

January 28, 2019

National Institute of Allergy and Infectious Diseases c/o Robin Schofield Room 6G51 5601 Fishers Lane Rockville, MD 20892

RE: FOIA Request Regarding Records of and Concerning NIH's Acquisition of Aborted Fetal Tissue to Transplant into Humanized Mice

Dear Ms. Schofield:

This letter is a request ("Request") in accordance with the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and the corresponding department/agency implementing regulations.

The Request is made by the American Center for Law and Justice ("ACLJ")¹ on behalf of itself and its members who demand accountability of our government and who respect the value of life. The ACLJ respectfully seeks expedited processing and a waiver of fees related to this Request as set forth in an accompanying memorandum.

To summarize, this Request seeks records from the National Institutes of Health ("NIH") to determine the ethical, legal, and moral considerations the NIH has taken in undergoing its continued research and creation of mice with humanized immune systems, and in coming to its decision to contract with the University of California at San Francisco ("UCSF"). The purpose of this request is to seek information that will then educate the American public about the NIH's considerations, practices, and procedures in its spending of U.S. tax-payer dollars.

¹ The ACLJ is a not-for-profit 50l(c)(3) organization dedicated to the defense of constitutional liberties secured by law. The ACLJ regularly monitors governmental activity and works to inform the public of such affairs. The ACLJ and its global affiliated organizations are committed to ensuring governmental accountability and the ongoing viability of freedom and liberty in the United States and around the world.

Background

Pursuant to Department of Health and Human Services ("HHS") FOIA regulation 45 C.F.R. § 5.21(3), this Background "provide[s] details that will help . . . identify and find the records" requested to the extent known.

According to recent news reports: "the National Institutes of Health signed [a federal contract] with the University of California at San Francisco [that] requires UCSF to obtain body parts from unborn babies to make at least two types of 'humanized mice." Also according to reports, "[t]his NIH contract was originally signed with UCSF for a one-year periods starting on Dec. 6, 2013 with the government retaining the option to renew the contract for up to six additional one-year periods running through Dec. 5, 2020."

On September 24, 2018, the Department of Health and Human Services issued a statement regarding a similar contract between the Food and Drug Administration ("FDA") and Advanced Bioscience Resources, Inc., through which the FDA acquired aborted-baby parts to creates mice with humanized immune systems. In that statement, HHS declared that it

is now conducting an audit of all acquisitions involving human fetal tissue to ensure conformity with procurement and human fetal tissue research laws and regulations. In addition, HHS has initiated a comprehensive review of all research involving fetal tissue to ensure consistency with statutes and regulations governing such research, and to ensure the adequacy of procedures and oversight of this research in light of the serious regulatory, moral, and ethical considerations involved. Finally, HHS is continuing to review whether adequate alternatives exist to the use of human fetal tissue in HHS funded research and will ensure that efforts to develop such alternatives are funded and accelerated.⁴

As the National Institutes of Health is a branch of the HHS, this statement appears to apply to any and all research conducted by NIH involving fetal tissue.

Records Requested

For purposes of this Request, the term "record" means "any information" that qualifies under 5 U.S.C. § 552(f), and includes, but is not limited to, the original or any full, complete and unedited copy of any log, chart, list, memorandum, note, correspondence, writing of any kind, policy, procedure, guideline, agenda, handout, report, transcript, set of minutes or notes, video, photo, audio recording, or other material. The term "record" also includes, but is not limited to, all relevant information created, stored, received or delivered in any electronic or digital format,

² Terence P. Jeffrey, \$13,799,501 Federal Contract Requires UC San Francisco to Obtain Aborted-Baby Parts to Humanize Mice, CNS NEWS (Oct. 17, 2018, 5:03 PM), https://www.cnsnews.com/news/article/terence-pjeffrey/13799501-federal-contract-requires-uc-san-francisco-obtain-aborted.

⁴ Press Release, Department of Health and Human Services (Sept. 24, 2018), available at https://www.hhs.gov/about/news/2018/09/24/statement-from-the-department-of-health-and-human-services.html.

e.g., electronic mail, instant messaging or Facebook Messenger, iMessage, text messages or any other means of communication, and any information generated, sent, received, reviewed, stored or located on a government or private account or server, consistent with the holdings of Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145 (D.C. Cir. 2016)⁵ (rejecting agency argument that emails on private email account were not under agency control, and holding, "If a department head can deprive the citizens of their right to know what his department is up to by the simple expedient of maintaining his departmental emails on an account in another domain, that purpose is hardly served.").

For purposes of this Request, the terms "NIH official" or "NIH employee" include, but are not limited to, any person who is (1) employed by or on behalf of the National Institutes of Health in any capacity; or (2) contracted for services by or on behalf of the National Institutes of Health in any capacity.

For purposes of this Request, and unless otherwise indicated, the timeframe of records requested herein is December 1, 2013 through the date of receipt of this Request.

Pursuant to FOIA, 5 U.S.C. § 552, ACLJ hereby requests that the NIH produce the following records:

- 1. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any NIH official or employee that concern or in any way discuss the ethical, legal, and/or moral considerations in contracting with UCSF in light of HHS's September 24, 2018 statement and ongoing audit including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, NIH electronic mail or message accounts, non-NIH electronic mail or message accounts, personal electronic mail or message accounts, NIH servers, or non-NIH servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to non-agency account recipients, and attachments to any electronic mail or message.
- 2. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any NIH official or employee that concern or in any way discuss the total number of aborted fetal tissue/parts that will be required and/or obtained by the NIH during any of the yearlong contracts with UCSF, including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, NIH electronic mail or message accounts, non-NIH electronic mail or message accounts, personal electronic mail or message accounts, NIH servers, or non-NIH servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to non-agency account recipients, and attachments to any electronic mail or message.

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⁵Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145 (D.C. Cir. 2016).

- 3. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any NIH official or employee that concern or in any way discuss the procedures through which UCSF obtains the aborted fetal tissue to then be sent to the NIH during any of the year-long contracts with UCSF, including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, NIH electronic mail or message accounts, non-NIH electronic mail or message accounts, personal electronic mail or message accounts, NIH servers, or non-NIH servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to non-agency account recipients, any electronic mail or message forwarded to non-agency account recipients, and attachments to any electronic mail or message.
- 4. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any NIH official or employee that concern or in any way discuss the required gestational age of the aborted fetal tissue that the NIH to acquired or intends to acquire from UCSF during any of the year-long contracts, including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, NIH electronic mail or message accounts, non-NIH electronic mail or message accounts, personal electronic mail or message accounts, NIH servers, or non-NIH servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to non-agency account recipients, any electronic mail or message forwarded to non-agency account recipients, and attachments to any electronic mail or message.
- 5. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any NIH official or employee that concern or in any way discuss required procedures through which UCSF was/is to obtain the aborted fetal tissue to ensure that the tissue is not damaged or spoiled in any way that makes it unsuitable for NIH's research, including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, NIH electronic mail or message accounts, non-NIH electronic mail or message accounts, personal electronic mail or message accounts, NIH servers, or non-NIH servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to agency account recipients, and attachments to any electronic mail or message.
- 6. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any NIH official or employee that concern or in any way discuss whether NIH will renew its contract with UCSF in light of HHS's audit of all acquisitions involving human fetal tissue, including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, NIH electronic mail or message accounts, non-NIH electronic mail or message accounts, NIH servers, or non-NIH servers, and personal servers, as well as any

electronic mail or message carbon copied to agency account recipients, any electronic mail or message carbon copied to non-agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to non-agency account recipients, and attachments to any electronic mail or message.

7. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any NIH official or employee that concern or in any way discuss regulatory, moral, and/or ethical considerations involved in current NIH research which utilizes fetal tissue, including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, NIH electronic mail or message accounts, non-NIH electronic mail or message accounts, personal electronic mail or message accounts, NIH servers, or non-NIH servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to agency account recipients, and attachments to any electronic mail or message.

CONCLUSION

If this Request is denied in whole or in part, ACLJ requests that, within the time requirements imposed by FOIA, your agency support all denials by reference to specific FOIA exemptions and provide any statutorily or judicially required explanatory information, including but not limited to a *Vaughn* Index.

Moreover, as explained in an accompanying memorandum, the ACLJ is entitled to expedited processing of this Request as well as a waiver of all fees associated with it. The ACLJ reserves the right to appeal a decision to withhold any information sought by this request and/or to deny the separate application for expedited processing and waiver of fees.

Thank you for your prompt consideration of this Request. Please furnish all applicable records and direct any responses to:

Jordan Sekulow, Executive Director
Abigail Southerland, Senior Litigation Counsel
Benjamin P. Sisney, Senior Litigation Counsel
American Center for Law and Justice

I affirm that the foregoing request and attached documentation are true and correct to the best of my knowledge and belief.

Respectfully submitted,

Joelan Schlas

Jordan Sekulow Executive Director Abigail Southerland Senior Litigation Counsel

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