

**Congress of the United States**  
**Washington, DC 20515**

July 17, 2019

The Honorable Alex M. Azar II  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Mr. Secretary:

Earlier this month, the Department of Health and Human Services (HHS) announced plans to discontinue intramural fetal tissue research by the federal government and limit funding opportunities for extramural researchers, following a purported “comprehensive review of all HHS research involving human fetal tissue from elective abortions.”<sup>1</sup>

The Department’s decision, which appears to have been made with no evidence of improper actions by researchers, threatens to interfere with important biomedical research and have long-term consequences. The Department’s decision also reflects this Administration’s continued prioritization of ideology over the critical work of the research community and at the expense of scientific advancement.

The use of fetal tissue has been standard practice in biomedical research for decades and has been instrumental in the development of vaccines against polio, rubella, measles, chickenpox, and treatments for rheumatoid arthritis, cystic fibrosis, and hemophilia.<sup>2</sup> In addition, fetal tissue research has been used to advance treatments for developmental disorders like autism, as well as degenerative diseases like Alzheimer’s disease, Parkinson’s disease, and Amyotrophic Lateral Sclerosis.<sup>3</sup>

The National Institutes of Health (NIH) historically has funded the majority of fetal tissue research in this country—in fiscal year 2018 alone, NIH spent \$103 million on fetal tissue

---

<sup>1</sup> Department of Health and Human Services, *Statement from the Department of Health and Human Services* (June 5, 2019) (online at [www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html](http://www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html)).

<sup>2</sup> *Fetal Tissue Research Is Essential for Scientific Discovery and Improving Human Health*, STAT (Oct. 5, 2017) (online at [www.statnews.com/2017/10/05/fetal-tissue-research-congress-nih/](http://www.statnews.com/2017/10/05/fetal-tissue-research-congress-nih/)).

<sup>3</sup> *Brief of Amici Curiae Fetal Tissue Researchers, Scientists, Physicians, Medical and Legal Ethicists and Academics in Support of Plaintiff-Appellee in National Abortion Federation v. Center for Medical Progress, Biomax Procurement Services, LLC, David Daleiden, aka Robert Daoud Sarkis, and Troy Newman*, National Abortion Federation (June 7, 2016) (online at [www.prochoice.org/wp-content/uploads/Fetal-Tissue-Researchers-Amicus-Brief-.pdf](http://www.prochoice.org/wp-content/uploads/Fetal-Tissue-Researchers-Amicus-Brief-.pdf)).

research.<sup>4</sup> The scientific community agrees that there is currently no adequate scientific alternative to fetal tissue for biomedical research.<sup>5</sup>

The Department's decision appears to be driven by outside forces that have pressured the Administration to take extreme ideological positions that are unsupported by science. On September 12, 2018, a coalition of ideologically-driven groups wrote to HHS Secretary Alex Azar urging him to cancel a contract between Advanced Bioscience Resources, Inc., a California-based nonprofit, and the Food and Drug Administration (FDA), for the provision of fetal tissue.<sup>6</sup>

Less than two weeks later, HHS terminated the contract between FDA and Advanced Biosciences Resources. The Department also announced an audit of all fetal tissue acquisitions "to ensure conformity with procurement and human fetal tissue research laws and regulations."<sup>7</sup>

On June 5, 2019, HHS went even further, announcing that it would not be extending a contract that began in 2013 with the University of California, San Francisco for research using fetal tissue and would no longer allow intramural researchers at NIH to use fetal tissue.<sup>8</sup> HHS also announced plans to employ a layered review process on top of traditional peer review for new extramural research projects involving fetal tissue. This process will now require an ethics advisory board to make a recommendation on each proposal after the peer review process has recommended the proposal for funding. Finally, HHS noted plans to adopt new "program integrity requirements" around the use of fetal tissue in scientific research.<sup>9</sup>

---

<sup>4</sup> *New Restriction on Fetal Tissue Research 'Was the President's Decision'*, Washington Post (June 5, 2019) (online at [www.washingtonpost.com/health/trump-administration-imposes-new-restrictions-on-fetal-tissue-research/2019/06/05/b13433c0-8709-11e9-a491-25df61c78dc4\\_story.html?utm\\_term=.0aaa7b3ec80b](http://www.washingtonpost.com/health/trump-administration-imposes-new-restrictions-on-fetal-tissue-research/2019/06/05/b13433c0-8709-11e9-a491-25df61c78dc4_story.html?utm_term=.0aaa7b3ec80b)); National Institutes of Health, *Estimates of Funding for Various Research, Condition, and Disease Categories* (online at [www.report.nih.gov/categorical\\_spending.aspx](http://www.report.nih.gov/categorical_spending.aspx)); National Institutes of Health, Budget (online at [www.nih.gov/about-nih/what-we-do/budget](http://www.nih.gov/about-nih/what-we-do/budget)).

<sup>5</sup> House Committee on Oversight and Government Reform, Testimony of Former President of the International Society for Stem Cell Research Sally Temple, Ph.D., *Hearing on Exploring Alternatives to Fetal Tissue Research*, 115th Cong. (Dec. 13, 2018) (online at [www.isscr.org/docs/default-source/policy-documents/dr-sally-temple-written-testimony-ogr-committee-13-december-2018.pdf?sfvrsn=2](http://www.isscr.org/docs/default-source/policy-documents/dr-sally-temple-written-testimony-ogr-committee-13-december-2018.pdf?sfvrsn=2)).

<sup>6</sup> Letter from Marjorie Dannenfelser, President, Susan B. Anthony List et al., to Secretary Alex Azar, Department of Health and Human Services (Sept. 11, 2018) (online at [www.sba-list.org/wp-content/uploads/2018/09/Group-Letter-to-Azar-FDA-and-fetal-tissue-FINAL-with-Signatures.pdf](http://www.sba-list.org/wp-content/uploads/2018/09/Group-Letter-to-Azar-FDA-and-fetal-tissue-FINAL-with-Signatures.pdf)).

<sup>7</sup> Department of Health and Human Services, *Statement from the Department of Health and Human Services* (Sept. 24, 2018) (online at [www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html](http://www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html)).

<sup>8</sup> Department of Health and Human Services, *Statement from the Department of Health and Human Services* (June 5, 2019) (online at [www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html](http://www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html)); *Trump Administration Threatens Future of HIV Research Hub*, Washington Post (Dec. 5, 2018) (online at [www.washingtonpost.com/national/health-science/trump-administration-threatens-future-of-hiv-research-hub/2018/12/04/f2e8e0ec-f7dd-11e8-863c-9e2f864d47e7\\_story.html?utm\\_term=.a829e042a779](http://www.washingtonpost.com/national/health-science/trump-administration-threatens-future-of-hiv-research-hub/2018/12/04/f2e8e0ec-f7dd-11e8-863c-9e2f864d47e7_story.html?utm_term=.a829e042a779)).

<sup>9</sup> Department of Health and Human Services, *Statement from the Department of Health and Human Services* (June 5, 2019) (online at [www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html](http://www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html)).

In contrast, research and medical organizations have voiced serious concerns about the Administration's efforts to restrict fetal tissue research. In a written statement submitted to the House Committee on Oversight and Government Reform in December 2018, more than 60 organizations and institutions—including the International Society for Stem Cell Research, the American Association for the Advancement of Science, and the Association of American Medical Colleges—stated: “Any new restriction on this critical work would obstruct research that is necessary for the development of new treatments for a wide range of serious diseases.”<sup>10</sup>

In response to the HHS policy announced earlier this month, the Infectious Diseases Society of America and its HIV Medicine Association stated:

The department's decision discounts the life-saving value of a research model that is considered a gold standard, and that is critical to developing treatments for devastating diseases. ... Further, this ban sets back growing hopes for progress that studies of fetal tissue have offered against some of the greatest threats to human life and health that we face today.<sup>11</sup>

The decision to halt funding for fetal tissue research could have unintended long-term consequences. The biomedical research community has looked to HHS to promote the highest standards of scientific autonomy, yet this latest step shows the Department is no longer fulfilling its leadership role.

To help us assess the scientific basis, if any, for the changes in fetal tissue research policy, we request that you produce the following documents by July 31, 2019:

1. All documents—including internal and external analyses—related to the HHS “audit and review” that have informed the Administration's decisions regarding fetal tissue research;
2. All records related to meetings and listening sessions conducted in the course of the comprehensive review of federal funding for fetal tissue research, including dates and locations of meetings, participants, and any meeting minutes or documents prepared in advance of or in the course of the meetings;
3. All communications among officials at HHS, NIH, FDA, and the Executive Office of the President, including the White House Domestic Policy Council, concerning the decision to cancel FDA's contract with Advanced Biosciences, Inc. and whether to continue federal funding for fetal tissue research; and

---

<sup>10</sup> Letter from the International Society for Stem Cell Research et al., to Chairman Jim Jordan, Subcommittee on Health Care, Benefits, and Administrative Rules, House Committee on Oversight and Government Reform, et al. (Dec. 13, 2018) (online at [www.isscr.org/docs/default-source/policy-documents/coalition-fetal-tissue-letter-to-ogr.pdf?sfvrsn=10](http://www.isscr.org/docs/default-source/policy-documents/coalition-fetal-tissue-letter-to-ogr.pdf?sfvrsn=10)).

<sup>11</sup> *HHS Fetal Tissue Research Ban Threatens Progress Toward Cure for HIV, Other Life-threatening Diseases*, HIV Medicine Association (June 6, 2019) (online at [www.hivma.org/es/news\\_and\\_publications/hivma\\_news\\_releases/2019/hhs-fetal-tissue-research-ban-threatens-progress-toward-cure-for-hiv-other-life-threatening-diseases/](http://www.hivma.org/es/news_and_publications/hivma_news_releases/2019/hhs-fetal-tissue-research-ban-threatens-progress-toward-cure-for-hiv-other-life-threatening-diseases/)).

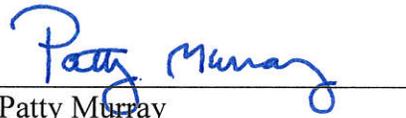
4. All communications between officials at HHS, NIH, FDA, and the Executive Office of the President, including the White House Domestic Policy Council, and outside entities concerning the decision to cancel FDA's contract with Advanced Biosciences, Inc. and the decision of whether to continue federal funding for fetal tissue research.

If you have any questions or would like to further discuss compliance with this request, please contact Miles Lichtman with the House Committee on Oversight and Reform staff, at (202) 225-5051 or Elizabeth Letter with the Senate Committee on Health, Education, Labor, and Pensions staff, at (202) 224-0767.

Sincerely,



Elijah E. Cummings  
Chairman  
House Committee on Oversight and Reform



Patty Murray  
Ranking Member  
Senate Committee on Health,  
Education, Labor, and Pensions

Enclosure

cc: The Honorable Jim Jordan, Ranking Member  
House Committee on Oversight and Reform

The Honorable Lamar Alexander, Chairman  
Senate Committee on Health, Education, Labor,  
and Pensions

## Responding to Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.
2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committees.
3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.
4. The Committees' preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.
5. Documents produced in electronic format should be organized, identified, and indexed electronically.
6. Electronic document productions should be prepared according to the following standards:
  - a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.
  - b. Document numbers in the load file should match document Bates numbers and TIF file names.
  - c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.
  - d. All electronic documents produced to the Committees should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION,  
BEGATTACH.

7. Documents produced to the Committees should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.
8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.
9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committees' letter to which the documents respond.
10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.
11. The pendency of or potential for litigation shall not be a basis to withhold any information.
12. In accordance with 5 U.S.C. § 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.
13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.
14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.
15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.
16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.
17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.
19. All documents shall be Bates-stamped sequentially and produced sequentially.
20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee on Oversight and Reform, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building. When documents are produced to the Committee on Financial Services, production sets shall be delivered to the Majority Staff in Room 2129 of the Rayburn House Office Building and the Minority Staff in Room 4340 of the O'Neill House Office Building. When documents are produced to the Permanent Select Committee on Intelligence, production sets shall be delivered to Majority and Minority Staff in Room HVC-304 of the Capital Visitor Center.
21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

### **Definitions**

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a

part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term “communication” means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.
3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.
4. The term “including” shall be construed broadly to mean “including, but not limited to.”
5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.
6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.
7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.
8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.
9. The term “individual” means all natural persons and all persons or entities acting on their behalf.