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Use of Aborted Fetal Tissue in Research and Presentation of Ethical Alternatives

Historical background into fetal tissue research using baby body parts

In 1988, President Reagan placed a moratorium on federal funding of transplantation research using aborted fetal tissue. That moratorium remained in place until lifted by President Clinton in January 1993. Subsequently, Congressman Waxman led an effort that resulted in a statute that says, "The Secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes." [42 U.S.C. 289g-1 and g-2]

Two large controlled trials were finally funded to transplant aborted fetal brain tissue into Parkinson's patients (available here and here). Those results, which came out in 2001 and 2003, showed that fetal tissue transplants did not help patients and actually ***made many patients worse***. The *New York Times* front-page story contained the doctors' descriptions of patients writhing, twisting, and jerking with uncontrollable movements; the doctors called the results "absolutely devastating," "tragic, catastrophic," and labeled the results "a real nightmare." The National Institutes of Health (NIH) is required to report to Congress its funding of fetal tissue research; it has not funded ***any*** clinical trials with fetal tissue in over a decade.

The only real success for transplants has come from adult stem cells, which have already helped roughly 2 million people, for dozens of diseases and conditions.

Basic laboratory research using fetal tissue is not covered by the statute. Federal funding of basic research is allowed at the discretion of the Director of NIH. Current taxpayer funding is approximately ***$120 million per year.***

Exposing the sale of baby body parts

The undercover work of the Center for Medical Progress (CMP) reveals a cynical culture of disregard for human fetuses as innocent human beings by high-level executives and senior abortion performers in Planned Parenthood (PP). In fact, some Planned Parenthood sites were revealed to be knowingly conducting illegal trade in human fetal tissue with commercial buyers. However, what's most troubling about the revelation of the CMP tapes is the recorded abortion providers' bland attitudes towards aborted fetuses as faceless commodities for sale, and in some cases for personal benefit.

In 2017, the *LA Times* reported that two related companies in California, DaVinci Biosciences and DV Biologics, "reached a $7.785-million settlement with the Orange County district attorney's office over allegations that they illegally sold fetal tissue to companies around the world." The same companies were featured in the CMP tapes for sourcing fetal tissue from Planned Parenthood. "The agreement also [required] the companies to admit liability for violations of state and federal laws prohibiting the sale or purchase of fetal tissue for research purposes…"

StemExpress, a biomedical tissue procurement firm that previously sourced electively aborted fetal tissue from Planned Parenthood, severed its ties with PP in the wake of the CMP tapes. The company no longer lists fetal tissues at its website.

Advanced Bioscience Resources (ABR) is an even more troubling case that was brought to light as a result of the CMP investigation. This company was contracted by the U.S. FDA to source fetal tissue from PP for use in government biomedical research. Though ethically objectionable, these transfers would still have been legal, except that ABR may have intentionally operated at a profit, which is illegal. U.S. Health and Human Services has since revoked the FDA contract with ABR, and House and Senate committees referred ABR to the U.S. Department of Justice for investigation into criminal wrongdoing.

Vaccine production without fetal tissue

Fresh aborted fetal tissue has never been used in vaccine production. The original Salk and Sabin polio vaccines used monkey tissue to grow virus. While there are a couple of historical cell lines that were grown from abortions in the 1960s, kept in cell culture, and used for some vaccines, even these cell lines are antiquated and no longer used for most vaccines today. For example, much of the polio vaccine today is made using the Vero monkey cell line.

Many modern vaccines use animal cell lines, even insect cell lines, as well as modern human cells that are not from fetal tissue. As just a couple of examples, the new Ebola vaccine – recently shown to be 97.5% effective – is produced using the Vero monkey cell line, and the recently approved shingles vaccine (Shingrix) which is a modern recombinant subunit vaccine produced in engineered hamster cells, also than 90% effectiveness while providing better protection than the historical vaccine produced in fetal cells.

Basic research funded by NIH

In FY 2018 NIH spent $115 million on grants involving human fetal tissue research and is estimated to spend $120 million in FY 2019. Most of these grants are for research conducted at universities (extramural), but roughly $21 million is for research at NIH facilities (intramural). NIH also gives out millions of federal dollars in contracts for specific projects using fetal tissue.

Projects funded for fetal tissue research include studies on normal and abnormal development, including brain development, retinal formation and degeneration, and infectious diseases including HIV infection. This means NIH and its researchers are purchasing aborted fetal brains, eyes, livers, hearts, and other organs for these studies.

NIH has given a multi-year contract to UCSF for production of a type of humanized mouse that contains a human immune system, to study HIV infection and potential HIV drugs. The total amount of this contract, through December 5, 2020, is $13,799,501; NIH has so far paid over $10 million. The project uses aborted baby livers, thymus, bone marrow, and intestinal tissue, and the contract calls for use of organs from at least 24 aborted “donors” per year. In fact, NIH requires the use of aborted fetal organs in this contract—all from babies between 17 to 24 weeks gestation. NIH renewed the contract for 90 days in December 2018, and again in March 2019. It was set for renewal on June 5, 2019, but thankfully the Trump administration has now taken a different approach.

Alternatives to use of aborted fetal tissue in research

One alternative is use of miscarried tissue, which can be used to study development, as well as causes of pregnancy loss. Another modern alternative is use of "organoids," which are constructed from adult stem cells and induced pluripotent stem (iPS) cells. Organoids are organ-like structures and tissues that have been shown to mimic normal development and can also be used to study abnormal development and causes of birth defects. Adult stem cells, iPS cells, and postnatal tissue (neonatal and adult) can also be used to study infectious diseases and therapies, including construction of "humanized mice" to study infections.

Humanized mice—options with fetal tissue and with ethical sources

Humanized mice are mice with a human immune system. These mice are severely immune compromised and unable to fight off infection and disease, but researchers are able to regenerate a functional human immune system in these mice by engrafting (transplanting) human immune cells and tissues derived from fetal or non-fetal sources. Humanized mice are used to study immune response to human-specific infections and disease, such as HIV/AIDS, tuberculosis, Dengue, Epstein-Barr Virus, and cancer, as well as to test new therapeutic drugs. Human fetal bone fragments are also transplanted into mice to study multiple myeloma.

There are several ways to make a humanized mouse. One controversial option is using fetal tissue from aborted children. For example, the bone marrow/liver/thymus "BLT" mouse model is generated by implanting dissected human fetal liver and thymus (16-22 weeks' gestation) under the kidney capsule of the mouse and injecting CD34+ blood stem cells from the remaining liver of the same fetus into the mouse tail vein.

Another way to make humanized mice is by using cells and tissues from living donors and discarded tissues, without killing the donor to harvest its tissue. Humanized mice can be generated using peripheral blood mononuclear cells (PBMCs), often referred to as the "hu-PBMC" or "hu-PBL" mouse. Another model is called the "hu-HSC" mouse, generated using CD34+ hematopoetic (blood) stem cells (HSCs), which can be obtained from bone marrow, cord blood, and peripheral blood. A newer option, called the "NeoThy" mouse uses neonatal thymus tissue from surgical procedures, which is 50 times more efficient and 1,000 times more cost effective than aborted fetal tissue for generating the same number of mouse models.

Medical breakthroughs using alternative research methods

We can use peripheral blood, cord blood, bone marrow, and neonatal thymus tissue to make humanized mouse. In fact, a recent study showed that the hu-HSC alternative mouse model is sufficient, meaning we don't need fetal tissue, for the study of HIV infection, pathogenesis, and therapy. And hu-PBMC mice are an ideal model for rapid drug discovery and were used in early testing of therapeutics including Enbrel for rheumatoid arthritis.

If we look only at the use of fetal tissue for generating humanized mice, we know that there are several advantages to using alternatives—the mice are easier to prepare at lower cost, more animals can be generated per cohort, there is negligible graft-versus-host disease and longer life span, chronic HIV infection is longer-lasting, and long-term safety and toxicity assessments are

possible. Humanized mice generated with fetal tissue are more technically difficult, costly, time consuming, and not as efficient as the other models.

Several examples exist of non-fetal sources used in the production of currently approved biotherapeutic agents including plant cells, insect cells, bacteria, yeast, Chinese hamster ovary (CHO) cells, murine cells, and HT-1080 cells (created from a tissue biopsy of a fibrosarcoma from a 35-year-old human male). In fact, CHO cells are the "workhorses behind more than half of the top-selling biologics on the market today," including Humira for arthritis and Crohn's disease, Herceptin and Perjeta for breast cancer, Avastin for metastatic colorectal cancer, Rituxan for six diseases including chronic lymphocytic leukemia and Non-Hodgkin's lymphoma, Prolia for osteoporosis, and Xolair for asthma, just to name a few. This does not include insulin made in bacteria and yeast to treat diabetes, and more than 70 successful treatments developed using adult stem cell sources.

HIV research

Some claim that fetal tissue is "needed" because BLT humanized mice generated with fetal bone marrow/liver/thymus tissue have been used to study HIV infection, human immune response, and antiretroviral treatments, and to test new therapies (i.e., Truvada). However, the BLT mouse is only one model among many other animal and non-fetal models that have been used to study HIV. There are several other model systems available to researchers for studying HIV, including nonhuman primates, which are considered the most relevant animal model for HIV/AIDS research to date.

Zika research

Because the Zika virus infects the brains of babies in utero, some researchers want to obtain brains of aborted babies (usually 9-13 weeks' gestation) in order to study viral infection. Some researchers perform direct observational studies on the brains while others will isolate stem cells from the tissue to study the mechanism of infection.

We know from published studies that organoids, three-dimensional organ-like structures constructed using modern stem cell techniques, are incredible models for studying Zika infection. These organoids have been instrumental in deciphering both normal brain development and the mechanism of Zika virus action on the developing brain. In one example, a seminal study in the journal *Science* showed that brain organoids can recapitulate the mechanism of how Zika infects human cells and causes the same microcephaly observed in humans.