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New Limitations on Federal Research Using Human Fetal Tissue

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On June 5, the Department of Health and Human Services (HHS) announced— following an audit and review of all HHS research involving the use of human fetal tissue from elective abortions— that the Administration has decided to discontinue intramural research (i.e., internal) projects involving fetal tissue from elective abortions at the National Institutes of Health (NIH), and will add additional ethics review for new extramural research (i.e., external) involving such tissue. In general, about 10% of NIH funding goes to intramural researchers at NIH-operated facilities and over 80% of NIH funding goes to extramural researchers at universities and other institutions.

According to an HHS spokeswoman, cited in a Reuters news article, the decision will affect three of 3,000 active intramural research projects, which can continue their work until the current supply of fetal tissue is exhausted. Additionally, HHS let expire a $2 million contract with the University of California at San Francisco involving fetal tissue for HIV/AIDs research. No existing extramural NIH grant-funded research projects are expected to be affected, though for *new* extramural projects or renewals, HHS indicated that a new ethics advisory board will review applications before funding is awarded. The board would be established pursuant to Public Health Service Act (PHSA) Section 492A. That section permits the HHS Secretary to withhold funds from a project approved by the scientific peer review process for ethical considerations if a majority of the board recommends that action because of such considerations. The decision may also affect medical research at the Department of Veterans Affairs, which follows NIH policy regarding funding for fetal tissue research.

On June 13, the House agreed to H.Amdt. 338, an amendment to introduced H.R. 2740 (LHHS appropriations), which would bar funds from being used to establish the board under PHSA Sec. 492A. The Senate has not taken any action regarding the HHS decision.

Many scientists oppose the Administration's decision, arguing that fetal tissue is needed for certain medical research, and asserting that current law sufficiently addresses ethical concerns. Others support the decision, contending that adequate research alternatives exist, and that taxpayer dollars should not fund research deemed morally objectionable.

The Role of Human Fetal Tissue in Research

Human fetal tissue is defined as "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth." Spontaneous abortions (e.g., miscarriages) or stillbirths often occur during unpredictable circumstances, and the tissue may have genetic or other abnormalities that preclude its use for research purposes.

Induced (elective) abortions are the main source of fetal tissue for research.

According to NIH, in FY2018, the agency directed $115 million in funding for 200 research projects involving human fetal tissue. Fetal tissue is used in research related to developmental biology, eye disease, HIV/AIDS and other infectious diseases (including Zika). Scientists may conduct studies using the tissue itself, especially to study human development. Scientists may also engraft the tissue to create humanized mice—mice with "human" organ systems (usually immune systems) that allow scientists to study disease in living human tissues.

While certain types of humanized mice can be created with adult stem cells and umbilical cord blood cells, only mice created with fetal bone marrow/liver/thymus cells (human fetal tissue) allow for a "complete and fully functional human immune system." Last year, scientists published a new way to create humanized mice using surplus thymus tissue from neonatal cardiac surgeries. Further studies are needed to compare this new model to the fetal tissue model.

Other potential alternatives to fetal tissue include reprogrammed adult stem cells (i.e., induced pluripotent stem cells; iPS cells) and organoids, three-dimensional lab-created models of human organs. While promising, these alternatives still face challenges as scientists endeavor to get iPS cells and organoids to mimic natural human cells and organs, as those from fetal tissue. Scientists contend that fetal tissue is needed as a comparison to validate potential alternatives.

In December 2018, NIH announced up to $20 million in funding for research into fetal tissue alternatives over two years. Many assert that for certain areas of research, alternatives to fetal tissue do not exist, such as for studying early human development.

Current Federal Laws and Regulations

The PHSA includes two provisions related to the use of human fetal tissue in research. PHSA Sec 498A addresses research involving the transplantation of fetal tissue for therapeutic purposes. As reported to Congress, NIH does not currently fund any research on the transplantation of fetal tissue for therapeutic purposes, and has not done so for many years. PHSA Sec. 498B addresses payments for human fetal tissue, and makes it unlawful for "any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." Under the provision, "valuable consideration" does not include "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."

The use of fetal tissue in research is also regulated under the Common Rule (45 C.F.R. Part 46), which addresses the protection of human subjects in research. Under 45 CFR §46.204, pregnant women cannot be offered monetary inducements to terminate a pregnancy, and individuals engaged in research "will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy" and "will have no part in determining the viability of a neonate." Under 45 CFR §46.206, research involving "the placenta, the dead fetus or fetal material" is subject to all applicable state, local, and federal laws. If such materials can be linked to a living and identifiable individual, the research is subject to pertinent human subjects research requirements (e.g., ethics review, informed consent).

Some states have laws regarding donation of fetal tissue and related to fetal tissue research, including informed consent requirements and bans on experimentation. NIH expects grantees and contractors to maintain documentation that informed consent was obtained at the time of fetal tissue collection.

Further Considerations

Scientists have been conducting research using fetal tissue since the late 1920s, and NIH has funded such research since the 1950s. Such research was used in the development of many vaccines, including for polio and rubella. Fetal tissue research was restricted previously under the Reagan and George H.W. Bush administrations.

Congress may consider whether to accept the Administration's decision, and/or whether the executive branch has authority to impose such restrictions on research. Congress may also consider whether the current laws and regulations governing such research are sufficient and appropriate to address any ethical issues this research may raise.