Congress of the United States Washington, DC 20515

September 21, 2021

The Honorable Merrick Garland United States Attorney General U.S. Department of Justice 950 Pennsylvania Avenue, NW, Room1145 Washington, D.C. 20530

The Honorable Francis Collins, M.D., Ph.D. Director National Institutes of Health U.S. Department of Health and Human Services Building One, Room 244 One Center Drive Bethesda, MD 20892 The Honorable Xavier Becerra Secretary of Health & Human Services U.S. Department of Health & Human Services 200 Independence Avenue SW Washington, D.C. 20201

Dear Attorney General Garland, Secretary Becerra, and Director Collins,

We are alarmed by public records obtained from the National Institutes of Health (NIH) which show that the University of Pittsburgh (Pitt) may have violated federal law by altering abortion procedures to harvest organs from babies who were old enough to live outside the womb. We ask for a complete investigation into the activities of this organization and a full report of findings and any remedial measures necessary.

The NIH documents detailing Pitt's grant request were obtained in response to a Freedom of Information Act (FOIA) request from the Center for Medical Progress. Between fiscal years 2016 and 2020, NIH awarded approximately \$1.5 million to Pitt for a project related to the GenitoUrinary Developmental Molecular Anatomy Project (GUDMAP)program.¹ The GUDMAP program was intended to provide the scientific and medical community tools to study "congenital diseases of the genitourinary tract (kidneys, bladder, ureter, uretha)" by obtaining such organs from aborted babies for research.² In its application for funding to be a GUDMAP "tissue hub and collection site" Pitt states that its Health Science Tissue Bank (HSTB) has been involved in procuring and disbursing the body parts of aborted babies for years, noting that "the fetal tissue IRB [Institutional Review Board] has been in place since 2005."³ The application contains references in several places regarding the HSTB to the Pitt Institutional Review Board (IRB)⁴ but also states that the IRB forms are in the process of being altered⁵ and the IRB review is pending.⁶

First, Pitt's application raises concern that it has failed to comply with federal law prohibiting the alteration of abortion procedures solely for the purpose of obtaining fetal tissue, which states that an attending physician may have "no part in any decisions as to the timing, method, or procedures used to

² NIH RePORT Project Details. "University of Pittsburgh as the GUDMAP Tissue Hub and Collection Site." Abstract Text. <u>https://reporter.nih.gov/search/p3w-bb6YsECf3hOTrF_iLA/project-details/9944639#history</u> ³ University of Pittsburgh, Application for Federal Assistance SF 424 (R&R), Page 7.

¹ Award Letter. Department of Health and Human Services National Institutes of Health. Grant number 1U24DK110791-01. September 12, 2016.

 ³ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Page 7.
<u>https://www.centerformedicalprogress.org/wp-content/uploads/2021/08/GUDMAP2015NIHappFOIA.pdf</u>
⁴ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Pages 7, 60, 61, 64.

⁵ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Pages 62, 65, 70.

⁶ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Page 6.

terminate a pregnancy."⁷ It is not clear that Pitt has complied with these legal requirements based on the following statements on Pitt's grant application:

- Pitt states that "ischemia time is minimized" when it obtains fetal tissue.⁸ NIH defines "ischemia" as "time a tissue, organ, or body part remains at body temperature after its blood supply has been reduced or cut off but before it is cooled or reconnected to a blood supply."⁹ It would be illegal for Pitt to alter the"timing, method, or procedures" of the abortion to minimize ischemia time.
- Pitt states that it "tailor[s] [its] collection processes on a case-by-case basis to maximize the needs of investigators."¹⁰ It would be illegal for researchers to have any part in the decisions surrounding the obtainment of fetal tissue from elective abortions.

Second, if the organs were harvested from babies born after induced abortion, we are concerned that some of these babies were born alive, could have survived with appropriate care, and may have died as a result of having their organs harvested. Pitt's application states that it can obtain access to the organs and tissues of unborn babies between 6-24 weeks gestation, but it partners with another organization to obtain unborn babies between 25-42 weeks gestation.¹¹ Babies as young as less than 22 weeks gestation have been known to survive outside the womb with appropriate care.¹² The statements about "warm ischemia" raise questions about the cause of death for these babies. As noted above, Pitt states that it sought to minimize the time between when the blood supply to an organ was reduced and when the organ is cooled or reconnected. If the organs are harvested from a baby born after induced abortion, it is possible the baby was delivered alive, and the removal of the organs was the cause of the baby's death.

Exploiting the body parts of aborted children for research purposes is repulsive and should stop, regardless of the outcome hoped for by researchers. Research using abortive fetal tissue is unethical, wrong, and has also been proven ineffective. Despite being used in clinical research since the 1920s, fetal tissue has not produced a single clinical treatment.¹³

Based on these considerations, for the federal awards given the project number 1U24DK110791, please provide fulland clear responses to the following information requests going back to the beginning of the grant project period to today:

• The number of cases at each gestational age involving abortion, miscarriage, stillbirth, and neonate utilized in the GUDMAP program during the grant project period;

⁹ <u>Definition of warm ischemia time - NCI Dictionary of Cancer Terms - National Cancer Institute</u> ¹⁰ "JW v HHS NIH July 2021 Records 00642 pg 170." Judicial Watch. August 3, 2021. https://www.judicialwatch.org/documents/hhs-cmp-responsive-records-july-2021-pg-170/

¹¹ University of Pittsburgh. Application for Federal Assistance SF 424 (R&R). Page 60.

¹² Ahmad, Kaashif A. et al. "Two-Year Neurodevelopmental Outcome of an Infant Born at 21 Weeks' 4 Days'
Gestation." *Pediatrics.* November 2017. <u>https://pediatrics.aappublications.org/content/early/2017/10/31/peds.2017-0103</u>

¹³ "Final Report." Select Investigative Panel of the Energy & Commerce Committee. 30 December 2016. Pg. 386.

⁷ 45 C.F.R. 46.204(i). This regulation extends to all Federally-funded human fetal tissue research the statutory requirements of 42 U.S.C. 289g-1, which states that, "no alteration of the timing, method, or procedures used to terminate the pregnancy [may be] made solely for the purposes of obtaining the tissue" for "research on the transplantation of human fetal tissue for therapeutic purposes."

⁸ "JW v HHS NIH July 2021 Records 00642 pg 170." Judicial Watch. August 3, 2021.

https://www.judicialwatch.org/documents/hhs-cmp-responsive-records-july-2021-pg-170/

- Detailed protocols for Dilation & Curettage, Dilation & Evacuation, and Labor Induction followed to obtain fetal tissue for the GUDMAP program;
- The detailed biospecimen collection IRB application and approval for the Health Science Tissue Bank;
- Documentation to verify the physiological status of babies delivered by labor induction upon tissue harvest;
- The number of fetal tissue collection procedures from babies delivered by labor induction;
- Documentation of the number of babies delivered by labor induction that were deceased, and cardiac activity had ceased prior to fetal organ and tissue collection;
- Documentation of when "warm ischemia" time was recorded with reference to death when collecting organs and tissue from abortion, miscarriage, stillbirth, and neonate;
- Documentation on the specific steps that were taken to minimize warm ischemic time when collecting organs and tissue from abortion, miscarriage, stillbirth, and neonate;
- Details on how specimens are collected and transferred to the Tissue Hub and the personnel involved at each step;
- Documentation of how compliance is ensured (including any reporting and oversight mechanisms) with regard to each of the following statutes and regulations:
 - The Partial-Birth Abortion Ban Act (18 U.S.C. 1531);
 - Research protections for pregnant women and fetuses (42 U.S.C. 289g, 289g-1, and 45 C.F.R. 46.204);
 - o Research protections for neonates (45 C.F.R. 46.205); and,
 - Prohibitions regarding fetal tissue (42 U.S.C. 289g-2, 45 C.F.R. 46.206).

We appreciate your attention to this matter and look forward to your prompt and thorough response to each of these requests. We ask for a response by the date of October 12, 2021.

Sincerely,

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Josh Hawley United States Senator

Lis C Mectain

Lisa McClain Member of Congress

Jeve Dains

Steve Daines United States Senator

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Ted Cruz United States Senator

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John Boozman United States Senator

Bill Cassidy, M.D.

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