THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

REGENERATIVE SCIENCES, INC.
403 Summit Boulevard
Suite 201
Broomfield, Colorado 80021

Plaintiff,

vs.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
5600 Fishers Lane
Rockville, MD 20857

And

DR. MARGARET A. HAMBURG, in her
Official Capacity as Commissioner of the
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857,

And

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
200 Independence Ave., S.W.,
Washington, D.C. 20201

and

KATHLEEN SEBELIUS, in her Official Capacity as Secretary of
the United States Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201,

Defendants.

Civil No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, Regenerative Sciences, Inc. ("Regenerative"), hereby files its complaint against Defendants, U.S. Food and Drug Administration, Dr. Margaret Hamburg, in her capacity as the

Commissioner of the Food and Drug Administration, ("FDA"), The U.S Department of Health and Human Services ("HHS"), and Kathleen Sebelius, Secretary of Health and Human Services ("Secretary Sebelius") (collectively "the Defendants") for a declaratory judgment and injunctive relief and alleges the following:

INTRODUCTION

Regenerative, by and through physicians licensed to practice medicine in the State of Colorado, performs a non-surgical procedure for patients suffering from moderate to severe joint, muscle, tendon or bone pain due to injury or other conditions. This procedure is known as the "Regenexx® Procedure" and is performed in the CentenoSchultz Clinic, located in Broomfield, Colorado. Drs. Centeno and Schultz are the majority shareholders of Regenerative; Regenerative owns the Regenexx Procedure, and licenses it to the clinic for the exclusive use of Regenerative.

The Regenexx® Procedure begins with a licensed physician taking a small bone marrow sample from the back of a patient's hip through a needle. Blood samples are also taken from a vein in the patient's arm. These samples are then sent to the Regenerative laboratory which is also in Broomfield, Colorado, just a few miles from the Clinic where the stem cells (and other tissue) are isolated from the bone marrow and then grown to greater numbers. This process uses the natural growth factors found in the patient's blood to grow the stem cells. After approximately 5 weeks, the expanded stem cells are placed back into the patient's injured area (i.e. knee, hip, rotator cuff). The stem cells then begin to repair the patient's degenerated or injured area. The repair process usually takes between 3-6 months but many patients demonstrate marked improvement within 1-3 months.

The FDA has conducted, and continues to conduct, inspections of Regenerative's facilities. The FDA is asserting that it has jurisdiction to regulate Plaintiff because the FDA alleges that the Regenexx® medical procedure constitutes the manufacture of a drug, over which the FDA has regulatory authority. The FDA has not permitted Regenerative to challenge its decision that Regenerative is a drug manufacturer and, as such, the decision that Regenerative is a drug manufacturer has taken on the character of final agency action. In fact, the Regenexx® Procedure, and the activities of the Clinic, constitutes the practice of medicine, which is outside the FDA's regulatory authority, and solely regulated by the several states. In a recent inspection, the FDA mandated that Regenerative treat itself as a drug manufacturer and institute procedures and protocols as a drug manufacturer, which will financially bankrupt the medical practice. These drug manufacture systems are designed for the mass manufacture of drugs sold interstate and are not used in medical practices or hospitals. Regenerative was informed by FDA that the decision classifying it as a drug manufacturer was made prior to onset of the FDA's inspections without FDA allowing any input, documentation, or arguments from Regenerative showing that it is a medical practice and not a drug manufacturer.

The FDA will soon issue and publish a Form 483 report of its inspection for public record, and cause a Cease and Desist Letter ("C&D") to issue; following such letter with an ex-parte application to federal court for an injunction, which will destroy the Plaintiff's medical practice. When the FDA takes these actions, irreparable harm will result, as patients, upon becoming aware of the Form 483, C&D letter, and further enforcement action, will avoid treatment at the Clinic, discontinue treatment already begun, cause the clinic to be liable to patients for refunds or legal actions, and otherwise bring the medical practice, Regenerative and its Regenexx® Procedure into disrepute. This despite the fact that the FDA has no authority to

regulate Regenerative or its practices. The actions of the FDA will cause the Clinic to go out of business and prevent Drs. Centeno and Schultz from practicing medicine as permitted under Colorado law. In addition, this action by the FDA will prevent patients from obtaining needed treatment for maladies, which would be contrary to the public interest.

As such, in order to save Regenerative's business and to allow it to continue to treat patients, thereby promoting the public interest, Plaintiff requests declaratory relief as to its rights regarding the FDA's lack of jurisdiction and authority to regulate its practice of medicine, a declaration that Regenerative is not a drug manufacturer, and injunctive relief against the FDA to prevent the issuance of the Form 483, a C&D letter, and to enjoin the FDA from seeking an ex-parte injunction from federal court which would ruin Regenerative's business and cause it to incur massive civil liability.

PARTIES, JURISDICTION AND VENUE

1. Regenerative Sciences, Inc. ("Regenerative") is a company with its principal place of business in Broomfield, Colorado.

2. HHS is a department of the United States Federal Government and oversees the FDA. Its principal place of business is located at 200 Independence Ave., S.W., Washington, D.C., 20201.

3. Secretary Sebelius is the Secretary of the HHS. She is sued in her official capacity. She maintains offices at 200 Independence Ave., S.W., Washington, D.C., 20201.

4. The FDA is a United States regulatory agency within the HHS, with its principal place of business at 5600 Fishers Lane, Rockville, Maryland 20857.

5. Dr. Hamburg is the Commissioner of the FDA and its senior official. She is sued in her official capacity. She maintains offices located at 5600 Fishers Lane, Rockville, Maryland 20857.

6. This Court has personal jurisdiction over the Defendants because they are either located in, conduct substantial business in, or have regular, systematic contact with this District.

7. This Court has subject matter jurisdiction under 28 U.S.C. § 1331. Declaratory Relief is authorized pursuant to 28 U.S.C. § 1651 (All Writs Act), 28 U.S.C. § 2201 (Declaratory Judgment Act); and 28 U.S.C. § 2202 (further relief).

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391 (e) since Defendants maintain headquarters or offices in this District.

9. There exists an actual, substantial and continuing controversy between the parties regarding the FDA's assertion and publication that Regenerative is a drug manufacturer while Regenerative asserts that its use of stem cells in the Regenexx procedure is a medical procedure not governed by the FDCA or PHSA. This Court may declare the rights and legal relations of the parties under 28 U.S.C. § 2201, *et. seq.*

10. Administrative remedies are futile, and as such are to be treated as exhausted.

FACTS

Regenerative and the Regenexx® Procedure

11. Regenerative Sciences, Inc., owned by Drs. Centeno and Schultz, employs physicians licensed to practice medicine in the State of Colorado to perform the Regenexx® Procedure at the Centeno Schultz Clinic ("clinic"). Regenerative owns the Regenexx Procedure.

12. The "Practice of Medicine" is defined, in pertinent part, as follows:

> Holding out one's self to the public within this state as being able to diagnose, treat, prescribe for, palliate, or prevent any human

> disease, ailment, pain, injury, deformity, or physical or mental condition, whether by the use of drugs, surgery, manipulation, electricity, or any physical, mechanical, or other means...(b)... administering any form of treatment, operation, or healing for the intended palliation, relief, or cure of any physical or mental disease,...injury...(c) The maintenance of an office or other place for the purpose of examining or treating persons afflicted with disease, injury, or defect of body or mind.

C.R.S. § 12-36-106(1).

13. The Regenexx® Procedure is performed only by physicians lawfully licensed to practice medicine in the State of Colorado.

14. The Procedure is for the treatment of orthopedic injuries and arthritis.

15. The Procedure requires the removal of stem cells and other tissue from a donor patient, the expansion of the stem cells, and the placement of the stem cells in the same patient for the treatment of the patient's degenerated or injured area of the body. Regenerative operates the facilities that performs these functions and does so exclusively for the Centeno Schultz Clinic for the Regenexx procedure.

The FDA Believes that the MSCs Used in the Regenexx® Procedure are Drugs

16. Regenerative is not engaged in the manufacturing of drugs. The stem cells used in the Regenexx® Procedure are not drugs, but human tissue, no different than any other body part. Rather than being a drug manufacturer, Regenerative is engaged in the practice of medicine as defined by the laws of the State of Colorado, and the Regenexx® Procedure involves merely the *in vivo* use of a patient's own stem cells for the treatment of an injury. Regenerative does not sell or distribute any product or stem cells in interstate commerce.

The 2010 Inspection.

17. On June 2, 2010, FDA served a Notice of Inspection on Regenerative. That notice erroneously identified Regenerative as a drug manufacturer.

18. FDA spent approximately two weeks inspecting Regenerative in June, 2010. The FDA, during that two week period, had investigators with a specialty in investigating drug manufacturers inspect the facility.

19. On June 16, 2010, the FDA conducted an exit interview with personnel from Regenerative. During that exit interview, FDA provided Regenerative with a Form 483 for the 2010 inspection. The Form 483 identifies Regenerative as a drug manufacturer, which it is not.

20. During the exit interview, FDA personnel stated in response to questions from Regenerative personnel that prior to the inspection, the decision was made at FDA that Regenerative is a drug manufacturer. This was stated three times during the exit interview. Regenerative personnel asked the FDA personnel how that decision could be challenged. FDA personnel stated that the decision had already been made and that they had been given instructions by their superiors to inspect Regenerative as a drug manufacturer. Therefore, Regenerative must comply with the Form 483 observations.

21. During the exit interview on June 16, 2010, an FDA investigator threatened Regenerative personnel that the consequences for failing to remedy observations of non-compliance in a Form 483 include a warning letter, C&D Letter, Civil Penalties, and a Court injunction to compel compliance under threat of closure and criminal prosecution.

22. The Form 483 provided to Regenerative identifies a number of alleged compliance deficiencies at Regenerative that are only pertinent to a drug manufacturer. Regenerative, however, is a medical practice, not a drug manufacturer.

23. Given that the decision that Regenerative is a drug manufacturer was already made by FDA, and FDA is conducting inspections of Regenerative consistent with the decision that Regenerative is a drug manufacturer, any attempt at obtaining administrative relief is futile obviating Regenerative's need to exhaust administrative remedies as to that decision..

24. FDA investigators have refused to hear any arguments from Regenerative that it is not a drug manufacturer, but merely a medical practice regulated by the State of Colorado, stating that decision has already been made.

The 2009 Inspection.

25. Back in February, 2009, FDA served a notice of inspection on Regenerative. Inspections by the FDA of Regenerative's Clinic were conducted on February 23 through March 17, 2009; March 19-23, 2009; April 8 and April 15, 2009. On April 15, 2009, the FDA issued Regenerative "inspectional observations," on a FDA Form 483.

26. The Form 483 stated that the FDA believes that Regenerative is "manufacturing a biological drug....without an Investigational New Drug Application (IND)."

27. Regenerative did not institute any proposed remedial measures to address FDA's concerns regarding the purported manufacturing of a drug, because the FDA had no jurisdiction to regulate Regenerative's medical practice, the proposed remedial measures did not impact patient safety, and FDA's inspectional observations were wholly unsuitable for a medical practice as opposed to a drug manufacturer.

28. FDA provided no forum, final agency action and did not accept any arguments from Regenerative that it was not a drug manufacturer. The decision had already been made.

Irreparable Harm

29. Responding to an FDA inspection is onerous and disruptive. Regenerative had to allocate multiple employees to assist FDA with its inspection and to respond to requests for information and documentation. Dr. Centeno of Regenerative had to transfer patients to another physician at the Clinic in order for him to deal with the requirements of the FDA inspectors. He spent more than 16 hours with inspectors and gathering information for their requests.

30. Regenerative's office manager spent approximately 32 hours copying documents and retrieving information during the FDA's inspection.

31. Regenerative's Practice Administrator spent approximately 24 hours retrieving documents and meeting with inspectors during the FDA's inspection.

32. Physicians at the Clinic had their practices interrupted and were otherwise distracted from patient care due to the interference from FDA investigators.

33. Lost overhead expense in the form of salaries and employment costs exceeded $16,000 due to the FDA's two week long inspection.

34. Due to the FDA attempting to exercise jurisdiction over the practice of medicine at Regenerative and the uncertainty such attempted exercise of jurisdiction and authority creates, investors have declined to invest in Regenerative. These investors have expressly stated that the reason for declining investment was the uncertainty created by the FDA's attempted regulation of Regenerative.

35. When the anticipated C&D letter or other enforcement action is issued and published by the FDA due to Regenerative's non-compliance with regulations and procedures governing drug manufacturers, Regenerative's patients will terminate dealings with the Clinic

due to the FDA's C&D letter. When this occurs, Regenerative will incur and suffer the following:

a. Regenerative currently has 43 patients scheduled for reinjections of their own stem cells. These patients paid Regenerative $236,500 for their procedures, and will demand refunds when the FDA issues a C&D letter.

b. Regenerative currently has 242 patients' stem cell samples in cryostorage, totaling over 1 million cells. Each of these 242 patients paid Regenerative $5-8,000 each for stem cell treatments. If Regenerative were to shut its doors due to a C&D letter, these samples would become unavailable and useless for stem cell treatment; patients will demand their money back.

c. When FDA issues its C&D letter or otherwise engages in any enforcement action, Regenerative will become liable for in excess of $1 million dollars in claims from patients. This will happen even though Regenerative was given no opportunity or forum to explain and argue to FDA why it is not a drug manufacturer; it is a medical practice exempt from FDA regulation.

d. Drs. Centeno and Schultz will be prevented from practicing stem cell therapy medicine.

e. Regenerative will be forced out of business.

The FDA Cannot Regulate the Practice of Medicine and Therefore Cannot Regulate Regenerative

36. The practice of medicine as recognized by the state in which the practicing physician practices – which includes the manipulation of stem cells, in the normal course of medical practice – is not regulated by FDA under the authority of the PHSA or the FDCA.

37. Similarly, a licensed physician's manipulation of bone marrow, in the normal course of medical practice, as recognized by the state in which the physician is licensed to practice, is not regulated by FDA under the authority of the PHSA or the FDCA.

38. Regenerative's activities are not within the scope of FDA regulation and oversight.

39. The Regenexx® Procedure, which is conducted solely within the State of Colorado, does not involve any interstate sale or distribution of any product. Consequently, Regenerative's medical practice invokes no aspect of federal regulatory jurisdiction.

40. The FDA has jurisdiction over neither the Regenexx® Procedure nor Regenerative's exclusive provision of laboratory services to the Centeno Schultz Clinic.

41. A bona fide, actual and present practical need for a declaration exists as to the rights and obligations of the parties.

42. The declaration concerns a present, ascertained or ascertainable state of facts or presents a controversy as to a state of facts.

43. An immunity, power, privilege or right of the Plaintiff is dependent upon the facts or the law applicable to the facts.

44. The actions of the Defendants will cause Regenerative to suffer irreparable and unnecessary harm to its business existence, reputation and character because of the decision made by the FDA that it is a drug manufacturer.

45. Regenerative will suffer irreparable and unnecessary injury to its finances, business, growth, and development because of the public dissemination of a Form 483 or a C&D letter by the FDA on its website and other media outlets which will label it a drug manufacturer,

which is false. Regenerative will also suffer irreparable harm in the event that the FDA seeks an ex-parte injunction from federal court to enforce the terms of a C&D letter.

CLAIMS FOR RELIEF

COUNT I

The Regenexx® Medical Procedure Constitutes the Practice of Medicine and is Beyond the Scope of the FDA's Regulatory Authority and Jurisdiction

46. Regenerative repeats and realleges paragraphs 1-45 as though fully alleged herein.

47. The Regenexx® medical procedure is performed by physicians lawfully licensed to practice medicine in the State of Colorado.

48. The Regenexx® medical procedure is performed only in the State of Colorado. No interstate distribution of product or stem cells occurs.

49. A licensed physician's use of stem cells and other tissue, taken from a patient, and placed back into that same patient to treat the patient's maladies, in the normal course of the physician's medical practice as recognized by the state in which the physician is licensed to practice, constitutes the Practice of Medicine and is not regulated by FDA under the authority of the FDCA or PHSA.

50. A licensed physician's manipulation of stem cells, bone marrow, autologous, allogenic, homologous or non-homologous, in the normal course of medical practice, recognized by the state in which the physician is licensed to practice, is not regulated by FDA under the authority of the FDCA and PHSA.

51. In the case of a licensed physician's use of stem cells, Congress has clearly precluded the FDA from asserting jurisdiction to regulate the practice of medicine.

52. In light of Congress's intent, the FDA's assertion of jurisdiction over the practice of medicine is precluded. Accordingly, the FDA is without authority to engage in the following:

a. Issuance of a Form 483 establishing that the medical practice of Regenerative is a drug manufacturing establishment;

b. Issuance of a C&D letter based on non-compliance with the Form 483;

c. Any ex-parte application for an injunction from a federal court to shut down Regenerative based on non-compliance with a C&D letter.

53. Enforcement of a C&D letter through the ex-parte application to a federal court for an injunction closing Regenerative will cause it irreparable harm.

54. The FDA's actions are in excess of statutory authority or limitations.

55. The FDA's actions are unwarranted by the facts.

56. There is a substantial likelihood that Plaintiff will succeed on the merits of its claim.

57. Plaintiff does not have an adequate remedy at law.

58. Defendants will not suffer irreparable harm or substantial hardship if injunctive relief is granted in Plaintiff's favor.

59. The public interest weighs in favor of injunctive relief in order to protect patients who need treatment at the Regenerative facilities for a variety of maladies and to preserve their access to stem cell treatment.

WHEREFORE, Regenerative respectfully requests that this Honorable Court **a)** enter a judicial decision pursuant to 28 U.S.C. § 2201 *et.seq.* declaring that the Regenexx® medical procedure constitutes the Practice of Medicine which is beyond the jurisdiction of the FDA; **b)** enjoin the FDA from regulating the Regenexx® medical procedure and otherwise publishing the Form 483 **c)** enjoin the FDA from issuing a Cease & Desist Letter and **d)** enjoin the FDA from any ex-parte action seeking to stop Regenerative from engaging in the practice of medicine; **e)**

assess costs and attorneys' fees; and **f)** grant such other relief that the Court may deem just and proper.

COUNT II

The Federal Food, Drug, and Cosmetic Act (FDCA), Does Not Give the FDA Jurisdiction Over Regenerative Because It Does Not Engage In Interstate Sale or Distribution of Any Products

60. Regenerative repeats and realleges paragraphs 1-45 as though fully alleged herein.

61. Regenerative is engaged in the practice of medicine wholly within the State of Colorado.

62. 21 U.S.C. Sec. 355 provides that no person shall introduce or deliver for introduction into interstate commerce any new drug without FDA approval.

63. All activities at Regenerative's laboratory exclusively serve the Centeno Schultz Clinic and the practice of medicine that occurs there. Both are located near each other in Colorado.

64. Neither Regenerative nor the Centeno Schultz Clinic engage in the interstate sale or distribution of any product, nor have they introduced, or delivered for introduction, any drugs into interstate commerce.

65. The FDCA does not grant the FDA jurisdiction to regulate the purely intrastate activities of a medical practice.

66. Regenerative will suffer irreparable harm as a result of the public dissemination of the Form 483.

67. Regenerative will suffer irreparable harm as a result of the issuance of any C&D letter or any other action posted on the FDA's website for the general public's consumption.

68. Enforcement of a C&D letter through the ex-parte application of the FDA for a federal court injunction against Regenerative will cause it to suffer irreparable harm.

69. Regenerative will suffer irreparable harm as a result of being forced to spend substantial funds to institute drug manufacturer protocols when it is not a drug manufacturer.

70. The FDA's actions are in excess of statutory authority or limitations.

71. The FDA's actions are unwarranted by the facts.

72. There is a substantial likelihood that Plaintiff will succeed on the merits of its claim.

73. Plaintiff does not have an adequate remedy at law.

74. Plaintiff will suffer irreparable harm if injunctive relief is not granted in its favor.

75. Defendants will not suffer irreparable harm or substantial hardship if injunctive relief is granted in Plaintiff's favor.

76. The public interest weighs in favor of the granting of injunctive relief in favor of Plaintiff in this case in order to protect patients who need treatment at the Regenerative facilities for a variety of maladies and to preserve their access to stem cell treatment.

WHEREFORE, Regenerative respectfully request that this Honorable Court **a)** enter a judicial decision, pursuant to 28 U.S.C. § 2201 *et.seq.*, declaring that the FDCA does not give the FDA jurisdiction to regulate Regenerative since it does not engage in the interstate sale or distribution of a product; **b)** enjoin the FDA from regulating the Regenexx® medical procedure; **c)** enjoin the FDA from issuing a Cease & Desist Letter; **d)** enjoin the FDA from any ex-parte action seeking to stop or enjoin Regenerative from using the Regenexx® procedure; **e)** assess costs and attorneys' fees; and **f)** grant such other relief that the Court may deem just and proper.

COUNT III

The FDA's Actions Deprive Regenerative of Due Process of Law Pursuant to the Fifth Amendment of the Constitution

77. Regenerative realleges paragraphs 1-45 as though fully alleged herein.

78. The FDA is asserting its authority to inspect and regulate Regenerative and will serve a C&D letter on Regenerative and seek other enforcement action when it does not have jurisdiction to do so, as the FDA does not regulate the practice of medicine.

79. The FDA has refused to accept or consider arguments from Regenerative that it is not a drug manufacturer but instead a medical practice, and engages in no interstate sale or distribution of a product, which make it exempt from FDA regulation.

80. The service and publication of a C&D letter on Regenerative's medical practice will cause irreparable harm to it due to the bad publicity such a letter would cause and because patients will choose not to be treated at Regenerative while it is under the cloud of a C&D. This will result in the closure of Regenerative and will also result in it incurring liability to patients for treatments which cannot be completed or cannot be performed.

81. Furthermore, the service and publication of a C&D letter will render it impossible for Regenerative to seek and obtain additional investment funds in order to fund and grow its business.

82. The service and publication of a C&D letter followed by the ex parte application by FDA for a court injunction against Regenerative will cause Regenerative to close its doors and to lay off employees and professionals employed at Regenerative even though FDA has no jurisdiction to regulate Regenerative.

83. Administrative remedies are futile in that the issuance of the C&D letter itself will cause irreparable harm to Regenerative, and because a decision has already been made at FDA, without input from Regenerative, and without final agency action, that it is a drug manufacturer.

84. Administrative remedies are futile as FDA has already decided it has the authority and jurisdiction to regulate Regenerative's practice of medicine as a drug manufacturer, without an adjudicatory decision nor without judicial consent or decision.

85. The defendants' actions, will deprive Plaintiff of its business, property and right to practice medicine without Due Process of Law in violation of the Fifth Amendment to the Federal Constitution.

86. The FDA's actions are in excess of statutory authority or limitations.

87. The FDA's actions are unwarranted by the facts.

88. There is a substantial likelihood that Plaintiff will succeed on the merits of its claim.

89. Plaintiff does not have an adequate remedy at law.

90. Plaintiff will suffer irreparable harm if injunctive relief is not granted in its favor.

91. Defendants will not suffer irreparable harm or substantial hardship if injunctive relief is granted in Plaintiff's favor.

92. The public interest weighs in favor of the granting of injunctive relief in favor of Plaintiff in this case as it will protect the rights of physicians to practice medicine and of the several states to regulate the practice of medicine. In addition, the granting of injunctive relief will allow patients to obtain the benefits of stem cell therapy to treat maladies and as such injunctive relief will be in favor of the public health.

93. WHEREFORE, Regenerative respectfully request that this Honorable Court **a)** enter a judicial decision, pursuant to 28 U.S.C. § 2201 *et.seq.*, declaring that the FDCA does not give the FDA jurisdiction to regulate the practice of medicine; **b)** enjoin the FDA from regulating the Regenexx® medical procedure; **c)** enjoin the FDA fromissuing a Cease & Desist Letter; **d)** enjoin the FDA from any ex-parte action seeking to stop or enjoin Regenerative from using the Regenexx® procedure; **e)** assess costs and attorneys' fees; and **f)** grant such other relief that the Court may deem just and proper.

Dated: June 22, 2010.

REGENERATIVE SCIENCES, INC.

By: /s/

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