

Dear Senator Blunt and Senator Cochran:

On behalf of the millions of patients throughout the nation and around the world, as well as the scientific and medical communities dedicated to advancing human health, the undersigned organizations and institutions write to express our collective and strong opposition to prohibitions or restrictions that would further impede the use of federal funding for fetal tissue or embryonic stem cell research. If enacted, this legislation would severely obstruct research that is necessary for the development of new treatments for a wide range of serious and incurable diseases.

Public policy that facilitates ethically responsible research and development is in the best interest of patients worldwide. Decades of thoughtful deliberation on fetal tissue and embryonic stem cell research has provided an ethical and policy framework for valuable medical research to progress, which has enabled the discovery of new treatments that would not otherwise have been possible. We believe the ethical considerations fall heavily in favor of permitting continued federal funding of fetal tissue research, conducted in accordance with current federal rules. To do otherwise would be disruptive and devastating to patients and biomedical science in the long term.

Fetal tissue research advances scientific knowledge, improves human health, and saves lives

Fetal tissue research has been critical for scientific and medical advances that have saved the lives of millions of people, including the development of vaccines against polio, rubella, measles, chickenpox, adenovirus, rabies, and treatments for debilitating diseases such as rheumatoid arthritis, cystic fibrosis, and hemophilia.

Fetal tissue remains a critical resource that enables research into how human tissues develop and are impacted by disease. Using fetal tissue allows researchers to more fully understand congenital defects such as those of the heart or nervous system and to understand how viruses like Zika virus impact fetal development. Indeed, the use of donated fetal tissue has been critical for understanding how Zika virus crosses the placenta and impacts human brain development. The insights gained through studies of Zika virus in human fetal tissue are already guiding the development of drugs that could protect unborn babies. These examples illustrate how, far from protecting life, legislation that limits human fetal tissue research would hinder the development of critical new treatments and thus potentially cost lives.

It has been incorrectly stated that other cells can be used to replace fetal tissue in biomedical research. In fact, fetal tissue represents a specific, formative period of human development, and the cells in fetal tissues have unique and valuable properties that often cannot be replaced by other cell types. Cells from fetal tissues are more flexible and less specialized than cells from adult tissue and can be expanded in culture. This is part of the reason why cells from fetal tissue were used in the generation of many of the vaccines that are used today. The study of human fetal tissues also helps researchers understand how birth defects arise and how they can be prevented. It provides an unparalleled window into the complexity of human tissue development, including why serious congenital defects sometimes arise.

Tissue from spontaneous abortions is not a reliable substitute for tissue from “induced” abortions. Spontaneous abortions often result from genetic defects, developmental abnormalities or other conditions that undermine the usefulness of the tissue for research and generally do not occur in settings where the fetal tissues can be adequately preserved for research.

Restricting NIH embryonic stem cell research will have a devastating impact on medical research

Embryonic stem cells have been used to test new drugs and to replace damaged organs in patients. Restrictions on these efforts could shut down critical academic and industry research necessary for the development of new treatments for a wide range of serious and incurable diseases. Such arbitrary limitations could force researchers to pursue their work abroad, leaving Americans to wait longer for medical progress.

Prohibiting research on human embryonic stem cell lines would not save a single human embryo from destruction because federal funding cannot be used to derive embryonic stem cell lines. Instead, such policies would block critical research and clinical application using human embryonic stem cell lines, potentially even the lines that were permissible to use under the Bush administration policy.

Human embryonic stem cells have the potential to make any cell type in the body in unlimited quantities. In contrast, stem cells from adult tissues are limited in the types and quantities of cells they can make. The discovery that human adult cells can be reprogrammed to an embryonic-like pluripotent state (human induced pluripotent stem or iPS cells) does not remove the imperative to pursue embryonic stem cell research. Human embryonic stem cells remain the benchmark for assessing pluripotency and the ability of cells to develop into all cell types in the body.

Embryonic stem cell research, together with breakthroughs in iPS and adult stem cell technologies, will yield the insights that make medical advances possible. We need to ensure that researchers are equipped to pursue all forms of stem cell research and to discover the root causes of disease and develop the breakthrough medicines of the future.

The impact of the original derivation and subsequent worldwide distribution of human embryonic stem cells unlocked an entire new field of regenerative medicine. The resulting progress in research and advances in technology were unimaginable just a quarter century ago. In the last 20 years, the initial five human embryonic stem cell lines have been distributed more than 4,500 times to over 2,000 investigators at nearly 800 separate institutions in 43 countries.

Research on embryonic stem cells has already yielded scientific breakthroughs that have contributed to our understanding of human development as well as disease processes, and it continues to do so. In addition to the Zika virus example, human embryonic stem cell research is producing innovative new approaches to treat diseases that represent major public health problems, and cells derived from human embryonic stem cells are now being tested in clinical trials as treatments for diabetes, spinal cord injury, heart failure, macular degeneration and Stargardt’s macular dystrophy. Neurons derived from human embryonic stem cells will enter clinical trials in 2018 to test a new treatment for Parkinson’s disease. Blocking federal funding

for human embryonic stem cell research and its applications would impede this research and slow the development of new therapies for these and many other diseases.

There is a well-established, rigorous oversight and regulatory framework for fetal tissue and embryonic stem cell research

Rigorous legal and ethical oversight of fetal tissue and embryonic stem cell research has been in place for decades and both areas of research have earned bipartisan support.

Fetal tissue research has garnered bipartisan support in the U.S. Congress and has been funded by the National Institutes of Health (NIH) for decades. In 1988, the agency appointed an advisory panel to evaluate the ethical, legal, and scientific issues surrounding fetal tissue research. After months of public hearings and deliberation, the panel concluded that the use of human fetal tissue in research following induced abortions is acceptable public policy.

In 1993, in an overwhelming bipartisan vote, Congress passed the National Institutes of Health Revitalization Act, which gave the NIH direct authority to fund fetal tissue transplantation research. The law also included requirements for informed consent for this research and a provision that criminalizes the sale or purchase of fetal tissue. The NIH Revitalization Act of 1993 imposes restrictions on fetal tissue transplantation for therapeutic purposes, mandating that it must be conducted in accordance with applicable state and local law, with written informed consent from the donor. The attending physician must also sign a written statement affirming that the decision to abort a fetus and to donate tissue for research are not related. Current law also imposes significant criminal and civil penalties for the purchase or sale of fetal tissue.

In 1994, the NIH Human Embryo Research Panel assessed the moral and ethical issues raised by embryonic stem cell research and ultimately recommended that some areas of human embryo research should be considered for federal funding, including embryos created solely for the purpose of research. In August 2001, President Bush enabled federal funding to be used to support research on human embryonic stem cells for existing lines. In 2004, hundreds of House and Senate members sent a bipartisan letter to President Bush urging him to increase the number of human embryonic stem cell lines eligible for public funding. President Obama later expanded this area of research by permitting NIH research scientists access to federal funds for research using the hundreds of human embryonic stem cell lines that had been created since the Bush 2001 policy.

In summary, fetal tissue and embryonic stem cell research are critical to addressing important questions in biomedical research, and for the development of new therapies. Legal and ethical frameworks in place ensure appropriate oversight, and that human embryonic and fetal tissue is obtained legally and with donor consent. We urge you to oppose restrictions to this research, and to support the families who are relying on biomedical research to develop new treatments for diseases that affect millions of the lives around the world.

Sincerely,