The Financial Barriers of Stem Cell-Based Therapies: A Policy Review of Cost, Access, and Reform

Sienna Aguayo[1]

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Humanity's expectation for the future of medicine is often characterized by the widespread accessibility to new innovative forms of medical treatments. Recently, one of the most rapidly developing fields of "futuristic" medical treatment is the field of regenerative medicine. So, if financial exclusivity in medical treatments is left unaddressed, the fight against socioeconomic disparities in healthcare may continue to limit life-saving therapies for patients in the future. Therefore, emerging innovations in regenerative medicine, specifically stem cell therapy, should be regulated to help ensure these therapies are made more affordable to a wider socioeconomic range of patients. This paper provides a narrative review of the policy and economic barriers of stem cell therapies and evaluates proposed reforms to address them. These reforms include outcome-based contracts, expanded awareness, advocacy for new stem cell donors, a proposed reexamination of FDA regulation, non-profit initiatives, and increased government investment in under-resourced areas and partnerships with scientists in emerging economies. Findings from the reviewed literature suggest that industry leaders in regenerative medicine, which include the United States' healthcare system, pharmaceutical companies, private non-profit institutions, and government, could contribute to driving down the costs of stem cell therapies in the United States. This review is guided by the principle that health is a fundamental human right, and that this right involves a shared responsibility to expand equal access to healthcare for all.

Introduction

Regenerative medicine is an umbrella term used to describe the creation and use of biomaterial to regenerate or replace damaged human tissue, which can be caused by either disease, aging, physical trauma, and other forms of degradation. This term includes gene-editing, artificial organ construction, personalized medicine, and stem cell therapies. Particularly, stem cell therapies utilize specialized human cells in order to repair damaged tissues in patients, and are the dominating force in the field of regenerative medicine.

The global stem cell therapy market is led by the United States, which is due to the country's significant investment in research, development, and clinical trials. For instance, Hematopoietic stem cell transplantation is an FDA-approved treatment and established for clinical use for patients with blood cancers and immune disorders, such as lymphoma, severe aplastic anemia, and more. For stem cell therapies that aim to treat other conditions such as chronic neurodegenerative diseases, cardiovascular diseases, osteoarthritis, and diabetes, remain in active clinical research rather than established treatments for patient-use, as none have yet proved their reliability and effectives. In addition, many unregulated clinics in the United States market continue to falsely advertise stem cell therapies and products that can treat or reverse these same conditions and more, which are not backed by FDA clinical evidence. However, FDA-approved stem cell therapies in the United States are often expensive and are largely inaccessible to the majority of the people who are in need of these life-saving treatments. To ensure that stem cell treatments become affordable to all socioeconomic backgrounds, the United States' public healthcare systems, non-profit institutions, and government should work to improve the systems that continue to limit widespread access to these therapies. This paper is a policy review that synthesizes existing health policy, economic, and ethical literature to evaluate reforms that have been proposed to improve the affordability of stem cell therapies in the United States.

Current Approval Status in the United States

As of 2026, a vast majority of stem cell therapies are still undergoing U.S. clinical trials, which are necessary to determine the effectiveness and safety of these treatments. These stem cell treatments that are currently undergoing clinical trials and have not yet been approved by the FDA include targeted therapies that focus on chronic diseases such as chronic kidney disease, Crohn's disease, chronic obstructive pulmonary disease, glioblastoma, and more [1]. For context, the range of manipulation for these stem cells used in these clinical trials can span from cell and gene modified therapies such as CAR-T, which

[1] *Flintridge Sacred Heart Academy, California , USA*

involves directly reprogramming a patient's own cells before reintroducing them to the body, distinguishing these products from minimally manipulated stem cells used in regenerative therapies, such as Hemacord. However, there are also many stem cell clinics in the U.S. market that utilize unapproved regenerative products and therapies to consumers with claims that have not been evaluated by the FDA for safety and effectiveness.

Currently, the U.S. Food and Drug Administration (FDA) has a total of 50 regenerative therapies and medicines approved for commercial use, which all fall under distinct regulatory classes: HCT/P, Biologic, CAR-T, Gene therapy, or MSC[2]. For instance, Hemacord, a Hematopoietic stem cell transplantation therapy derived from umbilical-cord blood, became the first FDA-approved stem cell therapy in 2011[2]. These types of therapies are used to treat disorders that impair the blood and immune system in patients[3]. According to FDA clinical testing, Hemacord's approval for patients with Severe Combined Immunodeficiency Disorder (SCID) was based on calculated survival rates of up to 60-65% for these patients after administration[4].

Another successful trial can be seen in patients suffering from beta thalassemia major, which revealed the survival rate plateaued at 60% with higher cell dosage, and disease-free survival ranged from 60-83% of patients overall[4]. These significant improvements in survival and disease-free survival rates highlight the crucial need to make these therapies more widely affordable and accessible for patients facing these types of disorders. However, early survival rates for patients facing Bone marrow failure, specifically Fanconi Anemia (FA) and Severe Aplastic Anemia (SAA), faced "high early mortality and high graft failure rate ... which may in part be due to alloimmunization from multiple transfusions"[4]. In all, the successful approval of Hemacord represents an important milestone in FDA approved stem cell therapies, which can enable a wider range of treatment options for patients with chronic diseases and disorders in the future.

Key Terms and Definitions

This paper primarily focuses on hematopoietic stem cell transplantation (HSCT), as it is the first stem-cell therapy approved by the FDA for commercial use, making it to be the foundational example for regulation and clinical expectations for stem-cell therapies, even though it represents only one of the 50 currently approved regenerative products described previously. Other cord-blood products are mentioned as a source of the stem cells utilized in HSCT, not as a separate category with its own cost or policy analysis. CAR-T cell therapy and gene therapy are mentioned in order to introduce the reimbursement model, outcome-based contracts, and are not conventional stem-cell products. Exosome therapy and unapproved regenerative products are mentioned to serve as examples of unregulated treatments that patients should be cautious of. Mesenchymal stromal/stem-cell products are discussed in order to introduce a more 'ethical' alternative to embryonic stem-cell therapy and are not discussed any further.

Methodology

This paper utilizes a narrative review approach, as the issues it addresses span several different areas including economics, FDA regulation, healthcare policy, and Catholic Social Teaching. A total of 39 sources were used. Regulatory and policy information was drawn primarily from the U.S. Food and Drug Administration (FDA.gov) and the Centers for Medicare & Medicaid Services (CMS.gov). Clinical and cost data came largely from peer-reviewed journal articles accessed through PubMed Central, and through publisher platforms including Elsevier/ScienceDirect, Frontiers, Wiley, Springer, and BioMed Central, along with a Springer Nature-affiliated journal. Institutional and industry sources included Mayo Clinic, the American Hospital Association, the American Cancer Society, HealthCare.gov, and Medscape. USCCB.org was used for the ethical framework around Catholic Social Teaching.

Keywords: "Stem cell therapy market", "stem cell affordability", "stem cell regulation", and "regenerative medicine cost".

Inclusion Criteria

If a source presented measurable data on market size, projected industry growth or treatment costs; explained federal regulation of stem cell products; discussed financial or insurance barriers that limited access to treatment; or represented a Catholic Social Teaching position on healthcare access and the ethics of stem cell research, then they would be implemented. Each source was required to have a credible source of origin, meaning a government agency, peer-reviewed journal, academic institution, or a well-established industry outlet with a clearly stated author or organization. Because of the rapidly changing stem cell market, sources that were published within the last ten years were prioritized, in order to most accurately reflect the current state of the field. However, a few older sources were used, as they either accurately describe foundational stem cell biology or gave insight on historical pharmaceutical investment in the field, since this content is not time-sensitive in the way market or regulatory data is. For claims surrounding regulatory systems and reimbursement policy, government body publications (FDA.gov, CMS.gov) were utilized as primary sources, since these agencies are the originating authority for the policies discussed. For claims

Table 1 FDA-approved cellular, gene, and stem-cell products for use [2].

Product Name	Cell Type	Indication	Approval Date	Regulatory class
ABECMA (idecabtagene vicleucel)	Autologous T cells transduced with anti-BCMA02 CAR LVV	Adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy	Mar 26, 2021	CAR-T
ADSTILADRIN (nadofaragene firadenovec-vcng)	Recombinant adenovirus serotype 5 vector containing a transgene encoding alfa-2b (IFNα2b)	For adult patients with high-risk Bacillus Calmette Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC)	Dec 16, 2022	Gene therapy
ALLOCORD (HPC, Cord Blood)	Allogeneic cord blood hematopoietic progenitor	Patients with disorders affecting the hematopoietic system	May 30, 2013	HCT/P
AMTAGVI (lifileucel)	Tumor-derived autologous T cells	For adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody	Feb 16, 2024	Biologic
TREGZI (Allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq)	Allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq	Treatment of adults with hematological malignancies	June, 30 2026	Biologic
AUCATZYL (obecabtagene autoleucel)	CD19-directed genetically modified autologous T cell	For the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)	Nov 8, 2024	CAR-T
BEQVEZ (fidanacogene elaparvovec-dzkt)	Adeno-associated virus (AAV) vector in vivo	For the treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency)	Apr 25, 2024	Gene therapy
BREYANZI (lisocabtagene maraleucel)	CD19-directed genetically modified autologous T cell	Adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL)	Feb 5, 2021	CAR-T
CARVYKTI (ciltacabtagene autoleucel)	BCMA-directed genetically modified autologous T cell	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy	Feb 28, 2022	CAR-T
CASGEVY (exagamglogene autotemcel [exa-cel])	Autologous CD34+ HSCs edited by CRISPR/Cas9	For the treatment of patients aged 2 years and older (STN 125787) or patients aged 12 years and older (STN 125785) with: Sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs). Transfusion-dependent β-thalassemia (TDT)	Dec 8, 2023	Gene therapy
CLEVECORD (HPC Cord Blood)	Hematopoietic progenitor cells, monocytes, lymphocytes, and granulocytes from human cord blood	For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution	Sep 1, 2016	HCT/P
Ducord, HPC Cord Blood	Hematopoietic progenitor cells, monocytes, lymphocytes, and granulocytes from human cord blood	For patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment	Mar 19, 2026	HCT/P

ELEVIDYS (delandistrogene moxeparvovec-rokl)	Adeno-associated virus serotype rh74 (AAVrh74), containing the ELEVIDYS micro-dystrophin transgene	For the treatment of patients 4 years of age and older with Duchenne muscular dystrophy (DMD) who are ambulatory and have a confirmed mutation in the DMD gene	Jan 10, 2024	Gene therapy
ENCELTO (revakinagene taroretcel-lwey)	Allogeneic encapsulated RPE (retinal pigment epithelial) cells	For the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel)	Mar 5, 2025	Gene therapy
GINTUIT (Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen)	Cellular sheet containing allogeneic human cells, human extracellular matrix proteins, and bovine collagen	For topical (non-submerged) application to a surgically created vascular wound bed in the treatment of mucogingival conditions in adults	Mar 9, 2012	Biologic
HEMACORD (HPC, cord blood)	Hematopoietic progenitor cells, monocytes, lymphocytes, and granulocytes from human cord blood	For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system	Nov 10, 2011	HCT/P
HEMGENIX (etranacogene dezaparvovec-drlb)	Non-replicating recombinant AAV5 containing a codon-optimized DNA sequence of the gain-of-function Padua variant of human Factor IX (variant R338L)	For treatment of adults with Hemophilia B (congenital Factor IX deficiency) who: Currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes	Nov 22, 2022	Gene therapy
HPC, Cord Blood	Hematopoietic progenitor cells, monocytes, lymphocytes, and granulocytes from human cord blood	For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution	May 24, 2012	HCT/P
HPC, Cord Blood - MD Anderson Cord Blood Bank	Hematopoietic progenitor cells, monocytes, lymphocytes, and granulocytes from human cord blood	For patients with disorders affecting the hematopoietic system	Jun 21, 2018	HCT/P
HPC, Cord Blood - LifeSouth	Hematopoietic progenitor cells, monocytes, lymphocytes, and granulocytes from human cord blood	For patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment	Apr 5, 2013	HCT/P
HPC, Cord Blood - Bloodworks	Hematopoietic progenitor cells, monocytes, lymphocytes, and granulocytes from human cord blood	For patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment	Jun 9, 2011	HCT/P
IMLYGIC (talimogene laherparepvec)	Live, attenuated HSV-1 that has been genetically modified to express huGM-CSF	For the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery	Dec 8, 2021	Gene therapy

ITVISMA (onasemnogene abeparvovec-brve)	Recombinant self-complementary AAV9 containing a transgene encoding the human survival motor neuron (SMN) protein	For the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with confirmed mutation in survival motor neuron 1 (SMN1) gene	Nov 24, 2025	Gene therapy
KEBILIDI (eladocagene exuparvovec-tneq)	Recombinant adeno-associated virus serotype 2 (rAAV2) based vector	For the treatment of adult and pediatric patients with aromatic L amino acid decarboxylase (AADC) deficiency	Nov 13, 2024	Gene therapy
KYMRIAH (tisagenlecleucel)	CD19-directed genetically modified autologous T cell	For patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse, relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL)	Aug 30, 2017	CAR-T
LANTIDRA (donislecel)	Allogeneic islets of Langerhans derived from a donor pancreas	For the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c	Jun 28, 2023	Biologic
LAVIV (Azficel-T)	Autologous cellular product composed of fibroblasts	Indicated for improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults	Jun 21, 2011	Biologic
LENMELDY (atidarsagene autotemcel)	Autologous CD34+ cells, containing hematopoietic stem cells (HSCs)	Indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD)	Mar 18, 2024	Gene therapy
LUXTURNA (voretigene neparvovec-rzyl)	Live, non-replicating adeno-associated virus serotype 2	For the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy	Dec 19, 2017	Gene therapy
LYFGENIA (lovotibeglogene autotemcel [lovocel])	Globin gene therapy consisting of autologous CD34+ cells	Treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events (VOEs)	Dec 8, 2023	Gene therapy
MACI (Autologous Cultured Chondrocytes on a Porcine Collagen Membrane)	Autologous cultured chondrocytes on a porcine collagen membrane	Indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults	May 31, 2019	Biologic
OMISIRGE (omidubicel-onlv)	Nicotinamide modified unrelated allogeneic hematopoietic progenitor cells	For patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection or patients 6 years and older with severe aplastic anemia (SAA)	Apr 17, 2023	Biologic

OTARMENI™ (lunsotogene parvec cwha)	Adeno-associated virus vector-based gene	For pediatric and adult patients with severe-to-profound sensorineural hearing loss (HL; any frequency $>$ 90 dB) associated with molecularly confirmed biallelic variants in the OTOF gene, preserved outer hair cell function, and no prior cochlear implant in the same ear	Apr 23, 2026	Gene therapy
PAPZIMEOS (zopapogene imadenovec-drba)	Non-replicating adenoviral vector-based immunotherapy	For the treatment of adults with recurrent respiratory papillomatosis.	Aug 14, 2025	Gene therapy
PROVENGE (sipuleucel-T)	Autologous peripheral blood mononuclear cells, including antigen presenting cells (APCs)	For the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer	Apr 29, 2010	Biologic
REGENECYTE (HPC, Cord Blood)	Hematopoietic progenitor cells, monocytes, lymphocytes, and granulocytes from human cord blood	For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system	Nov 20, 2024	HCT/P
RETHYMIC (allogeneic processed thymus tissue – agdc)	Allogeneic processed thymus tissue	For immune reconstitution in pediatric patients with congenital athymia.	Oct 8, 2021	Biologic
ROCTAVIAN (valoctocogene roxaparvovec-rvox)	Adeno-associated virus (AAV) vector-based gene therapy product	Indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity $<$ 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5	Jun 30, 2023	Gene therapy
RYONCIL (remestemcel-L-rknd)	Culture-expanded mesenchymal stromal cells	Indicated for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older	Dec 19, 2024	MSC
SYMVESS (acellular tissue engineered vessel-tyod)	Acellular tissue engineered vessel composed of human extracellular matrix (ECM) proteins typically found in human blood vessels	Indicated for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible	Dec 19, 2024	Biologic
SKYSONA (elivaldogene autotemcel)	Autologous cells are enriched for CD34+ cells, then transduced ex vivo with Lenti-D LVV, and cultured with growth factors overnight	Indicated to slow the progression of neurologic dysfunction in boys 4- 17 years of age with early, active cerebral adrenoleukodystrophy (CALD)	Sep 16, 2022	Gene therapy

STRATAGRAFT (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat)	Scaffold product with a fully-stratified epithelial layer	To promote durable wound closure & regenerative healing in the treatment of adult patients with debrided thermal burns that contain intact dermal elements, and for which surgical intervention is clinically indicated.	Jun 15, 2021	Biologic
TECARTUS (brexucabtagene autoleucel)	CD19-directed genetically modified autologous T cell immunotherapy	Adult patients with relapsed or refractory mantle cell lymphoma (MCL) or with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)	Jul 24, 2020	CAR-T
TECELRA (afamitresgene autoleucel)	Genetically modified autologous T cell immunotherapy	Adults and pediatric patients 12 years of age and older with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen	Aug 1, 2024	Gene therapy
VYJUVEK (beremagene geperpavec-svdt)	Live, replication defective HSV-1-based vector	Wounds in adult and pediatric patients with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.	May 19, 2023	Gene therapy
WASKYRA (etuvetidigene autotemcel)	Autologous hematopoietic stem cell-based gene therapy	Pediatric patients aged 6 months and older and adults with Wiskott-Aldrich Syndrome (WAS) who have a mutation in the WAS gene for whom hematopoietic stem cell transplantation (HSCT) is appropriate	Dec 9, 2025	Gene therapy
YESCARTA (axicabtagene ciloleucel)	CD19-directed genetically modified autologous T cell immunotherapy	For the treatment of adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy; adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL)	Oct 18, 2017	CAR-T
ZEVASKYN (prademagene zamikeracel)	Autologous cell sheet-based gene therapy	Treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB)	Apr 28, 2025	Gene therapy
ZYNTEGLO (betibeglogene autotemcel)	Autologous hematopoietic stem cell-based gene therapy	Treatment of adult and pediatric patients with β-thalassemia who require regular red blood cell (RBC) transfusions	Aug 17, 2022	Gene therapy
ZOLGENSMA (onasemnogene abeparvovec-xioi)	Adeno-associated viral vector-based gene therapy	Treatment of pediatric patients less than two years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene	May 24, 2019	Gene therapy

about clinical outcomes and cost, peer-reviewed primary studies were prioritized.

Exclusion Criteria

Evidence that presented claims with no medical-backing, advertised a specific stem cell clinic, or lacked a clear author or organization was excluded. When different sources presented the same data or findings, the first-hand source was used. For the drafting process, each source utilized was placed in a journal entry document, which included a full MLA 9 citation, the author or publishing institution, the publication date, a roughly 150-word summary of the relevant content, direct quotes to be used as evidence, and a short reflection connecting the source back to the research question. This record-keeping strategy allowed for a more organized and streamlined writing process. Once all entries were collected, the sources were organized thematically. The sources were grouped into five main themes: market growth, FDA regulation, ethical viewpoints from the Catholic Church, insurance and systemic financial barriers, and potential reforms. Because this is a narrative review, sources were informally weighted by authority: government agencies, peer-reviewed journals, and academic institutions were treated as highest-quality evidence, while industry outlets were treated as supplementary and were only used when they provided measurable figures not available from a higher-authority source. When possible, lower-authority figures were cross-checked against more authoritative sources, such as treatment cost estimates, to ensure that these statistics were reasonably consistent before including them.

Scientific Background: The Mechanics of Stem Cells

To understand how stem cell therapies work, it is important to know that the human body relies on specialized cells to ensure proper function of organs and tissues. Specialized cells include red blood, nerve, muscle, sperm, egg, bone, and skin cells, which all have their own function when regulating the body. Before stem cells become specialized cells, they are considered "undifferentiated" or "blank", meaning that the cell's structure and function have not yet been formed. At this level, the stem cell has the capacity to be manipulated into having a specific function. These undifferentiated stem cells must undergo the process of differentiation, where researchers can either use growth factors, chemical signaling, or complex substrates to alter the cell's structure in order to assign its function in the organism[11]. However, not all stem cells have the same differentiation abilities, which is dependent on the stem cell's origin and developmental stage. It is important to understand that a stem cell is distinguished by its potency, which is the range of cell types it can differentiate into. Totipotent stem cells have the ability to differentiate into any specialized body cell, including embryonic and extraembryonic[12]. Pluripotent stem cells have the capacity to differentiate into all types of embryonic layers that can later form into specialized body cells or tissues, with the exception of extraembryonic cells[12]. Lastly, Multipotent stem cells, also

Table 2 Terms and Definitions

Term	Definition
Hematopoietic stem cell transplantation (HSCT)	The restoration of blood cell production in patients with damaged bone marrow or an impaired immune system, which is achieved through the intravenous insertion of hematopoietic stem cells[5].
Cord-blood stem-cell products	Biological products containing processed hematopoietic progenitor cells that are extracted from the blood of placental blood vessels and umbilical cord[6].
Mesenchymal stromal/stem-cell products	Multipotent adult stem cells that are crucial for supporting homeostasis throughout tissue regeneration[7].
CAR-T cell therapy	A human gene therapy that utilizes Chimeric antigen receptor T cells, which are genetically modified to recognize and target specific antigens[8].
Gene therapy	A human gene therapy that is used to alter the gene expression or biological properties of living cells through either replacing a dysfunctional gene with a healthy copy, inactivating a faulty gene, or introducing a modified gene into the body to manage a disease[9].
Exosome therapy	A form of regenerative medicine that utilize micro-vesicles to promote cellular healing through key mechanistic pathways[10].
Unapproved regenerative products	Biological material, in the context of the U.S. stem cell regulation, that are not approved by the FDA (Food and Drug Administration), as they lack the proper evidence for safety and efficiency[3].

referred to as tissue-specific or adult stem cells, have the limited ability to differentiate into cell types of a specific tissue or organ lineage [12]. These varying levels of potency allow the complex human body to carry out all specific and crucial bodily functions simultaneously.

For instance, the most crucial bodily functions are the gas exchange of oxygen in the lungs and the beating of a human heart. The cells that make up the lungs are vastly different from the cells in the heart. During fetal development, the undifferentiated cells that will later become the lungs have to first be structurally modified. These modifications will allow the lungs to efficiently absorb oxygen from the outside environment and defend against airborne pathogens once the lungs are in use. Furthermore, the heart muscle cells must first differentiate to obtain the function that will allow them to contract, which is crucial to pump blood and oxygen throughout the body. With this knowledge of heart cell function, researchers have been able to create artificially differentiated stem cells and inject them "into the heart muscle" and these "healthy transplanted heart muscle cells could then contribute to repairing the injured heart muscle" [13]. These biological processes are crucial to understand the role and function that stem cells play in these therapies, as they can replace and repair the faulty specialized cells in the body.

Common Misconceptions

However, the scientific advancements have led to a considerable number of misconceptions to arise. These common misconceptions often set unrealistic expectations for these medical discoveries, which tarnishes the public reputation of stem cell therapies. The most widespread misinterpretation of these therapies is that they have the ability to cure every ailment and disease in the world. Given the current discoveries and limited technology in stem cell research, this ambitious claim is unfeasible as of now. However, it can be a possibility in the future as researchers are currently racing to create safe and effective therapies for a wide range of chronic diseases such as "leukemia, Hodgkin disease, non-Hodgkin lymphoma and some solid tumor cancers . . . aplastic anemia, immunodeficiencies and inherited conditions of metabolism" and are utilizing stem cells to research and "treat type 1 diabetes, Parkinson's disease, amyotrophic lateral sclerosis, heart failure, osteoarthritis and other conditions" [13].

Another common misconception is that stem cells are "illegal" in the U.S., meaning that stem cells are completely outlawed all together. While the FDA strictly regulates the manufacturing and distribution of stem cells, many patients that are desperately searching for cures often fall victim to overpromising marketing from unregulated stem cell clinics. The stem cells that are used in these illegally-operating clinics "have not been shown to be safe or effective, and, in some cases, may have significant safety issues that put patients at risk" [3]. These clinics claim to be able to "cure" conditions such as orthopedic, neurological, cardiovascular, or pulmonary diseases, which are disorders that have not been FDA-approved for stem cell treatment in the United States [3]. As of recent, there are only 50 FDA-approved regenerative medicines and therapies in the U.S. that can be viewed in Table 1.

Lastly, there is the misconception that the Catholic Church is entirely opposed towards the research and use of stem cell therapies. Historically, the Catholic Church has continuously expressed religious moral concern over the use of embryonic stem cells, as harvesting these cells include the destruction of a human embryo which is believed to be "deliberately destroying innocent human life" [14]. The divine value of human life is rooted in the belief that humanity "must respect life at all times" [14]. For context, embryonic stem cells are harvested from human embryos that are between 3 to 5 days old. During this stage, the embryo is a "spherical clump" of around 150 cells. However, researchers have strong interests in embryonic stem cells because they are "pluripotent", meaning that they can be differentiated into any cell of the human body and can efficiently replicate itself. These plastic and replenishing characteristics are some of the main reasons that many scientists and researchers frequently use embryonic cells for experiments and clinical trials, as they have the highest rates of potential [13].

However, there are other forms of stem cells that are considered to be more "ethically" sourced. Adult, Induced Pluripotent (iPSCs), and Perinatal stem cells are the other main forms that are used in global research and clinical trials. Adult stem cells, also known as mesenchymal stromal cells, are harvested in small amounts from adult tissues, such as bone marrow or fat. These stem cells are limited in their ability to be differentiated and divided in comparison to embryonic stem cells. Induced Pluripotent (iPSCs) are reprogrammed adult cells, whose genes are altered to mimic the properties of embryonic stem cells [13]. While this technique "may allow [the] use of reprogrammed cells instead of embryonic stem cells and prevent immune system rejection of the new stem cells", researchers do not know if "using altered adult cells will cause adverse effects in humans" [13]. Lastly, perinatal stem cells are harvested from either umbilical cord blood or amniotic fluid, which is the liquid inside of an amniotic sac that envelops a human fetus. These perinatal stem cells act the most identically to embryonic stem cells in their ability to replicate, but have a more limited scope of differentiation.

All of these different forms have the ability to transform into specialized cells in the body, leading scientists to further investigate these areas. In fact, the Catholic Church has been an active supporter in the development and research in forms of stem cells that derive from adult tissues and umbilical cord

blood, which they believe "poses no moral problem"[14]. Additionally, there have been efforts from the United States Conference of Catholic Bishops to push for the creation of a "nationwide public bank for umbilical cord blood stem cells, for research and the treatment of a wide variety of diseases"[14]. The Catholic Church demonstrates their initiative to aid in the development of ethical treatments reinforces the idea of "Thou shalt not kill" by setting "a clear limit in order to safeguard the value of human life, today we also have to say 'thou shalt not' to an economy of exclusion and inequality", as Pope Francis's Evangelii Gaudium explains[15]. The Catholic Church acknowledges the potential that stem cells hold to save the lives of patients and its investments in research and advocacy for a national stem cell bank aids in driving down the costs of these therapies. The Catholic Church actively follows the teaching that it is humanity's moral duty to expand equal opportunity to all, especially to the most vulnerable in society.

Discussion: Financial Barriers and Solutions

This idea of "equality for all" is relevant in the American healthcare system, where lower-income citizens are constantly excluded from receiving affordable healthcare. Therefore, it is essential to dismantle the financial barriers that limit access to affordable stem cell treatments, in order to ensure equal access to these life-saving treatments in the future.

Cost Definitions and Examples

First, it is important to distinguish the differences in terms such as total treatment cost, healthcare system cost, insurer reimbursement, patient out-of-pocket cost, and nonmedical costs. Total treatment cost is "all direct and indirect costs associated with an episode of care for a period of health care coverage"[16]. Healthcare costs include the "direct costs of the intervention itself (drugs, personnel, supplies, etc)"[17]. Insurer reimbursement is when providers "are reimbursed for each service they provide and beneficiaries pay a portion of the costs"[18]. Patient out-of-pocket-cost are the "expenses for medical care that aren't reimbursed by insurance" which include "deductibles, coinsurance, and copayments for covered services plus all costs for services that aren't covered"[19]. Lastly, non-medical costs are expenses that are not directly related to medical treatment or services, which include travel, lodging, lost work, and caregiver time.

For instance, as of November of 2025, the median healthcare system cost of hematopoietic cell transplantation for patients in the United States was $130,604, with an Interquartile Range (IQR) of $111,667–$2,234,007, which was surveyed from 54 child patients with Sickle Cell Disease (SCD) from Children's Healthcare of Atlanta and St. Jude Children's Research Hospital[20]. This IQR demonstrates the financial uncertainty for patients, which is driven by factors such as complication rates, length of hospitalization, and more, revealing that the true financial risk for each patient can vary significantly. The cost is dependent on several factors, such as the specific type of stem cells that is utilized, the amount of cells, the quality of the cells, the location of the laboratory, and the source of the stem cells. For instance, cell-based gene therapies, like CAR-T can typically range from $300,000 to $475,000 in manufacturing costs due to the complex nature of engineering and collecting these cells, which does not include the costs of "hospital admission, tests, procedures, and other expenses" and can lead to a total cost of over $500,000[21]. The CAR-T therapy demonstrates a crucial component that contributes to overall healthcare system cost. Additionally, many commercial insurances only cover "some of the costs of CAR-T therapy" and the amount of coverage "varies between commercial plans"[21].

Accordingly, the global stem cell therapy market is rapidly growing and is projected to reach $1,171.92 million by 2030, which is a directional estimate rather than a precise prediction. However, the systems in place to regulate the affordability of stem cell treatments are often left neglected by those overseeing the market[22]. This immense gap creates a financial hierarchy in regenerative medicine, which prioritizes the wealthy to have direct access to these treatments and leaves those who are less fortunate behind. These barriers derive from five challenges: incompatible payment plans for patients, FDA-regulatory hurdles, the pharmaceutical industry's profit-driven investment model, and a lack of scaled non-profit and government initiatives to dismantle these barriers.

Improving the affordability of stem cell treatments is a critical component that can help prevent the U.S. healthcare system from further becoming "an economy of exclusion and inequality" and "such an economy kills" those at the bottom of the system[15]. The rapidly growing regenerative medicine market creates an increased need for new ways to provide access to these treatments, which can be accomplished by first controlling the high up-front costs for patients. The existing fee-for-service model that dominates the U.S. healthcare system is unfit for stem cell therapies because it would require patients to pay the expensive costs out-of-pocket before these treatments are administered, which can be a financial burden if the treatments are ineffective. However, these out-of-pocket costs for healthcare are usually covered by private or public insurers, depending on the patient's economic standing. Public payers, who qualify for tax-funded medical services such as Medicare and Medicaid, pay little to no cost. Private, or commercial insurers collect monthly payments from patients in order to cover the cost of their healthcare.

The cost of HSCT therapies in the United States is roughly 15 times greater than that of the emerging economies listed in table 3. This major difference cannot be explained by clin-

Table 3 Comparative Cost of Hematopoietic Stem Cell Transplant (HSCT) by Country.

Country	HSCT Type	Cost	Year
United States	Myeloablative allogeneic HSCT (n=398)[23].	$289,283 (Median)	2017
	Nonmyeloablative/reduced-intensity allogeneic HSCT (n=195)[23].	$253,467 (Median)	2017
	Myeloablative autologous HSCT (n=969)[23].	$140,792 (Median)	2017
United Kingdom	HSCT (all types)[24].	£30,000–35,000 (Average)	2021
Japan	HSCT (all types)[25].	$70,000-$205,000 (Average)	2019
India	Autologous Bone Marrow HSCT (n=38)[26].	$12,500 (Median)	2014
	Allogeneic Bone Marrow HSCT (n=124)[26].	$17,914 (Median)	2014
Panama	Autologous HSCT (n=19)[27].	$9,000 (Average)	2021
	Allogenic HSCT (n=13)[27].	$18,000 (Average)	2021

ical difference alone, but likely reflects difference in pricing structure, market regulation, and healthcare insurance models.

To start, the public healthcare insurance systems, Medicare and Medicaid, have the authority to ensure affordability for patients in need of stem cell treatments. A possibility that would allow these therapies to become more affordable is through ensuring reimbursements for patients depending on the outcome of the treatment. However, a potential issue is that the Medicaid programs rely on the Diagnosis Related Group (DRG) system to compensate the hospitals for institutional care. This system can discourage hospitals from administering cell and gene therapies to patients, as the high costs can be more than the reimbursement amount. Another potential barrier is the difficulty in defining a "successful" or "failed" therapy outcome in order to determine what "will or will not be reimbursed"[28]. Nevertheless, these outcome-based contracts can offer hope to patients in need of these treatments because they can shift some of the financial risk of treatment failure or poor performance from payers onto the producers.

For instance, European countries such as Italy and Spain have implemented payment instalments tied to outcomes for advanced cell and gene therapies like Kymriah®, Yescarta®, Luxturna® and Zolgensma®, which was supported by 47% of payers that were surveyed[28]. This model gives patients the confidence that their money is being well-spent on effective therapies, as this system gives public and private healthcare insurance agencies the same level of financial risk as stem cell manufacturers, making them more enticed to deliver higher quality treatments and therapeutic materials to patients. Furthermore, the Centers for Medicare & Medicaid Services (CMS) have recently put forward a proposal called the Cell and Gene Therapy (CGT) Access Model that would implement outcome-based contracts for gene and cell therapies in the United States, focusing on gene therapy treatments for patients with sickle cell disease. While this model does not currently apply to stem-cell products, it introduces a potential policy framework that could extend to stem-cell therapies in order to improve affordability. This proposal would allow the CMS to coordinate and deliver outcome-based agreements for patients who are in need of these gene and cell treatments[29]. The proposal would modify the existing rules for providing separate payments for these therapies and possibly require manufacturers to rebate specific U.S. states in the case that the drugs used in these treatments were reimbursed in the form of a bundled payment. Moreover, it aims to include a "drug price verification survey", which would collect data on the various costs, uses, and pricing techniques that are associated with stem cell and gene therapies. The survey will provide insight on the pricing patterns, allowing for more financially aware decisions to be made regarding therapy affordability.

However, the many gaps in affordability are linked to both the public and private regulatory bodies in the U.S. healthcare system. Researchers suggest that some of the main issues are the complexity and cost associated with the FDA's strict regulatory requirements of these therapies and the pharmaceutical industry's profit-driven investment model, forcing these areas of research to be hindered. The FDA maintains strict regulation of stem cell therapy procedures, even simple ones. For instance, the FDA drafted guidance documents that aim to regulate adipose-derived autologous stem cell interventions, meaning that simply extracting a patient's fat and reinjecting it would be classified as FDA-regulated procedure[30]. This further complicates stem cell therapy, as plastic surgeons have argued that the FDA's regulatory language lacked the specificity needed to give physicians meaningful guidance[30]. In addition, surgeons have also warned that this draft has the ability to negatively impact patient care, as it can lead to "denial of appropriate treatment, delay of treatment, increased costs, and unnecessary burdens placed upon the treating physician"[30]. Yet, strict FDA regulation is ultimately necessary to ensure consumer protection in order to ensure the high quality of these treatments, since reduced pre-market oversight carries

real risks such as contamination, manufacturing variability, tumorigenicity, immune reactions, unvalidated potency, misleading marketing, and patient exploitation. With this, the effects of loosening the current regulatory framework should be treated as a hypothesis for future research in order to examine whether reclassifying minimally manipulated stem cell procedures as a practice of medicine rather than a drug could effectively lower treatment costs, without losing the critical safety protections that pre-market review currently provides. Further evidence that can demonstrate cost savings against these pre-market risks will enable lawmakers to determine the extent to which regulatory flexibility should be extended. Unlike the other barriers discussed in this paper, regulatory reform carries many safety tradeoffs that cannot be resolved without further evidence.

Beyond reclassification, there are more evidence-based reforms that can facilitate the progression of stem cell treatments to the market. Rather than loosening regulations entirely, the FDA can study Japan's implementation of "fast-tracks" for regenerative medical products to enter the market faster, while still prioritizing patient safety. For instance, the regulatory body that governs Japan's regenerative medicine approval, the Pharmaceuticals and Medical Devices Agency (PMDA), has implemented the Pharmaceuticals Medical Devices, and Other Therapeutic Products Act (PMD), which "introduces a conditional and time-limited approval system for regenerative medical products, allowing these therapies to reach the market more quickly". This conditional and time-limited pathway is an early marketing authorization, which is separate from full approval and not guaranteed. These regenerative products that are recommended for the PMD pathway are "typically reserved for products where safety is confirmed but efficacy data are insufficient"[31]. While the FDA offers its own "fast-track" option called the Regenerative Medicine Advanced Therapy (RMAT), which can expedite development and review for regenerative medical therapies directed towards life-threatening diseases or conditions, it does not grant market access in the way Japan's PMD Act does. The FDA could consider the model's "time-limited" market authorization, while also mandating post-market efficacy reassessment[31,32]. For instance, Japan has witnessed the withdrawal of a regenerative medicine product called "Heartsheet", which was removed from the market due to its "failure to provide efficacy evidence in the post-marketing trial", demonstrating the necessity to implement post-market reassessment of expediently-approved regenerative therapies if the FDA were to adopt a similar time-limited pathway[33].

Another issue is that the level of regulatory and financial risk that is associated with investing in stem cell therapy research significantly influences where pharmaceutical investment funds are granted. Pharmaceutical companies such as Pfizer, Novartis, Johnson & Johnson, and more, have been early investors in stem cell research, mainly using stem cells as tools for drug discovery in early investment stages, and are now taking the risk of developing stem cell-based medicines to the market[34]. The uncertainty faced with strict FDA regulation, as mentioned previously, is one contributing factor towards the hesitance of pharmaceutical from investing in cell/gene therapies; with this, stem cell products face a long and expensive approval pathway before ever reaching the market. For instance, findings show that an estimated $1.943 billion is required to "bring a new cell and/or gene therapy to market" after considering for R&D attrition rate such as failed programs[35]. These expenses are driven mainly by regulatory-related failure risks, as cell therapies face a discontinuation rate of $\sim$27.35%, which is a risk that pharmaceutical companies must factor into every investment decision[36]. In addition to these risks, FDA-mandated clinical holds on cell and gene therapy trials have notably increased in recent years, with certain cases losing support from their large industry partner or complete termination of similar trials from the same sponsor[37]. This demonstrates how regulatory intervention can swiftly cut off a company's return on investment mid-development. Without the financial aid from large private corporations, the development and scaling of these treatments are hindered, leaving them to stay expensive and experimental. Since this profit-driven and cautious investment model sets back advancements in this field, then private non-profit companies should be involved in bridging these gaps left behind by these public and private companies.

Non-profit companies can decrease cost by adopting new ways of expanding awareness to the general public and exerting control over the processes of the supply-chain. For example, non-profits in the U.S. should follow the models seen in other global non-profits such as one in India named DATRI, which "mobilize grassroots awareness campaigns sensitive to local cultural norms, which has extended to rural communities ... highlights the importance of awareness, education, and advocacy in improving social justice"[38]. This reveals how non-profits can aid in expanding affordability by first expanding awareness of these treatments and advocating for a larger, more diverse donor system, which in return can create more biological product to be used in these treatments and drives down material cost. Another example is Caring Cross, a non-profit dedicated to distributing affordable CAR-T and other cell therapies internationally, which created a global academic center network in order to collaborate with academic medical centers and organize Proof of Concept (POC) clinical trials. The chronic diseases that are included in Caring Cross's POC portfolio include CAR-T therapies that target HIV, relapsed and refractory leukemia and lymphoma, and intend to test stem cell gene therapy for Sickle Cell Disease (SCD) and β-thalassemia[39]. This demonstrates how non-profits can increase affordability for patients by controlling the multiple

stages of commercialization for these therapies, which allows them to build the distribution pathway needed to deliver affordable treatments directly to patients.

Lastly, the U.S. government has the power to significantly improve affordability of stem cell therapies. The United States is one of the key global players in stem cell banks and clinical systems, due to its significant investments in Research and Development (R&D). As of recently, governments and policymakers have been pressured to move more investments into regenerative medicine, as the market has been rapidly developing and expanding globally[22]. Many experts believe that the extremely strict requirements needed to gain a biological license, which were set by the FDA, are slowing down the progress of affordable stem cell therapy. To combat this, government assistance at a national and international level is needed to mobilize infrastructure, public funding, and legislation in order to expand affordability to the general public.

For example, there have been collaboration efforts from government incentives for commercially sponsored clinical trials that were hosted in under-resourced areas, which had mandatory inclusion of minorities in all clinical trials. In order to aid in the spread of these life-saving technologies to underprivileged areas, bio-networking programs aim to partner with scientists from emerging economies and to develop research hubs[38]. These efforts foster the development of new discoveries and advances in these treatments, as the government can provide opportunities for collaboration between diverse groups of scientists. This facilitation of ideas has the potential to drive down material costs, create new forms of stem cell treatments, improve existing stem cell treatments, and overall increase affordability.

Conclusion

However, relying solely on these systems to make the necessary changes needed to expand affordability will not be possible without the participation of its citizens. As technology advances tremendously each year, so does the potential for more innovations and discoveries to be made in the field of regenerative medicine. This goal can be further facilitated by encouraging future generations to become leaders, researchers, and doctors in this field, as they will be the ones to truly experience its full beneficial effect in the future.

Citizens can participate in a multitude of ways that do not include becoming a scientist in this field. Individuals can foster growing awareness of the common misconceptions that haunt the field of stem cell research, such as acknowledging that these forms of treatment as of current cannot “cure” every disease known to man, that they are not illegal treatments, and that there are other ways to ”ethically” source these cells that do not involve the destruction of a human embryo. Simultaneously, these simple forms of expanding research and awareness can significantly aid in paving the way for a future where the field of stem cell therapy faces less social, political, and religious denunciation. But most important of all, is to keep our humanity. When we as humans fail to acknowledge the worth of the vulnerable in our society, we strip away our own humanity and create division between one another.

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