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October 7, 2006

An Analysis of Missouri's Proposed Amendment 2

BACKGROUND

The following is an analysis of the proposed amendment to Missouri's Constitution, designated as Amendment 2, to be considered on the November 2006 general election ballot. The components found in this analysis are:

- I. Analysis Summary
- II. A list of Missouri First's concerns about the Amendment
- III. The official "Ballot Summary"
- IV. Full Text, with Comments, of Amendment 2

ANALYSIS SUMMARY

This analysis finds the proposed amendment to be very poor public policy for a number of ethical reasons as well as a basic concern about what is appropriate constitutional language.

The most basic concern is the detailed statute-like language of the amendment. Constitutional provisions should be general in nature, outlining principles that are the will of the people, leaving the procedural details to statutes adopted by the General Assembly. Too much micromanaging by the constitution usually results in unintended consequences and this amendment, in particular, not only forces detailed procedures, with the likelihood of yet unknown consequences, but also ties the hands of the legislature so they won't be able to deal with those consequences via legislation. This amendment is far too long and complex and if adopted will likely require future constitutional amendments to fix - a fix that is much more difficult than a revision of a state statute.

Two clauses, § 38(d) subsec. 3; § 38(d) subsec. 4, are repugnant to the basic rights of Missourians, since they take away the right of individuals to bring civil actions for violations of the amendment.

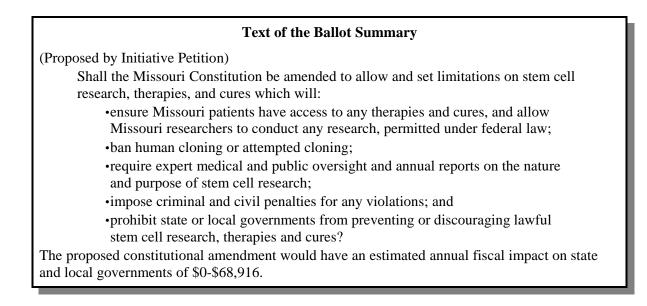
Additionally, this amendment is wrought with **deceptive language**, presenting one *apparent* meaning but a totally different legal application. A little insight into recent legislative efforts to restrict cloning and embryonic stem cell research in Missouri sheds a lot of light on the real intent of the drafters of this amendment. Their goal is **constitutional protection** of cloning and embryonic stem cell research – protection against legislative oversight. The amendment accomplishes that goal effectively, with the additional **benefits to researchers** of ensuring available public funding for such research, protection from civil lawsuits by citizens, and enhanced availability of eggs through a provision allowing "consideration" to be paid to the donors, thus creating a market for eggs.

Unfortunately, the typical voter will only see the <u>ballot summary</u> (next page) and not the <u>full text</u> of the amendment (following pages). A comparison of the two calls into question the trustworthiness and intentions of the drafters of the amendment. (See comments interspersed with amendment clauses in red.)

Concerns about The Missouri Stem Cell Research and Cures Initiative

- Inherently misleading; e.g. leading the casual observer to assume there are applicable federal laws and that the amendment actually bans cloning.
 § 38(d), subsec. 2; § 38(d)-subsec. 2(1) & § 38(d) subsec. 6(2);
- Constitutional protection of the destruction of human embryos created by in vitro fertilization.
 § 38(d) subsec. 2(7); § 38(d) subsec. 6(5); § 38(d) subsec. 6(6); § 38(d) subsec. 6(11)
- Constitutional protection of cloning and the destruction of the embryos so created.
 § 38(d) subsec. 2(7) & ; § 38(d) subsec. 6(2)
- Constitutional protection for growing cloned human beings in artificial wombs for body parts.
 § 38(d) subsec. 2(7) & § 38(d) subsec. 6(2)
- Precludes legislative oversight of embryonic stem cell research, including cloning.
 § 38(d) subsec. 2(7); § 38(d) subsec. 5; § 38(d) subsec. 7
- Guarantees public funding of embryonic stem cell research, including cloning. <u>§ 38(d) subsec. 5</u>
- Outlaws related civil lawsuits by citizens.
 § 38(d) subsec. 3; § 38(d) subsec. 4

Official Ballot Summary as will appear on the November 7, 2006 ballot.



IV. Full Text, with Comments, of Amendment 2

2006 Ballot Measure Constitutional Amendment 2

Stem Cell Initiative

Submitted October 11, 2005

NOTICE: You are advised that the proposed constitutional amendment may change, repeal, or modify by implication or may be construed by some persons to change, repeal or modify by implication, the following provisions of the Constitution of Missouri – Sections 2, 10, 14, and 32 of Article I; Section 1 of Article II; Sections 1, 21, 22, 23, 28, 36, 39, 40, 41, and 42 of Article III; Sections 1, 14, 36(a), 37, 37(a), 39, and 52 of Article IV; Sections 5, 14, 17, 18, and 23, and subsection 17 of Section 27 of Article V; Sections 18(b), 18(c), 18(d), 18(k), 18(m), 19(a), 20, 31, 32(a), and 32(b) of Article VI; Section 9(a) of Article IX; Sections 1, 6, 11(a), 11(d), and 11(f) of Article X; and Section 3 or Article XI.

THE PROPOSED AMENDMENT

Be it resolved by the people of the state of Missouri that the Constitution be amended:

One new section is adopted by adding one new section to be known as section 38(d) of Article III to read as follows:

Section 38(d). 1. This section shall be known as the "Missouri Stem Cell Research and Cures Initiative."

.2 To ensure that Missouri patients have access to stem cell therapies and cures, that Missouri researchers can conduct stem cell research in the state, and that all such research is conducted safely and ethically, any stem cell research permitted under federal law may be conducted in Missouri, and any stem cell therapies and cures permitted under federal law may be provided to patients in Missouri, subject to the requirements of federal law and only the following additional limitations and requirements:

(Comment: The only federal prohibitions to embryonic stem cell research relate to federal funding and don't affect privately funded or state funded research. Federal jurisdiction over such research is questionable at best, so there may <u>never</u> be federal law that regulates such activity - no matter how strong the support is..

Like Federal .08 blood alcohol standards for motor vehicle operators, Federal standards relating to this research usually must be implemented through state statutes. The Federal government offers "incentives" for compliance, such as withholding funds due the states or providing new funds if the new standards are adopted.

The net result will be no means of regulating embryonic stem cell research or cloning by either state or federal law.)

(1) No person may clone or attempt to clone a human being.

(Comment: "Clone" is defined in the amendment's <u>subsec. 6(2)</u>. The definition is NOT a true scientific definition of cloning and will not only permit cloning but also constitutionally protect the practice, precluding legislative regulation of it in the future.

(2) No human blastocyst may be produced by fertilization solely for the purpose of stem cell research.

(Comment: Blastocysts created for some other "reason" are fair game.)

(3) No stem cells may be taken from a human blastocyst more than fourteen days after cell division

begins; provided, however, that time during which a blastocyst is frozen does not count against the fourteen-day limit.

(Comment: This part, along with part (2) constitutionally guarantees the "right" to experiment on "excess" embryos created to help infertile couples have children.)

(4) No person may, for valuable consideration, purchase or sell human blastocysts or eggs for stem cell research or stem cell therapies and cures.

(Comment: The apparent meaning of this provision is totally negated by the definition of "valuable consideration" [below in <u>subsec. 6(17)</u>]. A market for human eggs will be created and women will still be allowed to sell their eggs.)

(5) Human blastocysts and eggs obtained for stem cell research or stem cell therapies and cures must have been donated with voluntary and informed consent, documented in writing.

(6) Human embryonic stem cell research may be conducted only by persons that, within 180 days of the effective date of this section or otherwise prior to commencement of such research, whichever is later, have

(a) provided oversight responsibility and approval authority for such research to an embryonic stem cell research oversight committee whose membership includes representatives of the public and medical and scientific experts;

(b) adopted ethical standards for such research that comply with the requirements of this section; and

(c) obtained a determination from an Institutional Review Board that the research complies with all applicable federal statutes and regulations that the Institutional Review Board is responsible for administering.

(7) All stem cell research and all stem cell therapies and cures must be conducted and provided in accordance with state and local laws of general applicability, including but not limited to laws concerning scientific and medical practices and patient safety and privacy, to the extent that any such laws do not (i) prevent, restrict, obstruct, or discourage any stem cell research or stem cell therapies and cures that are permitted by the provisions of this section other than this subdivision (7) to be conducted or provided, or (ii) create disincentives for any person to engage in or otherwise associate with such research or therapies and cures.

(Comment: This section, along with <u>subsection 7</u>, effectively precludes any and all legislative oversight or restrictions of experimentation on embryos, <u>whether created through fertilization or cloning</u>. Insight gained through future discoveries may affect the "ethics" of this process, but public policy will not be allowed to adapt to that new knowledge without another constitutional amendment.)

3. Any person who knowingly and willfully violates in this state subdivision (1) of subsection 2 of this section commits a crime and shall be punished by imprisonment for a period of up to fifteen years or by the imposition of a fine of up to two hundred fifty thousand dollars, or by both. Any person who knowingly and willfully violates in this state subdivisions (2) or (3) of subsection 2 of this section commits a crime and shall be punished by imprisonment for a period of up to ten years or by the imposition of a fine of up to one hundred thousand dollars, or by both. A civil action may be brought against any person who knowingly and willfully violates in this state any of subdivisions (1) through (6) of subsection 2 of this section, and the state in such action shall be entitled to a judgment recovering a civil penalty of up to fifty thousand dollars per violation, requiring disgorgement of any financial profit derived from such violation, and/or enjoining any further such violation. The attorney general shall have the exclusive right to bring a civil action for such violation. Venue for such action shall be the county in which the alleged violation occurred.

(Comment: While these penalty provisions sound tough, they really constitute protection for those involved in research and a restriction of the basic rights of Missouri citizens. For example, if a woman was mislead by researchers and her eggs were provided without the "voluntary and informed consent" required by subsection 2(5), she would have no civil recourse, but would, instead, be forced to rely on the attorney general to pursue the case.)

4. Each institution, hospital, other entity, or other person conducting human embryonic stem cell research in the state shall (i) prepare an annual report stating the nature of the human embryonic stem cells used in, and the purpose of, the research conducted during the prior calendar year, and certifying compliance with subdivision (6) of subsection 2 of this section; and (ii) no later than June 30 of the subsequent year, make such report available to the public and inform the Secretary of State how the public may obtain copies of or otherwise gain access to the report. The report shall not contain private or confidential medical, scientific, or other information. Individuals conducting research at an institution, hospital, or other entity that prepares and makes available a report pursuant to this subsection 4 concerning such research are not required to prepare and make available a separate report concerning that same research. A civil action may be brought against any institution, hospital, other entity, or other person that fails to prepare or make available the report or inform the Secretary of State how the public may obtain copies of or otherwise gain access to the report, and the state in such action shall be entitled as its sole remedy to an affirmative injunction requiring such institution, hospital, other entity, or other person to prepare and make available the report or inform the Secretary of State how the public may obtain or otherwise gain access to the report. The attorney general shall have the exclusive right to bring a civil action for such violation.

5. To ensure that no governmental body or official arbitrarily restricts funds designated for purposes other than stem cell research or stem cell therapies and cures as a means of inhibiting lawful stem cell research or stem cell therapies and cures, no state or local governmental body or official shall eliminate, reduce, deny, or withhold any public funds provided or eligible to be provided to a person that (i) lawfully conducts stem cell research or provides stem cell therapies and cures, allows for such research or therapies and cures to be conducted or provided on its premises, or is otherwise associated with such research or therapies and cures, but (ii) receives or is eligible to receive such public funds for purposes other than such stem cell-related activities, on account of, or otherwise for the purpose of creating disincentives for any person to engage in or otherwise associate with, or preventing, restricting, obstructing, or discouraging, such stem cell-related activities.

(Comment: The subsection ensures the availability of public funding since the phrase "eligible to be provided" may have very broad application, possibly applying to all of the state's general revenue funds. It might also be used by organizations such as abortion providers to regain public funding that has been previously denied them by the legislature. It is very bad public policy to force citizen participation, through taxation, in an area some believe to be be highly unethical.)

6. As used in this section, the following terms have the following meanings:

(1) "Blastocyst" means a small mass of cells that results from cell division, caused either by fertilization or somatic cell nuclear transfer, that has not been implanted in a uterus.

(2) "Clone or attempt to clone a human being" means to implant in a uterus or attempt to implant in a uterus anything other than the product of fertilization of an egg of a human female by a sperm of a human male for the purpose of initiating a pregnancy that could result in the creation of a human fetus, or the birth of a human being.

(Comment: This definition effectively embeds a right to clone in our constitution by redefining "clone". Traditionally, the scientific definition does not stipulate the location of the blastocyst or embryo, thus cloning by the true scientific definition takes place BEFORE implantation in a uterus.

This legal definition protects any cloning process that does not use a woman's uterus. Of particular concern are recent developments in ectogenesis. With the use of artificial wombs this amendment would result constitutionally protected growth of human bodies to any stage technologically achievable and the harvesting of organs from those individuals.)

(3) "Donated" means donated for use in connection either with scientific or medical research or with medical treatment.

(4) "Fertilization" means the process whereby an egg of a human female and the sperm of a human male form a zygote (i.e., fertilized egg).

(5) "Human embryonic stem cell research," also referred to as "early stem cell research," means any scientific or medical research involving human stem cells derived from in vitro fertilization blastocysts or from somatic cell nuclear transfer. For purposes of this section, human embryonic stem cell research does not include stem cell clinical trials.

(Comment: "somatic cell nuclear transfer" IS the process by which Dolly the cloned sheep was created. This definition includes in vitro fertilization. That means the amendment will provide <u>constitutional protection</u> for the destruction of embryos created by the fertilization of an egg with a sperm. Presently, federal funds can not be used for such research, but the amendment will preclude withholding state funds for the same.)

(6) "In vitro fertilization" means fertilization of an egg with a sperm outside the body.

(7) "Institutional Review Board" means a specially constituted review board established and operating in accordance with federal law as set forth in 42 U.S.C. 289, 45 C.F.R. Part 46, and any other applicable federal statutes and regulations, as amended from time to time.

(8) "Permitted under federal law" means, as it relates to stem cell research and stem cell therapies and cures, any such research, therapies, and cures that are not prohibited under federal law from being conducted or provided, regardless of whether federal funds are made available for such activities.

(Comment: Federal law does not, and arguably cannot, prohibit embryonic stem cell research and cloning. All it can constitutionally do is prohibit the use of federal funds. That means the state of Missouri will be helpless to regulate privately funded experiments if this amendment passes.)

(9) "Person" means any natural person, corporation, association, partnership, public or private institution, or other legal entity.

(10) "Private or confidential medical, scientific, or other information" means any private or confidential patient, medical, or personnel records or matters, intellectual property or work product, whether patentable or not and including but not limited to any scientific or technological innovations in which an entity or person involved in the research has a proprietary interest, prepublication scientific working papers, research, or data, and any other matter excepted from disclosure under Chapter 610, RSMo, as amended from time to time.

(11) "Solely for the purpose of stem cell research" means producing human blastocysts using in vitro fertilization exclusively for stem cell research, but does not include producing any number of human blastocysts for the purpose of treating human infertility.

(Comment: This definition results in <u>constitutional protection</u> for destroying embryos created by the fertilization of an egg with a sperm.)

(12) "Sperm" means mature spermatozoa or precursor cells such as spermatids and spermatocytes.

(13) "Stem cell" means a cell that can divide multiple times and give rise to specialized cells in the body, and includes but is not limited to the stem cells generally referred to as (i) adult stem cells that are found in some body tissues (including but not limited to adult stem cells derived from adult body tissues and from discarded umbilical cords and placentas), and (ii) embryonic stem cells (including but not limited to stem cells derived from in vitro fertilization blastocysts and from cell reprogramming techniques such as somatic cell nuclear transfer).

(14) "Stem cell clinical trials" means federally regulated clinical trials involving stem cells and human subjects designed to develop, or assess or test the efficacy or safety of, medical treatments.

(15) "Stem cell research" means any scientific or medical research involving stem cells. For purposes of this section, stem cell research does not include stem cell clinical trials.

(16) "Stem cell therapies and cures" means any medical treatment that involves or otherwise derives from the use of stem cells, and that is used to treat or cure any disease or injury. For purposes of this section, stem cell therapies and cures does include stem cell clinical trials.

(17) "Valuable consideration" means financial gain or advantage, but does not include reimbursement for reasonable costs incurred in connection with the removal, processing, disposal, preservation, quality control, storage, transfer, or donation of human eggs, sperm, or blastocysts, including lost wages of the donor. Valuable consideration also does not include the consideration paid to a donor of human eggs or sperm by a fertilization clinic or sperm bank, as well as any other consideration expressly allowed by federal law.

(Comment: This provision negates the apparent prohibition against a woman selling her eggs in subsec. 2(4).

7. The provisions of this section and of all state and local laws, regulations, rules, charters, ordinances, and other governmental actions shall be construed in favor of the conduct of stem cell research and the provision of stem cell therapies and cures. No state or local law, regulation, rule, charter, ordinance, or other governmental action shall (i) prevent, restrict, obstruct, or discourage any stem cell research or stem cell therapies and cures that are permitted by this section to be conducted or provided, or (ii) create disincentives for any person to engage in or otherwise associate with such research or therapies and cures.

(Comment: "Therapies and cures" could be construed to include growing cloned individuals in artificial wombs for the purpose of harvesting body parts, for instance. This clause prevents the people's legislature from prohibiting such practices. Federal actions are limited to withholding federal funds.)

8. The provisions of this section are self-executing. All of the provisions of this section are severable. If any provision of this section is found by a court of competent jurisdiction to be unconstitutional or unconstitutionally enacted, the remaining provisions of this section shall be and remain valid.