



## PROPOSAL 2008-02: HUMAN EMBRYONIC STEM CELL RESEARCH

*This CRC Memorandum is a summary of Report 353, a more detailed analysis of the statewide ballot proposal.*

On November 4, 2008, Michigan electors will vote on a citizen initiated proposal to amend the State Constitution to allow for research on human embryos and the creation of new embryonic stem cell lines in the

State of Michigan. The text of the ballot proposal is available on CRC's website at [www.crcmich.org/election/index.html](http://www.crcmich.org/election/index.html).

### Stem Cell Research in Michigan

**Michigan Law.** The State of Michigan currently has some of the most restrictive laws in the nation respecting human embryonic stem cell research. It is illegal for researchers to conduct research that jeopardizes the life or health of a human embryo, fetus, or neonate.<sup>1</sup> Michigan law also prohibits the cloning of a human embryo for both reproductive and research purposes.<sup>2</sup> Violations of these laws are felonies with maximum punishments of five and ten years in prison, respectively.<sup>3</sup> Michigan law effectively prohibits researchers from creating new human embryonic stem cell lines in the state, but it does not keep scientists from conducting research using embryonic stem cell lines created outside of the state. Michigan researchers may also study adult stem cells because that work does not involve the destruction of human embryos.

**Federal Policy.** Research on human embryos and embryonic stem cells is not restricted by federal law; however President Bush's policy restricts federal funding to research on human embryonic stem cell lines created prior to August 9, 2001 (the date that President Bush announced this policy).<sup>4</sup> Additionally, federally funded stem cell research must be conducted on stem cell lines derived from embryos that were created for reproductive purposes but no longer needed and donated with the informed consent of the donors without any financial inducements. Federal regulations do not restrict embryonic stem cell research using state or private funds. While this may not seem to place very stringent limits on embryonic stem cell research, federal funding is very important to scientific research and provides support for many researchers.

**Proposal 2008-02.** If passed, this proposal would insert a Section 27 into Article I of the Michigan Constitution to allow for research on human embryos and the derivation of new embryonic stem cell lines in the state. Research on human embryos in Michigan would be subject to federal regulations and restricted to embryos that were created for the purpose of fertility treatment, but are scheduled to be discarded because they were either 1) left over after fertility treatment and no longer needed by the donor or 2) unsuitable for implantation into a woman's uterus. Embryos could only be donated with the informed, written consent of the donor(s). The following stipulations would apply to human embryonic stem cell research:

- 1) No cells would be taken from an embryo more than 14 days old (this time limit is suspended while embryos are frozen). Most embryonic stem cells are derived from three- to five-day-old pre-implantation embryos called blastocysts.
- 2) It would be against the law to purchase or sell human embryos for stem cell research purposes.
- 3) All research would be required to be conducted in accordance with applicable state and local laws provided that these laws do not prevent, discourage, or create disincentives for permissible stem cell research. This section prevents the State or local governments from creating laws to restrict embryonic stem cell research beyond the restrictions listed in the proposed constitutional amendment and detailed here. This provides unique con-



stitutional protection to stem cell research. It is unclear how far-reaching this section would be: “discourage” is a subjective term and laws to regulate the research may be construed as discouraging it. How broadly this section of the proposal would be interpreted would depend on the courts.

If passed, research on human embryos would continue to be mainly regulated by the federal government. This would not make Michigan unusual; many states leave it to the federal government to

regulate human embryonic stem cell research. In addition to Michigan, only two states<sup>5</sup> ban research on human embryos (some other states restrict funding for research or ban cloning embryos for research purposes). Nine states<sup>6</sup> have laws specifically permitting the research, but it is permitted in all states that have not taken legislative action to ban it because the research is permitted under federal law.<sup>7</sup>

The proposal would not change Michigan’s current ban on the cloning of human embryos. Michigan’s ban prohibits cloning

embryos for reproductive purposes, which involves implanting a cloned embryo into a woman’s uterus, as well as for therapeutic or research purposes. The proposed language in section 27(1) states that “nothing...shall alter Michigan’s current prohibition on human cloning.” This language does nothing to strengthen Michigan’s law against human cloning because it does not put the actual ban into the Michigan Constitution. However, it also does not weaken or change Michigan’s current law prohibiting human cloning and does not condition the nature of future legislation.

## Stem Cells and Regenerative Medicine

Regenerative medicine<sup>8</sup> is a scientific and medical discipline that is focused on utilizing the body’s own regenerative capabilities to repair or replace diseased or defective tissues and organs in the human body and to find new therapies for diseases and conditions that currently have limited or no treatment options (e.g., Parkinson’s disease and paralysis) through a better understanding of stem cells, tissue engineering, and the ability of organs and tissues to repair themselves.

The human body consists of over 200 different types of cells and all of these cells originate from stem cells found in the early embryo. While nearly all of the cells in the human body contain the complete set of genes necessary to build and maintain a human being, as an embryo develops and its cells specialize, they turn off genes that they no longer need. Stem cells have three general properties:

- 1) They are capable of long-term self-renewal. A starting population of embryonic stem cells that proliferates for many months in a laboratory can yield millions of cells through cell division.
- 2) They are unspecialized cells meaning that they do not have tissue-specific structures that allow them to perform specific functions.
- 3) They can be induced to become cells with special functions, such as the beating cells of the heart muscle, through a process called differentiation.

It is believed that stem cells may be the basis for treating many diseases and conditions in the future, but scientists do not yet completely understand their function and essential properties. Current stem cell research is aimed at understanding the factors in living

organisms that normally regulate cell proliferation and self-renewal; determining how stem cells remain unspecialized for many years; and identifying the signals, from both inside and outside of cells, that cause stem cells to become specialized cells.

**Figure 1** compares three different types of stem cells: embryonic, adult and induced pluripotent (iPS). Embryonic stem cells are derived from 3- to 5-day-old pre-implantation embryos called blastocysts left over from fertility treatment and can produce all cell types in the human body. This makes them more flexible than adult stem cells, which are undifferentiated cells found among differentiated cells in a tissue or organ and are generally limited to producing the major specialized cell types of that tissue or organ (e.g., blood stem cells can differentiate into any type of blood cell). iPS cells are adult cells that

**Figure 1**  
**Comparison of Different Kinds of Stem Cells**

	<u>Advantages</u>	<u>Disadvantages</u>
<b>Embryonic Stem Cells</b>	<ul style="list-style-type: none"> <li>• Pluripotent: can produce all cell types</li> <li>• Good supply: large source of excess from IVF clinics</li> <li>• Relatively easy to collect, purify and maintain in the laboratory</li> <li>• Long-term self-renewal: can be induced to replicate themselves</li> <li>• Can be used to study early human cell development</li> </ul>	<ul style="list-style-type: none"> <li>• Limited number of cell lines available for federally funded research</li> <li>• Undifferentiated stem cells could not be used directly for transplants because they can cause tumors in humans</li> <li>• May cause problems of immune rejection if transplanted into patients</li> <li>• Ethical issues surround destruction of human blastocysts</li> </ul>
<b>Adult Stem Cells</b>	<ul style="list-style-type: none"> <li>• Have been used successfully to treat some patients (e.g., bone marrow transplants)</li> <li>• Stem cells genetically matched to patient</li> <li>• No ethical issues associated with using them</li> </ul>	<ul style="list-style-type: none"> <li>• Multipotent: can only produce a limited number of cell types</li> <li>• Not found in all tissues of the human body</li> <li>• Difficult to identify, isolate and grow in the laboratory</li> </ul>
<b>iPS Cells</b>	<ul style="list-style-type: none"> <li>• Pluripotent: can produce all cell types</li> <li>• Allows for creation of cell lines genetically customized to the patient (in theory)</li> <li>• Fewer ethical issues associated with using them</li> <li>• Fairly easy to create – does not require materials (i.e., human eggs or embryos) that are difficult to obtain</li> </ul>	<ul style="list-style-type: none"> <li>• Research is in the early stages – scientists may be years away from making iPS cells as versatile as embryonic stem cells</li> <li>• Created using a virus, which disposes them to cancer and makes them currently unsuitable for use in humans</li> </ul>

Sources: The National Academies, *Understanding Stem Cells: An Overview of the Science from the National Academies*; National Institutes of Health, *Stem Cell Basics*; University of Michigan, Stem Cell Research and Life Sciences Institute, Center for Stem Cell Biology.

have been induced in the laboratory into becoming more flexible like embryonic stem cells.

Because it is impossible to know where the next medical breakthrough will come from, research is currently being conducted on all types of stem cells. The National

Academies<sup>9</sup> issued ethical guidelines for stem cell research that offer a common set of ethical standards in an area that is without national standards due to the lack of comprehensive federal funding and federal oversight of stem cell research. The guidelines regulate the donation and use of embryos

in research (e.g., donors should not be paid for eggs or embryos) and prohibit reproductive cloning, among other things.<sup>10</sup> These guidelines, while adopted by many researchers voluntarily, are not legally binding. However, many institutions conducting this research

require researchers to follow these or similar guidelines.

**Potential Benefits and Hurdles to Stem Cell Research.** Many scientists believe that human embryonic stem cells have the potential to benefit medicine in many ways, including helping to understand the complex events that occur during early human development, giving them a better understanding of normal and abnormal cell development. Embryonic stem cells are fairly easy to grow in the laboratory and may prove useful in testing and screening new medications making drug discovery

more efficient and less dangerous by potentially eliminating the need for human test subjects. Embryonic stem cells have the potential to be used in cell-based therapies to provide cures and treatments for previously incurable diseases. While adult stem cells have great potential to benefit medicine as well, embryonic stem cells have unique potential due to their flexibility and ability to replicate.

The advancement of stem cell research is not without obstacles, including technical, financial, legal, and ethical hurdles. The ma-

major technical hurdle is that scientists do not yet understand stem cells or their processes well enough to reliably manipulate and control them. Financial hurdles include the limitation of federal funding to the 21 embryonic stem cell lines created prior to August 2001. Legal issues include intellectual property concerns and proper enforcement of diverse state and federal laws. And ethical concerns revolve around question of when life begins and the potential that embryos have to develop into a human being if implanted into a woman's uterus.

## Issues Raised by Human Embryonic Stem Cell Research

**Bioethics.** Bioethics is defined as “a field of study concerned with the ethics and philosophical implications of certain biological and medical procedures, technologies, and treatments...”<sup>11</sup> The ethical issues raised by embryonic stem cell research revolve around the question of when life begins and *in vitro* fertilization (IVF).

Opponents of embryonic stem cell research argue that life begins at the moment of conception, making research on “living” embryos unethical. If this premise is accepted, it has implications beyond embryonic stem cell research to abortion, fertility treatments, and even some forms of contraception that prevent implantation of a fertilized egg. Proponents of stem cell research counter that embryonic stem cells are derived from pre-implantation embryos that consist of approximately 150 undifferentiated cells with no heart, nervous system,

limbs, or specialized human tissues of any kind. They argue that the “pro-life” position is to fund and support research that has the potential to help scientists understand the cause of many diseases and provide therapies for those suffering from disease and injury.

IVF has been the subject of ethical debate because it leads to the creation of excess embryos that are either not suitable or necessary for implantation. Fertility patients have four options for their “left-over” embryos: 1) indefinite storage (at the patient's expense), 2) donation to others seeking fertility treatment (i.e., embryo adoption), 3) donation to research, or 4) discarding as medical waste. If Proposal 2008-02 passes, it will allow Michigan scientists to conduct research using donated embryos. It will not remove or alter patients' ability to donate their excess embryos to other patients seeking fertility treatment or to

discard them as medical waste.

Other ethical issues linked to embryonic stem cell research include abortion and cloning. Embryonic stem cells are derived from pre-implantation embryos, not from aborted embryos or fetuses so there is no direct link between abortion and stem cell research. Proposal 2008-02 would have no effect on Michigan's law prohibiting cloning, so this issue goes beyond the scope of the ballot proposal.

**Life Sciences Business Sector.** Regenerative medicine is driving the life sciences business sector in Michigan, the United States, and the rest of the world. Stem cell research, including human embryonic stem cell research, is seen by many as vital to advancing regenerative medicine. According to a 2006 U.S. Department of Health & Human Services report,<sup>12</sup> a conservative estimate of the worldwide market for regenerative medicine

by 2010 is \$500 billion. Not only do advancements in regenerative medicine have the potential to be an economic boon for the country, but they also may lower overall health care costs, which are in excess of \$2 trillion annually (16 percent of U.S. Gross Domestic Product),<sup>13</sup> if they lead to cures for chronic, and costly, diseases. However, the potential magnitude of the impact of stem cell research and regenerative medicine is speculative because it is impossible to know what will come of the current research.

While the U.S. is competing with other countries to build its life sciences industry, Michigan is competing with its fellow states for investment by the industry. An unfavorable research climate may make it less likely that the life sci-

ences industry will invest in Michigan and that researchers will locate or stay in Michigan. Eight states<sup>14</sup> are providing state funds for human embryonic stem cell research partly to attract further private investment and high paying jobs to their state.

Opponents of embryonic stem cell research counter that research using human embryos is just one piece of regenerative medicine and Michigan researchers are able to conduct research on human embryonic stem cells derived outside of the state and on all types of adult stem cells, including iPS cells and reprogrammed adult cells.

**Embryonic Stem Cells Are Not Currently Used in Therapies.** Opponents of embryonic stem

cell research argue that these stem cells are not being used to treat patients. While that is true, it does not mean that they do not hold potential for use in therapies in the future. Research has been conducted on human embryonic stem cells for only the past 10 years. Adult stem cells, which have been studied since the 1950s, are used to treat some patients. However, there is debate over how many diseases are currently treated with adult stem cells. According to many scientists, both embryonic and adult stem cells hold potential to provide cell-based therapies and cures for many chronic diseases and injuries. Only time, and future research, will tell what therapies are realized and which stem cells are necessary for those therapies.

## Michigan Impact

If Proposal 2008-02 passes, it will provide constitutional protection to embryonic stem cell research in Michigan. It will end the State's prohibition of research on human embryos and allow researchers to derive new human embryonic stem cell lines in Michigan. It will not alter Michigan's current law that bans human cloning for reproductive and therapeutic purposes. It does not provide state funds for embryonic stem cell research, but it would not prohibit a future proposal to provide state funds or the legislature from appropriating funds for the research.

Michigan is currently one of only three states that ban research on human embryos. If the proposal passes, it will put Michigan with the other nine states that have laws to specifically permit human embryonic stem cell research. While the research is permitted in all 47 states that do not have a law prohibiting it, passage of this proposal would insert into the State Constitution the citizens' intent to allow for research on human embryos and the derivation of embryonic stem cells in the state. This may make Michigan appear more hospitable to the life sci-

ences industry and lead to greater investment in Michigan and its universities and research institutions. The life sciences industry consists of the type of high paying jobs that Michigan is hoping to attract. However, it must be noted that Michigan already has some investment in the life sciences industry (e.g., the University of Michigan has a Center for Stem Cell Biology and an Exploratory Center for Human Embryonic Stem Cell Research). Passage of this proposal may simply make it easier to attract investment and jobs in the life sciences sector.

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## Endnotes

<sup>1</sup> Public Act 368 of 1978 (Public Health Code), MCL 333.2685.

<sup>2</sup> Public Act 368 of 1978 (Public Health Code), MCL 333.16274.

<sup>3</sup> Public Act 368 of 1978 (Public Health Code), MCL 333.2691; Public Act 328 of 1931 (The Michigan Penal Code), MCL 750.430a.

<sup>4</sup> National Institutes of Health. *NIH Funding of Research Using Specified Existing Human Embryonic Stem Cells*, NOT-OD-01-058. 23.Aug.01.

<sup>5</sup> Louisiana and South Dakota.

<sup>6</sup> California, Connecticut, Illinois, Iowa, Maryland, Massachusetts, Missouri, New Jersey, and New York.

<sup>7</sup> State Embryonic and Fetal Research Laws. In *Stem Cell Research* (World Wide Website). National Conference of State Legislatures, January 2008 (cited 5.Aug.08). Available at [www.ncsl.org/programs/health/genetics/embfet.htm](http://www.ncsl.org/programs/health/genetics/embfet.htm); and Vestal, Christine. "Embryonic Stem Cell Research Divides States." *Stateline.org*,

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<sup>8</sup> Information on regenerative medicine and stem cells was gathered from a multitude of sources: National Institutes of Health, *Stem Cell Basics*; The National Academies, *Understanding Stem Cells: An Overview of the Science and Issues from the National Academies*; University of Michigan, Stem Cell Research and Life Sciences Institute, Center for Stem Cell Biology; International Society for Stem Cell Research; WiCell Research Institute; University of Wisconsin-Madison Stem Cell and Regenerative Medicine Center.

<sup>9</sup> The National Academies consist of committees of experts in all areas of scientific and technological endeavor that address critical national issues and give advice to the federal government and public.

<sup>10</sup> National Research Council and Institute of Medicine. *2008 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research*. National Academy of Sciences, 2008.

<sup>11</sup> "Bioethics." *Dictionary.com*, 2008 (cited 5.Sep.08). Available at [dictionary.reference.com/browse/bioethics](http://dictionary.reference.com/browse/bioethics).

<sup>12</sup> U.S. Department of Health & Human Services. *2020: A New Vision – A Future for Regenerative Medicine*, 28.Mar.06 (cited 9.Sep.08). Available at [www.hhs.gov/reference/newfuture.shtml](http://www.hhs.gov/reference/newfuture.shtml).

<sup>13</sup> Zerhouni, Elias (Director, National Institutes of Health). "FY2008 Director's Budget Request Statement," testimony March 19, 2007 before the U.S. Senate Subcommittee on Labor—HHS—Education Appropriations. Available at [www.nih.gov/about/director/budgetrequest/fy2008directorsenatebudgetrequest.htm](http://www.nih.gov/about/director/budgetrequest/fy2008directorsenatebudgetrequest.htm) (cited 10.Sep.08).

<sup>14</sup> California, Connecticut, Illinois, Maryland, Massachusetts, New Jersey, New York and Wisconsin.