June 5, 2019

Statement from the Department of Health and Human Services

In September 2018, the Department of Health and Human Services (HHS) terminated a contract between Advanced Bioscience Resources, Inc. and the Food and Drug Administration that provided human fetal tissue from elective abortions to develop testing protocols. The Department was not sufficiently assured that contract included the appropriate protections applicable to fetal tissue research or met all other procurement requirements. As a result, HHS also <u>initiated</u> a comprehensive review of all HHS research involving human fetal tissue from elective abortions to ensure consistency with statutes and regulations governing such research, and to ensure the adequacy of procedures and oversight of this research in light of the serious regulatory, moral, and ethical considerations involved.

When the audit and review began, HHS had an existing contract with the University of California, San Francisco (UCSF) regarding research involving human fetal tissue from elective abortions. HHS has been extending the UCSF contract by means of 90-day extensions while conducting its audit and review. The current extension expires on June 5, 2019, and there will be no further extensions.

Promoting the dignity of human life from conception to natural death is one of the very top priorities of President Trump's administration. The audit and review helped inform the policy process that led to the administration's decision to let the contract with UCSF expire and to discontinue intramural research – research conducted within the National Institutes of Health (NIH) – involving the use of human fetal tissue from elective abortion. Intramural research that requires new acquisition of fetal tissue from elective abortions will not be conducted.

No current extramural research projects (research conducted outside NIH, e.g., at universities, that are funded by NIH grants) will be affected during their currently approved project period. For new extramural research grant applications or current research projects in the competitive renewal process (generally every five years) that propose to use fetal tissue from elective abortions and that are recommended for potential funding through NIH's two-level external scientific review process, an ethics advisory board will be convened to review the research proposal and recommend whether, in light of the ethical considerations, NIH should fund the research project—pursuant to a law passed by Congress.

HHS will also undertake changes to its regulations and NIH grants policy to adopt or strengthen safeguards and program integrity requirements applicable to extramural research involving human fetal tissue.

Finally, HHS is continuing to review whether adequate alternatives exist to the use of human fetal tissue from elective abortions in HHS-funded research and will ensure that efforts to develop such alternatives are funded and accelerated. In December 2018, NIH <u>announced</u> a \$20 million funding opportunity for research to develop, demonstrate, and validate experimental models that do not rely on human fetal tissue from elective abortions. HHS is committed to providing additional funding to support the development and validation of alternative models.