Congress of the United States
Washington, DC 20515

February 12, 2021

The Honorable Norris Cochran
Acting Secretary
Department of Health and Human Services
1600 Pennsylvania Avenue NW
Washington, D.C. 20500

Dear Acting Secretary Cochran:

RE: Establishment of Safeguards and Program Integrity Requirements for Health and Human Services-Funded Extramural Research Involving Human Fetal Tissue

We write in strong support of the U.S. Department of Health and Human Services (HHS) January 13, 2021 proposed rule titled "Establishment of Safeguards and Program Integrity Requirements for Health and Human Services-Funded Extramural Research Involving Human Fetal Tissue". The proposed rule will improve the integrity of fetal tissue research by strengthening informed consent requirements and ensuring compliance with the statutory ban on profiting from fetal tissue.

Unfortunately, the United States has a long history of unethical experiments in the name of medical research[1] involving human test subjects[2], aborted but still-living ex-utero infants[3], and recently aborted fetal body parts commonly referred to as fetal tissue. These experiments present serious ethical and legal challenges that harm the integrity of the research.

The proposed rule builds on suggestions from the medical research community and a comprehensive review HHS undertook of all HHS research involving human fetal tissue from elective abortion. The proposed safeguards will ensure consistency with the statutes and regulations governing fetal tissue research and help guarantee the adequacy of procedures and oversight of such research in light of the serious regulatory, moral, and ethical considerations involved.

The research and medical communities have recognized the importance of obtaining informed consent before engaging in human fetal tissue research. In June 2016, the American Medical Association (AMA) issued a Code of Medical Ethics Opinion discussing the number of ethical

[1] Beecher, "Ethics and Clinical Research," 1355.
[2] Heller, Human Guinea Pigs," Al.
[3] Cohn, "Live-Fetus Research Debated," Al.

considerations involving the use of human fetal tissue research. Specifically the AMA was concerned about the "possible financial benefit to those who are involved in the retrieval, storage, testing, preparation, and delivery of fetal tissues" and "the degree to which a woman's decision to have an abortion might be influenced by the opportunity to donate fetal tissue."[4] The AMA listed several steps a physician should take to protect the interests of pregnant women as well as the integrity of science and physicians who are involved in research that uses human fetal tissues, including obtaining the informed consent of the pregnant woman. Additionally, many states that allow fetal tissue research often require the consent of the pregnant woman for the fetal tissue donation. The informed consent protections in the proposed rule will ensure the donation of human fetal tissue from abortion is in fact voluntary and informed, and not motivated by any enticements, benefits, or financial considerations.

After disturbing reports surfaced of abortion providers altering procedures to maximize their profit off fetal tissue, Congress acted quickly to investigate these claims. The House Select Investigative Panel on Infant Lives[5] revealed organizations involved in fetal tissue harvesting and research failed to maintain any safeguards for the use of fetal tissue and were profiteering from fetal tissue trafficking. These new safeguards will end any adverse incentives for a woman to have an abortion or an abortion provider to alter the abortion, possibly endangering the life of the mother.

The House Select Investigative Panel also revealed certain institutional review boards lacked records regarding their oversight of fetal tissue research and transplantation, and the committee was unable to obtain access to records that could determine whether fetal tissue was obtained for valuable consideration. The proposed rule would improve the integrity of the research conducted by grant recipients by ensuring they comply with all federal statutes and guidelines.

We urge the HHS to finalize the rule to implement strong safeguards for the use of fetal tissue funded at the taxpayer's expense.

Sincerely,

Blaine Luetkemeyer
Member of Congress

Cindy Hyde-Smith
Member of Congress

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[4] *AMA Code of Medical Ethics Opinion 7.3.5, available at https://www.ama-assn.org/delivering-care/ethics/research-using-human-fetal-tissue.*

[5] The Select Investigative Panel Final Report, U.S. House of Representatives Energy and Commerce Committee, 114th Cong. (2016), https://republicans-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/Select_Investigative_Panel_Final_Report.pdf

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