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Regenokine Therapy: Strict FDA Regulation Has The Rich And Famous Traveling Abroad For Treatment

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Introduction

Since their discovery stem cells have had enormous potential in the medical field, but the surrounding controversy has hindered progress. Stem cells are sought after for their ability to develop into various cell types, replenish other cells, and work as an “internal repair system.”¹ The value of these cells lies in their ability to continuously divide, or under specialized conditions, their ability to form different body tissues/organs.² Typically, research has been geared towards two types of stem cells. The first is known as Embryonic Stem Cells, which are derived from the inner cell mass of embryos and cultured through in vitro fertilization.³ The second type, which will be the primary focus of this paper, are known as Adult or non-embryonic Stem Cells. Similar to their embryonic counter parts, adult stem cells can

¹ National Institutes of Health, U.S. Department of Health and Human Services, *Stem Cell Basics: Introduction*, available at <http://stemcells.nih.gov/info/basics/pages/basics1.aspx> (last visited April 16, 2013).

² *Id.*

³ THE PRESIDENT’S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH: A REPORT OF THE PRESIDENT’S COUNCIL ON BIOETHICS, pg. 8 (Pre-Publication Version Washington, D.C.: January 2004).

be cultivated to form various lineages of specialized cells,⁴ but are derived from a living human rather than an embryo. Although these adult cells are partially differentiated, they are believed to have a similar ability to form varying cell types. Nonetheless, ethical, moral, and social implications have limited the progress of research, and the development of cutting edge therapies with the potential to cure/mitigate a wide array of medical ailments.

In today's day and age, innovation and technology are at the forefront of our healthcare revolution. Modern medicine continues to evolve as researchers discover cures and treatments to a wide array of medical conditions. While scientists agree stem cells are full of potential, a lack of research and funding has limited the availability of treatments and therapies stemming from these "miracle cells."⁵ Stem cells are highly desired by virtue of the fact that they are unspecialized.⁶ Similar to a ball of clay, when certain conditions are met, these cells can be manipulated to form almost anything. Known as regenerative medicine, treatments involving use of these cells appear to be limitless on their face, but the use of cell therapy remains at an experimental stage, with no concrete proof as to the safety and efficacy and such treatments.⁷

This hesitation has led individuals to seek treatment elsewhere, often times traveling outside of the United States to dodge strict FDA regulation of these treatments. Most notably, this phenomenon can be traced to various professional

⁴ *Id.* at 10.

⁵ *Id.*

⁶ See Stem Cell Basics: Intro, *supra* note 1.

⁷ International Society for Stem Cell Research, *Frequently Asked Questions: Understanding Stem Cells*, available at <http://www.isscr.org/home/resources/learn-about-stem-cells/stem-cell-faq> (last visited April 18, 2013).

athletes who can afford the travel and costs of adult stem-cell therapy. This paper is designed to address this behavior, and compare the United States to other prominent countries more advanced in this field. While the future is full of possibilities, starting the race behind could make it difficult for the United States to catch up. Should this procedure remain outside the scope of FDA regulation? Or should the United States eagerly adopt these “unproven” practices in hopes of future success?

I. A Brief Overview of Stem Cell Regulation

A. Embryonic Stem Cell Research

Most of the controversy surrounds the use of embryonic stem cells. As mentioned above, these cells are the by products of in vitro fertilization. The government must balance the interest of this potential life, against the potential good that can result from the “destruction” of said embryos. Around the time of their discovery, Congress recognized an ethical battle surrounded the use of these cells. In 1996, Congress adopted what is known as the “Dickey Amendment,” prohibiting federal funding for research that destroys or seriously endangers human embryos, or creates them for research purposes.⁸ The amendment made no mention of using these techniques when private funding is involved.⁹ This has been a cause for controversy and led to various interpretations of the amendment. On one hand, the destruction of these embryos seems inherently wrong. On the other, the amendment does not prohibit what can or cannot be done, simply what actions are worthy of federal funding. Ever since its enactment, the Clinton and Bush

⁸ OMNIBUS APPROPRIATIONS ACT, PL 111-8, March 11, 2009, 123 Stat 524 (2009).

⁹ *Id.*

administrations have addressed the Dickey Amendment in hopes of clearing up the water. In reality, until recently the ban was left largely unchanged.

On March 9, 2009 President Obama issued Executive Order 13505,¹⁰ “Removing Barriers to Responsible Scientific Research Involving Human Stem Cells,” which attempted to expand the scope of embryonic stem cell research. The purpose of the order was to lift the earlier perceived limitations of the Bush administration and enhance the support of the Nation Institute of Health, (“NIH”), for research involving human stem cells.¹¹ Following this executive order, the NIH released new guidelines for federal funding surrounding stem cells. Human Embryonic Stem Cells can now be donated for research so long as certain conditions are met.¹² The stem cells must be created via in vitro fertilization, donated through voluntary written consent to be used for research, with no funding or coercion, accompanied by informed consent.¹³ Although these embryonic stem cells are thought to have more potential, they come with more barriers. While the limitations on research are gradually broadened, we are still years away from proven therapy. It will take time to test, develop, and implement an approved treatment using these embryonic cells. Although this is a step in the right direction, the fact of the matter is these embryonic cells remain highly controversial. The main focus of this paper will revolve around the use and development of treatments and therapies surrounding

¹⁰ Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, 74 FR 10667, Exec. Order No. 13505 (2009).

¹¹ *Id.*

¹² *Id.*

¹³ See Stem Cell Basics: Intro, *supra* note 1.

the less controversial, adult, non-embryonic stem cells, specifically what is known as Regenokine therapy.

B. Adult Stem Cell Research

Adult stem cells are themselves are undifferentiated, although they are found within cells that have already differentiated into a particular type of tissue.¹⁴ They are slightly more limited in their ability to develop into cell types and tissues different from the original from which they were derived.¹⁵ Most commonly, these cells are used to restore and repair dying tissue within the body.¹⁶ Since these cells are usually taken and later re-injected into the same individual, they are less controversial than the Embryonic Stem Cells, due to their autologous use. Given their ability to regenerate and self-renew, these adult stem cells have sparked much interest within the medical research community. Their cultivation does not involve the destruction of any embryos, nor does it raise the same ethical concerns as are present with the embryonic counterparts. The cells are drawn from the individual adult patient, and later put back into the same individual. If one decides to accept the risks, they should be able to reap the rewards, however the FDA takes a very different position. The FDA considers treatments involving these adult stem cells to be drugs within the scope of regulation, rather than medical practices, which they have no control over. This has led to controversy between those physicians willing to adopt these advanced medical procedures, and the governing body of the FDA.

¹⁴ See Stem Cell Basics: Intro, *supra* note 1.

¹⁵ National Institutes of Health, U.S. Department of Health and Human Services, *Stem Cell Basics: What Are Adult Stem Cells*, available at <http://stemcells.nih.gov/info/basics/pages/basics4.aspx> (last visited April 16, 2013).

¹⁶ *Id.*

II. Adult Stem Cells and Regenokine Therapy

In recent years, adult stem cell research has been put into practice as physicians have begun to treat patients using their own adult stem cells. While the treatment gains support among the medical community, recent litigation and legislation concerning FDA regulation has halted these practices in the United States.

A. Regenokine Method

Known as Regenokine therapy, this treatment was discovered and developed in Dusseldorf, Germany by Dr. Peter Wehling, a spinal surgeon.¹⁷ It involves a process of removing an individual's own adult stem cells, and later reintroducing said cells back into the body, for an "anti-inflammatory" effect.¹⁸ The procedure begins with a physician drawing approximately two ounces of blood from the individual.¹⁹ The blood is then incubated and kept at a slightly elevated temperature, essentially exposing the cells to a fever.²⁰ Next, the blood is placed in a centrifuge, where the various genetic materials begin to separate.²¹ Sometimes additional nutrients are added to the serum, or the serum is drawn and then directly injected back into the patient²². The treatment typically, lasts about five days and

¹⁷ See Nat'l Inst. Of Health, Stem Cell Basics: What Are Adult Stem Cells? *supra* note 15.

¹⁸ *Id.*

¹⁹ Singularity Hub, *Regenokine: The Unproven Treatment That Professional Athletes Are Flying to Germany For*, available at <http://singularityhub.com/2012/04/24/regenokine-the-unproven-treatment-that-professional-athletes-are-flying-to-germany-for/> (last visited Apr. 27, 2013).

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

consists of roughly six injections into the affected site.²³ According to Dr. Wehling, this treatment is seen as a less intrusive alternative to surgery for many athletes and individuals alike. The treatment focuses on problems of inflammation, rather than the actual structural make up of the joints.²⁴ Approved for use in Germany around 2003, Dr. Wehling contends most of his patients are experiencing positive results. Dr. Wehling asserts that the treatments success rate is 75 percent and lasts about 4 years, which is better than some of the procedures currently used in the United States to treat similar ailments.²⁵

While on the surface this procedure is viewed as a miracle cure, opponents of the therapy remain skeptical. Dr. Wehling combats this view by citing to a two-year study published in the journal of Osteoarthritis and Cartilage.²⁶ Dr. Wehling concluded “the results confirmed Orthokine/Regenokine therapy provides long term relief from pain and joint dysfunction, and in many patients more effectively than comparable treatments.”²⁷ The study of 310 individuals reported that following the treatment 188 showed improvements with pain and joint functionality.²⁸ Out of the remaining 122 individuals, some sought additional treatments but most agreed the pain levels were dramatically decreased.²⁹ Many prominent U.S sports stars

²³ *Id.*

²⁴ Nicholas Kulish, *Novel Blood Treatment Lures Athletes to Germany*, NEW YORK TIMES, July 10, 2012, available at <http://www.nytimes.com/2012/07/11/sports/athletes-with-chronic-pain-turn-to-novel-blood-treatment.html?pagewanted=all> (last visited April 20, 2013).

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

have traveled to see Dr. Wehling in order to undergo such treatment. Some notable names are: Kobe Bryant³⁰, Peyton Manning³¹, and Alex Rodriguez³².

The Regenokine treatment itself costs about \$7,500 U.S dollars.³³ Given the excessive salary caps of some of these athletes, the cost is merely pennies on the dollar. Kobe Bryant is a basketball super-star who plays for the Los Angeles Lakers. He is about to turn 34 and has had a long history and knee and joint problems. After traveling to Germany to meet Dr. Wehling, Kobe's recovery is nothing short of miraculous.³⁴ Contemplating retirement last season, Kobe seems to have a new spark of energy that can only be credited to the Regenokine treatment. Upon his return Kobe mentioned his knee feels like that of a 27-year old.³⁵ After speaking so highly of the treatment, he was able to convince Alex Rodriguez of the New York Yankees to undergo the same procedure.³⁶ "A-rod" sought treatment for knee and elbow inflammation and visited Dr. Wehling who has become the foremost specialist regarding this procedure³⁷The treatment was done over a period of 5 days, and allowed Alex Rodriguez to return to the field shortly after. As this is not a surgery,

³⁰ Jonah Lehrer, *Why Did Kobe Go To Germany*, GRANTLAND, April 11, 2012, available at http://www.grantland.com/story/_/id/7796225/kobe-bryant-dr-chris-renna-regenokine-knee-treatment (last visited April 23, 2013).

³¹ *Peyton Manning Underwent Stem Cell Treatment For Neck Injury*, HUFFINGTON POST, Sept. 20, 2011, available at http://www.huffingtonpost.com/2011/09/19/peyton-manning-stem-cell-treatment_n_970763.html (last visited April 23, 2013).

³² Marc Carig, *Yankees Slugger Alex Rodriguez Reportedly Goes to Germany for Knee Treatment*, STAR LEDGER, Dec. 28, 2011, available at http://www.nj.com/yankees/index.ssf/2011/12/yankees_slugger_alex_rodriguez_8.html (last visited April 24, 2013).

³³ *Id.*

³⁴ *Id.*

³⁵ Lehrer, *supra* note 30.

³⁶ *Id.*

³⁷ Carig, *supra* note 32.

the recovery time is drastically decreased. Additionally, after a debilitating neck injury, NFL quarterback Peyton Manning investigated a similar procedure for himself.³⁸ Suffering from a bulging disk, Manning underwent a series of four surgeries in attempts to remedy the problem.³⁹ Largely unsuccessful, Manning was left to explore other options if he had any hopes of returning to the NFL. He stumbled upon a procedure using adult stem cells, specifically his own fat cells, to resolve his neck injuries.⁴⁰ The procedure involved the use of “pluripotent cells” that are capable of being programmed into almost anything.⁴¹ His return to the NFL last season came with praise, as well as, reserve. Many were excited that the legendary quarterback would once again take the “field of battle.”⁴² On the other hand, lack of support and FDA approval caused many to cast doubt on the choice of treatment by Peyton.⁴³ Many believed the treatment was unsupported by scientific evidence, and placed Manning in the path of more harm than good. Skeptics request stringent clinical trials in order to prove the efficacy of such treatments, but the FDA seems to be the biggest hurdle in the way.

B. Implications For The United States

The reason these athletes are forced to seek treatment outside of the United States is because the Regenokine procedure has not been approved in the United States and faces much scrutiny from the FDA. Many doctors in the U.S are wary of

³⁸ *Id.*

³⁹ *See, Peyton Manning Underwent, supra* note 31.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

practicing adult stem cell therapy and biological medicine, fearing sanctions and injunctions from the FDA, as discussed *infra* in Part III.

As the current law sits, there are very few, if any, accepted procedures involving Regenokine therapy. The category of “biological medicine,” is expanding as medical innovations continue to be discovered. Unfortunately, these treatments are left to the rich and famous who can cover the costs of traveling to Germany and can pay for the therapy out of pocket. A lack of research and proven clinical trials has left the FDA skeptical of endorsing such therapies. Although the question remains, does the FDA actually have the power to over-see such practices? Or, is this a medical treatment/practice where the FDA has no authority to regulate?

Without FDA approval, physicians interested in performing these treatments are largely limited in their ability. These offices cannot advertise nor promote their therapies.⁴⁴ Most everyday Americans are unwilling to spend money on unproven practices. They would favor more conventional methods, although these are not necessarily more effective. The lack of FDA approval has effectively outsourced these procedures to countries in Europe, like Germany, where regulation is slightly less burdensome. This has created a small, but profitable market, open to only those willing to pay up and take the risks. Additionally, without the ability to advertise, most “average Joes,” are unaware that these alternatives exist. The center of Regenokine Therapy is located in Dusseldorf, Germany as mentioned above.⁴⁵ While

⁴⁴ Kulish, *supra* note 24.

⁴⁵ This demonstrates the method in which one would obtain an appointment with Dr. Wehling and learn about his practice. Wehling-Hartman, located in Dusseldorf, Germany, available at <http://www.wehling-hartmann.de/en/wir-ueber-uns/aerzteteam/> (last visited April 24, 2013).

advertised scarcely on the Internet, most everyday Americans do not have the means of acquiring such luxuries. Those in a position to seek treatment, might be dissuaded due the “lack of proof,” or existence of substantial clinical trials.⁴⁶ The Supreme Court of the United States confronted this issue, although it remains largely ambiguous and undecided. The issue is one of interpretation and framing, depending on the reading of various FDA regulations. It is clear that the government has an interest in preventing harm and spread of disease through untested procedure, but the obstacles do not need to be so burdensome. While the FDA and Surgeon General have an interest in regulations necessary to “prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States, or from state to state,⁴⁷this is unjustified in treatments where an individual is introducing his own biologic material into his own body.

By addressing and analyzing the current law, and pending litigation, we can predict future outcomes and the direction this new age treatment is heading. For the remainder of this paper I plan on discussing the pros and cons of our government’s approach, along with the slippery slope of consequences that could arise, if action is not taken soon.

III. FDA Regulation of Adult Stem Cell Therapies

A. The Statue and FDA Regulation

In 1938, Congress passed the Food, Drug, and Cosmetic Act, (“FDCA”). It provided the FDA with the power to, “regulate the introduction or delivery for

⁴⁶ *Id.*

⁴⁷ 42 U.S.C. §264A.

introduction into interstate commerce of any food, drug, device, or cosmetic, that is adulterated or misbranded,” in order to protect the public health.⁴⁸ As this was designed specifically for consumer goods, medical practices fall outside the scope of regulation. “The bill is not intended as a medical practices act, and will not interfere with the practice of the healing art by chiropractors and others in the States where they are licensed by law to engage in such practice.”⁴⁹ The intent appears to be clear, in the sense that Congress would continue to allow physicians to treat patients in accordance with state laws, and practices they deemed appropriate.⁵⁰ Fearing unintended consequences, the act was modified to ban the shipment of interstate drugs not deemed safe, unless a New Drug Application “NDA” was filed.⁵¹ This safeguard required manufacturers to disclose the drugs components, composition, manufacturing process, intended use, and additionally establish that the drug was in fact safe for its intended use.⁵² Additional Amendments passed in 1962 imposed liability on pharmaceutical companies for mislabeling or inaccurately advertising the drugs they manufactured. On the surface, it appears the Congress was still reluctant to govern the practice of medicine, although these measures imposed additional requirements on developers of drugs, not prescribers. The intent of Congress for physicians to be free from FDA involvement did not last long. The potential for intersection becomes more obvious when we consider the definition of “drug,” as defined by the FDCA in §321(g).

⁴⁸ 21 U.S.C §331(a).

⁴⁹ *Gonzalez v. Oregon*, 546 U.S. 243, 258 (2006).

⁵⁰ *Id.*

⁵¹ 21 U.S.C §335(b).

⁵² *Id.*

The FDA considers drug as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease,”⁵³ or “any substance intended to affect the structure or any function of the body.”⁵⁴ To determine what constitutes an intended use, the FDA focuses on the intent of the individual responsible for labeling such drugs.⁵⁵ Like most governmental agencies, the FDA is given a lot of deference and typically interprets their own definitions along with intended uses to determine whether a substance qualifies as a drug.⁵⁶ This has proved to be troubling and often causes difficulties for those wishing to challenge FDA interpretation.⁵⁷ This proves to be increasingly difficult when faced with new age products developed as biological cures or medicines.

Around 1944, Congress confronted this issue and passed the Public Health Service Act, (“PHSA”).⁵⁸ Recognizing a potential difference between biologics and drugs, this act imposed separate regulatory requirements. The FDA grants licensing for biologics proven to be “safe, pure, and potent.”⁵⁹ It is important to keep in mind these actions were taken prior to the discovery and implementation of stem cell therapies. Rather than being considered NDA’s the biologic material would have to apply for Biologic License Applications, (“BLA”). This led to confusion in determining exactly which substances were considered drugs, and which were

⁵³ 21 U.S.C §321(g)(1)(b) (2009).

⁵⁴ 21 U.S.C. §321 (g)(1)C (2009).

⁵⁵ 21 CFR §210.128 (2011).

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ 42 U.S.C. §262 (2010).

⁵⁹ 42 U.S.C §262 (a)2(c)(i)(I) (2010).

biologics. After much advancement in the medical field in the 1990's the FDA once again decided to take action.

With the advancement of biological medicine the FDA needed to find a way to regulate human cells, tissues, and other genetically comprised products. In 1997, the FDA enacted C.F.R §1271. Human cell and tissue-based products, ("HCT/P"), would come into the scope of regulation in 2001.⁶⁰ Recognizing that certain substances have inherently more risks than others, the FDA developed a three-tier system to address these HCT/P's.⁶¹

The first category of substances required no oversight by the FDA if two criteria were met. The manufacturer of the HCT/P's could not do more than (1) "minimally manipulate" the biologic substance, and (2) the use must be "homologous," effectively performing the same basic function in the recipient as the donor.⁶² While this provided some guidance, the term "minimally manipulated" fails to be defined within the regulation.

The second category of biologics requires minimal oversight by the FDA. Under §361 of the PSHA these products included cells, tissues, or other products posing a slightly higher risk.⁶³ Again the FDA laid out certain criteria that would qualify for minimal over-sight.⁶⁴ In addition to the two factors mentioned above, the FDA requires the manufactures to refrain from the combination of cells or tissues with other articles, and used for autologous use, in a first or second degree blood

⁶⁰ 21 C.F.R. 1271.10(a).

⁶¹ *Id.*

⁶² 21 C.F.R. §1271.3(d).

⁶³ *Id.*

⁶⁴ *Id.*

relative, or for reproductive use.⁶⁵ While the FDA recognized these substances as posing a slightly higher risk, they do not require NDA, BLA, or are considered to be Investigative New Drugs, (“IND”).⁶⁶ The FDA mentions that certain products when combined with other substances may induce a therapeutic effect, thus requiring stricter regulation. Therefore the FDA created a third category of biologics.

The final category falls under §351 of the PHSA.⁶⁷ The FDA considered these substances to be more than minimally manipulated, and intended for “non-homologous” use.⁶⁸ This includes products manipulated through gene or tissue culture and according have no biological precedent for such use.⁶⁹ Accordingly, products in these categories are required to undergo pre-market reviews and applications for a BLA.⁷⁰ Additionally, those involved in the manufacture of such products must follow current Good Manufacturing Practices.⁷¹

Following codification of the regulations, much confusion ensued. Physicians and manufacturers were unclear about which tier their products fell into and what level of regulation was required. In 2006, the FDA attempted to clarify their position by stating, “HTC/P’s are articles consisting or containing human cells or tissues that are intended for implantation, transplantation, infusion, or transfer to a human recipient.”⁷² While this clarification proved to be helpful, it made no more distinction between substances taken from one individual and implanted into another, as

⁶⁵ *Id.*

⁶⁶ 21 C.F.R. §207, §807 (2012).

⁶⁷ 42 U.S.C §262.

⁶⁸ *Id.*

⁶⁹ 21 C.F.R §1271.20.

⁷⁰ 42 U.S.C. §262(a).

⁷¹ 21 C.F.R. §207.3(a)(8).

⁷² 21 C.F.R. §1271.3.

opposed to procedures where the substance is taken and then implanted back into the same individual.

The FDA made additional attempts to clarify their regulations in 21 C.F.R §1271.3(4), where they define minimal manipulation for structural tissue as “processing that does not alter the original relevant characteristics of the tissue relating to the ability for reconstruction, replacement, or repair”.⁷³ For cells, minimal manipulation is considered “processing that does not alter the relevant biological characteristics of the cells.”⁷⁴ Additionally the FDA defined homologous use in 21 C.F.R §1271.3(c) as, “the repair, reconstruction, replacement, or supplementation of a recipients cells or tissues with an HCT/P that performs the same basic function in the recipient as the donor.”⁷⁵ According to the FDA the substance would need to be submitted as a BLA. Again this makes no mention or distinction if the recipient and donor are the same individual. While the biologic material performs the same basic function, the FDA does not address instances where the function is simply heightened or strengthened but at its core the function remains the same. As research and treatments continued to be discovered, other physician began to develop procedures using these substances. While the current state of the law is up for debate, the Regenexx case provides insight into the mind of the government and FDA.

B. Regenerative Sciences, Inc v. U.S. Food and Drug Administration

⁷³ *Id.*

⁷⁴ 21 C.F.R. §1271.3(4).

⁷⁵ 21 C.F.R §1271.3(c).

Regenerative Sciences, LLC owned and operated a clinic in Broomfield, Colorado. The procedure known as “Regenexx,” was viewed as an alternative to orthopedic surgery.⁷⁶ The procedure involved removing bone marrow samples from the patient, along with blood. The samples were then cultivated and induced to grow additional cells.⁷⁷ This solution was then re-injected back into the patient where the natural conditions of the body continued to encourage the growth, healing, and regeneration of cells.⁷⁸ After viewing this procedure, the FDA considered it to be a drug, inside the scope of regulation, thereby mandating FDA approval in order to market.⁷⁹ Regenerative Sciences in turn, challenged the findings of the FDA and brought suit claiming this practice falls outside the scope of the FDA’s jurisdiction.⁸⁰ In the following section I plan to break down the reasoning of the FDA, and discuss why the interpretation should favor the Regenexx Procedure, rather than discourage it. Additionally, I wish to contrast the Regenokine therapy mentioned above, from that of Regenexx. While courts typically give deference to regulatory agencies, it may nonetheless be misplaced and have unintended consequences

⁷⁶ Letter from Mary A. Malarkey, Dir. Of Compliance and Biologics Quality, U.S. Food and Drug Admin., to Christopher J. Centeno, M.D., Med. Dir., Regenerative Sci., Inc. (July 25, 2008) available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/UntitledLetters/ucm091991.htm> (last visited April 18, 2013).

⁷⁷ Regenexx, *Procedure Explained*, available at <http://www.regenexx.com/the-regenexx-procedure-explained> (last visited April 15, 2013).

⁷⁸ *Id.*

⁷⁹ 21 U.S.C. 321(g)(1) (2006), 42 U.S.C §262.

⁸⁰ U.S v. Regenerative Sciences, LLC, 878 F. Supp. 2d 248 (2012).

The main issue in the Regenexx case involved the Regenexx procedure and whether it constitutes a drug or biologic within the scope of FDA regulation, or on the other hand, a medical practice as intended by Congress to be out of the reach of the FDA. As mentioned above, the Regenexx procedure was a treatment using “bone-marrow derived stem-cells” to treat various joint injuries.⁸¹ After reviewing these procedures, the FDA concluded Regenexx was in violation of 21 C.F.R. §1271 and sought an injunction.⁸² Additionally, the FDA posted a letter on the Regenexx website stating their procedures were not approved and may have been unlawful.⁸³ The FDA concluded Regenerative Sciences Inc., was a drug manufacturer and in violation of federal regulations.⁸⁴ Accordingly, Regenexx filed a counter-claim challenging the findings of the FDA. The appeal was heard in 2012, and once again left the issue largely undecided.

Located in Colorado, Regenexx sought to defeat the FDA by citing to the pertinent law in their state⁸⁵. The FDA conceded that Regenexx is in fact engaged in the practice of medicine, but rather attacked the Colorado law for being too vague. The FDA rested their argument on the contention that the procedure is a drug as defined and falls into the scope of regulation.⁸⁶ Additionally, the FDA qualifies the Regenexx procedure as a prescription drug since, “due to its toxicity or other potentially harmful effect, or the method of its use, is not safe for use except under

⁸¹ *Id.*

⁸² *Regenerative Sciences, Inc., v. U.S. Food and Drug Admin.* 2010 WL 1258010.

⁸³ *Id.* at 253.

⁸⁴ *Id.*

⁸⁵ COLO Rev. Stat. Ann. §12-36-106(1) (2012).

⁸⁶ *Id.*

the supervision of a practitioner licensed by law to administer such drug.⁸⁷ Furthermore, the procedure according to the FDA is a biologic under the definition, as a substance may be both a biologic and a drug.⁸⁸ While the focus largely remained with the interpretation of the statutory language, the FDA additionally claims the use by Regenexx was more than minimal manipulation as provided in the regulations. The procedure involves a physician drawing a bone marrow sample from a patient through a syringe.⁸⁹ Small amounts of the patient's blood are also drawn, and sent to the Regenexx laboratory. Here, the mesenchymal stem cells, (MSC), are isolated from the bone marrow and then grown to a greater number.⁹⁰ Thus far, this seems to be only minimal manipulation. The cells are performing the same task as they do in the donor; the procedure simply cultivates a greater number of individual cells. The cells are then placed into a flask, kept in a warm environment, and mixed with the patient's own blood and a nutrient solution.⁹¹ This is perhaps where the FDA's concerns begin. This nutrient solution seems to be a cause for concern as it manipulates the way in which these individual cells function and grow. The FDA assumes that this goes beyond minimal manipulation⁹², but their conclusion is without merit. The procedure also calls for a substance to separate the cells to be used, from the flask they are stored in.⁹³ Again the FDA fails to recognize

⁸⁷ U.S v. Regenerative Sciences, LLC, 878 F. Supp. 2d 248 (2012).

⁸⁸ 42 U.S.C §262.

⁸⁹ U.S v. Regenerative Sciences, LLC, 878 F. Supp. at 251.

⁹⁰ *Id.*

⁹¹ *Id.* at 252.

⁹² *Id.*

⁹³ *Id.*

this as minimal manipulation. In response, Regenexx filed various counter-claims and disputed the findings of the FDA, but were ultimately unsuccessful.⁹⁴

The court acknowledges that the FDA is entitled to deference based on their expertise in evaluating scientific data.⁹⁵ Based on this language and deference, it was concluded that Regenexx was a drug and biologic manufacturer subject to FDA regulation.⁹⁶ Additionally, their product was subject to the highest tier of scrutiny requiring filing for IND, NDA, and BLA's, none of which Regenexx had done. The addition of more than minimal manipulation took the procedure outside of the scope of §351 substances.⁹⁷ Accordingly, the court granted the FDA's motion for summary judgment, dismissed the counterclaims of Regenexx, and instituted a permanent injunction⁹⁸. The issue is once again on appeal for the D.C Circuit.

C. Regenokine Therapy Different From The Regenexx Procedure

The Regenokine therapy performed by Dr. Wehling is fundamentally similar to the Regenexx treatment, although less intrusive and cumbersome. The procedure does not call for the use of bone marrow, only about 2 fluid ounces of blood.⁹⁹ The blood is then placed into an incubator where under this higher temperature its ability to relieve inflammation increases about one hundred times the normal amount.¹⁰⁰ After the blood develops a "fever," it is placed into a centrifuge and spun,

⁹⁴ U.S v. Regenerative Sciences, LLC, 878 F. Supp. at 251.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ 21 C.F.R §1271.10.

⁹⁸ U.S v. Regenerative Sciences, LLC, 878 F. Supp. at 251.

⁹⁹ *Graphic: Unique Knee Surgery*, CHICAGO TRIBUNE, August 22, 2012, available at <http://www.webcitation.org/6AASOJZat> (last visited April 24, 2013).

¹⁰⁰ *Id.*

until a viscous substance is formed.¹⁰¹ The “fever” involves a process where the temperature of the blood is raised to elicit a natural and biological response, as if a fever had occurred in the body of the patient. This substance is then drawn with a syringe and injected back into the patient.¹⁰² It does not appear that any additional drugs, minerals, or solutions are mixed with the patient’s blood. Aside from raising the temperature, and causing the cells to separate in the centrifuge, no additional alterations are necessary.¹⁰³ This clearly falls within the scope of minimal manipulation. Since no harmful materials are added, the blood solution should not be considered a drug. It is no different than an individual getting a blood transfusion, a medical practice that the FDA does not regulate. Furthermore, the blood is placed back into the patient, so the concern about the spread of infectious disease is drastically mitigated. Finally, the newly injected cells perform that same basic function as they did, prior to being removed. The only difference is in their strength and number. Just like your immune system thrives off of vitamin C, this therapy simply gives the body a boost of healing power. Nonetheless, the FDA remains firm in their belief that these therapies are actually drugs and since they involve biologic material, they are subject to the highest level of regulation. As mentioned, the term “minimally manipulated” remains largely undefined, but the FDA refuses to change their position, which makes practicing these new age treatments virtually impossible.

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

IV. Implications For Future Development of Adult Stem Cell Therapies In The United States.

The FDA consistently refuses to adopt such practices. They consider this to be a drug and biologic within the scope of regulation as mentioned by the Regenexx case. Although the case is up for appeal, physicians and scientists remain skeptical of adopting these treatments in the United States. This puts our nation at a great disadvantage compared to other countries where these therapies are not only being performed, but perfected on a daily basis. As mentioned above, this minimal development has caused those who can afford it, to travel abroad. The FDA is effectively outsourcing our healthcare system to countries with less stringent requirements. Although the long-term effects of these regenerative procedures have not been conclusively studied, the overwhelming success rate gives reason to remain optimistic.¹⁰⁴ Unlike purchasing prescription drugs, these procedures require individual visitation with a qualified physician, who will then perform the procedure. One cannot simply go into a pharmacy and purchase these cells. While Regenexx and Dr. Wehling maybe the people carrying out such treatments, it is a stretch to considered them manufactures of drugs, as the FDA contends. If anyone is to blame, it is the individual patients themselves. After all, the final solution initially comes from the patient, therefore holding him/her as the true manufacture. While strictly speaking the statutory language may allow the FDA to control these types of practices, in today's day and age this does more harm than good. The hindrance of progress and medical development directly contradicts the mission of the FDA. In

¹⁰⁴ Regenexx, *Procedure Explained*, available at <http://www.regenexx.com/the-regenexx-procedure-explained> (last visited April 15, 2013).

attempts to protect, they actually destroy any hopes of developing life-changing cures.

The strict yet ambiguous requirements of the FDA deter most U.S. companies, physicians, and scientists from engaging in potentially life changing procedures. This a phenomenon known as, “Stem cell tourism.”¹⁰⁵ As mentioned, this has become common among various athletes and prominent individuals, but more difficult for the “common man.” Even the late Pope John Paul II has endorsed this Regenokine procedure, outside of the United States away from the reach of the FDA.¹⁰⁶ Those willing to pay out of pocket can take advantage of these advanced procedures, while others are left to more intrusive surgeries. Physicians are faced with a “double-edged sword.” On one hand they can attempt to abide by the FDA requirements. This is troublesome since the FDA requirements regarding biologics remain unclear. Physicians would need to apply for NDA, IND, and BLA’s. This process would increase costs, delay progress, and impede access.¹⁰⁷ While the therapy overseas costs about \$7,500 dollars, these additional steps could potentially sky rocket the price in the United States. Insurance companies would be unwilling to cover risky or unproven treatments, and individual would again be forced to bear the costs on their own. These FDA hurdles delay access to the public. While many with chronic conditions are unable to travel outside of the United States, or afford

¹⁰⁵ Doug Sipp, *The Rocky Road to Regulation*, NATURE REPORTS STEM CELLS, Sep. 23, 2009 available at <http://www.nature.com/stemcells/2009/0909/090923/full/stemcells.2009.125.html> (last visited April 26, 2013).

¹⁰⁶ See Lehrer, *supra* note 30.

¹⁰⁷ Barbara von Tigerstrom, *The Food and Drug Administration: Regenerative Sciences, and the Regulation of Autologous Stem Cell Therapies*, 66 FOOD AND DRUG L.J., Start 479, 481 (2011).

expensive treatments, the FDA is taking no measures to further the availability of comparable treatments. On the other hand, those truly dedicated to the practice of biological and genetic medicine can follow the path of Regenxx. If a valid and successful treatment is discovered, they could attempt to remain under the radar and not advertise their procedure. This appears to be what the FDA is encouraging, since the formal process will most likely lead to an injunction or disproof of the newly discovered procedures.

Conversely, if the FDA decides to be “hands-off,” many unproven or hazardous treatments could come into the market. Physicians would be altering all different types of genetic material in hopes of finding cures to debilitating diseases, which in turn could actually cause more problems. Opponents of genetic therapies believe this outcome would turn the medical community into the “Wild Wild West,” of biological medicine. This seems to be stretch considering most physicians genuinely care about treating their patients. These regulations should be left to the states. Rather than travel to Germany, individuals could simply cross state lines if they wish to undergo certain procedures possibly un-adopted by their home state. I am by no means suggesting this new age medicine should be free of all regulation. Simply put, the current state of the law is a cause for concern. Regulation of genetic material is a necessary in the medical community, but as of right now the FDA has over-reached and gone too far. In order to catch up, create access, and endorse progress, the FDA should tone down the way in which they define, regulate, and control these practices. While it remains uncertain about how the Regenxx case will play out in the future, and what effect it will have on development, action should

be taken sooner than later. The point of health care reform is to provide equal access to all, although currently the rich and famous have many more access than the everyday man.

Conclusion

The unwillingness of the FDA to adopt clear “bright-line” rules and ease the tedious requirements of getting approval has severely diminished the abilities of physicians in the United States to engage in these break through procedures. Concerns about “stem-cell tourism” continue to grow, as the majority of the public has no alternative, but to seek treatment outside of this country. The FDA requirements as a whole continues to increase costs, cause delays, and impede access for those who cannot afford the luxury of traveling abroad. These autologous stem cell treatments are far less controversial than their embryonic counterparts, since the cells are drawn and later re-injected into the patient’s own body. Critics have called the FDA’s position “close-minded.” Patients should have the ability to weigh the risks and benefits for themselves, provided that they have access to information surrounding these treatments. Thus far, the FDA has limited the procedure itself, as well as the transmittal of information surrounding these treatments.

The FDA does not allow the commercialization of these treatments until proper approval is granted. The hurdles they put in place have a counter effect as they discourage physicians from engaging in said practices, for fear of injunctions and even worse, termination of one’s medical license. In today’s society, technology

is advancing each and every day, however access to this technology has slowed to a crawl due to the actions of the FDA. The potential of these adult stem cell therapies is tremendous, but unfortunately the United States continues to remain leagues behind due to the unfortunate position taken by the FDA. The current state of the law remains unclear, and it does not appear that the water will be cleared up anytime soon. Those brave physicians willing to embrace these new cutting edge treatments must constantly live in fear, as the FDA could “shut them down” at any minute. Without the ability to advance our healthcare system, we will never be able take the next step and actually use these adult stem cells to their full potential.