

State of California Office of the Attorney General

XAVIER BECERRA Attorney General

October 28, 2020

Secretary Alex M. Azar II U.S. Department of Health & Human Services 200 Independence Ave., S.W. Washington, DC 20201

Director Francis S. Collins, M.D., Ph.D. National Institutes of Health 9000 Rockville Pike Bethesda, MD 20892

Dear Secretary Azar and Director Collins:

We are writing to urge you to reject the recent recommendations made by the National Institutes of Health (NIH) Human Fetal Tissue Ethics Advisory Board ("Board").¹ The Board—which was created by the Trump Administration—recently issued a report recommending that federal funding be withheld from almost all fetal tissue research grant proposals.² These recommendations represent the culmination of the Trump Administration's two-year effort to block federally-funded research using fetal tissue.³ This effort is misguided, and is particularly troubling during a pandemic which

¹ On March 26, 2020, California submitted a multi-state letter on behalf of 15 Attorneys General objecting to the Trump Administration's severe curtailing of federal funding for scientific and medical research using fetal tissue. *See* Letter to President Trump, Secretary Azar, and Director Collins from 15 Attorneys General (March 26, 2020), <u>https://www.oag.ca.gov/system/files/attachments/press-docs/Multi-State%20Letter%20re%20Fetal%20Tissue%20Ban.pdf.</u>

² See NIH, Report of the Human Fetal Tissue Research Advisory Board-FY2020, 6-12 (2020), https://osp.od.nih.gov/wp-

content/uploads/HFT EAB FY2020 Report 08182020.pdf.

³ On June 5, 2019, President Trump directed the Department of Health and Human Services (HHS) to cancel a multi-million dollar contract with the University of California, San Francisco that used fetal tissue for developing HIV therapies, discontinue all intramural research conducted by NIH which uses fetal tissue, and subject all future extramural research projects to an additional layer of review and approval by a Board. *See* Amy Goldstein, New restriction on fetal tissue research 'was the president's decision,' WASH. POST (June 5, 2019, 12:03 PM),

https://www.washingtonpost.com/health/trump-administration-imposes-new-restrictions-

has killed more than 226,000 Americans.⁴ Leading scientists have encouraged the use of fetal tissue research to develop potential treatments and therapies to help combat COVID-19.⁵ Most recently, President Trump used Regeneron, an antibody therapy he received when he was hospitalized with COVID-19.⁶ Regeneron was tested with cells derived from fetal tissue, yet the Trump Administration is seeking to ban such federally funded research nationwide.

While the law establishing the Board requires that it be fairly balanced in terms of differing viewpoints, the composition of the Board primarily consisted of individuals opposed to abortion and/or fetal tissue research.⁷ The Board conducted nearly all of its work in a single closed session that was not open to the public, and issued recommendations that, in the words of the report's dissenting opinion, were "clearly an attempt to block funding of as many contracts and grants as possible."⁸ In addition, the Board and its findings contained the following deficiencies:

• It does not appear that any Board members represented patient advocacy groups or others who have directly benefitted from medical and scientific

content/uploads/HFT_EAB_FY2020_Report_08182020.pdf at 13.

on-fetal-tissue-research/2019/06/05/b13433c0-8709-11e9-a491-25df61c78dc4_story.html and Statement from the Department of Health and Human Services (June 5, 2019), https://www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-healthand-human-services.html.

⁴ See At least 226,000 people have died from coronavirus in the U.S., WASH. POST (Oct. 27, 2020, 7:25 p.m.),

https://www.washingtonpost.com/graphics/2020/national/coronavirus-us-casesdeaths/?itid=sf_coronavirus.

⁵ 90 leading scientific, medical, academic, and patient advocacy organizations have urged the Trump Administration to recognize that "[f]etal tissue research has the potential to accelerate the end to the pandemic, reduce human suffering, and enable the U.S. to better respond to future public health threats." *See* Letter to NIH Human Fetal Tissue Research Ethics Advisory Board-FY2020 (July 28, 2020), <u>https://www.isscr.org/docs/defaultsource/policy-documents/coalition-letter-to-nih-human-fetal-tissue-ethics-advisoryboard-july-2020.pdf?sfvrsn=b0a243b1_2.</u>

⁶ See KHN Morning Briefing (Oct. 9, 2020), <u>https://khn.org/morning-breakout/fetal-</u>tissue-research-trump-opposes-used-to-develop-antibody-therapy-he-praises-as-cure/.

⁷ See 5 U.S.C. app. 2 § 5(b)(2) (requiring "the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee."). Despite this requirement, at least 10 of the 15 Board members—a super majority—oppose abortion, fetal tissue research, or both. *See* footnotes 9 & 11.

⁸ See HHS Report of the Human Fetal Tissue Research Ethics Advisory Board- FY2020 (Aug. 18, 2020), <u>https://osp.od.nih.gov/wp-</u>

research using fetal tissue. The composition of the Board falls far short of being "fairly balanced," as required by the Federal Advisory Committee Act (FACA).⁹

- Public comment on the Board's lack of balance was not possible because HHS did not disclose the members of the Board in advance of the July 31, 2020 meeting.
- The Board's meeting and deliberations were not open to the public, as required by law.¹⁰ The Board held just one virtual meeting on July 31, 2020—convening publicly for only 42 minutes before transitioning to five hours of closed-door deliberations and votes on proposals.¹¹ That lack of transparency and denial of the public's right to attend the meeting violates longstanding federal law and undermines confidence in the process.¹²

For these reasons, we urge you to exercise your authority under 42 U.S.C. § 289a–1(b) to reject the recommendations of the Board and maintain federal funding for scientifically meritorious research projects using fetal tissue which have already been recommended for funding through NIH's review process.

As you know, research using fetal tissue has been essential for scientific and medical advances that have saved millions of lives in the United States and across the globe. Research using fetal tissue has led to the development of vaccines to combat

⁹ See, e.g., NAACP Legal Def. & Educ. Fund, Inc. v. Barr, No. CV 20-1132 (JDB), 2020 WL 5833866, at *1-2 (D.D.C. Oct. 1, 2020) (holding that the Trump Administration's Presidential Commission on Law Enforcement and the Administration of Justice was not fairly balanced because it included only law enforcement officials. There were no members representing civil rights or police accountability organizations). Here, FACA's requirement that boards are "fairly balanced in terms of the points of view represented" required a roughly equal number of board members who are pro-choice and support fetal tissue research. See 5 U.S.C. app. 2 § 5(b)(2).

¹⁰ See 5 U.S.C. app. 2 § 10(a)(1) ("Each advisory committee meeting shall be open to the public.").

¹¹ See Amy Goldstein, Fetal tissue research advisory board convenes, with a strong antiabortion tilt, WASH. POST (Aug. 4, 2020, 05:09 PM),

https://www.washingtonpost.com/health/fetal-tissue-research-advisory-board-conveneswith-a-strong-anti-abortion-tilt/2020/08/04/f138d08a-d5c7-11ea-930ed88518c57dcc_story.html.

¹² See 5 U.S.C. app. 2 § 10(a)(1) ("Each advisory committee meeting shall be open to the public.").

diseases like poliovirus, rubella, measles, and rabies.¹³ This research remains vitally important. Despite medical and technological advances, fetal tissue has unique properties that often cannot be replaced by other cell types. It remains the "gold standard" for vital biomedical research.¹⁴ And NIH's longstanding, rigorous, and multi-layered peer review process ensures that federally funded research projects are legally and ethically sound, in addition to being scientifically meritorious.¹⁵ Both Congress¹⁶ and the American Medical Association's Code of Medical Ethics¹⁷ have adopted stringent guidelines to ensure that research using fetal tissue is ethical and proper.

We urge you to reject the procedurally and substantively flawed Board recommendations. Especially as we battle the COVID-19 pandemic, restoring vital federal funding for scientifically worthy and ethically sound research is more important than ever.

Sincerely,

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¹⁵ See NIH Grants Policy Statement (Dec. 2019) IIA-27-IIA-28, https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

¹³ See Letter to Secretary Azar from 77 Scientific, Medical, Academic, and Patient Advocacy Organizations (Aug, 31, 2020) 2,

https://www.cogr.edu/sites/default/files/Coalition%20Letter%20to%20HHS%20on%20H FT%20EAB%20August%2031%202020.pdf.

¹⁴ See Letter to NIH Human Fetal Tissue Research Ethics Advisory Board-FY2020 (July 28, 2020) 1, <u>https://www.isscr.org/docs/default-source/policy-documents/coalition-letter-to-nih-human-fetal-tissue-ethics-advisory-board-july-2020.pdf?sfvrsn=b0a243b1_2.</u>

¹⁶ See, e.g., 42 U.S.C. §§ 289g, 289g-1.

¹⁷ See American Medical Association, Research Using Human Fetal Tissue: Code of Medical Ethics Opinion 7.3.5, <u>https://www.ama-assn.org/delivering-care/ethics/research-using-human-fetal-tissue</u>.

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