INITIATIVE FINANCIAL INFORMATION STATEMENT PROHIBITING STATE SPENDING FOR EXPERIMENTATION THAT INVOLVES THE DESTRUCTION OF A LIVE HUMAN EMBRYO

SUMMARY OF INITIATIVE FINANCIAL INFORMATION STATEMENT

Based on information provided through public workshops and information collected through staff research, the Financial Impact Estimating Conference principals note the following:

- The amendment is not expected to have an impact on state or local government expenses because no revenues of the state are currently being spent on experimentation involving the destruction of a live human embryo. It is assumed that state-funded research that is based on an existing line of stem cells would not be prohibited. The creation of a line that involves the destruction of a live human embryo, however, would be prohibited. No other experimental procedures that would be affected by the amendment were identified.
- The principals did not identify probable impacts on state or local government revenues because the future development of research and any associated activities that could be affected by this amendment is unknowable; therefore, the impacts, if any, are indeterminate.

FINANCIAL IMPACT STATEMENT

This amendment is not expected to have an impact on state or local government expenses.

I. SUBSTANTIVE ANALYSIS

A. Proposed Amendment

Ballot Title:

Prohibiting state spending for experimentation that involves the destruction of a live human embryo.

Ballot Summary:

No revenue of the state shall be spent on experimentation that involves the destruction of a live human embryo.

Statement and Purpose:

According to the sponsors, the purpose of the amendment is "to protect Floridians from the additional tax burden of state imposed funding for embryonic stem cell research, while allowing fruitful stem cell research to continue unencumbered." See http://www.scienceandethics.org/.

Amendment of Florida Constitution:

Be it enacted by the people of Florida that a new section for Article X of the Constitution is created to add the following:

No revenue of the state shall be spent on experimentation that involves the destruction of a live human embryo.

Effective Date:

This amendment will be effective on the first Tuesday after the first Monday in January following the election at which it is approved by vote of the electors.

B. Effect of Proposed Amendment

According to Citizens for Science and Ethics:

- The prohibition would involve only those revenues which enter the Florida Treasury and for which an appropriation is required. Of revenue sources for experimentation, the petition does not intend to preclude federal or private funds from being used by institutions in Florida, including those that receive state funds for other purposes.
- As specified in the language, the funding prohibition would only apply to experiments. Therapies (or treatments) if ever developed that involve the destruction of live human embryos would not be prohibited.
- To their understanding, no Florida revenues are being spent on experiments that involve the destruction of a live human embryo, so no savings to the state are expected by prohibiting projects that are currently funded. Since there will be no savings and no

new appropriations, there is no expected financial impact on state or local governments as a result of this proposed amendment's adoption.

Background

<u>Stem Cells and Diseases</u> Stem cells are unique and unspecialized cells. The purpose of stem cells in the adult body is to replace cells normally lost because of age, injury or disease. Two properties that make stem cells unique from other cells:

- 1. Stem cells can divide thousands of times without error and without breaking down. Scientists can cause one stem cell to produce hundreds of identical stem cells in what is called a line.
- 2. Stem cells can differentiate into a variety of different cells. Scientists can induce stem cells to become cells with special functions, such as the beating cells of the heart muscle or the insulinproducing cells of the pancreas.²

Human stem cells can be harvested from human embryos (embryonic stem cells) or from the tissue of an adult (adult stem cells). There are differences between adult and embryonic stem cells. Adult stem cells are limited in the variety of cells they can differentiate into and generally only develop into the cell types of the tissue from which they were isolated.³ Embryonic stem cells are pluripotent, that is, capable of differentiating into one of many cell types. After an egg is fertilized, it begins to divide from one cell into two, then from two cells into four, and so on. In the first few divisions, each embryo cell contains the ability to make all the cells in the human body. As the embryo continues to divide, the cells begin to specialize into particular organ cells.

Embryonic stem cells offer the possibility of a renewable source of replacement cells and tissues to treat a myriad of diseases, conditions, and disabilities including Parkinson's and Alzheimer's diseases, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis and rheumatoid arthritis. Scientists have been able to conduct experiments with human embryonic stem cells, however, only since 1998. Thus, although embryonic stem cells are thought to offer potential cures and therapies for many devastating diseases, research using them is still in its early stages.

In vitro fertilization (IVF) is a technique in which egg cells are fertilized outside the woman's womb. IVF is a major treatment in infertility where other methods of achieving conception have failed.

The process involves hormonally controlling the ovulatory process, removing ova (eggs) from the woman's ovaries and letting sperm fertilize them in a fluid medium. The fertilized egg (zygote) is then transferred to the patient's uterus with the intent to establish a successful pregnancy. The term in vitro, from the Latin, is used, because early biological experiments involving cultivation of tissues outside the living organism from which they came, were carried out in glass containers such as beakers, test tubes, or petri dishes. Today, the term in vitro is used to refer to any biological procedure that is performed outside the organism it would normally be occurring in, to distinguish it from an in vivo procedure, where the tissue remains inside the living organism within which it is normally found. The petri dishes used for in vitro fertilization, may be made of glass or plastic resins

¹ Susan Cutaia, electronic mail to conference principals, November 27, 2006 and follow-up memorandum, December 1, 2006.

² Human Stem Cells: An Ethical Overview. Center for Bioethics, University of Minnesota. Available at <<u>www.bioethics.umn.edu</u>>. ³ In Stem Cell Basics. [World Wide Web site] Bethesda, MD. National Institutes of Health, U.S. Department of Health and Human

Services, 2006. Available at http://stemcells.nih.gov/index.asp.

4 In Stem Cell Information [World Wide Web site]. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2006. Available at http://stemcells.nih.gov/info/health>.

or other materials (contemporary test tubes may also be made of glass or plastic resin).⁵ Since according to this definition, in vitro fertilization is a "treatment" of infertility it would not be considered "experimentation" for purposes of this amendment.

Federal Regulations

The Federal Register announcement *National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells*, published August 15 2001, Section II B, titled "Utilization of Human Pluripotent Stem Cells Derived from Human Fetal Tissue," governs human embryonic stem cell research. The guidelines establish procedures for investigators or institutions requesting National Institutes of Health (NIH) funds for research using human pluripotent stem cell lines derived from embryos or fetal tissue. The NIH maintains the official registry of stem cell lines meeting these criteria. The notice also outlines the procedures NIH will use to implement oversight of this process. Section III, titled "Areas of Research Involving Human Pluripotent Stem Cells That Are Ineligible for NIH Funding," affects both human embryonic stem cell and human embryonic germ cell research. Individual states have the authority to pass laws to permit human embryonic stem cell research using state funds. Unless Congress passes a law that bans it, states may even pay for research using human embryonic stem cell lines that are not eligible for federal funding.

In November 2001, President George W. Bush created The President's Council on Bioethics. The council's mission is to advise the president on bioethical issues that may emerge as a consequence of advances in biomedical science and technology. The council is authorized to study ethical issues connected with specific technological activities, such as embryo and stem cell research, assisted reproduction, cloning, uses of knowledge and techniques derived from human genetics or the neurosciences, and end of life issues. The council may also study broader ethical and social issues not tied to specific technology, such as questions regarding the protection of human subjects in research, the appropriate uses of biomedical technologies, the moral implications of biomedical technologies, and the consequences of limiting scientific research.⁷

Private Research

According to Dr. Amit Patel, a cardiac surgeon and director of Cardiac Cell Therapy at the University of Pittsburgh Medical Center, an incredible amount of research and a very large sum of venture capital and private investments is going to the stem cell research field. Stemnion, a small biotech firm in Pittsburgh, is working on using stem cells found in the placenta for healing wounds; Cellerant Therapeutics of San Carlos, California will start a human trial using highly purified adult stem cells found in bone marrow to treat patients with Sickle Cell disease; Osiris Therapeutics of Baltimore has several trials under way using adult stem cells to treat the intestinal inflammation knows as Crohn's disease, repair damaged tissue following a heart attack and prevent the progression of arthritis; and Geron of Menlo Park, California is performing animal studies on a variety of different cells derived from human embryonic stem cells, aiming to treat spinal cord injury, heart disease and diabetes. ⁸

Office of Tourism, Trade and Economic Development

As drafted, the proposed Constitutional Amendment, which states, "No revenue of the state shall be spent on experimentation that involves the destruction of a live human embryo," does not appear to have any impact on the funds that are distributed by the Office of Tourism, Trade, and Economic Development (OTTED) for the various incentive programs; however, specific expenditures are not tracked to determine if current incentive recipients have spent or will spend state funds on this type of research. Only recipients of the newly created Innovation Incentive accepted, as a condition to the receipt of funds, a paragraph which states, "To the extent applicable, Awardee agrees that it will

⁶ In *Stem Cell Information* [World Wide Web site]. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2006. Available at http://stemcells.nih.gov.info.faqs.asp.

⁷ Executive Order 13237, November 28, 2001.

⁵ Wikipedia

⁸ Forbes.com, Medicine & Markets: Despite Bush Veto, Stem Cell Research Abounds; July 21, 2006; 10:30 AM ET

not use stem cells that have not been approved by the National Institutes of Health, known as non-NIH stem cells, in its research activities within Florida using the Funds." Other incentive agreements do not have this paragraph, as this issue was not previously contemplated by OTTED.⁹

Department of Management Services

As currently drafted, there would be no financial impact to the State Group Health Insurance Program and/or State Employees' Group Health Self-Insurance Trust Fund should the Constitutional Amendment Petition that states, "no revenue of the state shall be spent on experimentation that involves the destruction of a live human embryo" result in a proposed constitutional amendment that was placed on the ballot and passed.¹⁰

Agency for Health Care Administration

Medicaid does not reimburse for experimental procedures per the Hospital Services Coverage and Limitations Handbook, page 2-39, where it states:

Experimental Procedures:

Experimental procedures are not reimbursable by Medicaid.

Experimental procedures are further defined in the Florida Medicaid Provider General Handbook, in Appendix D on page D-5, which states:

Experimental or Clinically Unproven Procedures:

Those newly developed procedures undergoing systematic investigation to establish their role in treatment or procedures that are not yet scientifically established to provide beneficial results for the condition for which they are being used.

Medicaid does not pay for any procedure that would destroy a human embryo, nor does Medicaid pay for assistive reproductive procedures.¹¹

Department of Health

The proposed constitutional amendment in which no state revenues shall be spent on experimentation that involves the destruction of a live human embryo will not have any known revenue or expenditure impacts on the Department of Health since the department does not currently spend state appropriated funds on experimentation that involves the destruction of a live human embryo.¹²

State University System

Various institutions from the State University System (FAMU, FAU, FGCU, FIU, FSU, NCF, UCF, UF, UNF, USF and UWF) were surveyed to determine the impact of the amendment on current funding and practices. Based on their responses (see the material at the following link: http://edr.state.fl.us/conferences/constitutionalimpact/2008%20Ballot/Prohibiting%20Funding%20for%20Destruction%20of%20Live%20Human%20Embryo/State%20University%20System%20response%20Part%201.pdf), it does not appear that the universities currently conduct experimentation or research that will be adversely impacted by the amendment. Nor do they have state-funded staff that could be affected by the provisions of the amendment. As expressed in written and oral testimony, their greater concern is related to the amendment's effect on future activity, and the environment that research takes place in.

⁹ Ted Bonanno, electronic mail to conference principal, December 5, 2006

¹⁰ Dick Barnum, electronic mail to conference principal, December 1, 2006

¹¹ Phil Williams, electronic mail to conference principals, December 4, 2006 and follow-up on electronic mail on December 7, 2006

¹² Susan Phillips, electronic mail to conference principals, December 6, 2006

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

Section 100.371, Florida Statutes, requires that the Financial Impact Estimating Conference ". . . complete an analysis and financial impact statement to be placed on the ballot of the estimated increase or decrease in any revenue or costs to state or local governments resulting from the proposed initiative."

As part of determining the fiscal impact of this proposed amendment, the Financial Impact Estimating Conference (FIEC) principals held three public meetings—Public Workshop on November 28, 2006; Principals' Workshop on December 4, 2006; and Formal Conference on December 11, 2006.

A. FISCAL ANALYSIS

The fiscal impact summary for this proposed constitutional amendment is based on independent research; testimony before the FIEC public workshops; written statements from the sponsor of the initiative; responses from the Department of Management Services, Division of State Group Insurance, the Agency for Health Care Administration, Medicaid/Medicare office, the Department of Health, the Office of Trade, Tourism and Economic Development, and the State University System; and discussions among the FIEC principals and other professional staff. Based on this information, the FIEC principals expect that the proposed constitutional amendment will have the following effect:

 The amendment is not expected to have an impact on state or local government expenses.

B. FISCAL IMPACT ON STATE AND LOCAL GOVERNMENTS:

1. Revenues:

There are no probable impacts on state or local government revenues because the future development of research and any associated activities that could be affected by this amendment is unknowable; therefore, the impacts, if any, are indeterminate/

2. Expenditures:

There is no expected financial impact to state and local expenses.