CHARLOTTE LOZIER INSTITUTE

Comment on Proposed Rule Establishing Safeguards and Program Integrity Requirements for HHS-Funded Human Fetal Tissue Research

Date: 12 February 2021

To: The Honorable Norris Cochran
Acting Secretary
Department of Health and Human Services

In response to: Proposed Rule: Establishment of Safeguards and Program Integrity Requirements for Health and Human Services-Funded Extramural Research Involving Human Fetal Tissue; published at 86 FR 2615

Reference: RIN 0991-AC15

Dear Acting Secretary Cochran:

This comment is submitted in response to the above-captioned Federal Register notice of a Proposed Rule, in which the Department of Health and Human Services (HHS) has requested comment on proposed changes to research and funding regulations related to the acquisition and use of fetal tissue from elective abortion. Our opposition to such research and its federal funding is a matter of public record.[1] Details regarding the history, science, ethics, and regulation of fetal tissue research are contained in our recent peer-reviewed comprehensive publication on this topic.[2] However, given that final resolution of this issue requires statutory changes enacted by Congress, we write in support of the current Proposed Rule as a way to address a number of serious concerns with the current federal regulations involving fetal tissue research.

[1] See, *e.g.*, Invited Scientific Testimony. "Exploring Alternatives to Fetal Tissue Research," Joint Hearing, Subcommittee on Healthcare, Benefits, and Administrative Rules and Subcommittee on Government Operations, House Oversight & Government Reform Committee, U.S. House of Representatives, December 13, 2018, Dr. Tara Sander Lee at https://lozierinstitute.org/written-testimony-of-tara-sander-lee-ph-d-in-support-of-ethical-alternatives-to-aborted-fetal-tissue-research/; Dr. David A. Prentice at https://lozierinstitute.org/written-testimony-of-david-a-prentice-ph-d-in-support-of-ethical-alternatives-to-aborted-fetal-tissue-research/

[2] Tara Sander Lee, Maria B. Feeney, Kathleen M. Schmainda, James L. Sherley and David A. Prentice (2020) Human Fetal Tissue from Elective Abortions in Research and Medicine: Science, Ethics, and the Law, *Issues in Law & Medicine* 35(1), 3-61; available at: https://www.sba-list.org/wp-content/uploads/2020/09/SanderLeeetal-2020-Human-Fetal-Tissue-from-Elective-Abortions-in-Research-and-Medicine-Science-Ethics-and-the-Law-ILM-Spring2020.pdf

The investigations by the House Select Panel on Infant Lives[3] and the Senate Judiciary Committee[4] exposed glaring violations in the interpretation and enforcement of current regulations regarding human fetal tissue research.

One significant problem exposed was a systemic failure to prevent profiteering and trafficking in fetal tissue and fetal organs obtained from induced abortion. In fact, contrary to the statute itself, the current regulatory environment provides perverse incentives to alter the timing and procedure of the abortion, risking the health of the woman so as to provide more efficient harvest of organs and tissues that are of better "quality" and more suitable for research. Indeed, the Congressional investigations and our previously-cited peer-reviewed publication uncovered fetal tissue research protocols in which fragmented fetal body parts were avoided in favor of organs from fetuses delivered intact, obtained by collaboration with the abortionist so as to maintain organ integrity. The potential for benefit and financial enrichment is facilitated at every step of the chain, from the abortionist to the procurement company to the middleman doing handling, shipping and processing to the end-user/researcher. Valuable consideration takes on a value-added dimension under the current regulatory scheme.

The Proposed Rule would address these issues in its regulations to prohibit such enticements, benefits, or financial incentives, whether to the pregnant woman, attending physician, tissue procurer, or researcher. The removal of for-profit agents and cost expense allowances and incentives from fetal tissue acquisition will provide needed transparency, and separation from real or apparent ethical and legal conflicts.

Another area of fetal tissue research regulation showing systemic abuse is the area of informed consent, including systematic violations of the HIPAA Privacy Rule. One of the most egregious examples was a consent form obtained from an abortion facility that claimed: "Research using . . . tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS."[5] Obviously there are no cures for these diseases, and most certainly not from fetal tissue research, but even to suggest that fetal tissue is an exclusive means necessary to develop advanced therapies is false, deceptive and coercive. In addition, investigations revealed that some institutional review boards lacked

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[3] Final Report, Select Investigative Panel of the Energy & Commerce Committee. US House of Representatives. December 30, 2016. A compilation of activities available at https://www.govinfo.gov/content/pkg/CPRT-114HPRT24553/html/CPRT-114HPRT24553.htm. Full Report accessed at: https://republicans-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/Select_Investigative_Panel_Final_Report.pdf

[4] Final Report, Committee on the Judiciary United States Senate. December 2016. Accessed at https://www.judiciary.senate.gov/imo/media/doc/2016-12-13%20MAJORITY%20REPORT%20-%20Human%20Fetal%20Tissue%20Research%20-%20Context%20and%20Controversy.pdf

[5] See: Majority exhibit A-3 from *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong. (Mar. 2, 2016), available at: https://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-20160302-SD030.pdf; Also quoted in questions by Mrs. Hartzler and by Mr. Harris in Hearing transcript: Final Report, Select Investigative Panel of the Energy & Commerce Committee. US House of Representatives. December 30, 2016. A compilation of activities available at https://www.govinfo.gov/content/pkg/CPRT-114HPRT24553/html/CPRT-114HPRT24553.htm. Also find at pages xx, 14, 166, 182, 207 and 361 in: Full Report accessed at: https://republicans-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/Select_Investigative_Panel_Final_Report.pdf

records regarding their oversight of fetal tissue research and transplantation. Despite repudiation, both by those who support and those who oppose research with fetal tissue from induced abortion, of the specific deceptive statement given above as well as the general laxness of consent form review and oversight, there have been no changes in federal regulations to address such abuses of consenting and the Common Rule, nor the lack of adequate oversight or record-keeping by institutional review boards.

The NIH Human Fetal Tissue Research Ethics Advisory Board established in 2020 by HHS was charged with reviewing the ethics of research involving human fetal tissue proposed in NIH grant and contract proposals.[6] In the Report delivered to the Secretary and to Congress,[7] a common theme was deficient consent forms. For almost every grant or proposal reviewed, there were problems noted regarding adequate consent and privacy. Critiques from the Ethics Advisory Board included "serious ethical concerns about the adequacy of the informed consent," "unclear language in the consent form," "deficiencies in the consent form," "underlying ethical problems with the informed consent forms," "consent forms included conflicting or misleading statements." Clearly there is continued need for reform in this area.

The Proposed Rule addresses these deficiencies and abuses of informed consent regarding fetal tissue research. The changes in regulations regarding consent forms and their statements, as well as record keeping and access to all related documentation, will provide clarity and reassurance that all ethical requirements are adhered to in this federally funded research.

Numerous states now have their own statutes and regulations regarding fetal tissue research. In addition, many states have passed provisions regarding the treatment and disposal of fetal remains and fetal tissue used in research. The Proposed Rule recognizes that adherence to state and local laws on this point is not only a statutory requirement but also good clinical practice and responds to public sensibilities, and the regulation for respectful treatment and disposal of fetal tissue no longer used in research is a welcome addition.

We support the Proposed Rule and encourage its approval.

Submitted on behalf of the Charlotte Lozier Institute.

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[6] Archives of the NIH Human Fetal Tissue Research Ethics Advisory Board – FY2020; available at: https://osp.od.nih.gov/biotechnology/nih-human-fetal-tissue-research-ethics-advisory-board/

[7] Report of the Human Fetal Tissue Research Ethics Advisory Board- FY2020, August 18, 2020; available at: https://osp.od.nih.gov/wp-content/uploads/HFT_EAB_FY2020_Report_08182020.pdf