A MEDICAL/LEGAL PERSPECTIVE ON STEM CELL THERAPY: A SCIENTIFIC BREAKTHROUGH OR SNAKE OIL?

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Science is an art, and science is a business. Unfortunately, the business aspect can cloud judgment.
–Tennille Ludwig, WiCell Stem Cell Bank [1]

A Google search of *stem cell therapy* yields over 200 million listings.[2] These references, however, will demonstrate a potpourri of mixed signals from those espousing the virtues of stem cells in the treatment of problems such as spinal cord injuries, strokes, Alzheimer's disease, diabetes, and heart conditions[3] to others who describe the therapy as a fraud,[4] fake treatment,[5] and a bogus cure.[6]

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[1] Karen Weintraub, *'Snake Oil' Stem Cell Clinics Peddle False Hope for High Prices*, MEDIUM HEALTH (Nov. 13, 2018), https://medium.com/s/thenewnew/snake-oil-stem-cell-clinics-peddle-false-hope-for-high-prices-2cbbed680b52 [https://perma.cc/JWK3-5G23].

[2] Stem Cell Therapy, GOOGLE, https://www.google.com (last visited Oct. 2, 2019) (searching *stem cell therapy*); *see also* Claudia Spits, *Stem Cell Therapy: Facts and Fiction*, FACTS, VIEWS & VISION OBGYN 195, 195 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3991398/ [https://perma.cc/RG8B-3EG4] ("If you open your browser and type 'stem cell therapy' into your search engine, you will get over 18 million results in the blink of an eye.").

[3] *See The Power of Stem Cells*, CAL. INST. FOR REGENERATIVE MED., https://www.cirm.ca.gov/patients/power-stem-cells [https://perma.cc/5XTK-962Y].

[4] *See* Katie LaGrone, *'That's Totally Fraud': A Leading Stem Cell Expert Responds to a FL Clinic's Stem Cell Pitch*, WPTV (May 11, 2018, 11:10 AM), https://www.wptv.com/news/local-news/investigations/-that-s-totally-fraud-a-leading-stem-cell-expert-responds-to-a-fl-clinic-s-stem-cell-pitch [https://perma.cc/4K9Q-YNLQ].

[5] *See Patients Crowdfunding for Fake Stem Cell Treatments: Study*, MEDICINENET, https://www.medicinenet.com/script/main/art.asp?articlekey=212274 [https://perma.cc/J699-BE4M]; Michael O. Schroeder, *Before You Undergo Stem Cell Treatment*, U.S. NEWS (July 30, 2019), https://health.usnews.com/conditions/articles/before-you-undergo-stem-cell-treatment [https://perma.cc/V4EN-GMSE].

[6] *See* Dennis Thompson, *Stem Cell Clinics Pitch Pricey, Bogus 'Cures' for Knee Pain*, UPI (Mar. 7, 2018, 1:03 PM), https://www.upi.com/Health_News/2018/03/07/Stem-cell-clinics-pitch-pricey-bogus-cures-for-knee-pain/9201520440802/ [https://perma.cc/4ZAH-WL4H].

The notion of a miracle cure and body tissue mending itself provides a unique appeal,[7] and there is little doubt that stem cell and regenerative therapies present great promise by offering potential treatment options for a host of maladies.[8] Regardless of the possibilities for this medical breakthrough, there is growing alarm about the increasing number of healthcare providers undermining the science.[9] This is the result of for-profit clinics and physicians making a number of unsupported assertions about the curative powers of stem cell therapy and in taking advantage of those in desperate circumstances who are eager to try any measure despite the negligible evidence of efficacy.[10] This Article will explore the controversy concerning stem cell therapy, and will explain why the government has become actively involved in regulating this field and why scientists and ethicists are advocating litigation as a way to curb for-profit stem cell therapy clinics.

I. WHAT ARE STEM CELLS?

Most people have heard of stem cells, but few understand their significance or role. They are the "body's master cells":[11] those from which all other cells with a specialized role are created.[12] This is because stem cells have the unique ability to transform into a variety of forms "during early life and growth."[13] In many places, stem cells act as an "internal repair system," separating without limit to create other cells.[14] As stem cells divide, each new unit has the ability either to stay a stem cell or to transform into another kind with a more

[7] *See* David Railton, *What Are Stem Cells and Why Are They Important?*, MED. NEWS TODAY (Feb. 18, 2019), https://www.medicalnewstoday.com/articles/200904.php [https://perma.cc/4TDT-M7LM].

[8] FED'N OF STATE MED. BDS., REGENERATIVE AND STEM CELL THERAPY PRACTICES 1 (2018), http://www.fsmb.org/siteassets/advocacy/policies/fsmb-stem-cell-workgroup-report.pdf [https://perma.cc/XDA7-DTFW].

[9] *Id.*

[10] *Id*; *see* David Gorski, *For-Profit Stem Cell Clinics, Universities, and "Pay-to-Play" Clinical Trials for Autism*, SCIENCE-BASED MED. (July 29, 2019), https://sciencebasedmedicine.org/for-profit-stem-cell-clinics-universities-and-pay-to-play-clinical-trials-for-autism/ [https://perma.cc/CY25-WJEX].

[11] Lawrence S.B. Goldstein & Meg Schneider, *What Are Stem Cells?*, DUMMIES, https://www.dummies.com/health/what-are-stem-cells/ [https://perma.cc/Z2L3-5SHS].

[12] *Stem Cells: What They Are and What They Do*, MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/bone-marrow-transplant/in-depth/stem-cells/art-20048117 [https://perma.cc/9FCF-UK7S].

[13] *Stem Cell Basics*, NAT'L INSTITUTES HEALTH, https://stemcells.nih.gov/info/basics/1.htm [https://perma.cc/K368-N3NE] (last modified Apr. 8, 2018).

[14] *Id.*

particular purpose, such as brain, liver or red blood cells.[15] In certain body parts, such as bone marrow, they regularly dispatch "replacement cells to repair worn out tissue."[16]

Several factors make stem cells unique. They are unspecialized cells that can recreate themselves through cell division even after being dormant for extended periods of time.[17] They can also be induced to become organ specific with unique functions.[18] For instance, in certain body parts, stem cells can split to restore damaged tissue while in others, such as the heart or pancreas, they only divide in specific situations.[19]

A. Types of Stem Cells

Stem cells are classified as either embryonic or adult.[20] The first type, also known as pluripotent, are created "from three- to five-day old embryos" and continue to recreate into any cell in the body,[21] which affords them the ability to regenerate or fix diseased tissues or organs.[22]

Adult stem cells form the second category and are classified as undifferentiated that split "to replenish dying cells and regenerate damaged tissues."[23] They can renew regularly to guarantee that a collection of stem cells are accessible to create specific cell types.[24] These units "are found in small numbers in most adult tissues, such as bone marrow or fat,"[25] and they are considered "multipotent" because they can create "several kinds of cells in their home tissues."[26] These cells, however, don't create cell types aside from their specific kind.[27] In other words, heart stem cells will not create

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[15] *Id.*

[16] Kevin Curran, *Scientists Have Been Experimenting with Stem Cells for Almost 40 Years*, RISING TIDE BIOLOGY, https://www.risingtidebio.com/history-stem-cell-therapy-benefits/ [https://perma.cc/D85K-3TWX] (last updated Aug. 12, 2019).

[17] *Stem Cell Basics*, *supra* note 13.

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] Goldstein & Schneider, *supra* note 11.

[22] *Stem Cells: What They Are and What They Do*, *supra* note 12.

[23] *Adult Stem Cell*, SCIENCEDAILY, https://www.sciencedaily.com/terms/adult_stem_cell.htm [https://perma.cc/FSX2-2XXG].

[24] *See* Goldstein & Schneider, *supra* note 11.

[25] *Stem Cells: What They Are and What They Do*, *supra* note 12.

[26] *See* Goldstein & Schneider, *supra* note 11.

[27] *Id.*

brain cells, and liver stem cells will not transform into pancreatic tissue.[28]

II. MEDICAL USE OF STEM CELLS

A. Embryonic Stem Cells

Stem cell research began in Germany in 1838 when Theodor Schwann and Matthias Schleiden became the first scientists to recognize that all life originates from cells and proposed the "cell theory of life."[29] Through microscopic analysis, doctors started to understand the various characteristics and functions of the two hundred cell types that form the human body.[30] As strange as it might seem, the discovery of stem cells happened as a result of the dropping of the atomic bomb on Japan in 1945.[31] Radiation was not responsible for the immediate deaths of the many people. Rather, radiation destroyed the stem cells that resided in their bone marrow.[32] It is now recognized that the stem cells in bone marrow grow into all of the cells in our blood stream and immune system.[33]

The study of stem cells in the United States started in the 1950s, and a physician at the University of Minnesota, performed the first successful bone marrow transplant in 1968 on a child with an immune deficiency.[34] Researchers consequently learned how to transform embryonic stem cells from mice, and in 1998, invented a way to extract them from a human embryo and cultivate them in a laboratory.[35] While these stem cells originate from embryos, researchers have invented a way to create comparable multiuse cells from these units.[36] This research, however, requires the destruction of embryos that are only a few days old and has been the subject of continuing ethical, religious, and political debate.[37] This controversy arises because some individuals believe that life begins at conception, so an embryo has the equivalent moral significance and entitlements

[28] *Id.*
[29] Curran, *supra* note 16.
[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] *See id.*
[34] Miriam Reisman & Katherine T. Adams, *Stem Cell Therapy: A Look at Current Research, Regulations, and Remaining Hurdles*, 39 P&T 846, 847 (2014).
[35] *Id.*
[36] *See id.* at 847, 854; *see, e.g.*, Kathleen Doody, Comment, *The Moral, Ethical, and Legal Controversy Surrounding Pluripotent Stem Cell Research*, 48 LOY. L. REV. 267, 271 (2002).
[37] Reisman & Adams, *supra* note 34, at 846.

of an adult or child.[38] Another reason is that certain societies and religious customs do not believe that a human life should be used "as a means to some other end" even though that application might be a noble one.[39]

These developments, nevertheless, excite the medical community because of the capacity of stem cells to transform into a variety of cells that can assist in the restoration of injured tissue and organs. This is especially true of embryonic cells because of their ability to change "into any cell in the body."[40] Federally funded researchers in the United States have expended $1.4 billion examining stem cells, and globally, "there are currently twenty-nine clinical studies looking at the potential uses of embryonic stem cells in medicine.[41] While the government wanted to stimulate interest in stem cell research, President George W. Bush enacted a law in 2001 "limit[ing] funding for embryonic stem cell research to 19 pre-existing human embryonic stem cell lines," thereby dealing a major blow to the research community.[42]

Fortuitously, funding was still available on the state level, and California led the pack in this regard.[43] During the 2000s, however, it became obvious that the federal limitation on research involving embryonic stem cells was an overreach.[44] President Obama recognized this problem and "removed many of these federal restrictions."[45]

B. Adult Stem Cells

Most of the political debate involving stem cells is focused on embryonic and not adult stem cells.[46] This has allowed clinical trials

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[38] Railton, *supra* note 7.

[39] Ananya Mandal, *Stem Cell Controversy*, NEWS MED. LIFE SCI., https://www.news-medical.net/life-sciences/Stem-Cell-Controversy.aspx [https://perma.cc/H4GE-UFUK] (last updated Apr. 22, 2019).

[40] Weintraub, *supra* note 1.

[41] *See id.* A number of well-known facilities are actively involved in looking at the regenerative powers of stem cells in the practice of medicine. For instance, an integrated team at the Mayo Clinic made up of "stem cell biologists, bioengineers, doctors and scientists work together" for this purpose. *Transplant Center*, MAYO CLINIC, https://www.mayoclinic.org/departments-centers/transplant-center/regenerative-medicine-consultation-service/gnc-20203917 [https://perma.cc/9F7M-NR59].

[42] Curran, *supra* note 16.

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *Id.*

using the latter cells to proceed,[47] and scientists have discovered a simple way to transform adult stem cells into pluripotent ones opening a world of regenerative possibilities.[48] Adult stem cells enjoy the widest application in blood-forming stem cells, which are the primary element in bone marrow and umbilical cord blood transplants; the only stem cell therapy that has been approved by the federal government.[49] In this regard, over seventeen thousand individuals with cancers of the blood are successful recipients of stem cell transplants.[50]

A major hurdle in using stem cells to treat illness is that physicians do not fully comprehend the many facets of disease including the genetic and molecular signals that cause abnormal cell division and variations that cause a specific disorder.[51] Another problem is the propensity of modified master stem cells to develop tumors in a living organism.[52] It turns out that using viruses to genomically change a stem cell can prompt the formation of cancer-causing genes.[53]

Adult stem cells offer much promise in regenerative medicine and a new source of multipotent stem cells is fat or adipose tissue.[54] This is because fat contains many blood vessels, making it a good reservoir for stem cells.[55] Unlike the cells taken from bone marrow, they can be easily obtained using minimally invasive techniques, much like liposuction, with a low morbidity rate.[56] As of 2016, more than 130 clinical studies dealing with this technique were listed on the website of the U.S. National Institutes of Health (NIH).[57] They cover a vast array of applications including "soft tissue regeneration, skeletal tissue repair, ischemic injuries, myocardial infarction[,] . . . immune disorders[,] . . . intervertebral disc degeneration and pulmonary disease."[58]

These fat cells, however, are limited in that they cannot be transformed into mature cells for most bodily tissue and can only be

[47] *Id.*

[48] Weintraub, *supra* note 1.

[49] *Id.*

[50] Reisman & Adams, *supra* note 34, at 846.

[51] *Id.* at 854.

[52] *Id.*

[53] *Id.*

[54] Laura Frese et al., *Adipose Tissue-Derived Stem Cells in Regenerative Medicine,* 43 TRANSFUSION MED. & HEMOTHERAPY 268, 268–69 (2016).

[55] *See* Samantha Bresnahan, *Patient Uses Fat Stem Cells to Repair His Wrist*, CNN (May 22, 2017, 4:35 AM), https://www.cnn.com/2017/05/22/health/fat-stem-cells-fix-wrist-injury-cartilage/index.html [https://perma.cc/5Y5B-F3HZ].

[56] *See id.*; Frese et al., *supra* note 54, at 268.

[57] Frese et al., *supra* note 54, at 269.

[58] *Id.*

utilized safely if they are properly fitted to the tissue and disease being treated.[59] In fact, "[t]he scientific consensus is that stem cells taken from fat or bone marrow are not as malleable as embryonic cells, meaning that rather than turn[ing] into completely different cells, they mostly create more of the same tissue."[60] The bottom line is that stem cell therapy is currently recommended for only a small number of blood disorders, such as leukemia and lymphoma.[61] Likewise, Europe, Japan and South Korea have a limited number of approved applications for stem-cell products.[62]

III. FOR-PROFIT CLINICS

The U.S. Food and Drug Administration (FDA) currently approves the use of stem cells for the treatment of about 80 diseases, but there is much excitement about other possible uses.[63] The years that have elapsed between the initial promise demonstrated by these cells and FDA support of them as a reliable and effective technique have led some patients to look for therapies beyond FDA-accepted channels.[64] The void has been filled by for-profit stem cell clinics, with the first facilities opening in countries with little government oversight such as China, Russia, and South Korea.[65] These enterprises offer stem cell treatment for patients suffering from myriad illnesses,[66] even though cancer is the only category for which "there is published, scientifically valid evidence" demonstrating that stem cell therapy may work.[67] Nevertheless, thousands of desperate people seek the

[59] Weintraub, *supra* note 1.

[60] Meryl Davids Landau, *Are Stem Cell Injections Really a Miracle Cure for Everything from Cancer to Cellulite?*, YAHOO! (Dec. 24, 2018), https://www.yahoo.com/lifestyle/stem-cell-injections-really-miracle-184600083.html [https://perma.cc/XRG8-TJB6].

[61] *Id.*; *High-Dose Chemotherapy and Stem Cell Transplant for Non-Hodgkin Lymphoma*, AM. CANCER SOC'Y, https://www.cancer.org/cancer/non-hodgkin-lymphoma/treating/bone-marrow-stem-cell.html [https://perma.cc/M65J-E9PJ].

[62] Curran, *supra* note 16.

[63] Benjamin Greene, *Stem Cell Tourism and Other Experimental Treatments*, CRYO-CELL INT'L, https://www.cryo-cell.com/blog/september-2017/stem-cell-tourism-and-experimental-treatments [https://perma.cc/D65U-KLZE] (last updated Jan. 24, 2019).

[64] *Id.*

[65] *See* Laurie McGinley & William Wan, *Miracle Cures or Modern Quackery? Stem Cell Clinics Multiply, with Heartbreaking Results for Some Patients*, WASH. POST (Apr. 29, 2018), https://www.washingtonpost.com/national/health-science/miracle-cures-or-modern-quackery-stem-cell-clinics-multiply-with-heartbreaking-results-for-some-patients/2018/04/29/80cbcee8-26e1-11e8-874b-d517e912f125_story.html [https://perma.cc/3BNE-DPCB].

[66] *Stem Cell Tourism: False Hope for Real Money*, HARV. STEM CELL INST., https://hsci.harvard.edu/stem-cell-tourism [https://perma.cc/B93L-2G4X].

[67] *Id.*

help of these foreign clinics that charge thousands of dollars for a variety of unverified therapies.[68]

Many for-profit clinics offer autologous treatment, which is the method described above, where stem cells are taken from one location, processed, and then injected back into the same persons.[69] As one study reported, sixty-one percent of the procedures performed in the United States involve the use of adipose stem cells for the treatment of orthopedic issues.[70] The questionable nature of this treatment for orthopedic problems is demonstrated in a variety of research papers, which tell a different story. For instance, a 2017 study found that stem cell injections provided relief of knee pain only somewhat better than injections of hyaluronic acid.[71] This achievement is nothing to be proud of since hyaluronic acid therapy does not work either.[72] The American Academy of Orthopedic Surgeons[73] will not recommend stem cell treatments, and a study in *Cartilage* reported that bone marrow shots were as effective in providing knee pain relief as saltwater injections.[74] An article in the *Journal of Bone and Joint Surgery* noted that "the value and effective use of cell therapy in orthopedics remain unclear," and the *British Journal of Sports Medicine* is no better in its assessment when it reported, "'We do not recommend stem cell therapy' for knee arthritis."[75] There is also the placebo effect.[76] It is known that some patients obtain pain relief from the use of placebos, and the more

[68] *Id.*

[69] Curran, *supra* note 16.

[70] *Id.*

[71] Liz Szabo, *Elite Hospitals Plunge into Unproven Stem Cell Treatments*, KAISER HEALTH NEWS (Apr. 2, 2019), https://khn.org/news/elite-hospitals-plunge-into-unproven-stem-cell-treatments/ [https://perma.cc/YU9M-XUKJ].

[72] *Id.*

[73] This organization issued an amended position statement on stem cells in December 2017, which states in part,

> The American Academy of Orthopaedic Surgeons (AAOS) believes that surgeons should be cognizant of the risks, benefits, regulatory status and labeled indications of the products they use. Unlike devices, the effects of these products may not be limited to the duration of their implantation. Autogenous products may be subject to regulatory review.

Position Statement: Use of Emerging Biologic Technologies, AM. ACAD. ORTHOPAEDIC SURGEONS (Dec. 2017), https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/position/Use%20of%20Emerging%20Biologic%20Therapies.pdf [https://perma.cc/S7US-BGJA].

[74] Szabo, *supra* note 71.

[75] *Id.*

[76] *See id.*

invasive the treatment, the better the pain relief from the fake treatment.[77]

A. Effect of Advertising

Americans discovered foreign stem cell clinics through websites, which advertise that they can treat or cure medical problems, such as muscular dystrophy, Alzheimer's, Parkinson's, and spinal cord injury, by injecting individuals with their own stem cells that "could develop into a missing nerve, a muscle or other cells and repair damage from an illness or an injury."[78] These clinics are largely unregulated and list glowing endorsements from patients, some of whom have monetary interests in the facilities.[79]

The lucrative nature of stem cell tourism has fueled their growth in the United States.[80] Only two clinics existed in 2009, but there are now more than seven hundred[81] with doctors willing to provide stem cell and regenerative therapies. More than 570 of these facilities use direct-to-consumer advertising, and counterintuitively, their growth has been most pronounced in locations with more rigorous regulatory schemes.[82]

Patients are attracted to these clinics by online direct-to-consumer marketing of information posted on websites and social media accounts.[83] Clinics have even resorted to large budget ads to promote unproven stem cell therapies in major newspapers.[84] Common selling points include "stem cells will help people avoid surgery and addictive medications"; "they can 'regenerate [and] repair . . .

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[77] *Id.*

[78] Gina Kolata, *A Cautionary Tale of 'Stem Cell Tourism'*, N.Y. TIMES (June 22, 2016), https://www.nytimes.com/2016/06/23/health/a-cautionary-tale-of-stem-cell-tourism.html [https://perma.cc/ZCE7-CCS5].

[79] *Id.*

[80] *See* Greene, *supra* note 63.

[81] McGinley & Wan, *supra* note 65. Most of these clinics are in California, Florida, Texas, Colorado, Arizona, and New York. Mitsu Jane McHugh, Clearly Misunderstood Rules of the Stem Cell Road: The Oxymoron of HCT/P Regulatory Policy 1 (2018) (unpublished paper, CERSI Writing Competition, John Hopkins University), https://www.jhsph.edu/research/centers-and-institutes/center-of-excellence-in-regulatory-science-and-innovation/training/Mitsi%20McHugh_CERSI_Competition_Submission.pdf [https://perma.cc/DU7V-AFD7].

[82] FED'N OF STATE MED. BDS., *supra* note 8, at 4.

[83] *See id.*; *Stem Cell Marketing*, JCIDM, https://www.jcidm.com/stem-cell-marketing/ [https://perma.cc/7WYC-P77T].

[84] Michael Joyce, *Stem Cell Ads: Promise Much, Deliver Little*, HEALTH NEWS REV. (July 19, 2017), https://www.healthnewsreview.org/2017/07/stem-cell-ads-promise-much-deliver-little/ [https://perma.cc/83AY-EBYB].

'naturally'" and "the treatments involve no pain, no side effects, [and] no prolonged recovery."[85]

The marketing of these unproven therapies typically downplay the risks and overemphasize the advantages.[86] The therapy services are usually supported by journal articles, patient testimonials, and tributes pertaining to either the facility or affiliated doctors and researchers.[87] These endorsements appear genuine, but they can also overstate, exaggerate, or misrepresent evidence obtained from legitimate or suspect sources.[88] Some of the facilities employ "tokens of scientific legitimacy" in support of the proposed therapy, or the excellence of the facility and its physicians. Examples of this hype include celebrity or patient endorsements, physician membership in academic and professional organizations, participation in clinical trials, or the listing of awards or honors.[89]

A number of the facilities advertising unproven stem cell therapies have attempted to register their clinical trials, but the results of such testing are rarely reported.[90] Not only do these clinics proactively market their studies in advance of review and approval, but "they often claim broader clinical benefits than can be justified by the specific indications they purport to have tested."[91] In fact, some list their unapproved procedures as "studies" on ClinicialTrials.gov, an NIH database.[92] Critics claim that these listings are inappropriate and are done to clothe the therapies with "an air of legitimacy."[93] The rub is that NIH does not verify the postings or note whether a "trial" listed in its database was checked by the FDA.[94] Most trials dealing with novel procedures "are overseen as part of the FDA's investigational new-drug program" unlike stem cell therapies offered by these for-profit clinics, which have scant review.[95]

It has also been noted that these clinics usually do not disclose their clinical protocols or publish peer-reviewed data, so little is actually known about what specific cells are being provided to their patients.[96]

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[85] *Id.*

[86] FED'N OF STATE MED. BDS., *supra* note 8, at 4.

[87] *Id.*

[88] *Id.*

[89] *Id.*

[90] Israel Berger et al., *Global Distribution of Businesses Marketing Stem Cell-Based Interventions*, 19 CELL STEM CELL 158, 158 (2016).

[91] *Id.*

[92] McGinley & Wan, *supra* note 65.

[93] *Id.*

[94] *Id.*

[95] *Id.*

[96] Leigh Turner, *Federal Regulatory Oversight of US Clinics Marketing Adipose-Derived*

Rather, when issuing their marketing claims, the clinics usually resort to using the catch-all phrase "stem cell therapies."[97] Many researchers, however, wonder whether these patients are actually receiving stem cells.[98] Lisa Fortier, a regenerative medical researcher at Cornell University, noted, "[S]uch products may not even contain stem cells."[99] In fact, she remarked that an analysis determined that one vendor selling eleven injectable products failed to contain stem cells let alone a single living cell of any type.[100] Other scientists compare the therapies to "snake oil" with "little oversight, [or] scientific rationale for the procedures and little proof they have any effect" on patient outcomes.[101]

A new method of soliciting patients is the "hard sell" whereby clinics are conducting informational seminars for small groups of people.[102] These presentations include "personal anecdotes and 'questionable medical claims'—including the assertion that '90% of patients had a 50% or better improvement.'"[103] Some clinics even tell those who cannot afford the costs, which can "range from $1,800 to more than $20,000—to launch GoFundMe pages or take out loans."[104]

It must be noted that several prestigious institutions have become actively involved in the use of stem cells for regenerative purposes, thereby giving these uses an air of legitimacy.[105] This includes facilities such as the Mayo Clinic, the Cleveland Clinic, and the University of Miami.[106] Their applications include injecting the joints of individuals "with their own fat or bone marrow cells," or cell fragments recognized for their ability to clot blood.[107] These institutions, however, are making sure that they follow the criteria

Autologous Stem Cell Interventions: Insights from 3 New FDA Draft Guidance Documents, 90 MAYO CLINIC 567, 567 (2015).

[97] *Id.*

[98] *Id.*

[99] Laurie McGinley & William Wan, *How a Stem Cell Treatment Left Patients Feeling Worse than Before*, INDEPENDENT (Mar. 12, 2019), https://www.independent.co.uk/news/long_reads/stem-cell-treatment-therapy-bacterial-infection-a8807351.html [https://perma.cc/47B6-DZJC].

[100] *Id.*

[101] *Id.*

[102] Michael Hiltzik, *These New Stem Cell Treatments Are Expensive; and Unproven*, L.A. TIMES (Aug. 19, 2016, 10:00 AM), https://www.latimes.com/business/hiltzik/la-fi-hiltzik-stem-cell-scam-20160821-snap-story.html [https://perma.cc/HV9Y-789Q].

[103] *Id.* It has been reported that a variety of athletes have used stem cell injection including Peyton Manning, tennis player Rafael Nadal, and baseball players Andrew Heaney and Garrett Richards. *Id.*

[104] McGinley & Wan, *supra* note 65.

[105] *See* Szabo, *supra* note 71.

[106] *Id.*

[107] *Id.*

mandates imposed by the FDA.[108] Nevertheless, they have not escaped criticism.[109] Leigh Turner, an associate professor at the University of Minnesota's Center for Bioethics commented, "While hospital-based stem cell treatments may be legal, there's no strong evidence they work . . . . [J]ust because something is legal doesn't make it ethical."[110]

B. Risk Versus Cure

Patients pay lip service to safety and efficacy but often ignore the risks of the therapy or absence of evidence of effectiveness to gain access to treatment, especially when "traditional treatment options seem limited or have been exhausted."[111] The potential for a possible cure influences how a patient seeks to gain command over their illness and its capacity for a cure, thereby placing them in a position of defenselessness.[112] As a result of this vulnerability, there is an increased risk for patient exploitation.[113] This has resulted in a number of tragic outcomes. For example, one survey revealed that 25 percent of patients who suffered complications from stem cell therapy reported adverse consequences such as strokes, quadriparesis, MS deterioration, sepsis, hepatitis, seizures, meningitis, infections, and spinal cord tumors,[114] and another study reported blindness and pediatric deaths.[115]

IV. WHEN THINGS GO WRONG

The use of these scientifically unproven therapies flew under the radar for years until a series of cases involving adverse outcomes attracted national attention in the news and articles in medical journals.[116] The case that is frequently referenced involves Doris

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[108] *See id.*

[109] *See id.*

[110] *Id.*

[111] FED'N OF STATE MED. BDS., *supra* note 8, at 6.

[112] *Id.* at 6–7.

[113] *Id.* at 7.

[114] *Stem Cell Clinics – Questions to Ask*, NAT'L MULTIPLE SCLEROSIS SOC'Y, https://www.nationalmssociety.org/Research/Research-News-Progress/Stem-Cells-in-MS/Stem-Cell-Clinics-Questions-to-Ask [https://perma.cc/Y2EN-HQXX].

[115] *See* Jamie Wells, *Fraud Alert! Unproven Stem Cell Use Prompts International Call to Action*, AM. COUNCIL ON SCI. & HEALTH (July 10, 2017), https://www.acsh.org/news/2017/07/10/fraud-alert-unproven-stem-cell-use-prompts-international-call-action-11526 [https://perma.cc/T528-9V5W].

[116] *See, e.g.*, *id.*

Tyler, a retired elementary school teacher.[117] Mrs. Tyler was slowly losing her vision due to macular degeneration.[118] Nevertheless, she was leading a normal life and "could still read large print, cook," and perform household chores.[119] The turning point occurred when she read the book *The Stem Cell Revolution,* "which suggested that her macular degeneration could be cured with stem cell therapy."[120]

She visited a Georgia clinic and was told that the only complication from having the procedure done would be that it might not work.[121] Since her insurance did not cover the treatment, Mrs. Tyler's son created a GoFundMe account to raise the $8,900 fee and was successful in securing the funds.[122] At the time of the procedure, she signed a detailed consent form, which explained the risks including the possibility that her vision could worsen.[123] She was then placed on an examining table, a tube was inserted into her abdomen and the syringe soon filled with yellow material.[124] Contained in the extracted fat were stem cells, which were then spun in a centrifuge and injected into her eyes one day after another.[125] A few days later, the clinic boasted on the internet "that it had performed the first such treatment in Georgia for macular degeneration."[126] "On Facebook, the clinic called Tyler 'our fabulous patient!' and urged others with her disease to book an appointment."[127]

Mrs. Tyler would soon regret her decision to undergo the procedure when her vision started to blur, and within a couple of weeks she developed a detached retina in the left eye.[128] This was followed by a detached retina in the right eye.[129] Remedial surgeries failed to correct the damage, and within a few months, Mrs. Tyler became blind.[130]

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117 *See* Weintraub, *supra* note 1.
118 *Id.*
119 *Id.*
120 *Id.*
121 *See* McGinley & Wan, *supra* note 65.
122 *Id.*
123 *Id.*
124 *Id.*
125 *See* Weintraub, *supra* note 1.
126 McGinley & Wan, *supra* note 65.
127 *Id.*
128 *Id.*
129 *Id.*
130 *Id.* When a reporter from *The Washington Post* contacted the plastic surgeon who had co-authored the book on stem cells and asked about the problems encountered by Mrs. Tyler, the plastic surgeon claimed that this case was "virtually" the only serious adverse consequence that had happened in his network of facilities, which had treated close to 8,000 patients. Laurie McGinley & William Wan, *As Stem Cell Clinics Multiply, so Do Legal Complaints*, WASH. POST (Apr. 29, 2018), https://www.sfgate.com/news/article/As-stem-cell-clinics-multiply-so-do-legal-

Suit was instituted in Fulton County, Georgia, alleging that the defendants had harvested stem cells containing adipose tissue, which were then injected into these patient's eyes.[131] It was averred that the defendants warranted that their stem cell therapy qualified as research that was of "university-quality" and capable of treating "a myriad of ailments and degenerative diseases."[132] Allegations were also advanced that the defendants made "false, materially incomplete, and misleading claims" regarding the risks associated with the treatment including

> that one's fat is loaded with stem cells that can be used . . . to treat and reverse a large number of inflammatory and degenerative conditions . . . ; that adult stem cells are safe and effective in a large variety of clinical conditions and that almost any condition caused by damage or degradation of one's body cells has the potential for being improved using stem cells; . . . that stem cell therapy procedures can produce healing results as early as a few hours after the procedure; . . . and that post-operative discomfort is minimal and there is minimal restriction on activity post-operation.[133]

Researchers who have examined this case opine that the protocol employed by the defendants violated basic safety principles including first treating only one eye so that the other would not be subject to a procedure in the event of complications, and the application of stem cells in the manner used on Mrs. Tyler hadn't been shown to be useful in treating macular degeneration.[134] As one scientist noted, "Fat stem cells can only turn into fat . . . . There's no reason to think they would do anything for diseases of the eye."[135] Others ridicule the idea

12873363.php [https://perma.cc/HCU3-LZ4K] [hereinafter McGinley & Wan, *Legal Complaints*]. The reporter noted, however, that an FDA report in July 2017 listed four adverse outcomes, including that experienced by Mrs. Tyler. *Id.* The physician countered that the other incidents were "very minor," and he then proceeded to label the concerns of the FDA as "sanctimonious garbage." *Id.*

[131] Complaint for Damages at 15–16, Tyler v. Stem Cell Center of Ga. LLC, No. 18EV001048 (Ga. State Ct. Mar. 7, 2018), https://www.ipscell.com/wp-content/uploads/2018/04/Stem-cell-lawsuit-Georgia.pdf [https://perma.cc/ADS5-JSL9].

[132] *Id.* at 8.

[133] *Id.* at 11–12. Doris and Donald Tyler were represented by Andrew Yaffe who reached confidential settlements for two women who had lost their vision following stem cell injections for macular degeneration. McGinley & Wan, *supra* note 65.

[134] Jeneen Interlandi, *The Trouble with Stem Cell Therapy*, CONSUMER REP. (Jan. 11, 2018), https://www.consumerreports.org/medical-treatments-procedures/trouble-with-stem-cell-therapy/ [https://perma.cc/R4LY-CQZK].

[135] *Id.*

that adult stem cells can move about the body fixing any problem. As Sally Temple, co-founder of the Neural Stem Cell Institute, noted, "This idea of a magic bullet that can go around and fill in gaps in the body is science fiction."[136]

This incident was followed by an article in the *New England Journal of Medicine* discussing three patients with macular degeneration who had developed severe vision loss after receiving injections of adipose tissue derived from stem cells.[137] Not only did they sustain retinal detachments, but their blindness may have developed because of the toxic effects of the injected material.[138] The authors noted that "many stem-cell clinics are treating patients with little oversight and with no proof of efficacy," and that "[a] distinction has been made between clinical studies of stem-cell therapies that are founded on solid preclinical research with strong scientific design and programs that lack preclinical research justification."[139] The article concluded by indicating that the outcome sustained by these patients evokes apprehension about the performance of procedures at stem-cell clinics that lack clinical or preclinical data to validate their practices.[140] A second *New England Journal of Medicine* article discussed a patient who had developed a large spinal tumor after receiving stem cells as well as a different individual who died following the injection of bone marrow stem cells into the blood vessels of her brain at a clinic in Florida.[141] Tragically, another patient died after the same physician injected stem cells into his bloodstream.[142] The Florida Board of Medicine subsequently revoked this doctor's license.[143]

The adverse publicity continued when the Centers for Disease Control and Prevention reported that it had received notice concerning twelve patients who had developed infections as the result of injections for pain and orthopedic conditions that contained bacterially contaminated stem cells.[144] A subsequent examination of

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[136] McGinley & Wan, *Legal Complaints*, *supra* note 130.

[137] Ajay E. Kuriyan et al., *Vision Loss After Intravitreal Injection of Autologous "Stem Cells" for AMD*, 376 NEW ENG. J. MED. 1047, 1048 (2017).

[138] *Id.* at 1052.

[139] *Id.* at 1050.

[140] *Id.* at 1052–53.

[141] McGinley & Wan, *Legal Complaints*, *supra* note 130.

[142] *Id.*

[143] *See id.*

[144] Kiran M. Perkins et al., Notes from the Field: *Infections After Receipt of Bacterially Contaminated Umbilical Cord Blood—Derived Stem Cell Products for Other than Hematopoietic or Immunologic Reconstitution—United States, 2018*, CENTERS DISEASE CONTROL & PREVENTION (Dec. 21, 2018), https://www.cdc.gov/mmwr/volumes/67/wr

unopened vials taken from the involved clinics uncovered the same kind of microbes that had infected the patients, which included *E. coli* and fecal bacteria.[145]

A natural reaction is that there is no danger in obtaining treatment that uses one's own stem cells, but that assumption would be incorrect. Patients have sustained a variety of serious injuries and multiple lawsuits have been filed in which plaintiffs have asserted that their treatment for such things as diabetes, lupus, and lung disease have caused harm.[146] The downside of performing these unproven stem cell therapies is highlighted by Scott Gottlieb, M.D., the Commissioner of the FDA, who noted, "[S]hoddy stem cell medicine does more than imperil unwitting consumers; it also threatens to undermine scientific progress being made. 'Products that are reliably and carefully developed will be harder to advance if bad actors are able to make hollow claims and market unsafe science.'"[147]

V. FDA REGULATIONS

The FDA's Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research are tasked with regulating therapeutic biological products, such as stem cells, "including premarket review and oversight."[148] In turn, a product such as stem cells does not require premarket approval if it meets the following four-part test:

- It is minimally manipulated.
- It is intended for homologous use as determined by labeling and advertising.
- Its manufacture does not involve combination with another article, except for water, crystalloids, or a sterilizing, preserving or storage agent . . . .

/mm6750a5.htm [https://perma.cc/R8YZ-XR2T].

[145] *Id.*

[146] Landau, *supra* note 60.

[147] Interlandi, *supra* note 134.

[148] *Frequently Asked Questions About Therapeutic Biological Products*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/frequently-asked-questions-about-therapeutic-biological-products [https://perma.cc/E4ZL-XHBZ] (last updated July, 7, 2015). Section 351 of the Public Health Service (PHS) Act defines a biological product as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product . . . or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." Public Health Service (PHS) Act § 351(i)(1), 42 U.S.C. § 262(i)(1) (2012).

- It does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function or, if it has such an effect, it is intended for autologous or allogenic use in close relatives or for reproductive use.[149]

The key part of this test is the phrase *minimally manipulated*. This is defined as "processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement."[150] This wording is fairly subjective,[151] but the FDA has noted that "cutting, grinding, shaping, soaking in an antibiotic solution, sterilization by gamma irradiation, lyophilization, freezing, and demineralization of bone are all examples of minimal manipulation."[152]

Some for-profit stem cell clinics try to circumvent these rules by asserting several theories. They initially argue that they are not subject to FDA oversight because their procedures amount to surgery and they are not manufacturing new drugs.[153] The FDA retorts that the treatment requires advance approval because stem cells are subject to "substantial processing before being used in ways that are different from their original purposes."[154] The clinics also claim that they are only performing minimal manipulation of the patient's fat, thereby falling within the exception.[155] This position is incorrect because minimal manipulation is limited to the minor handling of tissue such as rinsing to extract impurities.[156] Isolating stem cells from the body requires special licensing and possible inspection.[157]

Another exception from requiring FDA approval deals with a business that removes stem cells from a person and implants them into the same patient during an operation.[158] The FDA takes issue with using tissue extracted from stem cells to treat a problem

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[149] Jeffrey K. Shapiro, *Federal and State Requirements for HCT/Ps: An Overview*, MDDI ONLINE (May 2005), https://www.mddionline.com/federal-and-state-requirements-hctps-overview [https://perma.cc/2M3M-6UJE]; *see also* FED'N OF STATE MED. BDS., *supra* note 8, at 8–9 (showing the four-part test).

[150] 21 C.F.R. § 1271.3 (2019); Shapiro, *supra* note 149.

[151] It has been said that the FDA guidelines are ambiguous and insufficient thereby leaving their interpretation up to debate as to whether something is covered. McHugh, *supra* note 81, at 1.

[152] Shapiro, *supra* note 149.

[153] McGinley & Wan, *supra* note 65.

[154] *Id.*

[155] McHugh, *supra* note 81, at 5.

[156] *See id.* at 5–6.

[157] *See id.*

[158] *See* 21 C.F.R. § 1271.15 (2019).

unrelated to where the tissue is harvested.[159] For instance, a clinic that takes fat from the abdomen to treat multiple sclerosis or a detached retina would be treating a condition unrelated to the harvest site and would not be able to take advantage of the exemption.[160]

A. The Review Process

The federal government took a passive role in the enforcement of the regulatory laws for years, as physicians and scientists researched the healing abilities of stem cells.[161] The FDA did express concern that a number of people have sought stem cell therapies that are "illegal and potentially harmful," but noted that it is the job of the FDA to regulate the industry.[162] The FDA is tasked with regulating human cells and tissues designated for therapies "like implantation, transplantation, or infusion, primarily to prevent the transmission of disease."[163]

The FDA requires most investigational products to go through a detailed review so that "the safety and effectiveness of products" can be ascertained.[164] Researchers are required to explain how each product is made so that the FDA will be satisfied that the necessary steps are being employed to demonstrate the item's "safety, purity, and strength".[165] This includes the presentation of data involving animal studies to assist in determining the potential risks related to stem cell use.[166]

Despite this protocol, a number of clinics are known to improperly market stem cell trials without completing the FDA review process. For instance, some for-profit clinics incorrectly state that FDA review and approval for the stem cell therapy is not needed.[167] This failure means that the governmental watchdog has not evaluated stem cell use to ensure that it is reasonably safe.[168]

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[159] *See* McHugh, *supra* note 81, at 2, 3 tbl.1.

[160] *See id.* at 5–6.

[161] Johnny Edwards, *Despite FDA Crackdown, Stem Cell Therapy Still 'Wild West'*, AJC (Apr. 6, 2018), https://www.ajc.com/news/state—regional/despite-fda-crackdown-stem-cell-therapy-still-wild-west/VLPAk6xgCarNPmmcK22CJP/ [https://perma.cc/22JE-CWUP].

[162] *FDA Warns About Stem Cell Therapies*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies [https://perma.cc/6JK4-9HF5].

[163] Weintraub, *supra* note 1.

[164] *FDA Warns About Stem Cell Therapies*, *supra* note 162.

[165] *Id.*

[166] *Id.*

[167] *Id.*

[168] *Id.*

B. Increased Regulatory Efforts

The FDA decided to step up its enforcements efforts on August 28, 2017, to prevent "unscrupulous actors from being able to deceive patients and potentially harm their health" as well as making sure that "product developers know where the regulatory lines governing this new field are drawn."[169] The agency also issued guidelines "making clear that many [stem cell] products are unapproved drugs being marketed illegally."[170] This policy shift provides notice to for-profit clinics that they need to submit their research to the FDA for approval and stop using stem cells for unapproved therapies. Contemporaneously, the agency noted that it lacked the funds to engage in a "comprehensive crackdown on the sprawling stem cell industry."[171] These financial constraints are not surprising considering the detailed steps that must be followed in securing FDA approval for a new product.[172] The onerous requirements for approval also partially explain why clinics are reluctant to seek FDA authorization.[173]

C. The Approval Process

The approval process starts with a site visit by several FDA inspectors also dubbed consumer safety officers.[174] This inspection requires spending one to three weeks at the facility.[175] Upon the conclusion of that visit, the agency sends the clinic a detailed observation report.[176] This is followed by a prolonged administrative process that includes a clinic response to the report and a reply by the FDA to that answer.[177] If the information provided by the clinic is "inadequate," a warning letter is dispatched but it takes months

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[169] Scott Gottlieb, *Statement from FDA Commissioner Scott Gottlieb, M.D. on the FDA's New Policy Steps and Enforcement Efforts to Ensure Proper Oversight of Stem Cell Therapies and Regenerative Medicine*, U.S. FOOD & DRUG ADMIN. (Aug. 28, 2017), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-new-policy-steps-and-enforcement-efforts-ensure [https://perma.cc/ZE4D-HBQX].

[170] McGinley & Wan, *supra* note 99.

[171] *Id.*

[172] *See* Richard Jaffe, *King Canute and Why the FDA Will Never Stop the Private Stem Cell Clinics*, RICHARD JAFFE, ESQ. (Aug. 23, 2018), https://rickjaffeesq.com/2018/08/23/king-canute-and-why-the-fda-will-never-stop-the-private-stem-cell-clinics/ [https://perma.cc/KQF5-U9PL].

[173] *See id.*

[174] *Id.*

[175] *Id.*

[176] *See id.*

[177] *Id.*

for this to happen because such a letter requires an internal review at various divisions within the FDA.[178]

The facility is afforded the opportunity to respond to the warning letter and that response is the subject of additional administrative reviews in order to form an appropriate FDA answer.[179] If the agency determines that the clinic's reply to the warning letter is insufficient, the FDA must decide how to respond and whether to undertake additional review steps.[180]

The FDA can also choose to litigate, in which case the agency's attorney must review the file before it is sent to the civil division of the U.S. Attorney's office in the federal district in which the clinic is located.[181] The U.S. Attorney will then serve as counsel for the FDA, interjecting yet another layer of red tape.[182] Unfortunately, these federal prosecutors have little experience in the nuisances of stem cell practice so they must spend time becoming educated about this complex matter.[183] This cumbersome process demonstrates why the FDA devotes most of its resources to endeavors such as regulating the manufacturing of drugs and medical devices.[184] Regulating a small number of stem cell clinics ends up not being a priority.[185] Recent developments, however, may play a role in easing this cumbersome regulatory process. There has been a movement to create ways for a quicker or conditional approval process for regenerative medical therapies.[186] In this regard, forty-one states have passed "Right to Try" legislation that aims to provide terminally ill patients with the ability to use experimental treatments that have finished Phase I testing but have not received final FDA approval.[187] Congress also passed similar legislation that gives the terminally ill the right to try experimental medications that have not yet been

[178] *Id.*
[179] *Id.*
[180] *See id.*
[181] *Id.*
[182] *Id.*
[183] *See id.*
[184] *See id.*
[185] *See id.*
[186] *See* Claire Horner et al., *Can Civil Lawsuits Stem the Tide of Direct-to-Consumer Marketing of Unproven Stem Cell Interventions*, NPJ REGENERATIVE MED., Feb. 19, 2018, at 1, https://www.nature.com/articles/s41536-018-0043-6.pdf [https://perma.cc/7EZV-C2EQ].
[187] *What Is Right to Try?*, RIGHT TO TRY, http://righttotry.org/about-right-to-try/ [https://perma.cc/348G-CNVP]. Phase I typically takes dozens of healthy volunteers to determine a drug's most frequent side effects. FOOD & DRUG ADMIN., WHAT IS A DRUG AS DEFINED BY THE FDA 1, https://www.fda.gov/media/82381/download [https://perma.cc/3PCA-8H7N].

approved by the FDA.[188] The impact of these expedited measures remains to be seen.

D. The Government Crackdown

The regulatory administration of stem cell and regenerative therapies is in a state of flux and will continue to evolve in the future.[189] The FDA, however, did take positive steps to regulate stem cells by issuing revised guidelines in November 2017 that narrowed the definition of what constitutes permissible conduct by these clinics.[190] For instance, the agency has made it clear that they will only permit biological tissue to be utilized in the same part of the body from which the tissue is harvested.[191] Anything outside of the new parameters will constitute the selling of a drug which will mandate the appropriate licensing.[192] The problem with these more rigorous regulations, however, is that the FDA gave clinics three years to become compliant with the new rules.[193] Therefore, nothing is going to change in the near future.[194]

The FDA has issued a stern warning to rogue stem cell facilities to stop peddling unproven therapy that could be detrimental to patients.[195] This was done by way of letters.[196] For instance, one piece of correspondence warned a center creating "products from umbilical-cord blood that it was violating federal law, and other letters warned 20 clinics that they appeared to be subject to [FDA] review for approval and that they needed to contact the agency on how to comply."[197]

The latest warning by the government consisted of a five-page letter sent to Cord for Life, a Florida business, that the FDA said was

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[188] Morten Wendelbo & Timothy Callaghan, *What Is "Right to Try" and Will It Help Terminally Ill Patients?*, CBS NEWS (May 30, 2018, 2:35 PM), https://www.cbsnews.com/news/right-to-try-bill-trump-signing-will-it-help-terminally-ill-patients-today-2018-05-30/ [https://perma.cc/4U9W-2SEU].

[189] FED'N OF STATE MED. BDS., *supra* note 8, at 8.

[190] Curran, *supra* note 16.

[191] *Id.*

[192] *Id.*

[193] *Id.*

[194] *See* Michael Hiltzik, *The FDA Closes a Huge Loophole Used by Bogus Stem Cell Clinics, but Delays Serious Enforcement for 3 Years*, L.A. TIMES (Nov. 17, 2017, 1:30 PM), https://www.latimes.com/business/hiltzik/la-fi-hiltzik-fda-stem-cell-20171117-story.html [https://perma.cc/6LAF-SNKG].

[195] *See* Denise Grady, *Risky Stem-Cell Treatments Come Under F.D.A. Scrutiny—Again*, N.Y. TIMES (Apr. 3, 2019), https://www.nytimes.com/2019/04/03/health/stem-cells-fda.html [https://perma.cc/6QU3-6NSG].

[196] *Id.*

[197] *Id.*

making unapproved items from umbilical-cord blood that were then sold "in platinum, gold and silver categories."[198] The correspondence accused the firm of violating federal law by not securing FDA permission to market their products.[199] The FDA was also less than impressed with a site inspection that found Cord for Life had numerous sanitation violations.[200] The end result was that the company was given fifteen days to develop a corrective plan or face "seizure and/or injunction" from the FDA.[201]

VI. STATE LAWS

Since 2001, most states have had heated debates on whether stem-cell research should be prohibited on moral grounds or supported for its potential to cure illness and disease.[202] In 2004, New Jersey became the first jurisdiction to support embryonic stem cell research when it appropriated $10 million for this purpose.[203] This included a policy to support research involving the "use of human embryonic stem cells, human embryonic germ cells and human adult stem cells," which use will be permitted in the state.[204] Two years later, the legislature took its support one step further when it noted in a legislative pronouncement the advances made in the use of stem cells and their potential cure and treatment for certain diseases and injuries.[205] New Jersey's goal is to attract investment and scientists and, to that end, it wishes to finance facilities for those involved in stem cell research.[206]

Iowa, Massachusetts, and Missouri have made stem cell research legal, but have not provided any funding for that endeavor, while Arkansas, Indiana, Louisiana, Michigan, North Dakota, and South Dakota have restricted this type of scientific investigation.[207]

These legislative initiatives have mainly focused on embryonic stem cell use, which does not address the issue of for-profit clinics, which employ adult stem cells for a variety of non-approved

198 *Id.*
199 *Id.*
200 *See id.*
201 *Id.*
202 Christine Vestal, *States Take Sides on Stem-Cell Research*, PEW CHARITABLE TR. (Jan. 31, 2008), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2008/01/31/states-take-sides-on-stemcell-research [https://perma.cc/KH5G-ZK83].
203 *See id.*
204 N.J. STAT. ANN. § 26:2Z-2 (West 2019).
205 N.J. STAT. ANN. § 34:1B-21.32 (West 2019).
206 *Id.*
207 *See* Vestal, *supra* note 202.

applications.[208] California, however, addressed this issue head-on when it established limitations on clinics offering non-FDA approved stem cell therapies.[209] As the sponsor of the law noted, people are paying thousands of dollars for stem cell treatments and are uninformed about the "potential risks and dangerous side effects" of the procedures.[210] The statute itself mandates that any health care practitioner who performs a non-approved stem cell therapy communicate to the patient the following information in English:

> THIS NOTICE MUST BE PROVIDED TO YOU UNDER CALIFORNIA LAW. This health care practitioner performs one or more stem cell therapies that have not been approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care physician prior to undergoing a stem cell therapy.[211]

This warning must be prominently and conspicuously displayed in an area observable to patients at the entrance to the office and "be at least eight and one-half inches by 11 inches large."[212] Prior to the initiation of any stem cell treatment, the same notice must be given to the patient in writing.[213] The Medical Board of California is vested with jurisdiction to cite and fine healthcare providers who violate this mandate.[214]

This is not the first time that California has addressed stem cell therapy. In 2010, it enacted the California Stem Cell and Biotechnology Education and Workforce Development Act that noted the state's desire to retain its premier status in stem cell research and recognized the need to develop "stronger links" between the state's schools and the emerging industry.[215] In this regard, the voters approved Proposition 71, "which authorizes $3 billion in state bond funding for stem cell research at California universities and research institutions."[216]

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[208] *See, e.g.*, CONN. GEN. STAT. § 32-41jj (2019).

[209] Paul Knoepfler, *Groundbreaking New California Stem Cell Law Gives Consumer Protections on Clinics*, NICHE (Oct. 3, 2017), https://ipscell.com/2017/10/groundbreaking-california-stem-cell-law-gives-consumer-protections-on-clinics/ [https://perma.cc/MJ8C-C64T].

[210] *Id.*

[211] CAL. BUS. & PROF. CODE § 684 (West 2019).

[212] *Id.*

[213] *Id.*

[214] *Id.*

[215] CAL. EDUC. CODE § 33475.1 (West 2019).

[216] *Id.*

Washington followed California's lead and enacted a similar notification law.[217] That statute requires the clinic to provide the patient with the following written notice prior to the initiation of treatment:

> THIS NOTICE MUST BE PROVIDED TO YOU UNDER WASHINGTON LAW. This health care practitioner 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 prior to undergoing a stem cell therapy.[218]

The health care provider "must also obtain a signed consent form [from the patient] before performing the therapy."[219] The form must contain language that the patient can "reasonably be expected to understand" describing "[t]he nature and character of the proposed treatment . . . ; [t]he anticipated results . . . ; [t]he recognized possible alternative forms of treatment; and [t]he recognized serious possible risks, complications, and anticipated benefits involved in the treatment."[220] This consent is not needed if the facility is performing "stem cell therapy pursuant to an employment or other contract to perform the therapy on behalf of . . . an institution certified by the foundation for the accreditation of cellular therapy, the national institutes of health . . . or AABB," which is an accrediting agency.[221]

Texas, however, has bucked this trend by enacting a pro-clinic law loosening stem cell regulation if the patient has a severe chronic illness or terminal illness thereby becoming the first state to explicitly recognize this kind of experimental treatment.[222] The statute is known as Charlie's Law and defines *investigational stem cell treatment* as "adult stem cell treatment that is under investigation in a clinical trial and being administered to" patients as part of that experiment with non-approved treatment.[223] The

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[217] *See* WASH. REV. CODE § 18.130.420 (2019).

[218] *Id.*

[219] *Id.*

[220] *See id.*

[221] *Id.*

[222] Andrew Joseph, *Texas on Track to Become First State to Explicitly Back Stem Cell Therapies*, STAT (May 30, 2017), https://www.statnews.com/2017/05/30/stem-cell-therapies-texas/ [https://perma.cc/5YUB-YAR4].

[223] TEX. HEALTH & SAFETY CODE ANN. § 1003.051 (West 2019); Britni R. McAshan, *New Law Opens Doors for Regenerative Medicine in Texas*, TMC NEWS (Oct. 9, 2017), https://www.tmc.edu/news/2017/10/new-law-opens-doors-regenerative-medicine-texas/ [https://perma.cc/Y7NK-5MT3].

patient is able to undergo the treatment if the individual "has a severe chronic disease or terminal illness" and a physician determines that standard therapy "options are unavailable or unlikely to alleviate the significant impairment or severe" discomfort associated with that disease or illness.[224] The import of this "law potentially sets up a state-federal conflict,"[225] and advocates of direct-to-consumer stem cell clinics may use the statute as an opening to challenge the more restrictive approach advanced by the FDA.[226]

VII. LITIGATION

There has been a surprising call by scientists and ethicists for patients to use civil litigation as a way to safeguard their rights if they have been harmed following the use of an unapproved stem cell procedure.[227] They believe lawsuits should garner public attention thereby shaping the media narrative and gaining moral outrage on behalf of vulnerable and sympathetic claimants.[228] This type of remedy may also prompt the government and industry to tackle the problem on a more prominent and bigger scale.[229] Claims against health care providers may have the added benefit of encouraging other patients to step forward, such as what happened with the priest abuse scandal.[230] This approach has validity when one considers that certain types of stem cell therapies are outside the ambit of clinical research or FDA governance. These lawsuits can be premised on a variety of theories such as "falsely advertising treatments, . . . negligen[ce] in providing unproven stem cell interventions, . . . medical malpractice," and products liability claims.[231]

Not everyone agrees with this strategy. A. Rahman Ford, who possesses both a Ph.D. and a law degree, opines that there is little evidence to demonstrate that a "'war on stem cells' is supported by any real-world evidence."[232] He is concerned that these lawsuits will

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[224] TEX. HEALTH & SAFETY CODE ANN. § 1003.053.

[225] *New Texas Stem Cell Law May Open the Door*, WORLDHEALTH.NET (Mar. 7, 2019, 7:00 PM), https://www.worldhealth.net/news/new-texas-stem-cell-law-may-open-door/ [https://perma.cc/74BE-6P8A].

[226] *Id.*

[227] *E.g.*, Horner et al., *supra* note 186, at 1.

[228] *Id.* at 3.

[229] *Id.* at 1.

[230] *Id.* at 3.

[231] Claire Horner, *Civil Lawsuits as a Public Health Strategy: Can Cases Brought by Injured Plaintiffs Have a Broader Effect?*, NICHE (Mar. 12, 2018), https://ipscell.com/2018/03/civil-lawsuits-public-health-strategy-can-cases-brought-injured-plaintiffs-broader-effect/ [https://perma.cc/C7FX-VV96].

[232] A. Rahman Ford, *Should the 'War on Stem Cells' Be Fought in Court?*, PAIN NEWS

only harm those who need stem cells to treat their unrelenting pain and disability, and the critics may be better served by "advocating for the increased democratization and liberalization of stem cell policy."[233]

Regardless of which position is correct, stem cell litigation is occurring more frequently.[234] These types of claims have definitely attracted the attention of attorneys who are writing about the topic on their websites or talking about the stem cell cases that they have handled or wish to pursue.[235] The FDA has also stepped up its enforcement actions. For example, in 2019, the FDA sent a warning letter to a California firm that handles umbilical cord blood cells as part of a treatment plan noting that it is violating federal law.[236] This is a significant step that could develop into enforcement actions including product seizures and injunctions because the product caused the hospitalization of at least twelve patients in Florida, Texas, and Arizona subsequent to the infusions because of the development of cord blood cells that resulted in infections and abscesses.[237] The FDA also issued twenty letters to businesses that the agency noted "may be offering unapproved stem-cell products"[238] and had "regulatory correspondence" with forty-five others that offer stem cell therapies.[239]

A. Government Action

The first action against a stem cell clinic occurred in 2005[240] when a grand jury handed down an indictment of two individuals operating a company called Biomark International that marketed treatment for Lou Gehrig's disease, muscular dystrophy, and other incurable

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NETWORK (Feb. 28, 2018), https://www.painnewsnetwork.org/stories/2018/2/28/should-the-war-on-stem-cells-be-fought-in-court [https://perma.cc/48KA-R342].

[233] *Id.*

[234] Paul Knoepfler, *New Lawsuit Includes Big Stem Cell Clinic Chain, Cell Surgical Network*, NICHE (Apr. 19, 2018), https://ipscell.com/2018/04/new-lawsuit-includes-big-stem-cell-clinic-chain-cell-surgical-network/ [https://perma.cc/6Q7C-8ZMV].

[235] *See, e.g.*, *Stem Cell Treatment Cases*, MULLIGAN, BANHAM & FINDLEY, https://www.janmulligan.com/practice-areas/stem-cell-treatment/ [https://perma.cc/QM9B-R9N3].

[236] Liz Richardson, *FDA Acts to Stop Use of Unapproved Regenerative Medicine Products*, PEW (Apr. 2, 2019), https://www.pewtrusts.org/en/research-and-analysis/articles/2019/04/02/fda-acts-to-stop-use-of-unapproved-regenerative-medicine-products [https://perma.cc/289R-N5TA].

[237] *Id.*

[238] Thomas M. Burton, *FDA Probes More Stem-Cell Treatment Companies*, WALL STREET J. (Apr. 3, 2019, 4:27 PM), https://www.wsj.com/articles/fda-probes-more-stem-cell-treatment-companies-11554323245 [https://perma.cc/4QFL-HXHX].

[239] Grady, *supra* note 195.

[240] McHugh, *supra* note 81, at 3.

diseases.[241] It was asserted that the business treated these illnesses through the "injection of stem cells derived from cord blood, for a fee ranging from $10,000.00 to $32,000.00."[242] The defendants were charged with wire fraud and the introduction of misbranded drugs into interstate commerce with requested remedies that included a fine and forfeiture of certain properties.[243] These criminal charges shut down the business, but two of the defendants left the United States and set up new companies in South Africa and the United Kingdom.[244]

A civil enforcement action was filed in 2010 against Regenerative Services, LLC, for using stem cells to treat various orthopedic injuries and arthritis.[245] The government sought a permanent injunction, alleging that the defendant, in providing a mixture of the patient's stem cells that started with the extraction of the patient's bone marrow or synovial fluid, was "both a drug and a biological product that is adulterated and misbranded in violation of [federal law]."[246]

The defendant argued that the mixture is exempt from regulation because it is not a drug but a medical procedure.[247] The court disagreed and issued an injunction noting that a mixture containing the patient's stem cells was a drug for purposes of the Federal Drug and Cosmetic Act and a biological product under the Public Health Services Act.[248] This matter was eventually settled and the agreement prohibited the defendant from making claims that its products can treat conditions such as Parkinson's disease, autism, macular degeneration, and cerebral palsy.[249] "The settlement also impose[d] a partially suspended $3.31 million judgment" and mandated that the defendant notify its patients about the agreement.[250]

United States v. U.S. Stem Cell, LLC[251] involves an ongoing and fiercely contested case involving a Florida business that makes a

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[241] Indictment ¶¶ 1–3, United States v. Lauran Brown, No. 1:06CR1534 (N.D. Ga 2006), https://www.casewatch.net/doj/biomark/indictment.html [https://perma.cc/59EU-H7NE].

[242] *Id.* ¶ 3.

[243] *Id.* ¶¶ 29, 33–35.

[244] Stephen Barrett, *Stem Cell Swindlers Charged with Fraud*, CASEWATCH https://www.casewatch.net/doj/biomark/indictment.html [https://perma.cc/59EU-H7NE].

[245] United States v. Regenerative Sci., LLC, 741 F.3d 1314, 1318 (D.C. Cir. 2014).

[246] *Id.*

[247] *Id.* at 1318–19.

[248] *See id.* at 1318–19, 1326.

[249] Press Release, Fed. Trade Comm'n, FTC Stops Deceptive Health Claims by a Stem Cell Therapy Clinic (Oct. 18, 2018), https://www.ftc.gov/news-events/press-releases/2018/10/ftc-stops-deceptive-health-claims-stem-cell-therapy-clinic [https://perma.cc/969B-V7HR].

[250] *Id.*

[251] United States v. U.S. Stem Cell, LLC, No. 0:18-cv-61047-UU, 2018 WL 2144862 (S.D.

product from a patient's adipose tissue.[252] The defendant never filed for an application with the FDA for its product.[253] The government asserted that the stem cell solution is a drug and the clinic's public statements and information on its website demonstrated that the solution is designed to be used in the "cure, mitigation, or treatment of diseases in man and/or to affect the structure and function of the body."[254] It was also asserted that the solution comes within the definition of "human cells, tissues, or cellular or tissue-based products," which are defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient."[255] The complaint then listed a number of adverse events resulting from the use of the solution on patients with eye problems including the suffering of "bilateral vitreous hemorrhages, ocular hypertension, uveitis, . . . [and] detached retinas.[256]

On June 3, 2019, U.S. District Judge Ursula Ungaro granted the government's motion for summary judgment, finding that the defendants "adulterated and misbranded a stem cell drug product made from a patient's adipose tissue."[257] The FDA is taking the position that this decision gives it "the authority to define a certain kind of stem cell product as a drug" subject to government regulation.[258] The court noted that "unless the company is ordered to stop, 'there is a reasonable likelihood that Defendants will continue to violate'" government regulations concerning unapproved therapies.[259] This matter represents one of the FDA's most aggressive actions against a stem cell business. The implications of this case are enormous and some legal analysts opine that the matter

Fla. June 3, 2019).

[252] *Id.* at *1.

[253] Complaint at 4, *U.S. Stem Cell, LLC*, No. 0:18-cv-61047-UU, 2018 WL 2144862 (S.D. Fla. May 9, 2018).

[254] *Id.* at 6.

[255] *Id.* at 8 (quoting 21 C.F.R. § 1271.3(d) (2019)).

[256] Complaint at 13–14, *U.S. Stem Cell, LLC*, No. 0:18-cv-61047-UU, 2018 WL 2144862.

[257] Press Release, U.S. Food & Drug Admin., Federal Court Issues Decision Holding that US Stem Cell Clinics and Owner Adulterated and Misbranded Stem Cell Products in Violation of the Law, (Jun. 4, 2019), https://www.fda.gov/news-events/press-announcements/federal-court-issues-decision-holding-us-stem-cell-clinics-and-owner-adulterated-and-misbranded-stem [https://perma.cc/J3E6-GYRG]; *accord U.S. Stem Cell, LLC*, No. 0:18-cv-61047-UU, 2018 WL 2144862, at *14–15 (citations omitted).

[258] William Wan & Laurie McGinley, *FDA Wins Groundbreaking Case Against For-Profit Stem Cell Company*, WASH. POST (Jun. 4, 2019), https://www.washingtonpost.com/health/fda-wins-groundbreaking-case-against-for-profit-stem-cell-company/2019/06/03/498373fa-864e-11e9-98c1-e945ae5db8fb_story.html [https://perma.cc/ZF42-64FG].

[259] *Id.*; *accord U.S. Stem Cell, LLC*, No. 0:18-cv-61047-UU, 2018 WL 2144862, at *15.

could constrain stem cell enterprises that have been accused by physicians, attorneys, and federal agencies of harming patients.[260]

In a different action that is ongoing, the federal agency is also trying to obtain a permanent injunction to halt California Stem Cell Treatment Center, Inc., "from marketing . . . cellular products without FDA approval."[261]

Enforcement actions against stem cell clinics are also maintained on the state level. For instance, in April 2019, the New York State Attorney General instituted suit against a clinic in Manhattan seeking an injunction on the basis that the business markets fat cell injections for a multitude of medical problems that have not been approved.[262] In a press announcement, the state attorney general noted,

> Through advertising efforts, the clinic led vulnerable patients to believe it could treat a variety of serious medical conditions using the patients' own stem cells . . . . While stem cells hold promise for future use, there is currently no adequate scientific substantiation that stem cells can effectively treat any of these conditions.[263]

B. Civil Actions

A Westlaw search of the term *stem cells* discloses over 2,700 decisions that mention this biological material in some fashion including causes of actions ranging from such things as patent disputes to the failure of insurance companies to pay for treatments on the basis that they are experimental.[264] This search, however, failed to uncover any dispositive cases in which a patient requested momentary damages for a poor treatment outcome.[265] Nevertheless,

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[260] Laurie McGinley & William Wan, *This Clinic's Experimental Stem Cell Treatment Blinded Patients. Years Later, the Government is Still Trying to Stop It*, WASH. POST (Apr. 3, 2019), https://www.washingtonpost.com/national/health-science/this-clinics-experimental-stem-cell-treatment-blinded-patients-four-years-later-the-government-is-still-trying-to-shut-it-down/2019/04/03/432d6d04-ff2f-11e8-83c0-b06139e540e5_story.html [https://perma.cc/99RP-R39A].

[261] Press Release, *supra* note 257.

[262] Paul Knoepfler, *Why N.Y. AG Suit Against Manhattan Stem Cell Clinic Is Such a Big Deal*, NICHE (Apr. 7, 2019), https://ipscell.com/2019/04/why-ny-ag-suit-against-manhattan-stem-cell-clinic-is-such-a-big-deal/ [https://perma.cc/MG4S-P44N].

[263] *Id.*

[264] Search Results of the Term *Stem Cells*, WESTLAW EDGE, https://1.next.westlaw.com/Search/Home.html (last visited Oct. 20, 2019) (searching all state and federal cases, and sorting on relevance).

[265] *See id.*

the Internet contains numerous stories about such litigation, or proposed class actions,[266] and personal injury claims that were settled on a confidential basis.[267] The following is a sample of this litigation.

Sherley v. Sebelius[268] involves a complex history of multiple opinions and appeals.[269] This litigation was instituted by scientists who work with adult stem cells.[270] They sought a declaratory judgment and injunction against the Secretary of Health and Human Services to prevent the use of federal funding for the advancement of embryonic stem cell research.[271]

Starting in 1996, Congress has incorporated a proviso called the Dickey-Wicker Amendment in appropriation bills that blocks NIH from using any money for "(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero."[272] Since the law's original enactment, the use of stem cells has dramatically expanded beyond the single application involving the destruction of the human embryos.[273] In 2009, President Obama issued an Executive Order allowing NIH to "support . . . scientifically worthy human stem cell research."[274] This prompted the filing of the instant matter to block its enforcement on the basis that allowing NIH to release funds for stem cell research would violate the Dickey-Wicker Amendment.[275] The court disagreed and ruled in favor of allowing the funding pursuant to the President's Order to expand support for other uses of stem cells.[276]

A number of cases exist over payment for stem cell therapy with varying results that usually contains an emphasis on the policy language in making a determination. *Haggerty v. Crothall Services*

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[266] *See, e.g.*, Moorer v. StemGenix Med. Grp., No. 16-cv-2816, 2019 WL 2602536, at *1 (S.D. Cal. June, 24, 2019).

[267] *See, e.g.*, McGinley & Wan, *supra* note 65

[268] Sherley v. Sebelius, 689 F.3d 776 (D.C. Cir. 2012)

[269] *See id.* at 778–79 (quoting Sherley v. Sebelius, 704 F. Supp. 2d 63, 70 (D.D.C. 2010)) (first citing Sherley v. Sebelius, 686 F. Supp. 2d 1, 3 (D.D.C. 2009); then citing Sherley v. Sebelius, 610 F.3d 69, 72–75 (D.C. Cir. 2010); and then citing Sherley v. Sebelius, 644 F.3d 388, 390, 396 (D.C. Cir. 2011)), *cert. denied*, 568 U.S. 1087 (2013).

[270] *Sherley*, 689 F.3d at 778.

[271] *Id.*

[272] *Id.* at 779.

[273] *See id.* (citations omitted).

[274] *Id.* at 780.

[275] *See id.*

[276] *Id.* at 785.

Group[277] involves an employee who "tore her left rotator cuff and bicep tendon shaking a heavy bedspread," thereby requiring surgery.[278] A few months later, she again hurt herself and needed a second shoulder operation.[279] She was subsequently diagnosed with osteoarthritis and was approved by the compensation carrier to receive platelet-rich plasma injections.[280] Haggerty was subsequently told that "she would 'probably require' [a] total shoulder replacement," so she filed a motion to compel her employer's payment for the stem cell therapy.[281] The defendant countered by producing an article indicating that the treatment "was not approved by the U.S. Food and Drug Administration (FDA) except in limited circumstances involving blood production disorders."[282] This was countered by a letter from the claimant's treating physician that the use in this case was "'medically necessary' because it was the only option" left before the need for a complex shoulder replacement surgery.[283] The correspondence also "noted that stem cell treatment was 'widely used in professional sports.'"[284]

The worker compensation judge found that the stem cell therapy was an authorized expense because the employee did not want another operation, needed to keep working, and noted that she was aware that the procedure was not FDA approved.[285] On appeal, the employer argued that the therapy was not reasonable or medically necessary and did not satisfy the *Frye*[286] standard of general acceptance in the relevant scientific community.[287]

On appeal, the court noted that the workers' compensation judge determined the credibility of the employee's doctor based upon a telephone call, which "was not recorded and was not under oath."[288] Therefore, there was nothing for the appellate court to review in order to determine what was said,[289] and when an important issue is discussed, a record must be made.[290] Therefore, the lower court's

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[277] *See* Haggerty v. Crothall Serv. Grp., No. A-4478-17T4, 2019 WL 1975907 (N.J. Super. Ct. App. Div. May 3, 2019).

[278] *Id.* at *1.

[279] *See id*.

[280] *Id.*

[281] *Id.*

[282] *Id.*

[283] *Id.*

[284] *Id.* at *2

[285] *Id.*

[286] Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

[287] *Haggerty*, 2019 WL 1975907, at *2 (citing *Frye*, 293 F. 1014).

[288] *Haggerty*, 2019 WL 1975907, at *3.

[289] *Id.*

[290] *Id.* (quoting Klier v. Sordoni Skanska Const. Co., 766 A.2d 761, 766 (N.J. Super. Ct. App.

determination "lacked fundamental fairness" and must be reversed.[291] The court, however, made no decision in support or against the need for the stem cell treatment.[292]

Roberson v. Blue Cross & Blue Shield of Texas[293] is a troubling decision involving a patient "with diffuse systemic sclerosis, a . . . disease that causes the skin and other connective tissues in the body to tighten and harden."[294] Left untreated, the condition "is fatal once it infiltrates the tissues of the lungs or heart."[295] "Her treating physician . . . therefore recommended she have a . . . stem cell transplant."[296] Blue Cross denied the request on the basis that the treatment was "experimental, investigational, and unproven."[297] It further noted that "the data in peer-reviewed medical literature" shows that "stem cell transplant is not effective, reliable, and safe for auto-immune diseases, including systemic sclerosis."[298]

This decision was appealed, and the carrier cited the ERISA policy language, which stated,

> The source of screening criteria utilized as guidelines in making this determination was Blue Cross and Blue Shield of Texas Medical Policy Guidelines, which are developed by the Blue Cross and Blue Shield of Texas Medical Division and which take into consideration views of the state and national medical communities, the guidelines and practices of Medicare, Medicaid, or other government-financed programs, and peer reviewed literature.[299]

Robertson claimed that the defendant committed "a violation of ERISA procedural requirements . . . by failing to engage in a medical necessity analysis and by withholding the information it relied on in making its determination."[300] The court disagreed and upheld the determination by noting that Blue Cross did not violate ERISA and met the procedural requirement to give "'adequate notice in writing'

Div. 2001)).

[291] *Haggerty*, 2019 WL 1975907, at *4.

[292] *Id.*

[293] Roberson v. Blue Cross & Blue Shield of Tex., 99 F. Supp. 3d 1249 (D. Mont. 2015).

[294] *Id.* at 1253–54.

[295] *Id.* at 1254.

[296] *Id.*

[297] *Id.*

[298] *Id.*

[299] *Id.*

[300] *Id.* at 1256.

of the reasons for denial" based upon "the policy provision it relied on [and] that additional information was available upon request."[301]

Oney v. Crist[302] involves an evidentiary hearing on the admissibility of testimony regarding stem cell therapy.[303] The matter arises out of a motor vehicle accident when the plaintiff's car was struck by a truck.[304] The defendant challenged the proposed testimony of the claimant's treating doctor and the court held a *Daubert* hearing, at which time the judge determined that the expert could testify as to the proposed stem cell treatment.[305]

During the hearing, the physician "disagreed that . . . that stem cell injections have not gained general acceptance in the medical community."[306] He claimed that the treatment is "generally accepted among spine specialists and the evidence supports the use of stem cells to treat the intervertebral disc."[307] The expert "admitted that . . . stem cell injections for back pain is not FDA approved," but "he did not view the injections as experimental because not all treatments are FDA approved or have set protocols."[308] This decision was upheld on appeal because the "testimony was reliable and legally sufficient."[309] The physician's opinions were not formed just to testify.[310] Rather, they "were developed for the purpose of treating his patients."[311] Also, the record is not restricted to the expert's subjective opinions. The doctor stated that stem cell injections have gained "general acceptance among spine specialists."[312] He further noted that "stem cell injections have been independently tested [and] peer reviewed," that he is a pain management specialist, and that he has used stem cell therapies for ten years and lectures on stem cell injections.[313] Therefore, the court felt that the testimony was sufficient to establish a reliable foundation, and that the conclusion

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[301] *Id.* at 1256-57; *see also* Hillard v. BellSouth Med. Assistance Plan, 918 F. Supp. 1016, 1019, 1023, 1027 (S.D. Miss. 1995) (holding that the healthcare provider did not violate ERISA and that the denial of treatment involving stem cells was "consistent and in accordance with [the policy] terms").

[302] Oney v. Crist, 517 S.W.3d 882 (Tex. App. 2017).

[303] *See id.* at 895.

[304] *Id.* at 888.

[305] *See id.* at 896.

[306] *Id.* at 897.

[307] *Id.*

[308] *Id.*

[309] *Id.* at 896.

[310] *Id.*

[311] *Id.* (citing Transcontinental Ins. Co. v. Crump, 330 S.W.3d 211, 217 (Tex. 2010)).

[312] *Oney,* 517 S.W.3d at 897.

[313] *Id.* at 897.

to be drawn from the testimony went to the weight of the evidence and not its reliability.[314]

CONCLUSION

The potential for using stem cells in medicine is exciting and the implications are enormous. Being able to reprogram biological material into other tissue for purpose of regenerating damaged or diseased body parts seems like science fiction, but researchers around the world are diligently working on such applications. Billions of dollars have been devoted to this endeavor,[315] and the use of stem cells to treat cancers of the blood is already established with thousands of people being cured of leukemia and other blood disorders.[316] It is unfortunate, however, that this scientific breakthrough has been transformed into the realm of controversy that has pitted the government, scientists, and ethicists against for-profit stem cell clinics who are marketing their services for a multitude of unapproved applications.[317]

These facilities are proliferating with clinics and physicians charging thousands of dollars for services, that in most cases, are considered experimental, unproven, or not medically necessary.[318] Patients are being attracted to these providers mainly through direct-to-consumer marketing of information posted on websites, social media accounts, large budget ads, infomercials, and seminars.[319] Tokens of scientific legitimacy include the posting of unapproved "procedures as 'studies' on ClincalTrials.gov, a database maintained by the National Institutes of Health,"[320] but NIH does not verify these postings nor note whether a trial was checked by the FDA.[321]

The use of these unproven therapies went largely unnoticed for years especially because the FDA was lax in its enforcement of the rules involving stem cells being classified as a drug.[322] The publicity generated by some tragic outcomes involved stem cell patients and negative articles in the medical literature and the news have altered

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[314] *Id.* at 899 (citing *Crump*, 330 S.W.3d at 218, 220).
[315] Weintraub, *supra* note 1.
[316] Reisman & Adams, *supra* note 34, at 846; Landau, *supra* note 60.
[317] *See supra* Part III.
[318] *See Stem Cell Tourism: False Hope for Real Money*, *supra* note 66.
[319] *See supra* Section III.A.
[320] McGinley & Wan, *supra* note 65.
[321] *Id.*
[322] Edwards, *supra* note 161; McGinley & Wan, *supra* note 99.

this approach. Criminal changes have been filed in some cases; personal injury claims have been advanced; and the FDA is pursuing the most egregious offenders.[323]

One can only hope that the remedial outcomes being advanced turn out to be accurate. It would be a huge medical leap toward mitigating the effects of illness and diseases if these uses are proven accurate. In the meantime, these for-profit facilities have been placed under a microscope with personal injury attorneys ready to pounce on poor therapy outcomes, a result being advocated by some scientists and ethicists.

[323] *See supra* Sections VII.A, VII.B.