.blog/2020/04/09/what-role-should-the-government-play-in-patients-access-to-coronavirus-treatments/ (last visited on May 7, 2020)("Fortunately, Right to Try has given the FDA a new mandate to meet the immediate needs of patients facing life-threatening illness. Federal agencies are finally expanding approval for diagnostic tests and labs. The FDA has granted emergency authorization to make possible treatments available from the Strategic National Stockpile, a federally operated supply of medicine for use in public health emergencies. The Agency also just announced a new accelerated program to help expedite the clinical evaluation of potential vaccines and treatments. And as treatments are discovered and developed, patients are going to have more options to try those treatments than ever before.")
Right to Try has changed the way we think about what role the government should—and shouldn't—play in determining whether a patient should have access to a potential treatment. The coronavirus crisis is demonstrating the importance of this new mindset.).

to the patient justify the possible risks of the treatment, and those possible risks are not unreasonable given the disease or condition to be treated; (5) that providing the investigational medical production will not interfere with the clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access product.[23]

Based on the foregoing, the Goldwater Institute has demonstrated a compelling need for the expedited processing of the Request under FOIA because the Goldwater Institute is a "person primarily engaged in disseminating information" and that an "urgency to inform the public concerning actual or alleged Federal Government activity" exists. 5 U.S.C. § 552(A)(6)(E)(v). *See also* 21 C.F.R. § 20.44(c).

II. Goldwater Institute is Entitled to Expedited Processing of the February 8, 2016 FOIA Request Because There Is an Imminent Threat to the Life or Safety of an Individual

As seen in Section II, the Goldwater Institute has demonstrated a compelling need for the expedited processing of the Request under FOIA because "that a failure to obtain requested records on an expedited basis … could reasonably be expected to pose an imminent threat to the life or physical safety of an individual." 5 U.S.C. § 552(A)(6)(E)(v). COVID-19 is projected to take thousands of more lives in the weeks and months to come.[24] COVID-19 patients considering participation in the expanded access program have immense knowledge and benefit to gain in the fight of their lives, whether an expanded access submission is for access to plasma therapies through the FDA's collaboration with the Mayo Clinic or otherwise as additional unapproved therapeutics become available for potential use.

III. Goldwater Institute Is Entitled to A Fee Waiver for Processing of the February 8, 2016 FOIA Request

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.[25] Fourth, the contribution to the public understanding of

[23] *See, e.g., Expanded Access: Information for Patients,* U.S. FOOD & DRUG ADMINISTRATION, *available at* https://www.fda.gov/news-events/expanded-access/expanded-access-information-patients#process-work (last visited on May 7, 2020).
[24] *See, e.g., Interpretation of Cumulative Death Forecasts,* CENTERS FOR DISEASE CONTROL AND PREVENTION, *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/forecasting-us.html (last visited on May 7, 2020).
[25] *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

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[26], and the Goldwater Institute is a leading researcher and policy analyst on expanded access in the 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.

Conclusion

Based on the foregoing, the Goldwater Institute is entitled to expedited processing of the February 8, 2016 FOIA Request and that all responsive records pertaining to the Goldwater Institute's FOIA request dated February 8, 2016 be released as soon as practicable. 5 U.S.C. § 552(a)(4)(E)(iii) 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.

The contents of this letter and Exhibits 1, 2, 3, and 4 submitted in support of expedited processing are true and correct to the best of the undersigned individuals' knowledge and belief.

Thank you for your prompt attention in this matter. Should you have any questions regarding this expedited processing request, 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 expedited processing request within ten days. 5 U.S.C. § 552(A)(6)(E)(ii)(I).

Very truly yours,

FRIER & LEVITT

/s/ Nicole DeWitt

Nicole M. DeWitt, Esq.

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.

[26] *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, 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

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

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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*
- *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

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