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April 6, 2016
Responses to Additional Questions for the Record from Chairman Blackburn

1. **In response to a question about "obtaining embryos on demand" (referencing Exhibit F), you testified that "my concern is that researchers have come to count on induced abortions for their research."**

Please elaborate on what alternatives to fetal tissue from induced abortion that are available to researchers.

As I am neither a scientific or medical researcher, I am not qualified to respond to the availability of alternative sources. As a lawyer and bioethicist, I am aware of reports of successes in using ethical tissue sources, such as adult stem cells and induced pluripotent stem cells (iPSCs), to treat a broad range of diseases. Their availability and value would seem to be reflected in the allocation of public funds for research using these alternatives, including funding previously directed to embryo stem cell research.[1]

It may be that using ethical alternatives requires greater patience. Even if developing therapies for diseases takes longer, alternatives to fetal tissue must be employed. This is ethically preferable; I would argue that it is ethically mandated. These diseases have existed for centuries. Just because new techniques are available does not warrant unethical shortcuts in order to trim a few months or years from developing a therapy, if the cost is the destruction of presently existing human beings for the sake of unidentified future human beings.

Also, are there other steps that could be taken to reduce researchers demand for fetal tissue from induced abortions without jeopardizing research?

Again, I am not qualified to respond to researchers' demand for fetal tissue. However, I would note the obvious: demand for fetal tissue, and the reliance on its availability, exists because of the widespread practice of abortion. Were fetal remains not widely available, other avenues would be devised. In fact, recent research on vaccines or treatments for diseases which have garnered global public attention, such as the Ebola and Zika viruses, does not rely on fetal tissue.[2]

2. In response to a question about whether a series of emails (Exhibits B1-Be) raised any ethical concern, you testified that "it completely fails to isolate abortion from the decision about the fetal tissue and consent to use the fetal tissue" and that there was "no indication of consent prior to this procedure or for these specific parts to be excised."

What ethical concerns arise when there is a failure to isolate an abortion procedure from the patient consent obtained for fetal tissue donation prior to an abortion being performed?

The moral harm of abortion cannot be undone by donating the fetal remains for research. Nor can the mechanism of procuring the specific fetal body parts requested be separated from the abortion procedure. Research that relies on induced abortion is not simply a matter of using material that is available. An entire industry has grown up around the practice of abortion, to the extent that institutions routinely submit purchase orders not only for entire fetuses, but also for specific body parts. Ordering specific parts treats the fetus as a product to be dissected piecemeal, and the woman as a convenient incubator.[3] The purchase orders referenced in Exhibit A-1 indicate that a single fetus may be parsed among at least two institutions.

Separation of consent to abortion and consent to donation. Federal law makes clear that the woman's consent to donate fetal remains for research must be solicited separately from, and subsequent to, her decision to abort.[4] One of the reasons for this dividing line between the abortion decision and the donation decision is to ensure that a woman not be induced to obtain an abortion because of the possibility that "some good might come out of it." Whether or not donation is a significant inducement, it is a significant ethical consideration.

In the case of cadaveric organ donation, the discussion with the patient's family, and their decision about, continuation of life-sustaining treatment must be separated from discussion about organ donation. The same personnel should not conduct or even participate in both discussions, creating clear lines between when and where each informed consent conversation takes place, and who is involved.[5] In part, this ensures that the patient's best interests are protected. Also, it minimizes the possibility that a compelling organ procurement officer might induce the family to consent to donation and removal of life-sustaining treatment they otherwise would have continued. The Office of Inspector General of the Department of Health and Human Services notes that "Families are asked to give their consent at a point in time when they are extremely vulnerable."[6]

Preying upon the woman's vulnerability. In the abortion context, discussion about donation of fetal remains that is close in time, location, and with the same person, may unduly pressure a woman who is not only vulnerable, but may be ambivalent about the upcoming abortion. The stress of any surgery may make it difficult to process the long-term implications of an immediate decision, let alone future regrets or satisfaction. Contemplating an abortion is a stressful event. The UK Human Tissue Authority (HTA) writes that, "the loss or termination of a pregnancy, whatever the circumstances, is clearly an exceptionally sensitive and emotional time for a woman."[7] The HTA further notes that even if she does decide how to dispose of "pregnancy remains," she "may change her mind at a later date or ask about what arrangements were made."[8]

Time consuming process. As the Department of Health and Human Services makes clear, "informed consent is a process, not just a form."[9] Those who have years of experience with

cadaveric organ donation for transplant can attest that an adequate consent process is time-consuming, involving more than a perfunctory inquiry and a signature on a document.

Inadequacy of consent. The consent form presented at the hearing on "Bioethics and Fetal Tissue"[10] is grossly deficient. It misrepresents the state of fetal tissue research, alleging that through such research cures have been found for "such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS." A woman reading this statement might be induced to donate because she believes that her child's tissue might be used to "cure cancer."

If she were given fully informed consent, she might even change her mind about proceeding with the abortion. Specific elements of fully informed consent include how the tissue will be stored; notification if the tissue is deemed unusable; whether the tissue will be used outside the US; whether the tissue will be modified (e.g., into commercial products); receipt of a copy of the informed consent document; and, the morally relevant distinctions between the 'for profit' and 'nonprofit' organizations involved.[11] The schedule of graduated "bonus" payments to procurement technicians procuring a greater number of specimens[12] is a glaring ethical violation. It points toward a profit motivation in obtaining the woman's consent, particularly if the technician is the person designated to obtain consent. Her refusal to consent translates into reduced income for the technician.

Outside the abortion context, consent forms itemize the specific organs and tissues being donated. It should be no different for abortion: the specific body parts that will be harvested, whether a brain, spinal cord, liver, thymus, or lungs. This information is relevant, and might even give her pause about her abortion decision. The risk of "humanizing" the human fetus is no excuse for shoddy practices.

Separation of abortion procedure from request to harvest specific tissues. Further, there must be "no alteration of the timing, method, or procedure used to terminate the pregnancy solely for the purposes of obtaining the tissue."[13] Although the Exhibit A-3 consent form states that there will be "no changes to how or when my abortion is done," there must be independent corroboration of this statement. The woman's consent to the abortion and her separate consent for donation should be not only signed and dated, but also time stamped, and her medical records should note the same. The scheduling and method of abortion procedure should be noted in her records *prior* to any discussion of possible donation of fetal remains.

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[1] See, e.g., David A. Prentice, "Midwest Stem Cell Therapy Center – Kansas' Unique Initiative," Kansas Senate Ways and Means Committee, Senate Public Health and Welfare Committee, House Appropriations Committee, and House Health and Human Services Committee, February 8, 2016. Accessed online on April 7, 2016, at https://lozierinstitute.org/wp-content/uploads/2016/02/Prentice-KS-Senate-House-MSCTC-update-8Feb2016.pdf.

[2] See, e.g., Agnandji ST et al., "Phase 1 Trials of rVSV Ebola Vaccine in Africa and Europe — Preliminary Report," *New England Journal of Medicine*, published on April 1, 2015; doi: 10.1056/NEJMoa1502924; originally developed by the Public Health Agency of Canada, which patented it in 2003, http://www.google.com/patents/WO2004011488A2?cl=en (using a monkey cell line).

See also, Tang H *et al*., Zika Virus Infects Human Cortical Neural Progenitors and Attenuates Their Growth, *Cell Stem Cell* 18, 2016; *in press*, doi: 10.1016/j.stem.2016.02.016 (using human induced pluripotent stem cells (iPSCs). Accessed online April 7, 2016 at http://www.cell.com/cell-stem-cell/abstract/S1934-5909(16)00106-5.

[3] See Exhibit B-2, where emails sent during the procedure discuss the availability and condition of specific body parts (calvarium and limbs).

[4] 42 U.S.C. §289g-1 (2010).

[5] See, e.g., "Ethical Controversies in Donation after Cardiac Death," Policy Statement, American Academy of Pediatrics, *Pediatrics* 131, no. 5 (2015): 1021-1028. Available at http://pediatrics.aappublications.org/content/pediatrics/131/5/1021.full.pdf.

[6] U.S. Department of Health and Human Services "Informed Consent in Tissue Donation: Expectations and Realities" prepared by the Office of Inspector General, January 2001, 6.

[7] Human Tissue Authority, "Guidance on the Disposal of Pregnancy Remains Following Pregnancy Loss or Termination," published March, 2015, accessed February 29, 2016, 3. https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf

[8] Human Tissue Authority, "Guidance," 3–4.

[9] U.S. Department of Health and Human Services, *Informed Consent Tips (1993)*, prepared by the Office for Protection from Research Risks, last modified May 16, 1993, accessed February 29, 2016, http://www.hhs.gov/ohrp/policy/ictips.html.

[10] Exhibit A-3.

[11] Laura A. Siminoff and Heather M. Traino, "Consenting to Donation: An Examination of Current Practice in Informed Consent for Tissue Donation in the US." *Cell Tissue Bank* 14, no. 1 (2013): 85–95

[12] Exhibit A-2.

[13] 42 U.S.C. §289g-(b)(2)(A)(ii).