## TESTIMONY OF PAIGE COMSTOCK CUNNINGHAM, JD, EXECUTIVE DIRECTOR, THE CENTER FOR BIOETHICS & HUMAN DIGNITY TRINITY INTERNATIONAL UNIVERSITY DEERFIELD, ILLINOIS

## **HEARING ON**

## "BIOETHICS AND FETAL TISSUE" BEFORE THE SELECT INVESTIGATIVE PANEL OF THE COMMITTEE ON ENERGY AND COMMERCE U. S. HOUSE OF REPRESENTATIVES MARCH 2, 2016

Chairman Blackburn and members of the Panel, thank you for inviting me to present my views, which are consistent with those of my employer The Center for Bioethics & Human Dignity on the bioethical issues involving the use of fetal tissue for research and therapeutic purposes.

The Center is a Christian bioethics research center at Trinity International University in Deerfield, Illinois. Founded more than twenty years ago, the Center's mission is to ensure that academic and clinical discussions on bioethics include a robust understanding of human dignity within the broad Judeo-Christian Hippocratic traditions. By so doing, we endeavor to help others make sound ethical choices when faced with concerns that arise at the intersection of medicine, science, and technology.

As a lawyer who has turned her professional attention to bioethics, I am deeply concerned with the ethical issues surrounding the procurement and use of fetal bodies, organs, and tissues in research.

There should be no doubt that the use of cadaveric fetal organs and tissue for research and clinical applications raises serious moral and ethical concerns, concerns that are heightened when the organs and tissue are obtained as the result of elective abortion. A vast literature proves this fundamental point, as does a simple statement on the website of the Office of Intramural Research, National Institutes of Health: "Research using fetal tissues is not prohibited but is highly regulated." Were there is no controversy, the literature would not be vast, and the regulation would be light.

The fetus is a human subject entitled to the protections that both traditional and modern codes of medical ethics provide to human subjects. The fetus, as a uniquely vulnerable and dependent human person, merits the same (or even heightened) protections that modern declarations and codes of medical ethics impose on all human subject research. Current legal standards and other guidelines fail in this regard, giving insufficient recognition to the moral status of the fetus and violating norms of informed consent.

*Biological and moral status of the fetus.* (What follows is the briefest mention of serious philosophical arguments about the moral status of the fetus that have been addressed extensively elsewhere.) The human fetus, and in its earlier stages, the embryo, has been variously viewed as

<sup>&</sup>lt;sup>1</sup> National Institutes of Health Office of Intramural Research, "Fetal Tissue Research," last modified February 16, 2016, accessed February 29, 2016, <a href="https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/fetal-tissue-research">https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/fetal-tissue-research</a>.

"a nonpersonal organism;" tissue; a potential or future person; a human entity entitled to special respect or special regard; a human being whose moral standing increases during gestation; or an immature human being with the same moral status as an adult human being.

Science establishes that the nascent human, as a blastocyst, then an embryo, then a fetus, is an organism of the species *Homo sapiens*, and genetically distinct from both father and mother. She<sup>8</sup> is a determinate humane being, enduring over time, who directs her own integral organic functioning. Given time, nutrition, and a safe environment, the embryo, then fetus, will grow and develop through all the natural stages of human life. Rather than being a distinct—and lesser—form of human life, the fetus is a distinct human being at a particular developmental stage. As such, she is not a potential human being, but an actual human being, whose life should not be intentionally ended by force. It is "morally impermissible to engage in any research, for any purpose, that involves the destruction of human beings at any stage of their lives, including

<sup>&</sup>lt;sup>2</sup> National Commission for the Protection of Human Subject of Biomedical and Behavioral Research, *Research on the Fetus: Report and Recommendations*, report for the Commission of a prepared paper by Joseph Fletcher (Bethesda, MD: U.S. Department of Health, Education, and Welfare, 1975), 32.

<sup>&</sup>lt;sup>3</sup> National Commission for the Protection of Human Subject of Biomedical and Behavioral Research, *Research on the Fetus: Report and Recommendations*, report for the Commission of a prepared paper by Richard Wasserman (Bethesda, MD: U.S. Department of Health, Education, and Welfare, 1975), 39.

<sup>&</sup>lt;sup>4</sup> Alberto Giubilini and Francesca Minerva, "After-Birth Abortion: Why Should the Baby Live?" *Journal of Medical Ethics* 39, no. 5 (2013): 261–263.

<sup>&</sup>lt;sup>5</sup> Davis v. Davis, 842 S.W.2d 588 (Tenn. 1992).

<sup>&</sup>lt;sup>6</sup> Carson Strong, "The Moral Status of Preembryos, Embryos, Fetuses, and Infants." *Journal of Medicine and Philosophy* 22, no. 5 (1997): 457–478.

<sup>&</sup>lt;sup>7</sup> Robert P. George and Christopher Tollefsen, *Embryo: A Defense of Human Life*. (New York: Doubleday, 2008).

<sup>&</sup>lt;sup>8</sup> The fetus may be variously referred to as 'it,' 'him,' 'her,' or 'him/her.' None should be interpreted to diminish the full humanity and moral status of the fetus.

<sup>&</sup>lt;sup>9</sup> Maureen Condic, "Human Embryology: Science Politics versus Science Facts," *Quaestiones Disputatae* 5, no. 2 (2015): 47–60.

the embryonic stage, or in any condition, however weak or dependent." Those who are responsible for terminating the life of a fetus have failed to recognize this fundamental principle of human dignity, and thus have no moral claim to be able to donate or assign the body, organs, or tissues of the fetus to others, regardless of the nobility of purpose.

Legal status of the fetus. The legal status of the embryo and fetus is at odds with the scientific facts and moral reality. In *Roe v. Wade,* The U.S. Supreme Court decided that the fetus is not a "person" for purposes of constitutional rights. <sup>11</sup> Elective abortion, the source of most fetal tissue used in research, has been permitted throughout pregnancy since 1973. <sup>12</sup> Lamentably, the US is one of only four nations that permit abortions after viability. <sup>13</sup> Unlike born human beings, the fetus-to-be-aborted lacks meaningful constitutional, statutory, or regulatory protection. This exposure makes the fetus vulnerable to callous disregard for her well-being, and makes it easier to regard her as the "other," as an object of interest to researchers, rather than as a human being with interests of her own. Human fetal tissue procurement entities facilitate acquisition of cadaveric fetal organs and tissue, but this does not, in itself, insulate researchers from the moral concerns. Yet, the history of medical research ethics is one of increasingly rigorous protections, particularly for vulnerable populations, such as children as those who may not benefit directly from the research. The fetus-to-be-aborted would seem to be among the most

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<sup>&</sup>lt;sup>10</sup> George and Tollefsen, 25.

<sup>&</sup>lt;sup>11</sup> Roe v. Wade, 410 U.S. 113 (1973).

<sup>&</sup>lt;sup>12</sup> See, e.g., Elizabeth Moore, "Moral Sentiments in Judicial Opinions on Abortion," *Santa Clara Law Review* 15, no. 3 (1975), 633: The Court, "in practical effect ... legalized abortion on demand in this country."

<sup>&</sup>lt;sup>13</sup> The other three nations are Canada, China, and North Korea. Americans United for Life, "United States Abortion Policy in the International Context," accessed February 29, 2016, <a href="http://www.aul.org/united-states-abortion-policy-in-the-international-context/">http://www.aul.org/united-states-abortion-policy-in-the-international-context/</a>.

vulnerable human beings of all, yet due to the mother's elective abortion, is beyond the reach of most regulatory consideration.

Human subject research ethics. If the fetus is a human being, then he or she should be entitled to legal and ethical protections for human subject research. Contemporary ethical guidelines for using human subjects in medical research generally adhere to the principles of respect for persons or autonomy, beneficence, nonmaleficence, and justice. Beginning with the Nuremberg Code of 1947 and its condemnation of research on unwilling subjects, principles of medical research have expanded protections for children and other vulnerable populations, ensured that consent is genuinely informed and voluntary, required that risks to participants be minimized, and expanded access for participants to the benefits of the research. The World Medical Association's Declaration of Helsinki in 1964 laid down the cornerstone principles for physicians and other participants in medical research involving human subjects. Two of its provisions included separating the roles of physician and investigator, and distinguishing therapeutic research from that which was "purely scientific and without therapeutic value to the person subjected to the research." Further, the Declaration applies not only to human subjects, but also to research on "identifiable human material" or identifiable data." <sup>15</sup> In fact, international studies using fetal cadaveric tissue report compliance with the Declaration of Helsinki in the procurement and processing of tissue or organs. 16 Even companies that do not conduct trials or studies *in vivo* follow the principles of the Declaration. <sup>17</sup>

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World Medical Association, *Declaration of Helsinki*, 1964, "Introduction."

<sup>&</sup>lt;sup>15</sup> World Medical Association, *Declaration of Helsinki*, 2000, para. 1.

<sup>&</sup>lt;sup>16</sup> See, e.g., Roderick C. Slieker, Matthias S. Roost, Liesbeth van Iperen, H. Eka D. Suchiman, Elmar W. Tobi, Françoise Carlotti, Eelco JP de Koning, P. Eline Slagboom, Bastiaan T. Heijmans, and Susana M. Chuva de Sousa Lopes. "DNA Methylation Landscapes of Human Fetal Development," *PLoS Genetics* 11, no. 10 (2015), 1–19; see especially page 12.

A few years after the Declaration of Helsinki was adopted, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1975 addressed research involving living, nonviable fetuses. Although much of the report focused on the to-beaborted fetus, a majority of the members also approved the use of the dead fetus, fetal tissue and fetal material. The use of fetal tissue was more directly addressed in 1998 by the NIH Human Fetal Tissue Research Transplantation Panel. New guidelines had to be developed for research using cadaveric fetal organs and tissue. The NIH panel attempted to erect a barrier between abortion and fetal tissue research, to keep the contested morality of abortion from tainting the ethics of using aborted fetal remains. The Committee for Pro-Life Activities of the National Conference of Catholic Bishops contended that taken in the abstract, even if "it may not be wrong in *principle*", it was difficult to see how the *practice* could avoid "a morally unacceptable collaboration with the abortion industry." Current events suggest that the problem has not been resolved, and that morally unacceptable collaboration continues.

Federal law permits and regulates transplantation of fetal tissue from induced abortion, as well as spontaneous abortion and stillbirth.<sup>20</sup> Although originally drafted in response to fetal tissue transplantation experiments, §289g-1 of Title 8 of the Code of Federal Regulations is

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<sup>20</sup> 42 U.S.C. §289g-1 and §289g-2 (2010).

Christina Krabbe, Sara Thornby Bak, Pia Jensen, Christian Von Linstow, Alberto Martínez Serrano, Claus Hansen, and Morten Meyer. "Influence of Oxygen Tension on Dopaminergic Differentiation of Human Fetal Stem Cells of Midbrain and Forebrain Origin," *PloS One* 9, no. 5 (2014), 1–16; see especially page 2.

<sup>&</sup>lt;sup>17</sup> See, e.g., Genoskin, "Declaration of Helsinki & Human Skin Research," accessed on February 29, 2016, <a href="http://www.genoskin.com/en/declaration-of-helsinki/">http://www.genoskin.com/en/declaration-of-helsinki/</a>.

<sup>&</sup>lt;sup>18</sup> National Commission for the Protection of Human Subject of Biomedical and Behavioral Research, *Research on the Fetus*, 75.

Department of Health and Human Services/National Institutes of Health, "Report of the Fetal Tissue Transplantation Research Panel: Volume 2," (Bethesda, MD: 1988), E41.

interpreted to apply to the use human fetal tissue in research.<sup>21</sup> Fetal tissue research is also subject to the Common Rule, which requires that an Institutional Review Board (IRB) approve the research protocol.<sup>22</sup> The woman's participation must be solicited separately from, and subsequent to, her decision to abort. 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."<sup>23</sup> Whether any alteration was in fact made is not independently verified; the physician merely has to sign a statement to that effect. There is no effective oversight to ensure compliance with this regulation, as the vast majority of abortions take place in clinics that are outside the ordinary system of healthcare, and thus are not subject to established institutional oversight and accreditation requirements that exist in hospitals and ambulatory surgical centers. Further, they rigorously resist health standards that are imposed on other ambulatory surgical centers from being applied to their abortion clinics.

More recent guidelines for federally funded research exhibit solicitude for living fetuses as research subjects, but not for cadaveric fetuses.<sup>24</sup> If the research involves a fetus-to-be-born, both mother and father must consent. But if the mother chooses to terminate her pregnancy, only her consent is required for research using the fetal remains. To insulate fetal tissue donation from

<sup>&</sup>lt;sup>21</sup> Congressional Research Service, Fetal Tissue Research: Frequently Asked Questions by Kristin Finklea et al. (July 31, 2015), accessed February 29, 2016. http://www.fas.org:8080/sgp/crs/misc/R44129.pdf

<sup>&</sup>lt;sup>22</sup> "The Common Rule is the informal name given to core federal regulations governing the protection of human subjects in research supported or conducted by the federal government." Ibid., 8, fn. 33.

23 42 U.S.C. sec, 289g-1(2)(A)(ii) (2010).

<sup>&</sup>lt;sup>24</sup> 45 C.F.R. 846.204.

encouraging abortion, the woman must not be offered monetary or other inducement to terminate her pregnancy.<sup>25</sup> Again, this takes place outside of established institutional oversight.

Two provisions of the recent revision of the Declaration of Helsinki in 2000 are worth noting. First is the revision's statement that "considerations related to the well-being of the human subject should take preference over the interests of science and society." Although the "human subject" applies to living subjects, it does seem that the interests of "science and society" have outweighed concern for the fetus whose death is not due to accident or disease, but due to her vulnerable status of being undesired by her mother. Second, the Declaration rejects using people as a means to an end, particularly vulnerable populations, that is, "those who will not benefit personally from the research." Of course, even if the research could benefit *other* fetuses in utero, this would still be a case of using *this* fetus as a means to that end.

For the most part, the trajectory of the development of public policy on protection of human subjects in medical research is one of continual expansion, and heightened concern to ensure that vulnerable populations are not disadvantaged or exploited. This circle of concern ought to include the fetus-to-be-aborted. Consequently, the only permissible research involving human fetuses ought to be research that is for their benefit, or if not for their benefit, research that causes no more than minimal harm.<sup>28</sup>

Thus far, my comments have focused on the general principles of research ethics that ought to be applied to research involving fetal tissue obtained as the result of elective abortion. I now turn to the specific issue of informed consent, a prerequisite for ethical research on human

<sup>&</sup>lt;sup>25</sup> 45 C.F.R. §46.204(h).

<sup>&</sup>lt;sup>26</sup> Declaration of Helsinki, 2000, para. 5.

<sup>&</sup>lt;sup>27</sup> Declaration of Helsinki, 2000, para. 8.

<sup>&</sup>lt;sup>28</sup> This might include research such as observational studies and nonintrusive measurement.

subjects. In this specific context, the ethics of consent cannot be limited to the standard criteria of competence, capacity, understanding, and ability to communicate. In addition, we must consider the moral agency of the person called upon to give consent, that is, the mother of the fetus-to-beaborted. Our assessment of her moral agency will in turn depend on our position regarding the status of the unborn child, and the ethics of abortion.

If one takes the perspective that the fetus possesses diminished moral interests, or none at all, her decision to abort is not problematic. Thus, the mother might choose to consent for the sake of "advancing research" or "eradicating a disease." Or, she might project what her unborn child would have wanted. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research discussed the "principle of proximity," the view that we would want to help those most like us. Thus, where therapies or research are being developed to help pregnant women, fetuses, and premature neonates, the fetus might be viewed as a subject who would "want" to help those proximate others.

Some ethicists would go further and argue that each of us has an obligation to provide our our own body to the human community upon our death, and, by extension, impute this obligation to the fetus. Thus, the mother would be "consenting" on behalf of her fetus, fulfilling an imputed fetal obligation to the community he is not permitted to enter. In her analysis of fetal tissue transplantation, Kathleen Nolan elaborates on a problem with this view:

In the setting of elective abortion a cruel irony thus emerges: fetuses that have been excluded from membership in the human community by a societally sanctioned maternal

decision to abort now have obligations to that same community because of membership in it  $^{29}$ 

We reject this "cruel irony." The fetus's "obligation" to the human community does not warrant overriding the principles of protection and informed consent.

A similar perspective is expressed in the advocacy of universal organ conscription, based on the principle that "dead bodies are a public resource that may be deployed to serving the common goal of saving human life." The U.S. has not adopted a moral theory of organ donation based upon "obligation to the community" or "public resource." Neither have we adopted the rule of "presumed" or "mandatory" consent. Instead, we have preserved the long-standing rule of prospective actual consent.

In consenting to terminate her pregnancy by abortion, the mother compromises her moral agency to also consent to the use of the fetal remains by others. Even though she is not the primary actor in the death of her unborn child, her consent is necessary to others carrying out the procedure. By virtue of her choice to end her child's life, she is morally disqualified from "donating" that child's remains. So, too, are the other participants in the abortion procedure. Thus, we are left with no one morally qualified to consent, an ethical barrier not reflected in the current regulatory framework, a framework that unreflectively presumes full moral agency on the part of the mother and the abortion provider.

<sup>&</sup>lt;sup>29</sup> Kathleen Nolan, "Genu ist Genug: A Fetus Is Not a Kidney," Hastings Center Report 18, no. 6 (1988): 13–19

<sup>&</sup>lt;sup>30</sup> Ibid., 14.

<sup>&</sup>lt;sup>31</sup> See, e.g., Robert D. Orr, "Addressing Issues of Moral Complicity: When? Where? Why? And Other Questions," The Center for Bioethics & Human Dignity, published May 22, 2003, accessed February 29, 2016, <a href="https://cbhd.org/content/addressing-issues-moral-complicity-when-where-why-and-other-questions">https://cbhd.org/content/addressing-issues-moral-complicity-when-where-why-and-other-questions</a>.

Even if it were morally permissible for a woman seeking abortion to donate fetal remains for research, we question whether the process for obtaining such consent meets current norms for obtaining informed consent. To illustrate this concern, I will now examine key principles of informed consent that are placed at risk or violated outright by current procedures for obtaining consent to fetal tissue donation.

*Process.* As stated by the Department of Health and Human Services, "informed consent is a process, not just a form." Thus, valid consent is more than a point in time, or a signature on a document. Procedures should be "designed to educate the subject population in terms that they can understand." An informed consent process takes time, and time represents a business cost/expense, and optimally involves someone who accompanies the patient.

Patient perspective. As someone who has sat in on informed consent discussions with a physician, either as a family member or for myself, I have experienced the well-known phenomenon of a competent patient not remembering details of what was discussed. Had I not been present, taking notes, and asking questions, much of the conversation would have been lost. Where surgery was contemplated, the informed consent discussion took place twice, the second time just before the procedure. The stress of 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. As the UK Human Tissue Authority (HTA) writes that, "the loss or termination of a pregnancy, whatever the circumstances, is clearly an

33 Ibid.

<sup>&</sup>lt;sup>32</sup> 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, <a href="http://www.hhs.gov/ohrp/policy/ictips.html">http://www.hhs.gov/ohrp/policy/ictips.html</a>.

exceptionally sensitive and emotional time for a woman."<sup>34</sup> 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."<sup>35</sup>

Whether the mother's decision to consent to the use of her fetus's body, organs, or tissue for research can be truly informed is problematic. Federal law requires that she must consent to the abortion prior to being solicited to consent to research using the aborted fetal tissue. How is the solicitation to donate tissue insulated from her abortion decision? Does it occur moments before the surgery? It would be relevant to know the timing of the solicitation, who is talking to the patient, and the nature of the discussion. Is the woman given a copy of the informed consent form(s) she signs? Do they contain detailed information about the kind of research being conducted, potential benefits expected from the research, and how the identity and origin of the tissue will be disclosed or protected? Is she made aware of the specific body parts that will be harvested? The request may be for the unborn child's eyes, his brain, his kidneys that might

<sup>&</sup>lt;sup>34</sup> Human Tissue Authority, "Guidance on the Disposal of Pregnancy Remains Following Pregnancy Loss or Termination," published March, 2015, accessed February 29, 2016, <a href="https://www.hta.gov.uk/sites/default/files/Guidance\_on\_the\_disposal\_of\_pregnancy\_remains.pdf">https://www.hta.gov.uk/sites/default/files/Guidance\_on\_the\_disposal\_of\_pregnancy\_remains.pdf</a>, 3.

<sup>35</sup> Human Tissue Authority, "Guidance," 3–4.

<sup>&</sup>lt;sup>36</sup> 42 U.S.C. sec. 289g-1(b) (2010).

<sup>&</sup>lt;sup>37</sup> 45 C.F.R. Subtitle A sec. 46.116(a)(3).

<sup>&</sup>lt;sup>38</sup> See, e.g., U.S. Department of Health and Human Services, *Informed Consent Tips* (1993), which states: "The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence."

Andrea K. McDaniels and Meredith Cohn, "Scientists Say Fetal Tissue Important in Research," *Baltimore Sun*, August 15, 2015, accessed on February 29, 2016, http://www.baltimoresun.com/health/bs-hs-fetal-tissue-20150815-story.html.

Wadman, Meredith, "The Truth about Fetal Tissue Research," *Nature*, December 7, 2015, last modified January 4, 2016, accessed February 29, 2016, http://www.nature.com/news/the-truth-about-fetal-tissue-research-1.18960.

be transplanted into a rat, <sup>41</sup> his thymus, or pancreas. <sup>42</sup> But the greatest demand might be for his liver. <sup>43</sup> Women might find this factual information relevant to their decision.

Current practices involving adults justify raising these concerns. A comprehensive study by Siminoff and Traino in 2013, of over 1,000 cases of adult tissue donation noted that specific elements of informed consent were often missing, such as 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 such as penile enlargements, or reconstructive surgeries such as eyelid repair); family receipt of a copy of the informed consent document; and, the morally relevant distinctions between the 'for profit' and 'nonprofit' organizations involved. Siminoff and Traino's findings are echoed by the conclusions of the HHS Office of Inspector General's report that "tissue banking and processing practices have gradually diverged from donor families' expectations in recent years. In fact, donors may think that their loved one's body will be used for immediately life-saving procedures or for medical education, only to learn to their horror and dismay, that all "usable" body parts were

<sup>&</sup>lt;sup>41</sup> Susan Scutti, "Kidney Harvested from Aborted Human Fetus Grown in Rat: An End to Organ Donor Shortage, Scientists Say," *Medical Daily*, January 23, 2015, accessed February 29, 2016, <a href="http://www.medicaldaily.com/kidney-harvested-aborted-human-fetus-grown-rat-end-organ-donor-shortage-scientists-319186">http://www.medicaldaily.com/kidney-harvested-aborted-human-fetus-grown-rat-end-organ-donor-shortage-scientists-319186</a>.

<sup>&</sup>lt;sup>42</sup> Tetsuya Ishii and Koji Eto, "Fetal Stem Cell Transplantation: Past, Present, and Future," in *World Journal of Stem Cells* 6, no. 4 (2014): 404–420.

<sup>&</sup>lt;sup>43</sup> See Rossella Semeraro, Vincenzo Cardinale, Guido Carpino, Raffaele Gentile, Cristina Napoli, Rosanna Venere, Manuela Gatto, Roberto Brunelli, Eugenio Gaudio, and Domenico Alvaro, "The Fetal Liver as Cell Source for the Regenerative Medicine of Liver and Pancreas," *Annals of Translational Medicine* 1, no. 2 (2013): 1–10. The authors note that "fetal liver is becoming the most promising and available source of cells" and is "highly available" (1).

<sup>&</sup>lt;sup>44</sup> 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.

<sup>&</sup>lt;sup>45</sup> 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, iii.

harvested,<sup>46</sup> or that the body was used as a crash test dummy.<sup>47</sup> One study revealed that 73% of families were not aware that the body tissue of their loved one would be bought and sold, and they objected to sale for any purpose.<sup>48</sup>

*Privacy.* Concerns about privacy are not limited to disclosure of identifiable information. (This raises the question: who is the subject here? Does "identifiable information" apply on to the fetus, or does it extend to the mother as well? As they are genetically distinct human beings, her DNA would not be involved, unless placental and umbilical tissues were harvested.) There may be additional concerns about how the woman is selected for solicitation. Who has access to her medical records, and are they authorized by law to do so?

*Discrimination.* In the history of the use of human bodies and tissues for medical education and research, there is a disturbing pattern of first seeking access to the bodies and organs of the most disadvantaged in society. The 1975 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research noted that there had been "instances of abuse in the area of fetal research" and "that the poor and minority groups may bear an inequitable burden as research subjects." It would be important to know the demographic profiles of women who are solicited to donate. Is there a disproportionate representation from

<sup>&</sup>lt;sup>46</sup> See, e.g., Kate Wilson, Vlad Lavrov, Martine Keller, Thomas Maier, and Gerard Ryle, "Skin, Bones and Tissue for Sale: How the Dead Are Being Used for Grisly Trade in Human Body Parts," *Daily Mail*, July 17, 2012, accessed February 29, 2016, <a href="http://www.dailymail.co.uk/news/article-2175006/Skin-bones-tissue-sale-How-dead-used-grisly-trade-human-body-parts.html">http://www.dailymail.co.uk/news/article-2175006/Skin-bones-tissue-sale-How-dead-used-grisly-trade-human-body-parts.html</a>.

<sup>&</sup>lt;sup>47</sup> Mark Katches, William Heisel, Ronald Campbell, "Body Donors Fueling a Booming Business," *Orange County Register*, April 17, 2000. Available at <a href="http://www.sweetliberty.org/issues/hate/bodybrokers.htm">http://www.sweetliberty.org/issues/hate/bodybrokers.htm</a>. Accessed February 29, 2016.

<sup>&</sup>lt;sup>48</sup> Laura A. Siminoff, Heather M. Traino, and Nahida Gordon, "Determinants of Family Consent to Donation," *Journal of Trauma* 69, no. 4 (2010): 956–963.

<sup>&</sup>lt;sup>49</sup> National Commission for the Protection of Human Subject of Biomedical and Behavioral Research, *Research on the Fetus*, 62.

poor or educationally disadvantaged women? From minority groups? In her discussion of the use of fetal tissue for transplantation, Nolan notes that if we make the move toward "routine salvage," this could signal a move toward the same treatment of adult cadavers "as a basic mode of cadaveric treatment," demonstrating the "harsh but fairly consistent historical practice of looking first to society's outcasts when new necrogenous materials (such as autopsy specimens) are needed." Further, the informed consent process itself may be discriminatory. The first comprehensive study in the U.S. on consenting to tissue donation noted that older adults and nonwhites (African Americans, Asians, and Hispanics/Latinos) were given less information that younger, white decision makers. 51

If such ethical problems exist in research involving adult cadaveric tissue, where institutional oversight is presumably rigorous, how much more reason do we have to think that they exist in the less-regulated context of free-standing abortion clinics?

There is yet another reason to oppose the current practices of fetal tissue research: it is unnecessary. While fetal tissue research has been going on for decades, its results have been meager. There are three general areas of application: fetal tissue transplantation, vaccine development, and basic biological research. Fetal tissue transplantation has had few successes, and a number of lamentable, even "devastating" results. Although early vaccine lines, most

<sup>&</sup>lt;sup>50</sup> Nolan, 15.

<sup>&</sup>lt;sup>51</sup> See Siminoff and Traino, 1.

<sup>&</sup>lt;sup>52</sup> See summary and references compiled by David A. Prentice, "Written Testimony: Wisconsin Assembly Committee on Criminal Justice and Public Safety." August 11, 2015. Accessed online on February 29, 2016, at <a href="https://lozierinstitute.org/written-testimony-of-david-a-prentice-ph-d-in-support-of-wisconsin-bill-to-prohibit-sales-and-use-of-fetal-body-parts-from-abortion/">https://lozierinstitute.org/written-testimony-of-david-a-prentice-ph-d-in-support-of-wisconsin-bill-to-prohibit-sales-and-use-of-fetal-body-parts-from-abortion/</a>.

<sup>&</sup>lt;sup>53</sup> Gina Kolata, "Parkinson's Research Is Set Back by Failure of Fetal Cell Implants," *New York Times,* March 8, 2001, accessed February 29, 2016,

notable poliovirus, were developed from tissue harvested from aborted fetuses, "newer cell lines and better culture technique make this reliance on fetal cells an antiquated science." The CDC and medical experts have agreed that no new fetal tissue is needed to develop rubella and other vaccines that grow in human cell culture. Basic research also "relies on antiquated science and cell cultures." More progressive alternatives include induced pluripotent stem (iPS), an unlimited, ethically-derived source of cells, "which can be produced from tissue of any human being, without harm to the individual donor, and with the ability to form virtually any cell type for study and modeling, or potential clinical application." Very little of current fetal tissue research is germane to improving fetal health. The few theoretical surveys of fetal development, for example, when certain genes are expressed, have little to no practical benefit near term.

Meanwhile, ethically derived alternatives are growing in numbers and successes. Current advances in non-destructive stem cell research hold the promise to obviate the need for cadaveric fetal tissue in research and therapy. The NIH/FDA database reports over 3,300 approved ongoing

 $\underline{http://www.nytimes.com/2001/03/08/us/parkinson-s-research-is-set-back-by-failure-of-fetal-cell-implants.html?pagewanted=all.}$ 

<sup>&</sup>lt;sup>54</sup> Prentice, Testimony.

<sup>&</sup>lt;sup>55</sup> See, e.g. Amy Otto, who quotes the CDC (a quote which is no longer available at the CDC website): "Some vaccines such as rubella and varicella [were] made from human cell-line cultures, and some of these cell lines originated from aborted fetal tissue, obtained from legal abortions in the 1960s. No new fetal tissue is needed to produce cell lines to make these vaccines, now or in the future." (Amy Otto, "Don't Let Planned Parenthood Use 'Medical Research' to Whitewash Its Baby Body Parts Atrocities," *The Federalist*, July 22, 2015.

<sup>&</sup>lt;sup>56</sup> Prentice, Written Testimony: Wisconsin Assembly Committee on Criminal Justice and Public Safety.

<sup>&</sup>lt;sup>57</sup> Prentice, Testimony.

<sup>&</sup>lt;sup>58</sup> See, e.g., Nahid Waleh, Ryan Hodnick, Nami Jhaveri, Suzanne McConaghy, John Dagle, Steven Seidner, Donald McCurnin, Jeffrey C. Murray, Robin Ohls, and Ronald I. Clyman. "Patterns of Gene Expression in the Ductus Arteriosus Are Related to Environmental and Genetic Risk Factors for Persistent Ductus Patency," *Pediatric Research*, 68, no. 4 (2010): 292–297, where authors "speculate" about benefit to fetal health.

or completed clinical trials using adult stem cells.<sup>59</sup> Worldwide, over 70,000 people receive adult stem cell transplants each year, for dozens of different conditions. Use of these therapies show no signs of slowing down, with well over one million adult stem cell transplants total.<sup>60</sup>

Rather than pursuing morally objectionable sources of human tissue for research, we would urge robust support for continuing life-saving and health-improving research and clinical applications using ethically-derived cells. We should not seek to restore our own bodies at the cost of using the tiny bodies of others, whose only offense was to be growing in the "wrong" womb at the "wrong" time. As a people, we deserve better, and as a nation we are called to be better.

A just society has no moral or other claim on electively aborted fetal bodies, organs, or tissues. Unborn children scheduled for termination by induced abortion are among the most vulnerable, if not *the* most vulnerable, populations in the human family. As has been said by many leaders in many ways, a society will be judged by how it treats its weakest, most vulnerable members. Curbing the current practice of fetal tissue research would be a small but very significant step to honor that maxim.

59 According to ClinicalTrials.gov, accessed February 28, 2016, http://www.clinicaltrials.gov/ct2/results?term=adult+stem+cell+transplants&type=Intr.

Alois Gratwohl et al., "One Million Haemopoietic Stem-Cell Transplants: A Retrospective Observational Study," *The Lancet Haematology* 2, no. 3 (2015), e91–e100.