IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, by Department of Justice Office of Consumer Litigation P.O. Box 386 Washington, DC 20044 Plaintiff, v. REGENERATIVE SCIENCES, LLC, a corporation, and CHRISTOPHER J. CENTENO, M.D., JOHN R. SCHULTZ, M.D., and MICHELLE R. CHEEVER, individuals, Defendants.	)	Civil Action No.

COMPLAINT

The United States of America, plaintiff, by and through undersigned counsel, respectfully represents as follows:

1. This statutory injunction proceeding is brought pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to enjoin Regenerative Sciences, LLC, a corporation, and Christopher J. Centeno, M.D., John R. Schultz, M.D., and Michelle R. Cheever, individuals (hereafter, collectively, "Defendants"), from violating 21 U.S.C. § 331(k), by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), and misbranded within the meaning of 21 U.S.C. §§ 352(f)(1) and 353(b)(4), while such drugs, or one or more of their components,

are held for sale after shipment in interstate commerce.

Jurisdiction and Venue

2. Jurisdiction to restrain such violations is granted to the district courts of the United States pursuant to 21 U.S.C. § 332(a). This Court also has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345.

3. Defendants have waived any objection to personal jurisdiction and venue in this Court.

The Defendants

4. Defendant Regenerative Sciences, LLC ("Regenerative Sciences") is incorporated under the laws of the State of Colorado and its laboratory is located at 6850 West 116th Avenue, Unit D, Broomfield, Colorado. Regenerative Sciences' corporate address is located at 403 Summit Boulevard, Suite 201, Broomfield, Colorado. Regenerative Sciences manufactures and distributes a cultured cell product that is a drug within the meaning of the FDCA and a biological product within the meaning of the Public Health Service Act.

5. Defendant Christopher J. Centeno, M.D., an individual, is the Medical Director and acting Chief Executive Officer of Regenerative Sciences. He is also a partial owner of that corporation. Dr. Centeno is the person most responsible for the overall conduct of Regenerative Sciences.

6. Defendant John R. Schultz, M.D., an individual, is a partial owner of Regenerative Sciences and serves on the corporation's board of directors. He also holds the position of "researcher" at Regenerative Sciences.

7. Defendant Michelle R. Cheever, an individual, is Regenerative Sciences' Laboratory Director. As Laboratory Director, she is responsible for the day-to-day operations of the Regenerative Sciences laboratory. Among other things, she oversees the production of Defendants' cultured cell product. Ms. Cheever wrote the firm's laboratory procedures and is responsible for ensuring that those procedures are followed by laboratory employees. According to an article co-authored by Ms. Cheever, she holds equity ownership in Regenerative Sciences. See Centeno CJ, Schultz JR, Cheever M, Robinson B, Freeman M, Marasco W, Safety and Complications Reporting on the Re-implantation of Culture-Expanded Mesenchymal Stem Cells using Autologous Platelet Lysate Technique, Current Stem Cell Research & Therapy, 2010; 5:81-93.

8. Defendants Centeno and Schultz also jointly own Centeno Schultz, P.C., a Colorado corporation, which does business as the Centeno-Schultz Clinic (hereafter, "the Clinic"). The Clinic is located at 403 Summit Boulevard, Suite 201, Broomfield, Colorado.

9. Regenerative Sciences manufactures a biological drug product, referred to herein as the cultured cell product, that is adulterated because the methods used in, and the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to and are not operated in conformity with current good manufacturing practice ("CGMP") to assure that such drug meets the requirements of the FDCA as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess. Additionally, Regenerative Sciences' cultured cell product is misbranded because its labeling does not bear adequate directions for use and its label does not bear the symbol "Rx only."

Defendants' Cultured Cell Product

10. Regenerative Sciences promotes its cultured cell product in connection with the "Regenexx™ procedure." When a patient undergoes the Regenexx™ procedure, the Centeno-Schultz Clinic aspirates (withdraws using a needle) bone marrow from the patient's hip or synovial fluid from the patient's knee and also draws some whole blood from the patient. The Clinic then delivers these materials to Regenerative Sciences, which manufactures them into the cultured cell product.

11. Regenerative Sciences isolates what it describes as mesenchymal stem cells (MSCs) from the bone marrow or synovial fluid, expands them using growth factors from the patient's blood (e.g., platelet lysate) and reagents (e.g., Dulbecco's Modified Eagle's Medium), and combines them with other drug products (such as heparin and doxycycline). The process of expanding the cells typically takes two to three weeks and involves multiple steps in which the cells are centrifuged (with certain cell and plasma layers then removed) and placed in culture media in an incubator, thereby causing the cells to divide and expand in number. When the cells expand to a certain point, they are exposed to an enzyme, trypsin, which digests some of the proteins on the surface of the cells and causes the cells to detach from the plastic flask in which they were contained. Regenerative Sciences then harvests the detached cells, treats them with media to stop the action of the trypsin, washes them with fresh media, and either puts the cells into other flasks for further expansion, prepares them for cryo-preservation, or prepares them for injection. Ultimately, after one or more cell passages (and, in some cases, following cryo-preservation), the expanded cells, along with a drug product that has been shipped in interstate

commerce and other additives, are placed into syringes. Regenerative Sciences distributes the filled syringes in sterile bags to the Clinic, where they are injected into patients.

12. Defendants' cultured cell product is intended solely for autologous use. Autologous use refers to the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered. 21 C.F.R. § 1271.3(a).

13. Defendants manufacture the cultured cell product using components that are shipped in interstate commerce from places outside the State of Colorado. For example, Regenerative Sciences includes doxycycline in the cultured cell product that it distributes for patient injection, and that doxycycline has been shipped in interstate commerce from Illinois to Colorado. Defendants also use various drugs, excipients, and reagents in the manufacture of the cultured cell product that have been shipped to Defendants from locations outside of the State of Colorado, including, but not limited to: Dulbecco's Modified Eagle Medium, heparin, and Minimum Essential Medium Alpha.

Defendants' Cultured Cell Product is a Drug under the FDCA

14. Under the FDCA, a "drug" includes any article that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), or that is "intended to affect the structure or any function of the body . . . ," 21 U.S.C. § 321(g)(1)(C).

15. The "intended use" of a product refers, in turn, "to the objective intent of the persons legally responsible for the labeling of drugs," and is determined by such persons'

expressions or may be shown, for example, by "labeling claims, advertising matter, or oral or written statements by such persons or their representatives. . . ." 21 C.F.R. § 201.128.

16. Defendants' cultured cell product is a "drug" within the meaning of the FDCA, 21 U.S.C. § 321(g)(1)(B)&(C), because Defendants' labeling and promotional literature, including information contained on Regenerative Sciences' website, establish that their cultured cell product is intended to be used in the cure, mitigation, and treatment of diseases in man and to affect the structure and function of the body. For example:

a. Defendants' Regenexx™ pamphlet states that "The Regenexx procedure is safe and can often prevent the need for surgery." The pamphlet lists the following conditions and diseases as "candidates" for the procedure: "Patients with non-healing bone fractures"; "Osteoarthritis of the knee, hip, ankle, shoulder, hands"; "Chronic bulging lumbar disc"; "Injuries to the meniscus, rotator cuff"; "Avascular Necrosis of the shoulder, hip"; and "Chronic Bursitis."

b. The Regenerative Sciences' website, www.regenexx.com, describes the Regenexx™ procedure as "an Alternative to Traditional Surgery." See http://www.regenexx.com/ the-regenexx-procedures/ (accessed July 20, 2010). The frequently asked questions section of the website states, "What types of problems can be treated? Fractures that have failed to heal, joint cartilage problems, partial tears of tendons, muscles, or ligaments, chronic bursitis, avascular necrosis of the bone, and lumbar disc bulges." See http://www.regenexx.com/ common-questions/ (accessed July 20, 2010). In addition, the website states, "The Regenexx™ procedure has been shown to be safer than tradtional [sic]

surgical techniques in published research and can often prevent the need for surgery." See http://www.regenexx.com/the-regenexx-procedure-explained/ (accessed July 20, 2010).

17. Defendants' cultured cell product is administered by injection into, for example, the patient's joint or intervertebral disc using a type of x-ray device. Defendants' cultured cell product is a "prescription drug" within the meaning of 21 U.S.C. § 353(b)(1)(A) because, due to its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, it is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.

18. There have been no adequate and well-controlled studies performed on Defendants' cultured cell product demonstrating that it is safe or effective for any orthopedic (or any other) indication.

19. Defendants' cultured cell product is a "new drug" within the meaning of 21 U.S.C. § 321(p)(1), because it is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under each of the conditions prescribed, recommended, or suggested in its labeling. The cultured cell product is also a "new drug" within the meaning of 21 U.S.C. § 321(p)(2), because it has not been used to a material extent or for a material time under the conditions prescribed, recommended, or suggested in its labeling.

20. There is not now, nor has there ever been, an approved new drug application ("NDA") filed with FDA pursuant to 21 U.S.C. § 355(b) or (j) for Defendants' cultured cell product.

21. There is not now, nor has there ever been, an approved investigational new drug application ("IND") filed with FDA pursuant to 21 U.S.C. § 355(i) for Defendants' cultured cell product.

Defendants' Cultured Cell Product is a Biological Product Under the Public Health Service Act

22. Under the Public Health Service Act ("PHSA"), a "biological product" includes any "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i).

23. Defendants' cultured cell product is a "biological product" within the meaning of the PHSA, 42 U.S.C. § 262(i), because it is an "analogous product" that is applicable to the treatment and cure of various diseases and conditions of human beings, including, but not limited to, osteoarthritis, avascular necrosis of the shoulder and hip, chronic bursitis, non-healing bone fractures, and chronic bulging lumbar discs.

24. A product may be both a drug and a biological product. A product that has been licensed under the PHSA is not required to also have an approved NDA under the FDCA. 42 U.S.C. § 262(j). However, the FDCA's adulteration and misbranding provisions, 21 U.S.C. §§ 351 & 352, apply to biological drug products. 42 U.S.C. § 262(j).

25. There is not now, nor has there ever been, an approved biologics license application ("BLA") filed with FDA pursuant to 42 U.S.C. § 262 for Defendants' cultured cell product.

Defendants' Cultured Cell Product Is Not Exempt from Regulation under the FDCA

26. FDA has, by regulation, defined "Human cells, tissues, or cellular or tissue-based products (HCT/Ps)" as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d). FDA has determined that, in limited circumstances not applicable here, certain HCT/Ps can be regulated effectively solely by controlling the infectious disease risks they present through the regulations set forth at 21 C.F.R. Part 1271, even if such HCT/Ps would otherwise meet the FDCA's definition of a "drug" or "device" or the PHSA's definition of a "biological product." All HCT/Ps that do not meet the criteria for regulation solely under 21 C.F.R. Part 1271 are regulated as drugs, devices, and/or biological products. 21 C.F.R. § 1270.20. (There are also exceptions from 21 C.F.R. Part 1271 set forth in 21 C.F.R. § 1271.15, but they are not applicable to the cultured cell product at issue here.)

27. The criteria for distinguishing HCT/Ps that are subject to regulation as drugs, devices, and/or biological products under the FDCA and section 351 of the PHSA (42 U.S.C. § 262) from those that are regulated solely under 21 C.F.R. Part 1271 are set forth in 21 C.F.R. § 1271.10. Products that do not meet *all* of the criteria in 21 C.F.R. § 1271.10, and that do not meet any of the exceptions in 21 C.F.R. § 1271.15, remain subject to the provisions of the FDCA and the PHSA, including the adulteration, misbranding, and premarket approval requirements. 21 C.F.R. § 1271.20.

28. The criteria in 21 C.F.R. § 1271.10 include the requirement that the HCT/P be only "minimally manipulated." 21 C.F.R. § 1271.10(a)(1). For cells, "minimal manipulation" means processing that does not alter the relevant biological characteristics of the cells. 21 C.F.R.

§ 1271.3(f). FDA has explained that expansion of cells in culture does not qualify as "minimal manipulation." See Final Rule on Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447, 5457 (Jan. 19, 2001) (stating that the FDA does "not agree that the expansion of mesenchymal cells in culture or the use of growth factors to expand umbilical cord blood stem cells are minimal manipulation."); see also Proposed Rule, Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26744 (May 14, 1998) ("Examples of manipulation not considered minimal, based on current scientific knowledge, include cell expansion . . . .").

29. Defendants' cultured cell product fails to meet 21 C.F.R. § 1271.10's requirement that the HCT/P be only "minimally manipulated." 21 C.F.R. § 1271.10(a)(1). The product's manufacture involves many steps, including selective culture and expansion of a multitude of different types of blood-forming and rare bone marrow stromal cells using plastic flasks, additives and nutrients, and environmental conditions such as temperature and humidity, to determine the growth and biological characteristics of the resulting cell population. Such conduct constitutes more than minimal manipulation of the MSCs and, as a result, Defendants' cultured cell product is regulated as a drug under the FDCA and a biological product under section 351 of the PHSA.

Defendants' Cultured Cell Product is Adulterated

30. Regardless of whether a drug is actually deficient in any respect, a drug is deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP to assure that such drug meets the requirements of the FDCA as to safety

and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B).

31. FDA investigators inspected Regenerative Sciences between February 23, 2009 and April 15, 2009. That inspection showed that the methods used in, and the facilities and controls used for, the manufacture, processing, packing, or holding of the cultured cell product do not conform to and are not operated or administered in conformity with CGMP. See 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210-211; see also 21 C.F.R. Parts 600-680 (setting forth additional standards applicable to biological products). At the close of the 2009 inspection, FDA investigators issued a list of inspectional observations (Form FDA 483) to Regenerative Sciences' Acting CEO, Dr. Centeno, with Dr. Schultz and Ms. Cheever present. The CGMP violations observed during the 2009 inspection included, but were not limited to, the following:

a. Failure to establish and follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile, as required by 21 C.F.R. § 211.113(b); see also 21 C.F.R. § 610.12;

b. Failure to perform appropriate laboratory testing of each batch of drug product required to be free of objectionable microorganisms, as required by 21 C.F.R. § 211.165(b);

c. Failure to establish scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity, as required by 21 C.F.R. § 211.160(b);

d. Failure to ensure, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product prior to release, as required by 21 C.F.R. § 211.165(a); and

e. Failure to establish an adequate system for monitoring environmental conditions during product manufacturing, as required by 21 C.F.R. § 211.42(c)(10)(iv).

32. FDA investigators inspected Regenerative Sciences again between June 2, 2010 and June 16, 2010. That inspection also showed that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or holding of Defendants' cultured cell product do not conform to and are not operated or administered in conformity with CGMP. At the close of the 2010 inspection, FDA investigators issued a list of inspectional observations (Form FDA 483) to Dr. Schultz. Ms. Cheever was present and Dr. Centeno attended by telephone. The CGMP violations observed during the June 2010 inspection included, but were not limited to, the following:

a. Failure to establish scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that in-process materials and drug products conform to appropriate standards of identity, strength, quality, and purity, as required by 21 C.F.R. § 211.160(b);

b. Failure to ensure, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, prior to release, as required by 21 C.F.R. § 211.165(a);

c. Failure to establish and follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile, as required by 21 C.F.R. § 211.113(b); see also 21 C.F.R. § 610.12;

d. Failure to perform appropriate laboratory testing of each batch of drug product required to be free of objectionable microorganisms, as required by 21 C.F.R. § 211.165(b);

e. Failure to establish an adequate system for monitoring environmental conditions during product manufacturing, as required by 21 C.F.R. § 211.42(c)(10)(iv);

f. Failure to establish and follow an aseptic gowning qualification program to assess the ability of aseptic processing technicians to maintain the quality of the gown after performance of manufacturing operations, as required by 21 C.F.R. § 211.113(b);

g. Failure to perform cleaning validation on the biological safety cabinet aseptic processing surfaces or on all other surfaces in the aseptic processing laboratories, as required by 21 C.F.R. § 211.42(c)(10)(v); and

h. Failure to maintain separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination during aseptic processing, as required by 21 C.F.R. § 211.42(c)(10)(iii).

33. As a result of the CGMP violations documented during the 2010 inspection, the Defendants' cultured cell product is adulterated within the meaning of the FDCA.

Defendants' Cultured Cell Product is Misbranded

34. FDA's inspections of Regenerative Sciences also showed that Defendants are causing the cultured cell product to be misbranded. When the manufacturing of the cultured cell

product is complete, it is loaded into a syringe and placed into a sterile bag. According to Defendants' standard operating procedures, the bag is labeled only with the patient's name, date of birth, laboratory notebook number, cell passage number, day in culture, cell number, number of cells cryo-preserved, and condition of cell suspension. The bag is then placed into a cooler and distributed to the Clinic.

35. Defendants' cultured cell product is misbranded within the meaning of the FDCA, 21 U.S.C. § 352(f)(1), because it is a drug and its labeling fails to bear adequate directions for use, and because it is not exempt from the requirements of 21 U.S.C. § 352(f)(1).

36. Defendants' cultured cell product is misbranded within the meaning of 21 U.S.C. § 353(b)(4) because it is a prescription drug and, at times prior to dispensing, its label fails to bear, at a minimum, the symbol "Rx only."

Defendants Violate the FDCA

37. Defendants violate 21 U.S.C. § 331(k) by causing the adulteration of the cultured cell product within the meaning of 21 U.S.C. § 351(a)(2)(B), while it is held for sale after shipment of one or more of its components in interstate commerce, as alleged in ¶¶ 13-16, 30-33.

38. Defendants violate 21 U.S.C. § 331(k) by causing the misbranding of the cultured cell product within the meaning of 21 U.S.C. § 352(f)(1), while it is held for sale after shipment of one or more of its components in interstate commerce, as alleged in ¶¶ 13-18, 34-35.

39. Defendants violate 21 U.S.C. § 331(k) by causing the misbranding of the cultured cell product within the meaning of 21 U.S.C. § 353(b)(4), while it is held for sale after shipment of one or more of its components in interstate commerce, as alleged in ¶¶ 13-17, 34, 36.

40. Defendants have been notified that the cultured cell product is subject to regulation as a drug and a biological product under the FDCA and PHSA, respectively. FDA stated in the preamble to the 2001 Registration and Listing Final Rule that expansion of MSCs in culture is not "minimal manipulation" and that products that are more than minimally manipulated are regulated as drugs under the FDCA and as biological products under section 351 of the PHSA. See 66 Fed. Reg. 5449 & 5457.

41. FDA also sent a letter to Dr. Centeno as a representative of Regenerative Sciences on July 25, 2008, in which the agency advised the company that it was promoting cells used in the Regenexx™ procedure for uses that cause them to be drugs under 21 U.S.C. § 321(g) and that failure to obtain a valid BLA or an IND before introducing the cell product into interstate commerce would be a violation of the FDCA and the PHSA. In addition, at the close of the February/April 2009 inspection, the FDA investigators' list of inspectional observations (Form FDA 483) notified Defendants that their cultured cell product is a biological drug under the PHSA. However, Defendants have maintained that their conduct is not subject to regulation under the FDCA or the PHSA.

42. FDA investigators have also notified Defendants that their cultured cell product is not manufactured in compliance with CGMP. At the close of the February/April 2009 inspection, FDA investigators issued a list of inspectional observations to Regenerative Sciences' Acting CEO, Dr. Centeno, with Dr. Schultz and Ms. Cheever present. Defendants did not promise to correct the deficiencies observed during the inspection, either during their discussion with the FDA investigators or thereafter. Instead, on April 24, 2009, Defendants' counsel informed the FDA investigators that Regenerative Sciences was reviewing the investigators' "issuance of the

Form 483, as well as the statements made [by FDA investigators] during the April 15 exit interview, in the context of ongoing litigation between Regenerative Sciences and the United States. (Civil Action No.: 09-CV-00411 WTD-BNB in the United States District Court for the District of Colorado.)" and that Defendants would "respond to [the] issuance of the Form 483 in a reasonable period of time in the course of this litigation." On March 26, 2010, the complaint in Civil Action No. 09-cv-00411-WYD-BNB (D. Colo.) was dismissed on ripeness grounds. See Order of Dismissal (Docket No. 42).

43. During the 2010 inspection, Defendants stated that they would correct some of the CGMP violations observed during that inspection, but they refused to correct many others because they do not believe that Regenerative Sciences is a drug manufacturer.

44. Defendants' conduct demonstrates their refusal to comply with the law. Unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. § 331(k) by causing the adulteration and misbranding of drugs in the manner alleged herein.

WHEREFORE PLAINTIFF PRAYS:

I. That Defendants, Regenerative Sciences, LLC., a corporation, and Christopher J. Centeno, John R. Schultz, and Michelle R. Cheever, individuals, and each of their officers, agents, representatives, employees, attorneys and all persons in active concert or participation with any of them, be permanently restrained and enjoined from directly or indirectly doing any act with respect to a drug (including a biological product) that results in the drug being adulterated or misbranded within the meaning of the FDCA if such act is done while such drug, or one of its components, is held for sale (whether or not the first sale) after shipment in interstate commerce, in violation of 21 U.S.C. § 331(k).

II. That FDA be authorized pursuant to the injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug and drug component to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

III. That the Court award plaintiff costs and other such relief as the Court deems just and proper, including equitable monetary relief.

DATED this 6th day of August, 2010.

Respectfully submitted,

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