IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

REGEN BIOLOGICS, INC., a Delaware Corporation 411 Hackensack Avenue, 10th Floor Hackensack, New Jersey 07601 Plaintiff	:	CIVIL ACTION NO.
v.	:	
KATHLEEN SEBELIUS, Secretary of Health and Human Services (in her official capacity) 200 Independence Avenue, S.W. Washington, D.C. 20201	:	Case: 1:11-cv-01006 Assigned To : Wilkins, Robert L. Assign. Date : 5/31/2011 Description: Admn. Agency Review
MARGARET A. HAMBURG, M.D., Commissioner of Food and Drugs (in her official capacity) 1007 Switzer Building 330 C St., S.W. Washington, D.C. 20204	:	
U.S. FOOD AND DRUG ADMINISTRATION 10903 New Hampshire Avenue Silver Spring, Maryland 20903 Defendants	:	

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff ReGen Biologics, Inc. ("ReGen"), by and through its attorneys, for its Complaint hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action to review and set aside a final action of the United States Food and Drug Administration ("FDA") pursuant to the Administrative Procedure Act ("APA"), 5

U.S.C. § 702 *et seq.*, and for related declaratory relief under 28 U.S.C. § 2201-02 and an injunction. The action relates to a device manufactured by ReGen known as the Collagen Meniscus Implant ("CMI"). By letter dated December 18, 2008 (attached as Exhibit A1), FDA classified the CMI as a "Class II" device under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FD&C Act"), finding that it was substantially equivalent to a legally marketed predicate device, a surgical mesh. Based upon this classification, ReGen undertook the commercial distribution of the CMI in the United States. Subsequently, a new director of the agency's Center for Devices and Radiological Health ("CDRH") sought to overturn the final agency action of his predecessor. On March 30, 2011, the FDA issued a letter (attached as Exhibit B) purporting to rescind its prior classification of the CMI as a Class II device. The purported purpose and effect of this ruling was to reclassify the device into Class III. As a result, the device could not be legally distributed in the United States without FDA's approval. As a direct result of this FDA action, ReGen was forced into bankruptcy.

2. Pursuant to the APA, ReGen now seeks an order setting aside the March 30, 2011 rescission letter as arbitrary, capricious, an abuse of discretion and not in accordance with law, and in excess of statutory jurisdiction, authority and limitations, within the meaning of 5 U.S.C. § 706(2)(A) and (C), and declaring that the purported rescission is unlawful and a nullity. Further, ReGen seeks injunctive relief from the Court to require FDA to obey its laws and regulations insofar as the classification status of the CMI device is concerned, and to cease release of information about the CMI, except under the Freedom of Information Act, 5 U.S.C.

§ 552, or pursuant to lawful process, and distribution of information that is intended to discourage persons from using the device, except pursuant to lawful authority.

PARTIES

3. ReGen is a publicly held Delaware corporation with its principal place of business located at 411 Hackensack Avenue, 10th Floor, Hackensack, New Jersey 07601. ReGen filed a Chapter 11 bankruptcy petition in the United States Bankruptcy Court for the District of Delaware on April 8, 2011, and now functions as a debtor-in-possession.

4. Defendant Kathleen Sebelius is the Secretary of Health and Human Services ("Secretary"), and as such is responsible for the regulation of devices under the FD&C Act. Secretary Sebelius is sued here in her official capacity only. The Secretary's office is located at 200 Independence Avenue, S.W., Washington, D.C. 20201.

5. Defendant Margaret A. Hamburg, M.D., is the Commissioner of Food and Drugs ("Commissioner"). As the senior official of the FDA, she possesses responsibility delegated from the Secretary for the regulation of devices under the FD&C Act. Commissioner Hamburg is sued here in her official capacity only. The Commissioner has an office located at 1007 Switzer Building, 330 C St., S.W., Washington, D.C. 20204.

6. Defendant FDA, an agency of the United States Government within the Department of Health and Human Services, has responsibility for the regulation of devices under the FD&C Act, as directed by the FD&C Act and delegated by the Secretary. The headquarters

and principal place of business of the FDA is 10903 New Hampshire Avenue, Silver Spring, Maryland 20903.

JURISDICTION AND VENUE

7. This Court has original subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 702.

8. Venue in this Court is proper pursuant to 28 U.S.C. § 1391(e).

REGULATORY FRAMEWORK

9. Under the FD&C Act devices are classified into one of three regulatory classes that describe the controls necessary to provide reasonable assurance of safety and effectiveness. *See* § 513(a)(1)(A) – (C) (21 U.S.C. § 360c(a)(1)(A) – (C)). Class I devices are the least risky and the FD&C Act's general misbranding and adulteration controls are adequate to provide such an assurance. Class II devices range from the most risky to those of considerably less risk for which Class I controls are inadequate and sufficient information exists to establish special controls to reasonably assure safety and effectiveness. Class III devices represent the most risky devices, *i.e.*, those devices that are life-supporting or life-sustaining, of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury, and for which not enough is known to place them into Class II to provide a reasonable assurance of safety and effectiveness.

10. Devices are also identified as preamendment, new (or postamendment), or transitional devices.

11. A "preamendment" device is one that was introduced or delivered for introduction into interstate commerce *before* May 28, 1976, the enactment date of the "Medical Device Amendments of 1976." Preamendment devices were classified by FDA by generic types, *i.e.*, groups of devices that do not differ significantly in purpose, design, material, function or other features related to safety and effectiveness and can be effectively regulated by similar controls, *see* 21 CFR § 860.3(i). These preamendment generic types of devices were reviewed by classification panels of experts. After review, these expert panels made classification recommendations to FDA. Thereafter, the FDA classified these generic types of devices through rulemaking. There were about 1,500 generic types of preamendment devices. Congress chose to classify new or postamendment devices differently. By the nature of their development, new devices would come into existence one-by-one, and therefore, rulemaking would be an inefficient and impractical way to classify them.

12. This case involves the classification of what is known as a "new" or "postamendment" device, *i.e.*, a device first proposed for introduction into interstate commerce *on or after* May 28, 1976. For new devices, Congress set up a premarket notification system to achieve an initial classification for each new device. Under section 510(k) (21 U.S.C. § 360(k)), persons required to register, *e.g.*, manufacturers, would have to notify FDA 90 days before introducing, or delivering for introduction, a device into interstate commerce for commercial distribution. Under the FD&C Act, this notification was to be in a form of report that FDA would specify in regulations. Such a report would provide the agency information to classify each new device to determine the regulatory controls applicable to each such device. The

method for classifying devices subject to 510(k) premarket notification is described in section 513(f)(1) of the FD&C Act (21 U.S.C. § 360c(f)(1)).

13. Under section 513(f)(1) of the FD&C Act (21 U.S.C. § 360c(f)(1)), if a new device is substantially equivalent to a preamendment device, then it takes on the same classification status as that preamendment device. For example, the CMI, at issue in this action, was found to be substantially equivalent to a Class II surgical mesh already on the market; the CMI was therefore classified in the same Class II status and subject to the same regulatory controls as marketed surgical meshes. If, however, a new device is not substantially equivalent to a preamendment device, it is automatically classified into Class III. Such a Class III device would require premarket approval of its safety and effectiveness from the FDA prior to marketing because of its novelty, unless the device was reclassified under the FD&C Act into Class I or II, *see* § 513(f)(3) (21 U.S.C. § 360c(f)(3)) (reclassification provision for not substantially equivalent new devices). Devices found substantially equivalent to preamendment devices are reclassified under section 513(e) (21 U.S.C. § 360c(e)), the reclassification provision for preamendment devices, because preamendment devices define the classification of these new devices.

14. In 1990, Congress added section 513(i) (21 U.S.C. § 360c(i)) to, among other things, further define substantial equivalence. Now, by statute, any legally marketed device (including a "new" device) may serve as a predicate for classifying other new devices. With limited exceptions not relevant here, each such "predicate" device, however remote from its

preamendment ancestor, stands on the same footing as a preamendment device for purposes of serving as a predicate for classification and reclassification.

15. Historically, greater than 95% of devices have gone to market through the 510(k) premarket notification process. New devices that are found substantially equivalent to predicate devices typically may proceed directly to market because there are no additional premarket requirements for Class I or II devices, or Class III preamendment devices not yet subject to premarket approval requirements, prior to marketing. A device classification under the 510(k) premarket notification process, however, is not an approval. Indeed, under FDA regulations, any representation that a 510(k) classified device is "approved" is a misbranding. *See* 21 CFR § 807.97 ("[a]ny representation that creates an impression of official approval of a [510(k)] device" will misbrand the device).

16. Congress was clear that the remedy for an incorrect classification was reclassification. To that end, Congress created separate reclassification provisions for each category of device: preamendment, postamendment (or new) and transitional devices. ("Transitional" devices were placed into Class III by law to ensure continuity of regulation because before the enactment of the "Medical Device Amendments of 1976" these devices were regulated as new drugs.) Section 513(e) (21 U.S.C. § 360c(e)) provides for reclassification by regulation of preamendment devices and those devices substantially equivalent to them, mimicking the original means of classification of preamendment devices. Section 513(f)(3) (21 U.S.C. § 360c(f)(3)) provides for reclassification of not substantially equivalent postamendment devices by order, reflecting that new device classification is determined by order and derived

from the FD&C Act's automatic classification process for devices found not substantially equivalent under section 513(f)(1) of the FD&C Act (21 U.S.C. § 360c(f)(1)). Section 520(l)(2) (21 U.S.C. § 360j(l)(2)) also provides for reclassification of transitional devices by order. When appropriate, the reclassification process for preamendment, postamendment, or transitional devices is defined by sections 513(e), 513(f)(3) and 520(l)(2), respectively; these are the only authorities under the FD&C Act that permit reclassification of preamendment, postamendment and transitional devices.

17. There is no explicit or implicit authority in the FD&C Act to change a device's classification through rescission. Reclassification of the CMI was entirely inappropriate under the FD&C Act. Were reclassification of the CMI appropriate, the only authority that provides the process to reclassify the type of device is contained in section 513(e) of the FD&C Act (21 U.S.C. § 360c(e)). The attempt to change the CMI's Class II status through FDA's so-called rescission authority was without legal basis.

FACTUAL BACKGROUND

18. The menisci are half-moon shaped pieces of soft tissue of the knee that are between the ends of the thigh bone (femur) and the shin bone (tibia). They function to distribute body weight on the knee joint to prevent damage to the underlying articular cartilage (dense soft tissue that covers the ends of the bones of the knee). The menisci also act as shock absorbers and secondary stabilizers, and they provide joint lubrication and nutrition for the articular cartilage. Meniscus injuries are among the most common injuries seen and treated by orthopedic surgeons. Most people who suffer from meniscus tears will have no alternative but to have a surgical

procedure known as a partial meniscectomy that will leave them with a permanent loss of meniscus volume.

19. The CMI is a resorbable collagen-based surgical mesh composed primarily of bovine type I collagen. It is used to reinforce damaged or weakened meniscal soft tissue in the knee and to provide a resorbable scaffold for replacement by a patient's own soft tissue. The CMI is provided in a semi-lunar shape, consistent with the anatomy of the knee, and is reshaped by surgeons to fit the void created by the removal of damaged cartilage in a partial meniscectomy procedure. Partial meniscectomy is a minimally invasive arthroscopic procedure that has been the standard of care for decades. A partial meniscectomy is not done to install a CMI, although the CMI may be used in the context of a partial meniscectomy procedure, when appropriate. A partial meniscectomy is a minimally invasive procedure, whether or not a CMI is part of the surgical plan.

20. The name Menaflex was adopted as the product name for US marketing of the CMI device. The device was known throughout most of its development and European marketing as the Collagen Meniscus Implant ("CMI") and is still distributed outside the US under that name. For purposes of the US regulatory submissions the device was referred to as the Collagen Scaffold ("CS").

21. In Europe, the CMI received certification to market in 2000 for use in medial meniscus injuries and in 2006 for use in lateral meniscus injuries. Over the last ten years, it has been used in Europe in almost 3000 surgeries with very good results.

22. Neither the labeling nor indications for use suggest that the CMI should be used to replace torn meniscus tissue that can be repaired surgically. Like other surgical meshes, its use is limited to repairing and reinforcing compromised tissue.

REGEN'S JULY 22, 2008 510(K) SUBMISSION AND THE ORIGINAL FDA ORTHOPEDIC ADVISORY PANEL FINDINGS AND RECOMMENDATIONS

23. Following the suggestion of Dr. Schultz, the then Director of FDA's Center for Devices and Radiological Health ("CDRH"), on July 22, 2008, ReGen submitted a 510(k) premarket notification with an indication for use limited to patients with chronic meniscus injuries.

24. On August 18, 2008, ReGen representatives and CDRH spoke by phone. The call included two ReGen employees and an orthopedic surgeon who was an investigator in the Menaflex multicenter clinical trial and an author of the *Journal of Bone and Joint Surgery* article that was relied upon in ReGen's 510(k) premarket notification submission, *see* Rodkey WG, DeHaven KE, Montgomery WH 3rd, et al., (2008), Comparison of the collagen meniscus implant with partial meniscectomy; a prospective randomized trial, *J Bone Joint Surg Am* 90(7):1413–1426. CDRH's representatives included Dr. Schultz, Mr. Melkerson (Director, Division of General, Restorative and Neurological Devices), Dr. Buch (Deputy Director, Division of General, Restorative and Neurological Devices), and Les Weinstein (the CDRH Ombudsman).

25. It was clear from the call that the review team representatives and Dr. Schultz were applying an incorrect review standard -- as the FDA itself later acknowledged in a

September 2009 Report, discussed *infra*. Specifically, the FDA requested a showing that the CMI was superior to partial meniscectomy in the primary outcomes measures of the clinical trial. This comparison of a device to a procedure is contrary to what the law requires: sections 513(f)(1) and 513(i) (21 U.S.C. § 360c(f)(1) and (i)) require a comparison of a new device to a legally marketed device to determine the new device's classification. Under the FD&C Act, a device classification cannot be legally determined by comparing a device to a procedure.

26. On October 8, 2008, ReGen received a letter from Dr. Schultz stating that the review of ReGen's 510(k) premarket notification submission would include advice and recommendations from an independent group of experts in the field of orthopedic surgery and sports medicine. Accordingly, an FDA-convened Orthopedic Advisory Panel ("Panel") was scheduled for November 14, 2008.

27. ReGen shared with FDA its concerns that the agency was applying an incorrect review standard to its premarket notification submission and that none of the more than 400 surgical meshes classified under the FDA's 510(k) premarket notification classification procedure, including those with new indications for use, had required an Advisory Panel review. These concerns notwithstanding, the FDA decided to move forward with the Advisory Panel. Meanwhile, other pressures (not fully known to ReGen at the time) were apparently driving the FDA's decision to move forward with a public Panel instead of a more normal "homework assignment" that would involve referring device premarket review questions to two or three panel members for their informal review. A November 17, 2008 New York Times article revealed that on October 14, 2008, a group of eight FDA scientists/reviewers had sent a letter to

Congress alleging generally that managers at CDRH had interfered with the scientific review of medical devices (the letter did not include any reference to ReGen). *See FDA Scientists Accuse Agency Officials of Misconduct*, New York Times, November 18, 2008.

28. The article further explained that on May 31, 2008, this same group of scientist/reviewers sent a similar letter to FDA Commissioner von Eschenbach, who assigned the FDA's Assistant Commissioner for Integrity and Accountability to investigate. The Assistant Commissioner is the same person who was simultaneously vetting all interactions between ReGen and CDRH, in response to the company's allegations that CDRH staff scientists were applying the wrong review standard to ReGen's submission.

29. The Orthopedic Advisory Panel Meeting on November 14, 2008, lasted almost seven hours. It included a detailed discussion of all of the FDA's questions and issues, and there was input obtained from each Panel member on every FDA question.

30. On the whole, the Panel's recommendations were favorable to the CMI, and the FDA's publicly released Panel summary stated that "[t]he Panel generally believed that the ReGen CS was able to withstand physiological forces, would foster ingrowth of unorganized fibrocartilage tissue, was appropriate for both acute and chronic meniscal soft tissue injuries, and was as safe and effective as the predicate devices." The predicate devices to which the expert panel found that the CMI had equivalent safety and effectiveness were all classified as Class II surgical meshes by the FDA.

31. On December 18, 2008, ReGen received a letter from the FDA that classified the device into Class II because it was substantially equivalent to a legally marketed device, a surgical mesh. *See* Exhibit A1. The Director of CDRH provided the basis for his December 18 substantially equivalent decision in two documents. *See* Exhibits A2 & A3. As a result, ReGen could begin commercial distribution of the CMI because there were no additional premarket barriers to marketing a Class II surgical mesh. Surgical meshes are preamendment devices classified into Class II by regulation (21 CFR § 878.3300), and now include a broad variety of meshes as a result of the 510(k) premarket notification process -- for example, resorbable surgical meshes like the CMI.

32. In reliance on the FDA's Class II designation for the CMI, ReGen incurred substantial expenses in preparation for marketing and selling the CMI to the US market. The company first commercially distributed the device in the United States on April 10, 2009.

33. In particular, ReGen hired: (1) marketing and sales people for the US, including a Vice-President of Marketing; (2) a process engineer to allow its manufacturing division to manufacture an increased number of the CMI devices; (3) employees to help train surgeons (and ReGen incurred the expenses needed to run courses that were used to train more than 140 surgeons in the US); (4) outside consultants to work on developing marketing and sales materials to support the US marketing of the product (and ReGen purchased marketing materials related to those efforts); and (5) consultants to work on US reimbursement.

34. ReGen also began manufacturing enough product to support sales in the US for the first year after receipt of FDA's order classifying the device into Class II.

FDA'S SEPTEMBER 24, 2009 REPORT CREATED A PRETENSE TO JUSTIFY RE-REVIEW OF THE CMI CLASS II STATUS

35. On March 6, 2009, the Wall Street Journal ran an article about the CMI entitled *Political Lobbying Drove FDA Process.* Upon information and belief, the article included information that was not released by FDA under the Freedom of Information Act, not included in the FDA's or ReGen's publicly available panel materials, and not made public by ReGen. ReGen is unaware of any lawful basis for the reporter's possession of internal agency documents.

36. On May 11, 2009, three members of the United States House of Representatives' Committee on Energy and Commerce that has oversight over the FDA sent a letter to Dr. Joshua M. Sharfstein, the recently appointed Principal Deputy Commissioner and Acting Commissioner of FDA. The Congressmen's letter cited documents from FDA scientists that expressed concerns about the CMI's substantial equivalence determination and asked Dr. Sharfstein to look into this matter.

37. In September 2009, the FDA issued a preliminary report entitled: "Review of the ReGen Menaflex: Departures from Processes, Procedures and Practices Leave the Basis for a Review Decision in Question." That September 2009 Preliminary Report concludes that during the review of the CMI there were a number of departures from FDA processes, procedures and practices, departures that undermined the ability of the FDA to withstand alleged lobbying on behalf of ReGen. It further concludes that a "focused scientific reevaluation of the decision to clear the CS device is warranted," although neither impugning the Advisory Panel's findings or recommendations, nor providing evidence that the device was unsafe or ineffective.

38. While the September 2009 Preliminary Report purports to be a balanced account of the FDA's internal investigation of its processes related to the review and classification of the CMI, it contains inaccuracies, misrepresentations, and speculative conclusions, and it omits material information. The preliminary report purports to identify internal FDA problems, but essentially attributes them to an outsider, ReGen.

39. The FDA issued the September 2009 Preliminary Report without soliciting any input from ReGen, although the company offered to participate in FDA's review. ReGen, in a March 12, 2010 letter to Commissioner Hamburg, identified numerous inaccuracies, misrepresentations, and omissions of material information in the September 2009 Preliminary Report. The FDA and the Commissioner failed to respond, despite 45 CFR § 17.7 that requires the head of an agency to issue a retraction or correction of misleading information or misstatements of fact.

40. Following the September 2009 Preliminary Report, the FDA permitted the CMI to remain on the market for one and a half years, and it did not take any steps to enjoin the use of the device.

41. At the September 24, 2009 Media Briefing on the FDA's Preliminary Report, CDRH Director Dr. Jeffrey Shuren was asked " . . . What is the status of this product and is it safe?" His response was:

> The device has been cleared by the FDA. And we have no basis to question the safety of this device. So it will remain on the market. What we have concluded is the integrity of our process for reaching a decision was compromised in this case and so we are

revisiting and re-evaluating the record and the basis for making that decision.

FDA CONVENES UNPRECEDENTED SECOND ORTHOPEDIC ADVISORY PANEL MEETING

42. On October 7, 2009, ten months after the CMI was classified by FDA into Class II, Dr. Schultz's successor as the director of CDRH, Dr. Shuren, and two members of his staff met with ReGen representatives to explain the process the FDA would follow for an unprecedented re-examination of the CMI 510(k) Class II designation. Dr. Shuren laid out a 180-day timeline with milestones. He further stated that the review team would include a core of reviewers who were not directly involved in the original review, but that certain managers involved in the original review would be involved in the re-examination. He stated that the review team would conduct its review, go through the administrative record, contact ReGen with any questions it had, and then present its findings to senior CDRH supervisors and ultimately to him. At no time did Dr. Shuren or his staff identify a legal basis for the process FDA would pursue to reopen the classification of the CMI device.

43. Dr. Shuren stated that if the review team or the record did not support the CMI's substantial equivalence to a predicate device, then a new Orthopedic Advisory Panel would be convened. Dr. Shuren informed ReGen that within forty to sixty days of the Advisory Panel Meeting, the FDA would notify ReGen of its final decision.

44. During this re-review of ReGen's Class II device, ReGen expressed concerns regarding the review process. These concerns included the FDA's application of an improper review standard different from that prescribed by law, and the agency's treating the CMI

differently from other surgical meshes that were classified into Class II through the premarket notification process under sections 510(k) and 513(f)(1) and (i) (21 U.S.C. §§ 360(k) and 360c(f)(1) and (i)).

45. On January 11, 2010, Dr. Shuren notified ReGen that the FDA would be bringing the CMI issues to a second and unprecedented Orthopedic Advisory Panel Meeting on March 23, 2010. Although ReGen believed that Advisory Panel review was inappropriate, the company had no choice but to participate in the panel meeting.

46. The FDA's questions to the Advisory Panel for that meeting and the Advisory Panel procedures prejudiced ReGen. Specifically, the FDA drafted five groups of questions, each preceded by a descriptive preamble. On the whole, the questions were leading, suggesting negative implications regarding ReGen's data, while failing to describe the positive clinical results described in ReGen's 510(k) clinical data.

47. The consensus of the experts on the Advisory Panel was that the CMI device, like other predicate meshes, functions to reinforce and repair soft tissue. This meant that the CMI had the same intended use as a surgical mesh, which is to "...reinforce soft tissue or bone where weakness exists." After FDA presented the first question to the Advisory Panel, the panel experts concluded that the CMI's intended use was the same as that of its surgical mesh predicates -- *i.e.,* it reinforces and repairs soft tissue and bone -- and it is therefore a surgical mesh. With different agency representatives, the agency twice approached the expert panel to re-ask Question 1. Each time the panel rebuffed the agency's efforts to undo its expert opinion. If the panel had answered in the negative, the conclusion would have been that the CMI is not a

surgical mesh and therefore could not be substantially equivalent to a surgical mesh. However, the Panel's affirmative response that the CMI is a surgical mesh coincided with former CDRH Director Schultz's conclusion when he suggested that the company submit a 510(k) premarket notification to FDA with a modified surgical mesh indication for use. The former CDRH Director is no longer with the FDA.

THE FDA'S DECISION TO SEEK RESCISSION OF THE CMI CLEARANCE

48. On October 14, 2010, CDRH's Director, Dr. Shuren, informed ReGen of his intention to rescind the CMI's Class II designation principally based on his conclusion that the CMI did not have the same intended use as predicate surgical meshes.

49. Dr. Shuren's conclusion is directly at odds with the conclusions of two Advisory Panels of independent experts (selected by the FDA), and the conclusions of Dr. Shuren's predecessor, Dr. Daniel Schultz, who through the appropriate supervisory review procedures, and with the benefit of the expert panel's recommendations, found the device to be substantially equivalent to a predicate surgical mesh.

THE FDA'S MARCH 30, 2011 RESCISSION OF THE CMI

50. On January 14, 2011, the FDA offered ReGen the opportunity to request a hearing, pursuant to 21 CFR Part 16, regarding the proposed rescission of its earlier 510(k) classification determination for CMI. There is no legal basis under the FD&C Act or Part 16 to rescind, or to conduct a hearing on a rescission of, a classification determination under sections 510(k) and 513(f)(1) and (i) (21 U.S.C. §§ 360(k) and 360c(f)(1) and (i)). Title 21 of the Code

of Federal Regulations cannot create substantive authority for FDA, when no such authority exists under the FD&C Act.

51. By letter dated March 21, 2011, ReGen informed the FDA that, in light of ReGen's experiences with the FDA over the last six years, it was the company's position that a Part 16 hearing would be a costly and futile exercise.

52. By letter dated March 30, 2011, the FDA illegally rescinded the CMI's Class II designation that was lawfully obtained from FDA through the premarket notification classification process. (A copy of that letter is attached as Exhibit B.) The March 30, 2011 letter does not include a legal citation or reference to any statutory, regulatory or other basis for rescission of the CMI's Class II designation.

53. At the press briefing held when the FDA issued its Preliminary Report on September 24, 2009, the following question was asked of the FDA: "...I'm wondering what legal authority FDA has to repeal a 510(k) clearance should the subsequent review determine that that's appropriate?" Dr. Shuren, the CDRH Director, responded, "In that circumstance we would move to reclassify the device. And we would up-classify it to a Class III, then it would be subject to pre-market approval application, rather than a 510(k)."

54. On April 8, 2011, on behalf of ReGen, counsel from Gibbons P.C. spoke by telephone with FDA counsel. Counsel for ReGen asked FDA counsel to identify the statutory or regulatory basis for the March 30, 2011 order of rescission so that ReGen could determine the proper forum for review.

55. FDA counsel declined to answer ReGen counsel's telephone inquiry, stating that disclosure of the statutory basis for the order would be the equivalent of providing "legal advice," and that it is FDA's policy not to do so.

56. In an April 8, 2011 letter, counsel for ReGen explained to FDA counsel that:

> Absent knowing what authority the FDA is relying upon, ReGen cannot determine with any certainty the applicable timeframes or jurisdictions in which ReGen must seek any judicial review of the agency's actions. As I indicated, if ReGen elects to pursue judicial review of the FDA's decision, the company would prefer to work openly and together with the FDA to streamline that process, including avoiding protracted litigation. Assuming the FDA agrees with that approach, we see no reason for ReGen to be kept in the dark on these timing issues.

57. Counsel for ReGen has not received a response to the April 8, 2011 letter.

58. There is no statutory or regulatory basis for a rescission of a device classification under sections 510(k) and 513(f)(1) and (i) of the FD&C Act (21 U.S.C. §§ 360(k) and 360c(f)(1) and (i)), and it does not fall within the categories for Court of Appeals review in 21 U.S.C. § 360g. Nonetheless, because the FDA refused to state the legal basis for its order, ReGen filed a protective petition in the Court of Appeals within the applicable 30-day deadline specified in section 360g.

CONSEQUENCES OF THE FDA'S UNLAWFUL RESCISSION ORDER

59. While ReGen continues to manufacture the CMI for its European customers, the FDA's rescission of the device's 510(k) Class II designation effectively bars ReGen from selling

the CMI in the United States without risking prosecution for civil and criminal penalties under the FD&C Act, and the very large cost of defending itself.

60. This result prejudices patients who could benefit from the CMI. For example, a recent publication in the American Journal of Sports Medicine ("AJSM") from the Rizzoli Institute concludes: "Pain, activity level, and radiological outcomes are significantly improved with use of the MCMI [medial Collagen Meniscus Implant] at a minimum 10-year follow-up compared with PMM [partial medial meniscectomy] alone." (*Prospective Long-Term Outcomes of the Medial Collagen Meniscus Implant Versus Partial Medial Menscectomy: A Minimum of 10-Year Follow-Up Study*. Zaffagnini et.al, *Am J Sports Med.* 2011;39(5): 977-985.)

61. FDA removed a safe and effective device from use without the statutory process required under the FD&C Act. During the extended marketing period after the release of the FDA's September 24, 2009 Preliminary Report, FDA never brought an enforcement action against ReGen. Had it done so, it would have had the burden of proof to demonstrate that the device was unsafe or ineffective, or otherwise not in compliance with the law. The agency did not bring any enforcement action.

62. Additionally, the FDA's rescission action against the CMI creates substantial uncertainty in the device industry because the FDA could decide to revisit other products that were legally classified through the 510(k) premarket notification process without observing lawful processes.

63. As a result of negative press, the issuance of the September 2009 Preliminary Report, and the March 30, 2011 rescission order, ReGen was forced to lay off many of its employees, including all of its U.S. marketing and sales personnel.

64. ReGen is a startup company manufacturing a beneficial device that expert panels twice agreed was a surgical mesh and was as safe and effective as predicate surgical meshes. Defendants' arbitrary and unlawful conduct resulted in needless costs to ReGen and ultimately crippled its U.S. business.

65. As a direct result of FDA's actions, on April 8, 2011, ReGen filed a Chapter 11 bankruptcy petition in the United States Bankruptcy Court for the District of Delaware. ReGen now functions as a debtor-in-possession.

COUNT I
(Administrative Procedure Act)

66. ReGen incorporates by reference the allegations of paragraphs 1 - 65 above, as if fully set forth here.

67. The FDA's letter of March 30, 2011, purporting to rescind the classification of the CMI as a Class II device and reclassify the device into Class III, is a final agency action within the meaning of 5 U.S.C. § 704.

68. The FDA's action in purporting to rescind the classification of the CMI as a Class II device and reclassify the CMI into Class III has no lawful basis under the FD&C Act.

69. The FDA's action in purporting to rescind the classification of the CMI as a Class II device and reclassify the device into Class III was arbitrary, capricious, an abuse of discretion and not in accordance with law, and in excess of statutory jurisdiction, authority, and limitations, within the meaning of 5 U.S.C. § 706(2)(A), (C).

70. ReGen has no other adequate remedy in a court. The agency's action should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2).

COUNT II
(Declaratory Relief)

71. ReGen incorporates by reference the allegations of paragraphs 1 - 70 above, as if fully set forth here.

72. An actual controversy within the meaning of Article III of the United States Constitution exists between ReGen and the Defendants as to whether the classification of the CMI has been lawfully rescinded, whether as a result the CMI was lawfully reclassified into Class III, and whether the device may be lawfully marketed in the United States.

73. ReGen is entitled to a declaration that the actions of the Defendants as set forth herein are arbitrary, capricious, an abuse of discretion and not in accordance with law, and in excess of their authority, and that Defendants' March 30, 2011 Order of Rescission is a nullity and without legal effect, and thus, that the device may be legally marketed in the United States.

COUNT III
(Injunctive Relief)

74. ReGen incorporates by reference the allegations of paragraphs 1 - 73 above, as if fully set forth here.

75. Defendants' acts are arbitrary, capricious, an abuse of discretion and not in accordance with law, and in excess of their authority.

76. ReGen has already suffered serious injury, including the inability to sell its sole product in the United States, which has forced the company into bankruptcy, and it faces both the reality and the immediate threat of irreparable harm as a direct and proximate result of the Defendants' acts. Remedies at law are unavailable or inadequate.

77. No other party or person would be substantially injured, and the public interest would be furthered, by the entry of an appropriate injunction.

78. ReGen is entitled to a permanent injunction directing Defendants to cease: asserting authority to rescind the CMI Class II classification under section 510(k) and 513(f)(1) and (i) (21 U.S.C. §§ 360(k) and 360c(f)(1) and (i)); challenging the CMI's Class II designation, except as authorized by the FD&C Act and FDA's implementing regulations thereto; and releasing information except under the Freedom of Information Act, 5 U.S.C. § 552, or pursuant to lawful process, and distributing information that is intended to discourage persons from using the device.

79. Other remedies are unavailable or futile.

PRAYER FOR RELIEF

WHEREFORE, ReGen respectfully requests that this Court enter a judgment:

A. Setting aside the FDA's purported rescission as arbitrary, capricious, an abuse of discretion and not in accordance with law, and in excess of statutory jurisdiction, authority, and limitations;

B. Declaring that the purported rescission is a nullity without legal effect and that the CMI can be lawfully marketed in the United States;

C. Enjoining Defendants to cease: asserting authority to rescind the CMI Class II classification under section 510(k) and 513(f)(1) and (i) (21 U.S.C. §§ 360(k) and 360c(f)(1) and (i)); challenging the CMI's Class II designation, except as authorized by the FD&C Act and FDA's implementing regulations thereto; and releasing information about the CMI, except under the Freedom of Information Act 5 U.S.C. § 552, or pursuant to lawful process, and distributing information that is intended to discourage persons from using the device;

D. Awarding ReGen its costs and expenses, including reasonable attorneys' fees; and

E. Awarding such other and further relief as is necessary and appropriate.

Dated: May 31, 2011

Respectfully submitted,

By: 
Mark A. Heller, DC Bar No. 357046

Of Counsel:

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Attorneys for Plaintiff
ReGen Biologics, Inc.

EXHIBIT A1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2008

Mr. John Dichiara
ReGen Biologics
411 Hackensack Avenue
Hackensack, NJ 07601

Re: K082079
Regen Collagen Scaffold
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OLC
Dated: July 22, 2008
Received: July 23, 2008

Dear Mr. Dichiara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Daniel G. Schultz, M.D., F.A.C.S.
Director
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K082079

Device Name: ReGen Collagen Scaffold (CS)

Indications for Use:

The ReGen Collagen Scaffold (CS) is intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the medial meniscus. In repairing and reinforcing medial meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the CS must extend at least into the red/white zone of the meniscus to provide sufficient vascularization.

The CS reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue. The CS is not a prosthetic device and is not intended to replace normal body structure.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH

EXHIBIT A2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2008

Mr. John Dichiara
Senior Vice President
Regulatory, Clinical and Quality
ReGen Biologics
411 Hackensack, NJ 07601

Re: k063827 & k082079
ReGen Collagen Scaffold (CS)

Dear Mr. Dichiara:

This letter is in response to the letters submitted by you in reference to the above premarket notification submissions for the CS (see enclosures).

During the review of your previous 510(k), k063827, the Division of General, Restorative and Neurological Devices (DGRND) determined that the CS device was not substantially equivalent (NSE) based on lack of performance data. Donna-Bea Tillman, Ph.D., M.P.A., Director, Office of Device Evaluation, concurred and issued an NSE letter based on lack of performance data on August 20, 2007. After receipt of that NSE decision, you began interacting with me regarding the CS device. Based on our correspondence and discussions, you submitted a new 510(k), k082079 for the CS device on July 22, 2008. You did not appeal the decision on k063827. However, because k082079 was submitted in response to our letter of August 20, 2007, I have, on my own initiative, also reconsidered our letter of August 20, 2007

DGRND reviewed k082079 and determined that the device as described in this 510(k) was also NSE due to lack of performance data. This NSE recommendation was discussed with DGRND management and Dr. Tillman, and, later, with me. Based on concerns regarding the performance data in this 510(k), I decided that this 510(k) should be reviewed by the Orthopedic and Rehabilitation Devices Panel (the Panel) at a Panel meeting to obtain their recommendation to the Center for Devices and Radiological Health (CDRH).

The Panel met on November 14, 2008, and recommended to CDRH that the CS device be cleared for both chronic use, as requested in k082079, and acute use based on your Panel presentation. The Panel also made recommendations regarding labeling and training on the use of the device.

Following a review of the Panel meeting transcript by Dr. Tillman and me, and based on the Panel recommendations, Dr. Tillman and I agreed that the CS device be found substantially equivalent for both chronic and acute use for the medial meniscus, as described in your indications for use, with revised labeling and training for the licensed

practitioners. This letter revisits the issues discussed in the letter of August 20, 2007 and reaches the conclusions reflected in the attached determination of substantial equivalence.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Center for Devices and
Radiological Health

Enclosures

Attachments omitted

EXHIBIT A3

Memorandum to the Record
K082079
Regen Collagen Scaffold

Date: December 20, 2008

From: Daniel Schultz, MD
Director, CDRH, FDA

This memo addresses my finding that the device is substantially equivalent to the predicate device, and records thoughts and analyses that I discussed with CDRH staff during my review of this application.

After careful consideration of the sponsor's application, the administrative record, the scientific opinions rendered by CDRH staff, the recommendations of the Orthopedic Advisory Panel at a meeting that I attended on November 14, 2008, and the memorandum from Dr. Donna-Bea Tillman dated December 15, 2008, I have reached the following conclusions which are consistent with conclusions reached by Dr. Tillman and the recommendations of the Orthopedic Advisory Panel:

- K082079 is Substantially Equivalent to cited legally marketed predicates for the treatment of acute and chronic injuries of the medial meniscus.

- The basis of my decision is the preclinical and clinical data in the submission considered in the context of the target population and the interpretation of the data by a panel of independent experts in the field who clearly and unanimously found the device to be at least as safe and as effective as the other surgical mesh products currently used in orthopedics.

- The panel was provided with, and asked to review, all of the data associated with this device and it was apparent to me from the depth of discussion at the panel meeting and the way in which the issues were addressed that they were extremely conversant with the data and very familiar with the clinical risks and benefits associated with this device, how the risk/benefit profile compared to the use of mesh in other orthopedic applications, and the risk/benefit profile of other treatment modalities currently used to treat injuries of the meniscus.

- The length of the review process associated with this submission is directly attributable to the sponsor's unwillingness to recognize and address the legitimate scientific concerns raised by CDRH. While surgical meshes may be classified from a regulatory standpoint under a single classification regulation, the question of how they affect clinical outcomes for new and different clinical applications is not only relevant, but central to our ability to determine substantial equivalence for this device.

This point was emphasized at the panel meeting by the sponsor's own mesh expert, Dr. Badylak:

"The last point that I want you to think about during the next few slides is that the microenvironment of the implantation site is an absolutely critical determinant in how well this surgical mesh is going to function."

"So the individual sites are all different, and this is important because they define how well the surgical meshes are going to work."

"And, finally, microenvironmental factors including mechanical forces such as those that are seen in the knee are absolutely critical determinants in the remodeling process and the downstream results."

- Since the preclinical data alone were not able to predict the clinical performance of the CS device, it was absolutely imperative that a thorough and objective review of the available clinical data be performed. The sponsor requested and was granted a meeting at which their own clinical experts expressed their support of this device and their belief that it was in the best interest of patients for FDA to make it available for use in the U.S. I also met with the review staff including medical officers from the Office of Device evaluation and heard their concerns regarding lack of statistical significance for the primary endpoints of the IDE study and the very real safety issues associated with the placement of a foreign body like the CS device in the knee.
- The process by which FDA adjudicates scientific differences, particularly where those differences may have a significant impact on public health, is through an open public meeting utilizing an independent panel of experts in the field. The deliberations and recommendations of the panel are documented in the panel transcript and reflect both the complexity of the data as well as a clear conclusion that making this device available for use by surgeons who are capable of selecting appropriate patients in accordance with the labeling and individual patient characteristics and performing advanced arthroscopic procedures in the knee, is in the best interest of public health.
- Throughout the course of this review process, as reflected in the administrative record, there are multiple references by the sponsor to bias and application of inappropriate review standards to this application. The sponsor, and particularly their consultants, repeatedly expressed their disdain for the FDA review process and the individuals involved in the review of this application. The sponsor's efforts to demonize the staff and circumvent the process, the final decision notwithstanding, did nothing but complicate and delay this decision. In conclusion, I want to state for the record my belief that this application was reviewed without bias and in accordance with appropriate scientific and regulatory standards and with a single goal to protect and promote the public health.

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Certified Mail
Return Receipt Requested

ReGen Biologics, Inc.
c/o Gerald E. Bisbee, Jr., Ph.D.
Chairman and Chief Executive Officer
411 Hackensack Avenue
10th Floor
Hackensack, New Jersey 07601

MAR 3 0 2011

Re: Order of Rescission of K082079 - Collagen Scaffold Device

Dear Dr. Bisbee:

In our letters dated October 14, 2010, and January 14, 2011, the agency informed you of its intention to rescind the clearance of your 510(k) premarket notification for the Collagen Scaffold (CS) device (marketed as the Menaflex®), K082079, subject to your right to a hearing, because our December 18, 2008, substantial equivalence determination for this device was in error. As discussed in these letters, we have determined your CS device (Menaflex®) is not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to any device which has been classified into class I (General Controls) or class II (Special Controls).

Our January 14, 2011 letter further informed you of the opportunity for a hearing under 21 CFR Part 16 and provided notice that a final order of rescission would issue unless, within 30 days of receipt of our letter, you requested a hearing regarding the proposed rescission in accordance with 21 CFR Part 16.22(b). In response to your request of January 21, 2011, for additional time to decide whether to request a hearing, by letter dated January 31, 2011, we granted you a 30 day extension to make this request, which expired on March 22, 2011. You informed us in your letter dated March 21, 2011 that you would not be requesting a hearing. Accordingly, we are rescinding our determination of substantial equivalence for the CS (Menaflex®) device. This letter constitutes an order of rescission for K082079.

Therefore, the CS (Menaflex®) device is classified by statute into class III (Premarket Approval), under Section 513(f) of the Federal Food, Drug, and Cosmetic Act (the Act). Section 515(a)(2) of the Act requires a class III device to have an approved application for premarket approval (PMA) before it can be legally marketed, unless the device is reclassified.

Any commercial distribution of this device prior to approval of a PMA, or the effective date of any order by the Food and Drug Administration reclassifying this device into class I or II, would be a violation of the Act. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

If you are currently marketing this device in the United States, you must immediately cease all distribution of those devices that are still under your control. You also may not export these devices except within the provisions of section 801(e) of the Act. If you have general questions regarding the provision of section 801(e), please contact:

Food and Drug Administration
Center for Devices and Radiological Health
Division of Small Manufacturers, International and Consumer Assistance (DSMICA)
10903 New Hampshire Avenue
WO66-5429
Silver Spring, MD 20993
dsmica@fda.hhs.gov
(800) 638-2041
(301) 796-7100

Any distribution or marketing of the device may result in enforcement action being initiated by the Food and Drug Administration.

If you have any questions regarding this notice you may contact Michael Ryan, Regulatory Advisor, at (301) 796-6283.

Sincerely yours,

Christy Foreman

Christy Foreman
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health