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Congress of the United States
House of Representatives
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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September 9, 2020

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

The Honorable Francis Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Secretary Azar and Director Collins,

In February of this year, HHS established a new NIH Human Fetal Tissue Research Ethics Advisory Board with the mission to "make recommendations to the Secretary of HHS regarding the ethics of research involving human fetal tissue (HFT) proposed in NIH grant and cooperative agreement applications and R&D contract proposals, described below and as set forth in the NIH Guide Notice NOT-OD-19-128." The Advisory Board met on July 31, 2020 to discuss a number of applications for NIH grant funding that featured HFT in their research proposals.[1] Following that meeting, the Board issued recommendations that NIH withhold funding from 13 out of 14 funding proposals, primarily on the assertion that the proposal had not provided "adequate ethical justification" for the use of HFT.[2]

We believe that actions recommended by the Fetal Tissue Advisory Board, if carried out, may constitute a violation of the NIH Scientific Integrity policy. The Committee on Science, Space, and Technology set into motion the development of Federal-wide scientific integrity principles in

[1] https://www.federalregister.gov/documents/2020/07/15/2020-15241/notice-of-meeting-nih-human-fetal-tissue-research-ethics-advisory-board-fy2020.
[2] https://www.washingtonpost.com/health/trump-fetal-tissue-research/2020/08/18/85902fcc-e157-11ea-8dd2-d07812bf00f7_story.html

Sec. 1009 of the *America COMPETES Act of 2007* [P.L. 110-69]. In March 2019, the Committee reported the bipartisan *Scientific Integrity Act*, H.R. 1709, that would codify the principles implemented across agencies under the previous Administration. As you know, the *NIH Policies and Procedures for Promoting Scientific Integrity*, developed as part of that process, has been in place since 2012 and memorializes NIH's strategies for ensuring the highest degree of scientific integrity in its operations, including in the award process for extramural research.[3] In particular, *Policies and Procedures says*:

> "To increase transparency, HHS policy also requires that grant applications be evaluated according to the review criteria specified in the Funding Opportunity Announcement..."

At its July 31 meeting, the Advisory Board proposed *de facto* a new agency policy – in essence, to ban NIH grant funding for extramural medical research that uses HFT. The only proposal for which the Board recommended an exception would require the use of HFT only for the purposes of identifying alternatives for future research, i.e., to "obviate the need" for HFT.[4] Note that these proposals were not drafts, but final proposals already submitted to NIH prior to the date of the Advisory Board meeting.

Applicants were presumably made aware of HHS's 2019 Guide Notice NOT-OD-19-128, which states that all extramural research proposals featuring HFT received after September 25, 2019 would be required to include additional documentation on the use of HFT in their proposal, demonstrate compliance with all legal requirements, and undergo an "ethics review" by an advisory board to be established by the NIH.[5] But the 2019 Guide Notice did not explain what specific ethical questions or concerns the Board would consider in evaluating applications, and how or whether it might be even be possible for applicants to present an "adequate ethical justification" according to the Board.

This is completely at odds with NIH's transparent, consistent, and well understood approach to scoring and awarding grant funding proposals against a clearly stated set of review criteria, as acknowledged in *Policies and Procedures*. If NIH did not make plain in its Funding Opportunity Announcements that the use of HFT would likely disqualify these proposals, then to reject them specifically for their use of HFT would amount to a retroactive change to NIH's review criteria. In short, the Advisory Board is calling for NIH to move the goalposts on its applicants.

It is critical for NIH to adhere to principles of scientific integrity in all cases, even when politics or special interests may seek to interfere. It is also critical for NIH and all federal science agencies to maintain a trusted partnership with the external research community, and that means using clear and consistent evaluation criteria in grantmaking.

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[3] https://www.nih.gov/sites/default/files/about-nih/nih-director/testimonies/nih-policies-procedures-promoting-scientific-integrity-2012.pdf

[4] https://www.washingtonpost.com/health/trump-fetal-tissue-research/2020/08/18/85902fcc-e157-11ea-8dd2-d07812bf00f7_story.html

[5] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html

With this in mind, we urge you not to reject these applications strictly on the recommendations of the NIH Human Fetal Tissue Research Ethics Advisory Board, and going forward, to evaluate all research proposals according to scientific merit and the NIH *Policies and Procedures*. We also urge caution against any additional policy limitations to HFT in medical research, as they would have a devastating effect on research into treatments and cures for debilitating diseases like cancer and H.I.V. and on vaccines for deadly infections – including COVID-19, which has already killed over 190,000 Americans.

Sincerely,

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space, and Technology

Bill Foster
Chairman
Subcommittee on Investigation & Oversight