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**Health and Human Services Finance Committee
H.F. 2865, Aborted Fetal Tissue Research at the University of Minnesota
March 31, 2016**

To the Distinguished Chair, Rep. Matt Dean, and Honorable Members of the Committee:

Thank you for giving me the opportunity to testify before you today about the importance of establishing a fetal tissue research center at the University of Minnesota that would provide oversight on the ethical procurement and use of fetal tissues at the university. *The opinions expressed here are my own and do not represent the official position of my institution.*

I have 20 years of experience studying the pathologic basis of disease with an emphasis on inherited genetic disorders in children. I earned a PhD in Biochemistry from the Medical College of Wisconsin, which involved the study of novel proteins in blood cell development and leukemia. I completed postdoctoral training in cell and molecular biology at Harvard Medical School, which focused on mechanisms of cardiac valve development and vascular disease. This work was continued at the Medical College of Wisconsin, where I directed a research lab for 5 years. As part of these studies, we obtained discarded heart valve tissue from children undergoing surgical procedures to repair their congenital defect. This tissue was then used to identify key pathways involved in heart development. I am currently conducting research on SIDS where we obtain postmortem tissue from autopsies to detect genetic variants that contribute to unexplained death in children. I also direct a molecular diagnostics lab in Pathology and Laboratory Medicine that performs clinical testing using various specimen types for the diagnosis and treatment of children with disease including cystic fibrosis, epilepsy, hearing loss, DiGeorge Syndrome, and hypercoagulation disorders. As such, I am testifying as a scientist with first-hand knowledge that ethical human tissue sources exist and are available for conducting successful research.

I want to begin by defining the term fetal tissue. Fresh fetal tissue is material procured from a baby that died from an induced abortion or from a spontaneous abortion (miscarriage). Cells can be isolated from fetal tissues and used for research as well (either as primary cells or established cell lines that may be cultured indefinitely), such as the HEK293 cell line, which was established from human embryonic kidney cells of an aborted fetus. Several investigators use cell lines established from induced abortions. Even though I would like to see these cells replaced with alternatives, I want to make the clear distinction that, to my best of knowledge, this bill would not impact investigators currently conducting research using cell lines, such as HEK293, from induced abortions. According to the recent Huron Report, this bill only impacts 8 current faculty at the University of Minnesota that are using, or have used since January 1, 2010, fetal tissue for research. Nationwide, NIH budgeted over \$30 billion dollars to research and only 0.25% (\$76 million) of this funding is allocated to fetal research. The establishment of this center will provide an opportunity for these few investigators to continue conducting fetal tissue

research through the procurement of fetal tissue from miscarriages, while satisfying ethical concerns.

For those that claim research will stop and discoveries delayed if limitations are placed on fetal tissue research, it needs to be clear that no current medical treatments exist that have required research using fetal tissues from induced abortions for their discovery or development. Even Dr. Goldstein, who is Director of the UC San Diego Stem Cell Program and actively conducts research using fetal tissue from induced abortions stated in response to his testimony at the federal hearing for the US House of Representatives Select Investigative Panel on March 2nd that he is “not aware of any [therapies] that have been definitely solved using fetal tissue”. There is ample evidence in support of how ethical tissue sources in research have made significant advancements in medicine. For example, blood is a rich source for treatment of leukemia, lymphoma, and various genetic diseases of the blood. This treatment is commonly referred to as a bone marrow transplant, where adult stem cells from a donor’s bone marrow are transplanted into another patient with disease (Gratwohl et al, 2015). The production of biologic therapies and vaccines has also proven to be successful using non-fetal sources. Examples include the use of bacteria to develop insulin for diabetes (Agrawal and Bal, 2012) and Chinese hamster ovary cells to develop HerceptinTM for breast cancer (Li et al., 2010). Several vaccines exist in the U.S. that are also made with non-fetal cell lines (some exclusively so), including Hepatitis B, DTaP, flu, and meningitis (<https://cogforlife.org/vaccine-overview/>). Unfortunately, some manufactures have not invested the time or money needed to produce ethical versions of vaccines, especially in light of the heavy regulatory burden that exists for such changes, and for this reason, all MMR, chicken pox and Hepatitis A vaccines available in the US are still made with cells from aborted babies.

So what compels researchers to pursue fetal tissue? The cells from fetal tissue are considered valuable because they divide rapidly, adapt to new environments easily, are less susceptible to rejection than adult cells when transplanted, and consist of specific cell types important for specific areas of research (such as astrocytes in the study of Alzheimer’s). An investigator that desires to work with fetal tissue has the choice to either obtain fetal tissue from induced abortions that is readily available through procurement organizations such as StemExpress and Advanced Bioscience Resources or from spontaneous abortions and ectopic pregnancies. The first choice is morally objectionable and wrought with ethical concerns, which my colleague, Dr. Feeney, will explain in the next testimony. The second choice to use tissue from miscarriages is an ethical solution. However, this type of tissue is not as readily available commercially, which is why this bill creates an outstanding opportunity for the University of Minnesota to establish such a center.

Those opposed to using fetal tissue from miscarriages argue that an insufficient amount of suitable tissue would be available for certain studies, such as transplantation. Several papers published by Dr. Maria Michejda at Georgetown University School of Medicine outline very clearly that spontaneous miscarriages are a useful and ethical alternative source of fetal stem cells for hematopoietic cell transplantation (for review see Michejda, 2002, 2004), and other labs have agreed with her findings (Low et al, 1994; Wu et al., 1999). An additional report characterized 12 and 18 week old fetuses from spontaneous abortions and was able to study key cells involved in brain development (Virgintino et al., 1998). Another study was recently conducted using fetal tissues from both induced and spontaneous abortions, side-by-side (Kang et al., 2016).

Other arguments against the use of fetal tissue from miscarriages include the unknown

time of death and possible genetic abnormalities. In regard to timing, numerous reports, together with Dr. Michejda's epidemiological studies, have indicated that over 15% of the 300,000 second-trimester miscarriages studied were suitable for transplantation (which has some of the most rigorous requirements for tissue viability), when collected and preserved properly (Michejda, 2002). In response to genetic concerns, a fetus can appear "normal" until an inherent genetic abnormality manifests itself after birth. In fact, birth defects are the leading cause of infant deaths, accounting for 20% of all infant deaths (Matthews et al., 2015). So like miscarriages, fetal tissue from induced abortions can also carry genetic abnormalities. In addition, the use of the abortion drug, mifepristone (RU-486), and prostaglandins for the medical termination of pregnancy may substantially reduce the availability of human fetal tissues from induced abortions (Branch et al., 1995). Furthermore, if there are concerns that tissues from miscarriages are not "normal", comprehensive screening tools are available and can be used to identify relevant genetic abnormalities.

I believe the University of Minnesota is poised to make an important decision that will impact generations to come. You have a unique opportunity to establish a nationally renowned fetal tissue center that would focus on the ethical procurement of tissues for research. I am excited by this possibility and encourage you to pass this bill, from both a moral and scientific perspective.

Respectfully,
Tara Sander Lee, PhD

**The opinions expressed here are my own and do not represent the official views of the Medical College of Wisconsin or Children's Hospital of Wisconsin*

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