**Patients First Act of 2017 (HR 2918 / S 2956, 115th Congress)**

Promotes and facilitates stem cell research showing evidence of substantial clinical benefit to patients, while placing restrictions on the creation, injury, and destruction of embryos for such research.

Updated last **June 25, 2018**
for the 06/15/2017 version of HR 2918 and the 05/24/2018 version of S 2956.

**WHAT IT DOES**

The Patients First Act of 2017 (**HR 2918** / **S 2956**) aims to:

- Intensify and promote **stem cell** research (using cells that are “ethically obtained,” though the bill does not define this specification) that could contribute to a better understanding of diseases, adverse health conditions, and their treatments; and
- Promote the “derivation of **pluripotent** stem cell lines without the creation of human embryos…” and without harm to a human embryo.

Section 3 of amends the Public Health Service Act (**42 U.S.C. 284 et seq.**) to include clauses that achieve the bill’s goals. These clauses will require:

- The Department of Health and Human Services (HHS) to carry out and support research meant to develop techniques for the “isolation, derivation, production, testing, and human clinical use of stem cells” that could be of substantial clinical benefit to patients; and
- The prioritization of research with the greatest potential for clinical benefit (determined by documented evidence from research findings or clinical practice), provided that the research does not involve the creation of, destruction of, or risk of injury to a living human embryo.

“Risk of injury” is defined as the subjection of a human embryo to “risk of injury or death greater than that allowed for research on fetuses in utero,” as described in **45 CFR 46.204b** and any successor regulations.

The bill also requires HHS and the National Institutes of Health (NIH) to issue final guidance within 90 days of the bill’s enactment to elaborate on its provisions. Furthermore, HHS must submit annual reports to Congress that include the number of relevant research proposals that were peer reviewed, a list of the proposals that were not funded, and an accompanying explanation for each one as to why they did not receive funding.

**RELEVANT SCIENCE**

**Stem cells** are unspecialized cells with the potential to develop into various types of **differentiated** (i.e., specialized) cells, such as heart, nerve, or blood cells. Stem cells also have a far greater capacity than differentiated cells to produce new cells through **cell division**.

There are two main types of stem cells found in the human body – embryonic stem cells and adult stem cells – and both are used in medical research. **Embryonic stem cells** are derived from embryos at or before the **blastocyst** stage (when the embryo is about five days old) in a process that results in the destruction of the embryo. These stem cells can reproduce almost indefinitely in laboratory settings without differentiating. Additionally, embryonic stem cells are **pluripotent**, meaning they are capable of differentiating into any cell type present in the body. Human embryonic stem cells are not derived from eggs fertilized inside a woman’s body, but are instead taken from eggs that have been fertilized **in vitro** and donated to scientific research with the informed consent of their
In vitro fertilization (from the Latin “in glass”) is the process through which an egg cell and sperm cell are united in a laboratory dish or test tube in an in vitro clinic rather than in a woman’s body.

Human **adult stem cells**, on the other hand, are undifferentiated cells “found among differentiated cells in a tissue or organ.” These specialized stem cells (also found in children, despite the name) contribute to the function of organs and tissue like ordinary specialized cells, but can also repair damaged tissue and replace dead cells through frequent cell division (e.g., **bone marrow** stem cells). Compared to embryonic stem cells, adult stem cells are more limited in their ability to renew themselves, and their ability to differentiate into specialized cells types is thought to be limited to particular tissues or organs. They are also more difficult to grow and manipulate in laboratory settings.

**Induced pluripotent stem cells** are different from both embryonic and adult stem cells in that they are produced in a laboratory setting by converting adult cells into an embryonic stem cell-like state using known stem cell-relevant genes and other factors. The difference between these cells and embryonic stem cells is an active area of research. However, induced pluripotent stem cells are already important tools in research and could one day be used in human transplantation, where they would be directly added into the body to repair tissues or organs.

Due to their unique capabilities and versatility, stem cells are valuable for biological and medical research. Scientists first derived embryonic stem cells from early mouse embryos in 1981, and by 1998, they had discovered a technique for deriving human embryonic stem cells and continuing their growth in laboratories. Stem cells’ regenerative properties make them useful for the treatment, by transplantation, of medical problems like heart disease, diabetes, Alzheimer’s disease, Parkinson’s disease, and cancer.

**BACKGROUND**

Embryonic stem cell research has a history of controversy in the United States. After the Supreme Court ruled on **Roe v Wade** in 1973, the US Congress placed a temporary moratorium on the use of federal funds in research that experimented on human fetal tissue through the 1974 **National Research Act**. As designed, this moratorium was lifted in 1975 when the Department of Health, Education and Welfare (the precursor to HHS) issued regulations in regard to federally funded research on fetuses. Interestingly, the regulations also covered research on **in vitro** fertilization (IVF), requiring research applications to be approved by an Ethical Advisory Board (EAB) in order to be federally funded. However, the EAB’s charter expired in 1980 before it approved any individual research studies for federal funding.

In 1988, a new moratorium was put in place in response to clinical research in which fetal tissue was transplanted into the brains of patients with Parkinson’s disease as a therapy. In early 1993, the Clinton administration lifted the moratorium. Later that year, the US Congress passed the **NIH Revitalization Act of 1993**, which included a clause that nullified the HHS regulation (previously 45 CFR 46.204(d)), which had mandated that IVF-related research proposals be approved by an EAB in order to receive federal funding. Shortly thereafter, the NIH extended an invitation for research applications regarding IVF, and thus research regarding human embryos. In response, the **Dickey-Wicker Amendment**, an addition to appropriations legislation named “The Balanced Budget Downpayment Act, I,” forbade the use of federal funds for the creation of, destruction of, or risk of injury to an embryo for research purposes.

In 2000, the NIH, in consultation with HHS, concluded that the Dickey-Wicker Amendment did not prohibit federal funding of research on embryonic stem cells, so long as the creation and destruction of the embryo (past, present, or future) is accomplished without federal funding (e.g., in private industry). In 2001, President Bush restricted this interpretation to limit federal funds only to research on already-existing lines of stem cells. Though Congress passed the **Stem Cell Research Enhancement Acts of 2005 and 2007**, which would have loosened restrictions on stem cell research, President Bush vetoed both bills. However, during this time, several states including New Jersey, California, Connecticut, and Illinois passed state-level legislation allocating funds to stem cell research. In 2009, President Obama eased the Bush-era limitations (Executive Order 13505) by allowing use of federal funds on stem cell research that does not create or destroy embryos. Later that year, the NIH issued “**National Institutes of Health Guidelines for Human Stem Cell Research**” to implement the executive order. In 2016 the NIH proposed limited changes to the guidelines...
(SciPol brief available here), but has not yet issued final, updated guidelines. As of publication of this brief, embryonic stem cell research is still subject to these guidelines.

Research on adult stem cells and induced pluripotent stem cells, which are adult cells that have been forced to revert to their embryonic stage, does not involve the use of embryos and consequently, is relatively noncontroversial in comparison to embryonic stem cell research.

ENDORSEMENTS & OPPOSITION

Endorsements:

- The National Right to Life Committee supports HR 2918, describing the bill as “promoting ethical stem cell research.”

Opposition:

- There is no recorded public opposition to this bill, but individuals and groups in favor of expanding stem cell research or loosening regulations in the field may oppose this bill.

STATUS

HR 2918 was introduced to the House on June 15, 2017 before being sent to the Committee on Energy and Commerce. It was referred to the Subcommittee on Health the next day.

S 2956 was introduced to the Senate of May 24, 2018 and sent to the Committee on Health, Education, Labor, and Pensions on the same day.

RELATED POLICIES

The Safe RESEARCH Act (HR 1203, 115th Congress, SciPol brief available here) aims to ban the use of human fetal tissue which has been donated to biomedical research following an abortion. The bill was introduced on February 17, 2017.

POLICY HISTORY

Previous versions of the Patients First Act are nearly identical to the present bill and seek to accomplish the same goals. The previous versions are:

- The Patients First Act of 2015 (HR 2921, 114th Congress)
- The Patients First Act of 2013 (HR 1740, 113th Congress)
- The Patients First Act of 2011 (HR 2951, 112th Congress)
- The Patients First Act of 2009 (HR 877, 111th Congress)
- The Patients First Act of 2007 (HR 2807, 110th Congress)

Each of these bills were referred to the Committee on Energy and Commerce and the Subcommittee on Health, but none were enacted.

SPONSORS
HR 2918

Sponsor: Representative Jim Banks (R-IN-3)

Cosponsor: Representative Daniel Lipinski (D-IL-3)

S 2956

Sponsor: Senator Roger F. Wicker (R-MS)

Cosponsors:

- Senator Steve Daines (R-MT)
- Senator Roy Blunt (R-MO)
- Senator James Lankford (R-OK)

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