ARIZONA HOUSE OF REPRESENTATIVES

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Majority Research Staff

Senate: HHS DP 4-3-0-0 | Third Read 18-12-0-0
House: HHS DPA 9-3-0-0

SB 1214: stem cells; regenerative therapy
Sponsor: Senator Shamp, LD 29
House Engrossed

Overview
Provides regulations for the use of stem cell and regenerative therapies that are not approved by the U.S. Food and Drug Administration (FDA).

History
The U.S. FDA is the federal agency responsible for regulating clinical research, clinical trials and the therapeutic use of stem cell and birth tissue products. Stem cell therapies derived from pluripotent stem cells, adult stem cells or birth tissues may be evaluated through clinical trials conducted under FDA oversight. In most cases, stem cell products must undergo clinical testing through an Investigational New Drug application and obtain FDA approval before they may be marketed for treatment (FDA).

Stem cells are undifferentiated cells capable of developing into many different types of cells in the body and can self-renew to produce functional tissues. Pluripotent stem cells, such as human embryonic stem cells (hESCs) and induced pluripotent stem cells (iPSCs), have the ability to develop into any cell type in the adult body. Adult, or somatic, stem cells typically differentiate into the specific tissue type from which they originate. hESCs are derived from the inner cell mass of preimplantation human embryos, whereas iPSCs are created by reprogramming adult cells to behave like embryonic stem cells. Adult stem cells may be obtained from the patient, a donor or certain birth-related tissues (NIH).

State law defines *destructive human embryonic stem cell* research as research in which a human embryo is disaggregated or otherwise destroyed to obtain pluripotent stem cells. A person may not intentionally or knowingly engage in destructive human embryonic stem cell research, and a violation of this prohibition is a class 6 felony. Creating or transferring certain human-animal hybrid organisms is prohibited as well as the sale or purchase of a human embryo (A.R.S. §§ 36-2311, 36-2312, 36-2313).

Provisions
1. Permits a provider to perform stem cell or regenerative therapy that is not approved by the FDA if the:
   a. stem cell or regenerative therapy is within the provider's lawful scope of practice;
   b. provider has completed a nationally recognized, accredited or board-recognized continuing education training in stem cell or regenerative therapy;
   c. stem cell or regenerative therapy complies with prescribed sourcing requirements; and

☐ Prop 105 (45 votes) ☐ Prop 108 (40 votes) ☐ Emergency (40 votes) ☐ Fiscal Note

d. provider obtains written informed consent before performing any stem cell or regenerative therapy. (Sec. 1)

2. Specifies that any cells, exosomes or biologic materials used for therapeutic purposes must be sourced exclusively from a facility as outlined. (Sec. 1)

3. Prescribes the requirements for properly retrieving, manufacturing and storing stem cells and regenerative medicines, including inspection, registration, certification and accreditation of the facility. (Sec. 1)

4. Mandates lot-specific sterility reports and certificates of analysis be provided with each product before use with the provider's patient. (Sec. 1)

5. Prohibits a provider who performs stem cell or regenerative therapy from obtaining stem cells or regenerative medicines from any facility that does not have a valid certification or accreditation. (Sec. 1)

6. Stipulates that any contract or agreement by which a provider obtains stem cells or regenerative medicines for therapies from a credited or accredited manufacturing facility must include the outlined data. (Sec. 1)

7. Directs any manufacturing facility that provides stem cells or regenerative medicine to a provider for stem cell or regenerative therapy to notify the provider receiving the stem cells or regenerative therapy within 30 days after any change in certification or accreditation status. (Sec. 1)

8. Instructs a provider to ensure that all products used in stem cell or regenerative therapy are obtained from a manufacturing facility complying with current good manufacturing practices in accordance with the Federal Food, Drug and Cosmetic Act and federal regulations. (Sec. 1)

9. Requires any provider advertising stem cell or regenerative therapy to include in any form of advertisement, in a type size of at least the largest type used elsewhere in the advertisement, the disclosure: *This notice is required by Arizona law. This provider offers one or more stem cell or regenerative therapies that are not approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care provider before undergoing any stem cell or regenerative therapy.* (Sec. 1)

10. Requires a provider, before performing any stem cell or regenerative therapy, to obtain a signed informed consent form from the patient or patient's authorized representative, as outlined. (Sec. 1)

11. Requires a provider administering a stem cell or regenerative therapy to maintain accurate treatment records and document any clinical outcomes or adverse events, including reporting requirements as outlined. (Sec. 1)

12. Permits a provider to voluntarily submit de-identified data to professional clinical registries. (Sec. 1)

13. Declares it an act of unprofessional conduct for a provider to violate requirements relating to stem cell and regenerative therapy. (Sec. 1)

14. Exempts a licensed provider who acts in good faith and in compliance with stem cell and regenerative therapy requirements from being subject to professional disciplinary action or license revocation, except in cases of gross negligence, medical fraud or intentional misconduct. (Sec. 1)

15. Permits any individual who receives a stem cell or regenerative therapy treatment that violates applicable statutory requirements to bring a civil action to recover statutory damages in an amount of $10,000 per violation, plus attorney fees and costs. (Sec. 1)

16. Contains a legislative intent clause. (Sec. 2)

17. Defines terms. (Sec. 1)

18. Cites the legislation as the *Arizona Stem Cell and Regenerative Therapy Act*. (Sec. 3)