FLORIDA HOUSE OF REPRESENTATIVES
BILL ANALYSIS

This bill analysis was prepared by nonpartisan committee staff and does not constitute an official statement of legislative intent.

BILL #: CS/CS/HB 1617	**COMPANION BILL:** CS/CS/SB 1768 (Trumbull)
TITLE: Stem Cell Therapy	**LINKED BILLS:** None
SPONSOR(S): Buchanan	**RELATED BILLS:** None

Committee References

Health Professions & Programs	➤	Health & Human Services
16 Y, 0 N, As CS		22 Y, 0 N, As CS

SUMMARY

Effect of the Bill:

CS/CS/HB 1617 authorizes allopathic and osteopathic physicians to perform stem cell therapies that have not been approved by the United States Food and Drug Administration (FDA) relating to orthopedics, wound care, and pain management. The bill establishes the type of stem cells that may be used and the type of facilities from which a physician may obtain stem cells. The bill requires physicians to provide notice and informed consent to patients receiving non-FDA approved therapies and provides for discipline for violations.

Fiscal or Economic Impact:

The bill has a negative, indeterminate fiscal impact on the Department of Health (DOH) for enforcement, which DOH can absorb within existing resources. To the extent physicians profit from providing certain stem cell therapies, the bill has a positive, economic impact on the private sector.

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ANALYSIS

EFFECT OF THE BILL:

Stem Cells

Stem Cell Therapy

Current Florida law neither authorizes nor prohibits certain stem cell therapies relating to orthopedics, wound care, and pain management. Stem cell therapies are regulated by the United States Food and Drug Administration (FDA).

Authorized Activities

The bill authorizes allopathic and osteopathic physicians to perform stem cell therapies that have not been approved by the FDA relating to orthopedics, wound care, and pain management. Under the bill, stem cell therapy is a treatment involving the use of afterbirth placental perinatal stem cells or human cells, tissues, or cellular or tissue-based products (HCT/Ps) that complies with regulatory requirements. Stem cell therapy does not include treatment or research using human cells or tissue derived from a fetus or an embryo after an abortion. (Sections 1 and 2).

Under the bill, HCT/Ps are articles containing or consisting of human cells or tissues obtained from umbilical cords or cord blood for the purpose of implantation, transplantation, infusion, or transfer into a human recipient. Umbilical cord and cord blood donors must be residents of the United States. (Sections 1 and 2).

The bill expressly excludes ten classes of articles from the HCT/Ps authorized for use under the bill:

- Vascularized human organs for transplantation;
- Whole blood, blood components, or blood derivative products regulated by the Florida Drug and Cosmetic Act;[1]
- Secreted or extracted human products, such as milk, collagen, and cell factors. However, the bill includes semen as a state recognized class of HCT/Ps;
- Minimally manipulated[2] bone marrow for homologous use and not combined with another article, except for with water, crystalloids, or a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow;
- Ancillary products used in the manufacture of HCT/Ps;
- Cells, tissues, and organs derived from animals other than humans;
- In vitro diagnostic products;
- Blood vessels recovered with an organ, as defined in s. 42 C.F.R. s. 121.2, which are intended for use in organ transplantation and labeled, "for use in organ transplantation only";
- Fetal-derived stem cells; and
- Adipose-derived mesenchymal stem cells for transplantation.

The bill also expressly excludes two HCT/Ps sourcing activities, which includes:
- Treatment or research using human cells or tissues derived from a fetus or embryo after an abortion.
- The sale, manufacture, or distribution of computer products created using HCT/Ps.

Stem Cell Acquisition

The bill requires physicians to adhere to current good manufacturing practices (CGMP)[3] for the collection, removal, processing, implantation, and transfer of stem cells or products containing stem cells. (Sections 1 and 2).

To that end, the bill prohibits a physician who performs stem cell therapy from acquiring stem cells for such therapies from a facility unless the facility maintains valid accreditation or certification through the FDA and at least one of the following entities: the National Marrow Donor Program, the World Marrow Donor Association, the Association for the Advancement of Blood and Biotherapies, or the American Association of Tissue Banks. In a contract or other agreement for the acquisition of stem cells, a physician must include terms that require the facility to disclose the following information to the physician:
- The name and address of the facility.
- The certifying organization.
- The type and scope of certification.
- The effective and expiration dates of the certification.
- Any limitations or conditions imposed by the certifying organization. (Sections 1 and 2).

The bill also requires such contract or agreement to require the facility to notify the physician within 30 days of any change to the facility's certification status (i.e., renewal, suspension, revocation, or expiration). (Sections 1 and 2).

According to the Department of Health (DOH), the bill's provisions authorizing physicians to perform non-FDA approved stem cell therapies may subject a physician who performs these therapies and stem cell suppliers to regulatory action by the FDA. The FDA has issued warnings about the widespread marketing of unapproved

[1] Ch. 499, Pt, 1, F.S.
[2] The bill gives minimal manipulation two meanings. For structural tissue, minimal manipulation is a process that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement. For cells or nonstructural tissues, minimal manipulation means a treatment involving the use of afterbirth placental perinatal stem cells or human cells or tissues or tissue-based products. Minimal manipulation does not include treatment or research using human cells or tissues that were derived from a fetus or embryo after an abortion.
[3] *See* 21 U.S.C. § 301, et. seq.; 21 C.F.R. Part 1271.

regenerative medicine products, noting that approval is granted only after rigorous evaluation in clinical trials to ensure safety and efficacy.[4]

Patient Disclosure Requirements

Written Notice

The bill requires the physician to provide prospective stem cell therapy patients with written notice, which must contain a particular disclosure, presented in any form of advertisement. Specifically, a physician must provide a patient with written notice before performing a non-FDA approved stem cell therapy on a patient which must state:

> "THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW. This physician performs one or more stem cell therapies that have not yet been approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care provider before undergoing any stem cell therapy."

The bill requires the notice to be clearly legible and in a type size no smaller than the largest type size used in the advertisement. (Sections 1 and 2).

Informed Consent

The bill requires a physician to obtain written informed consent, signed by the patient, prior to performing non-FDA approved stem cell therapies which must include:

- The nature and character of the proposed treatment, including whether FDA approves the treatment.
- The anticipated results of the proposed treatment.
- The recognized possible alternative forms of treatment.
- The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including the nontreatment option.
- The option for the patient to consult with his or her primary care provider before undergoing stem cell therapy. (Sections 1 and 2).

Licensure Discipline

The bill states that violations of the bill's requirements may subject allopathic and osteopathic physicians to disciplinary action by the Board of Medicine or the Board of Osteopathic Medicine, as applicable. (Sections 1 and 2).

Exemptions

The bill expressly exempts a physician from the requirements from the bill's provisions if:

- The FDA approved the physician's application for an Investigational New Drug or Investigational New Device for use of the human cells, tissues, or cellular or tissue-based products.
- The physician performs stem cell therapy under an employment or other contract on behalf of an institution certified by the Foundation for the Accreditation of Cellular Therapy, the Blood and Marrow Transplant Clinical Trials Network, the Association for the Advancement of Blood and Biotherapies, or an entity with expertise in stem cell therapy, as determined by DOH. (Sections 1 and 2).

[4] U.S. Food & Drug Administration, Important Patient and Consumer Information About Regenerative Medicine Therapies, (Jun. 3, 2021), https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies (last visited Apr. 2, 2025).

Stem Cell Suppliers

The bill establishes requirements for the origin and preparation of the stem cells used for the therapies authorized by the bill. The stem cells must be manufactured in a clean room certified by the FDA for the use of high-efficiency particulate air (HEPA) filtration or ultra-low penetration air filtration to minimize contamination. Additionally, the facility where the stem cells are retrieved, manufactured, and stored must be registered and regulated by the FDA and licensed or registered with one of four specified organizations: the National Marrow Donor Program, the World Marrow Donor Association, the Association for the Advancement of Blood and Biotherapies, or the American Association of Tissue Banks. (Sections 1 and 2).

The stem cell product lot used by a physician for therapies must also contain viable or live cells. The bill requires the stem cell supplier to conduct a post-thaw viability analysis of the stem cells for each product lot sent to a physician, and provide a report on that analysis to the physician. (Sections 1 and 2).

These requirements are enforced upon the physician using the stem cells.

The effective date of the bill is July 1, 2025. (Section 3).

RULEMAKING:

The bill authorizes the Board of Medicine and the Board of Osteopathic Medicine to adopt rules necessary to implement the bill. (Sections 1 and 2).

Lawmaking is a legislative power; however, the Legislature may delegate a portion of such power to executive branch agencies to create rules that have the force of law. To exercise this delegated power, an agency must have a grant of rulemaking authority and a law to implement.

FISCAL OR ECONOMIC IMPACT:

STATE GOVERNMENT:

The bill has a negative, indeterminate fiscal impact on DOH. DOH believes that the enforcement workload for its Consumer Services Unit and Prosecution Services Unit may increase to protect the public from unauthorized performance of stem cell therapies; but enforcement costs can be absorbed within existing resources and budget authority.[5]

PRIVATE SECTOR:

To the extent allopathic and osteopathic physicians increase their revenues due to the performance of additional stem cell services, the bill has a positive, indeterminate economic impact on the private sector. However, to the extent these physicians also increase their costs for obtaining supplies, advertising, and workload, the magnitude of the economic impact through the bill is indeterminate.[6]

[5] *Id*. at pp. 7.
[6] *Id*. at pp. 8.

RELEVANT INFORMATION

SUBJECT OVERVIEW:

Stem Cells

Stem cells, the body's foundational building blocks, transform into more than 200 specialized cells, including blood, bone, and muscle cells, and repair damaged tissue. Stem cells continuously renew and divide to make exact replicas of themselves, and they also have the ability replenish or repair specific cell types.[7]

Stem cells help medical researchers understand how disease develops, how damaged or unhealthy cells can be replaced, and how to prepare and test new treatments and medications. To do so, medical researchers source stem cells from three donated sources:[8]

- Embryonic (pluripotent) stem cells: These cells, extracted from embryonic stem cells from donated blood cords or embryos developed during in vitro fertilization, can transform into any cell type.
- Tissue-specific (multipotent or unipotent) stem cells: These cells, extracted from a specific tissue, can regenerate to support tissue of the same kind.
- Induced pluripotent stem cells (iPS): These cells are lab-made to resemble and act like embryonic stem cells.

Stem Cell Therapy

Stem cell therapy is the treatment of a condition or illness with stem cells or cells produced from stem cells. Currently, the range of diseases for which there are proven stem cell therapies is small. Nonetheless, treatments for disorders of the blood and immune systems and acquired loss of bone marrow can in some cases be treated effectively with blood stem cells. Tissue-specific and organ-specific treatments such as those for skin and corneas have also proven successful. Most other stem cell therapies are still experimental and have not yet been shown to be safe or effective.[9]

Stem Cell Regulation

The Food and Drug Administration

The Center for Biologics Evaluation and Research

The Center for Biologics Evaluation and Research (CBER), within the United States Food and Drug Administration (FDA), regulates biological products for human use.[10] CBER regulates human cells, tissue, and cellular and tissue-based products (HCT/P), which are human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient.[11] Examples of HCT/Ps are bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes and semen. CBER does not regulate the transplantation of vascularized human organ transplants such as kidney, liver, heart, lung or pancreas. The Health Resources Services Administration (HRSA) oversees the transplantation of vascularized human organs.[12]

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[7] Cleveland Clinic, Stem Cells, (last reviewed Mar. 22, 2023) https://my.clevelandclinic.org/health/body/24892-stem-cells (last visited Mar. 24, 2025).
[8] *Id.*
[9] Department of Health, Agency Bill Analysis for HB 1617 (2025), pp. 2 (Mar. 19, 2025) (on file with the Health and Human Services Committee).
[10] United States Food and Drug Administration, Center for Biologics Evaluation and Research, United States Department of Health and Human Services, (last updated Sept. 18, 2024) https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber (last visited Mar. 24, 2025). CBER's authority derives from the Public Health Service Act (42 U.S.C. § 264) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.). Applicable federal regulations are found primarily in 21 C.F.R., part 1271.
[11] United States Food and Drug Administration, Tissue & Tissue Products, United States Department of Health and Human Services, (last updated Mar. 1, 2024) https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products (last visited Mar. 24, 2025).
[12] *Id.*

An establishment that manufactures human cells, tissues, and cellular and tissue-based products (HCT/Ps), must register with CBER, if:[13]

- The HCT/P is minimally manipulated;
- The HCT/P is intended for homologous use only;
- The manufacture of the HCT/P does not involve the combination of cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and, either
    - The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
    - The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
        - Is for autologous use;
        - Is for allogeneic use in a first-degree or second-degree blood relative; or
        - Is for reproductive use.

An establishment is not required to comply with registration and reporting requirements if the establishment:[14]

- Uses HCT/P's solely for nonclinical scientific or educational purposes;
- Removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure;
- Is a carrier who accepts, receives, carries, or delivers HCT/P's in the usual course of business as a carrier;
- Does not recover, screen, test, process, label, package, or distribute, but only receives or stores HCT/P's solely for implantation, transplantation, infusion, or transfer within their facility;
- Only recovers reproductive cells or tissue and immediately transfers them into a sexually intimate partner of the cell or tissue donor; or
- Is an individual under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment; however, it must comply with all other applicable requirements.

The HCT/P is regulated as a drug, device, or biologic product under the Public Health Service Act and/or the Food, Drug, and Cosmetics Act, if it does not meet the above-referenced requirements or qualify for an exemption. In 2017, the FDA published a comprehensive regenerative medicine policy framework. The only stem cell-based therapies that have been approved by the FDA for use in the United States consist of blood-forming stem cells derived from cord blood.[15] CBER regulates cellular therapy products which includes cellular immunotherapies, cancer vaccines, and other types of both autologous and allogeneic cells for certain therapeutic indications, including hematopoietic stem cells and adult and embryonic stem cells.[16]

Donated cord blood is the only embryonic stem cell treatment approved by the FDA.[17] Federal law does not explicitly prohibit the use of fetal-derived stem cells obtained from elective abortions; however, such use is subject to ethical oversight, particularly in federally funded research. The National Institutes of Health requires review by an ethics advisory board for proposed research involving fetal tissue.[18]

Current Good Manufacturing Practices

[13] Department of Health, Agency Bill Analysis for HB 1617 (2025), pp. 3 (Mar. 19, 2025) (on file with the Health and Human Services Committee).
[14] *Id.* at pp. 3.
[15] *Id.* at pp. 2-3.
[16] United States Food and Drug Administration, Cellular & Gene Therapy Products, United States Department of Health and Human Services, (last updated Mar. 20, 2023) https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products (last visited Mar. 24, 2025)
[17] Cleveland Clinic, Stem Cells, (last reviewed Mar. 22, 2023) https://my.clevelandclinic.org/health/body/24892-stem-cells (last visited Mar. 24, 2025).
[18] National Institutes of Health, Policies and Procedures for the Use of Human Fetal Tissue (HFT) in Non-Transplantation Research, https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/policies-procedures-use-human-fetal-tissue-hft-non-transplantation-research (last visited Apr. 2, 2025).

The FDA requires establishments that manufacture or manipulate HCT/Ps to register with CBER and to comply with current Good Tissue Practices (cGTPs) under 21 C.F.R. part 1271, subpart D.[19] These practices are designed to prevent the introduction or transmission of communicable diseases. The FDA conducts inspections, issues warning letters, and may pursue civil or criminal enforcement actions against facilities or providers offering unapproved or noncompliant stem cell therapies.

The FDA has issued warnings about the widespread marketing of unapproved regenerative medicine products, noting that approval is granted only after rigorous evaluation in clinical trials to ensure safety and efficacy. The FDA has received reports of serious adverse events associated with unapproved regenerative medicine therapies, including blindness, tumor formation, and infections.[20] Consumers are advised to exercise caution and are encouraged to report any adverse effects or file complaints related to these products directly to the FDA.

In the past, the FDA has issued a warning letter to at least one Florida-based provider for illegally using stem cell therapies not approved by the FDA and without an investigational new drug application or a valid biologics license in effect. The FDA required this Florida-based provider to provide a written response within 15 days outlining the corrective action planned to correct the violations and prevent their reocurrance.[21]

Practitioner Regulation

Oversight by the Florida Boards of Medicine and Osteopathic Medicine

The Florida Board of Medicine (BOM), under the DOH, is responsible for licensing, regulating, and disciplining medical doctors, a.k.a. allopathic physicians, pursuant to ch. 458, F.S. The Board of Osteopathic Medicine (BOOM), pursuant to ch. 459, F.S., exercises the same authority for osteopathic physicians. The BOM has the authority to impose disciplinary sanctions, including license suspension or revocation, for violations of the standard of care, deceptive advertising, or failure to obtain proper informed consent, under s. 456.072, F.S., and related provisions of the Medical Practice Act. The BOOM has the authority to impose similar disciplinary sanctions under s. 459.015, F.S., which governs grounds for disciplinary action against osteopathic physicians.

In recent years, the BOM has reviewed complaints against providers advertising unproven stem cell treatments for conditions such as orthopedic pain and neurodegenerative disorders. Some of these providers have been subject to formal investigations, fines, and, in certain cases, license restrictions or revocations. In 2013, the BOM revoked the licenses of two physicians in administrative cases involving stem cells for failing to meet the standard of care. In 2015, the BOM warned physicians and consumers that they should be aware of the risks involved accessing stem cell therapies and regenerative medicine that was not approved by the FDA. The BOM further warned that a physician providing stem cell treatment should do so only with an investigational new drug application (IND) or a single patient IND for Compassionate or Emergency Use.[22]

[19] *See* U.S. Department of Health & Human Services, Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), https://www.hhs.gov/guidance/document/current-good-tissue-practice-cgtp-and-additional-requirements-manufacturers-human-cells (last visited Apr. 2, 2025).
[20] U.S. Food & Drug Administration, Important Patient and Consumer Information About Regenerative Medicine Therapies, (Jun. 3, 2021), https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies (last visited Apr. 2, 2025).
[21] U.S. Food and Drug Administration, Division of Biological Products Operations, Warning Letter #OBPO 19-05 Cord for Life, Inc., MARCS-CMS 572770 – March 29, 2019.
[22] Department of Health, Agency Bill Analysis for HB 1617 (2025), pp. 3-4 (Mar. 19, 2025) (on file with Health and Human Services Committee).

BILL HISTORY

COMMITTEE REFERENCE	ACTION	DATE	STAFF DIRECTOR/ POLICY CHIEF	ANALYSIS PREPARED BY
Health Professions & Programs Subcommittee	16 Y, 0 N, As CS	4/3/2025	McElroy	DesRochers
THE CHANGES ADOPTED BY THE COMMITTEE:	• Revised the definition of "human cells, tissues, or cellular or tissue-based products." • Provided a statement of legislative intent.			
Health & Human Services Committee	22 Y, 0 N, As CS	4/22/2025	Calamas	DesRochers

THE CHANGES ADOPTED BY THE COMMITTEE:	• Revises definitions.
	• Authorizes physicians to perform certain stem cell therapies for orthopedics, wound care, or pain management which are not approved by FDA but comply with state requirements.
	• Requires stem cells used by physicians to:
	  ○ Be manufactured in FDA-certified clean room spaces with certain filtration systems.
	  ○ Be retrieved, manufactured, and stored in FDA-registered and regulated facilities which must also be licensed or registered at least one professional entity.
	  ○ Contain viable or live cells upon post-thaw analysis and be included in a post-thaw viability analysis report for the product lot which the facility sends to the physician.
	• Prohibits physicians whom perform stem cell therapies from contracting with a facility in the stem cell supply chain unless the facility maintains valid accreditation or certification.
	• Requires physicians who perform stem cell therapies to:
	  ○ Ensure any contract with a facility in the stem cell supply chain includes certain disclosures.
	  ○ Use stem cells or products containing stem cells produced by a facility which adheres to the federal standards for current good manufacturing practices.
	  ○ Provide specific notice in advertisements for stem cell therapy.
	  ○ Secure signed consent from the patient or patient's representative that includes certain disclosures in plain terms.
	• Exempts allopathic and osteopathic physicians with FDA approval for a stem cell therapy or who perform stem cell therapy under an employment or other contract on behalf of certain certified institutions who from the requirements of the bill.
	• Authorizes the Board of Medicine and the Board of Osteopathic Medicine to adopt rules necessary to implement the bill.			

THIS BILL ANALYSIS HAS BEEN UPDATED TO INCORPORATE ALL OF THE CHANGES DESCRIBED ABOVE.
