REGEN BIOLOGICS, INC. v. SEBELIUS et al Doc. 75

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IVY SPORTS MEDICINE, LLC, Plaintiff, v. **KATHLEEN SEBELIUS, et al.,** Defendants.	Civil Action No. 11-cv-1006 (RLW)

MEMORANDUM OPINION

This litigation is the latest chapter in a decades-long effort seeking government approval of a medical device. Plaintiff Ivy Sports Medicine, LLC ("Ivy"), or its predecessor ReGen Biologics, Inc. ("ReGen"), have been trying to get the medical device at issue in this litigation approved for at least 16 years; that is when ReGen began clinical research trials. The Food and Drug Administration ("FDA")[1] rejected multiple applications from ReGen before eventually approving the device in December 2008. But at present, the device is no longer allowed on the market because the agency changed the device's classification in March 2011. The parties agree a mistake was made. For the FDA, the mistake occurred when they approved the device in December 2008, because they claim the process by which they did so was marred by procedural irregularities. For Ivy, however, the agency's mistake occurred when the agency changed the classification of the device in March 2011 using inherent authority rather than a statutory procedure.

[1] The Defendants in this action are Health and Human Services Secretary Kathleen Sebelius and FDA Commissioner Dr. Margaret A. Hamburg in their official capacities, and the FDA (collectively "Defendants" or the "FDA").

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The case is now before this Court on cross-motions for summary judgment, and is ripe for a decision. (Dkt. Nos. 22 & 28). Based on the Court's review of the Administrative Record, the parties' briefs, the relevant law, and the arguments of counsel during the hearing held on March 14, 2013, and for the reasons stated below, Defendants' Motion for Summary Judgment (Dkt. No. 28) is **GRANTED** and Plaintiff's Motion for Summary Judgment (Dkt. No. 22) is **DENIED**.

I. FACTUAL SUMMARY

A. Regulatory Framework

Certain medical devices intended for human use are regulated for safety by the FDA under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. There are "two basic paths" by which new devices reach the market. *Cytori Therapeutics, Inc. v. FDA*, Nos. 11-1268, 11-1279, 2013 WL 1164775, at *1 (D.C. Cir. Mar. 22, 2013). The "premarket approval" path involves more scrutiny, usually requires clinical research demonstrating the safety of the device, and can be a lengthy process. *See* 21 U.S.C. § 360e. The "premarket notification" path, far more common, is a more streamlined process that requires the new device to be "substantially equivalent" to a device already on the market. *See* 21 U.S.C. §§ 360(k), 360c(i). There are three established classes for medical devices, which help determine whether a new medical device proceeds along the "premarket approval" or "premarket notification" path. *See* 21 U.S.C. § 360c(a)(1). Devices in Class I are the least risky, Class II devices are more risky than Class I and may require "special controls,"[2] and devices in Class III are the most risky of all

[2] Such special controls include "the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary . . . ." 21 U.S.C. § 360(a)(1)(B).

and require premarket review and approval. *See* 21 U.S.C. § 360c(a)(1)(A)-(C) (describing all three Classes).

In addition, devices can be identified as preamendment or new (postamendment). Preamendment devices are any of about 1,500 generic types of devices used before the enactment of the Medical Device Amendments on May 28, 1976. *See* 21 C.F.R. § 860.3(i). A device is categorized as postamendment if it was first proposed for use on or after May 28, 1976. Anyone seeking to register a postamendment device can submit a premarket notification, which has come to be known as a 510(k) application, in an effort to demonstrate the device is "substantially equivalent" to a device already approved by the FDA, also known as a "predicate device." *See* 21 U.S.C. §§ 360(k) (Section 510(k) of the FDCA), 360c(f). The criteria for substantial equivalence are set out at 21 U.S.C. § 360c(i)(1)(A). *See also* 21 C.F.R. § 807.100(b). If the agency determines a new device is substantially equivalent to a predicate device, the new device is cleared and subject to the same regulatory Class controls as the predicate. *See* 21 U.S.C. § 360c(f). If not, the new device is classified into Class III, and subject to premarket approval of its safety and effectiveness. *See* 21 U.S.C. § 360c(f). The law was changed in 1990 to clarify that most devices, including postamendment devices, can serve as a predicate for classifying other new devices. *See* 21 U.S.C. § 360c(i).

Congress has provided procedures for the FDA to follow for device classification changes if the agency determines a device has been incorrectly classified. At the time the device

at issue in this case was reviewed by FDA,[3] a key statutory provision, 21 U.S.C. § 360c(e)(1)(A), provided that

> [b]ased on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (A) change such device's classification, and (B) revoke, because of the change in classification, any regulation or requirement in effect . . . with respect to such device. In the promulgation of such a regulation respecting a device's classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) of this section a recommendation respecting the proposed change in the device's classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change.

B. Device at Issue: Collagen Scaffold ("CS")

The meniscus is made of tissue and is found between the knee bones. The menisci distribute body weight to prevent damage to the underlying articular cartilage, they "act as shock absorbers and secondary stabilizers, and they provide joint lubrication and nutrition for the articular cartilage." (Dkt. No. 1, at ¶ 18). Unfortunately, meniscus injuries are quite common, and often result in a surgical procedure known as a partial meniscectomy. That procedure removes torn meniscus cartilage interfering with knee joint function. (*See* Dkt. No. 69, at 9 n.2). The product at issue in this litigation is a Collagen Scaffold ("CS") manufactured by Ivy that was marketed in the United States as Menaflex. According to Ivy, the CS is intended "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." (Dkt. No. 1, at ¶ 19). A partial meniscectomy would involve use of a CS only if a doctor determined such use was appropriate. According to Ivy, although debated by the FDA as explained below, use of the CS is limited to repairing and reinforcing tissue, and the CS is not intended to replace tissue. (*See* AR 2648-49, 2661).

[3] This section was amended slightly, with changes not relevant here, by the Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 1055 (2012).

ReGen began clinical research on the safety of the CS around 1997, and sought premarket approval in 2004. (*See* AR 37). Later, instead of pursuing premarket approval, ReGen submitted its first 510(k) application in 2005, describing the CS as "a resorbable collagen-based surgical mesh" that "serves to reinforce and repair soft tissue." (AR 559). The FDA rejected the 510(k) application in February 2006 as not substantially equivalent to a predicate surgical mesh, stating its "decision is based on the fact that the performance data you have provided did not demonstrate your device to be as safe and effective as legally marketed devices." (AR 1097). The agency reconsidered its rejection and requested additional information from ReGen, but in July 2006 the FDA's lead reviewer concluded that the CS "has a new intended use and is *not substantially equivalent* to other surgical mesh or bone fixation devices." (AR 1193) (emphasis in original). That same month the agency again rejected the 510(k) application, "based on the fact that your device has a new indication (i.e., the reinforcement and repair of soft tissue where weakness exists, including, but not limited to . . . meniscus defects) that alters the therapeutic effect, impacting safety and effectiveness, and is therefore a new intended use." (AR 1207) (ellipses in original). ReGen appealed unsuccessfully to the FDA's Office of Device Evaluation. (AR 1266-67).

ReGen submitted a second 510(k) application in December 2006, describing the device's use as "repairing and reinforcing meniscal defects." (AR 1286). The FDA's lead reviewer found the device not substantially equivalent to a predicate device, and wrote that the CS "was not used to repair and reinforce a repair but to replace tissue that has been removed after partial meniscectomy." (AR 1930). After the agency again requested and received additional information from ReGen, in August 2007 the FDA ultimately again rejected ReGen's application. The agency "determined the device is not substantially equivalent to devices

marketed in interstate commerce prior to May 28, 1976 . . . or to another device found to be substantially equivalent through the 510(k) process," and stated this was because data provided on the CS suggested an increased risk and uncertain benefits as compared to predicate devices. (AR 2426-28).

In December 2007, both of New Jersey's United States Senators, and two members of its United States House of Representatives delegation, wrote to the FDA on behalf of ReGen, asking for the agency's review of the current submission and requesting a meeting to "discuss this situation." (AR 2431). ReGen's principal place of business is in New Jersey. (Dkt. No. 1, at ¶ 3).

Following the suggestion of Dr. Daniel G. Schultz, the then Director of the FDA's Center for Devices and Radiological Health ("CDRH"), (AR 2627), ReGen later submitted a third 510(k) premarket notification to the FDA on July 22, 2008 for its CS, noting an indication that the device "is intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the meniscus," (AR 5467). On August 14, 2008, the FDA's lead reviewer recommended that the CS be found not substantially equivalent "for lack of performance data," and also noted that "the subject device is being used to replace the meniscus in an area that cannot be repaired." (AR 2836). Representatives from ReGen and CDRH spoke on August 18, 2008, and notes of the call conclude by stating that the "FDA needs data that supports benefit of the device, as well as clear labeling that explains what the device does and how best to use it." (AR 2924). Multiple staff of the FDA, including the Director of the Office of Device Evaluation, recommended in September that the CS be found not substantially equivalent. (AR 2936, 2957). The agency did not deny the CS, however, and notified ReGen in October 2008 that review of the CS would include input from an Orthopedic Advisory Panel scheduled to meet

on November 14, 2008. (AR 2958-59). The agency gave the panel one week, rather than the usual three to five, to prepare, and because of the short notice several standing members could not attend. (AR 3498-99). A summary of the meeting prepared by the FDA 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 [Class II] predicate devices." (AR 2976). A report by the FDA examining the panel one year later wrote that the transcript of the panel meeting reflects "confusion" and contains internal inconsistencies that are "difficult to reconcile." (AR 3505). The same FDA report stated that ReGen "succeeded in excluding the Review Division from speaking at the Panel meeting." (AR 3499). The Review Division included "staff most knowledgeable about the CS device and the 510(k) submission for it." (AR 3505). After the panel, some FDA staff continued to believe the CS was not substantially equivalent. (AR 3230-31; *see also* 3234 ("After considering the Panel recommendations, the ODE review team continued to find that the data were insufficient to demonstrate substantial equivalence . . . .")).

The Director of the Office of Evaluation, who had recommended a finding of not substantially equivalent in September, noted in a December 2008 Memorandum to the Record that, "Dr. Schultz and I have discussed this submission in detail, and *he believes* that ReGen has provide[d] sufficient clinical data to demonstrate that the new indications for use ha[ve] a similar risk/benefit profile to previously cleared indications for surgical mesh. *Therefore, I have concluded* that the ReGen CS device is substantially equivalent to predicate surgical meshes, in that the new indication does not constitute a new intended use." (AR 3236) (emphasis added). By letter dated December 18, 2008, Dr. Schultz informed ReGen of the agency's decision to

classify the CS as a Class II device under the FDCA, because the agency had "determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices . . . 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)." (*See* AR 3240-42). The agency at that time determined the CS to be substantially equivalent to an approved surgical mesh. Surgical meshes are regulated as Class II devices. *See* 21 C.F.R. § 878.3300 (a mesh is "intended to be implanted to reinforce soft tissue or bone where weakness exists"). As a result, ReGen began commercial distribution of the CS in the United States, and first distributed the device in April 2009. (Dkt. No. 24-5, at ¶¶ 4-5).

Shortly before they began distribution, however, an article about the approval of ReGen's CS appeared on the front page of the *Wall Street Journal*. Alicia Mundy, *Political Lobbying Drove FDA Process*, WALL ST. J., Mar. 6, 2009, at A1. The article purports to document, for example, "emails show[ing] the FDA's integrity office excising language from a draft letter an FDA lawyer said would 'document special treatment for ReGen.'" That day Senator Charles Grassley contacted the FDA about the substantial equivalence determination for the CS device, and within days members of the United States House of Representatives' Committee on Energy and Commerce had done the same. (*See* AR 3251-60, 3276-91). The agency began an internal review at the end of April 2009. (AR 3269). Members of the House Committee on Energy and Commerce wrote to the FDA on May 11, 2009, stating: "We understand that you may be reexamining the decision to approve this device for marketing. Given the questions raised by FDA scientists about the lack of data on the safety and efficacy of this device, we believe this is

a prudent course of action." (AR 3300). ReGen was aware of this, as they commented on this letter on June 9, 2009. (*Id.*).

As part of its internal review process, the FDA issued a September 2009 report entitled "Review of the ReGen Menaflex: Departures from Processes, Procedures, and Practices Leave the Basis for a Review Decision in Question." (AR 3485-3578). The report found "procedural irregularities" in the review of ReGen's 510(k) application, including "highly unusual . . . Congressional involvement," and called for "a focused scientific reevaluation of the decision to clear the CS device." (AR 3488, 3494, 3497). It stated that, "[t]he Director of FDA's Office of Legislation described the pressure from the Hill as the most extreme he had seen and the agency's acquiescence to the Company's demands for access to the Commissioner and other officials in the Commissioner's office as unprecedented in his experience." (AR 3494). It also referred to "the agency's failure to respond appropriately to external pressure on decision-makers; the exclusion of individuals, if not viewpoints, from parts of the scientific debate; and the excessive reliance on advisory panel deliberations in reaching the final decision to clear the CS device for marketing." (AR 3488). At a press conference that September regarding the CS, new CDRH Director Dr. Jeffrey Shuren stated: "[W]e have no basis to question the safety of this device. . . . 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." (Dkt. No. 24-9, at 4) (emphasis added).

The following month, on October 7, 2009, the FDA and ReGen met. At the meeting the agency told the company that a new team would reconsider the decision to clear the CS. (AR 3579-84). That team reported in December 2009 that the CS "*is intended for replacement of the meniscus* and there are *no legally marketed predicate devices* intended for replacement of the

meniscus. . . . Therefore, the current review team does not believe the record supports a determination of substantial equivalence for the" CS. (AR 3649) (emphasis in original). The FDA notified ReGen in January 2010 that the agency planned to convene a second Orthopedic Advisory Panel two months later. (AR 3928-30). For the most part, the panel that met in March 2010 found that the CS is "generally considered safe," but had "some concerns about efficacy." (AR 4502). Panel members from the March 2010 meeting also "provided mixed responses regarding whether the CS device was intended to or could repair and/or reinforce the meniscus." (AR 5464) (citing March Panel Transcript at 216-29).

The FDA's lead reviewer recommended in a September 2010 Memorandum that the CS be found not substantially equivalent. (AR 5404-57). She stated that the CS was intended "*to replace the meniscus to prevent or delay the progression of osteoarthritis of the knee joint*," and not for "reinforcement and repair of soft tissue injuries of the medial meniscus." (AR 5407) (emphasis in original) (footnote omitted). With respect to a comparison to predicate devices, the September 2010 Memorandum stated: "The indications for use statement for the CS device is not the same as the indications for use statements of the predicate meshes because no meshes are cleared for use in the medial meniscus. . . . [B]ecause the CS device has a new intended use . . . we would conclude that the device is not substantially equivalent to legally marketed predicates." (*Id.*).

On October 14, 2010, the FDA (via Dr. Shuren) informed ReGen of its intention to rescind the CS's Class II designation, noting "[t]he review team concluded that the CS device is intended to replace meniscal tissue that has been surgically excised rather than to repair and reinforce soft tissue or bone." (AR 5458-80, at 5460). Dr. Shuren also wrote that, "even if the CS device had the same intended use as any of the identified predicate devices, the differences

between the technological characteristics of the CS device and each of the predicate devices raise different questions of safety and effectiveness." (AR 5458). In January 2011, the FDA offered ReGen the opportunity to request a hearing on the proposed rescission of Class II designation for the CS device, but the company declined, believing both that there was no legal authority for such a hearing, and also that it would be futile. (*See* AR 5517-34). On March 30, 2011, the FDA wrote to ReGen that the CS "is not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976 . . . or to any device which has been classified into class I (General Controls) or class II (Special Controls)." (AR 7342-43). The agency stated it was "rescinding our determination of substantial equivalence." (*Id.*). This caused reclassification of the CS to Class III, meaning the device could not be marketed in the United States without approval of the FDA. "As a direct result of this FDA action," ReGen filed for bankruptcy on April 8, 2011. (Dkt. No. 1, at ¶¶ 1, 65).

C. Procedural Posture

ReGen filed this action pursuant to the Administrative Procedure Act, 5 U.S.C. § 702 *et seq.*, for related relief under 28 U.S.C. §§ 2201-02, and an injunction. (Dkt. No. 1, at ¶ 1). Ivy Sports Medicine, LLC Inc. ("Ivy") became the successor in interest to ReGen, and this Court granted Ivy's motion to substitute for ReGen. (Dkt. No. 12). Ivy asks for a judgment that "(1) the rescission order is illegal and null and void, and (2) the December 18, 2008 Substantial Equivalence Order remains in effect." (Dkt. No. 69, at 52). The company also requests this Court "enter an injunction barring FDA from attempting to reclassify the CS device other than through the reclassification process set forth in § 513(e) [21 U.S.C. § 360c(e)]." (*Id.*). Ivy filed a motion for summary judgment (Dkt. No. 22), the FDA filed a cross-motion (Dkt. No. 28), and both motions are fully briefed. During the summary judgment briefing, Ivy moved to

supplement the administrative record. (Dkt. No. 36). This Court granted in part and denied in part the motion to supplement. (Dkt. No. 52). The parties appeared for a hearing on the summary judgment motions, and the Court heard over two hours of argument.

In addition, ReGen filed a petition for review of the FDA's March 30, 2011 rescission order in the United States Court of Appeals for the District of Columbia Circuit on April 29, 2011. Pet. for Review of Agency Decision, *ReGen v. FDA*, Case No. 11-1123. The D.C. Circuit granted the FDA's motion to dismiss because the rescission order did not "fall[] within any of the categories as to which direct review in this court is authorized. *See* 21 U.S.C. § 360g." Order, *ReGen v. FDA*, Case No. 11-1123, Sept. 1, 2011.

III. SUMMARY JUDGMENT STANDARD

The APA requires a court to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C), (D). When ruling on summary judgment motions in a case involving final review of an agency action under the APA, the normal standards of Federal Rule of Civil Procedure 56 do not apply because of the limited role of the court in reviewing the administrative record.[4] *See Charter Operators of Alaska v. Blank*, 844 F. Supp. 2d 122, 126-27 (D.D.C. 2012). Summary judgment serves as a mechanism for deciding, as a matter of law, whether the administrative record supports the agency action and whether the agency action is consistent with the APA standard of review. *See Richards v. INS*, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977).

[4] Local Rule 7(h)(1) requires that a party moving for summary judgment attach a Statement of Undisputed Facts. In cases where judicial review is based solely on the administrative record, however, a Statement of Undisputed Facts is not required. LCvR 7(h)(2).

IV. ANALYSIS

Ivy argues that because the law provides a reclassification procedure that the FDA did not use, the agency violated the law. "This case presents one issue for the Court's consideration: Whether the FDA acted within the scope of its lawful authority when it purported to rescind the Substantial Equivalence Order and reclassify the CS into Class III." (Dkt. No. 69, at 9). This issue breaks down into three sub-issues: (1) did the FDA need to comply with procedures at 21 U.S.C. § 360c(e) to reclassify the CS, or did it have inherent authority to do so; (2) did the FDA act in a timely manner to reclassify the CS; and (3) did the FDA evaluate the CS based on its intended use. They will be addressed in turn.

A. Whether the FDA needed to use 21 U.S.C. § 360c(e), or could act under the agency's inherent authority

As a threshold matter, this Court must decide whether the FDA acted properly in how it reclassified the CS device. Ivy argues that the FDA had only one option: to use the statutory procedure for reclassification found at 21 U.S.C. § 360c(e). Because it did not do so, Ivy argues, the agency acted in violation of the law, and this ends the litigation in their favor. The FDA disagrees that § 360c(e) was its only option, and instead argues that it properly used its inherent authority to reclassify the CS. The agency argues that because of serious procedural irregularities in the approval process, and because there is no statutory limitation on their power to reconsider, the agency acted properly. The debate hinges primarily on starkly different interpretations of a handful of cases.

One of the key cases on the issue of inherent authority, if not the key case, is *American Methyl Corp. v. EPA*, 749 F.2d 826 (D.C. Cir. 1984). *American Methyl* is a case involving the Clean Air Act in which EPA had granted a waiver to American Methyl for the introduction of a

methanol/gasoline blend called Petrocoal. Just over two months after EPA granted the waiver, another organization, the Motor Vehicle Manufacturers Association ("MVMA"), filed a petition for administrative reconsideration that the agency seems to have ignored. Over one year after that, MVMA filed a supplemental petition "accompanied by new data purporting to show that Petrocoal caused automobiles to exceed limits for evaporative emissions of hydrocarbons." *Id.* at 829. Eventually, the EPA proposed to rescind the waiver, "assert[ing] the agency's inherent authority to revoke a waiver pursuant to section 211(f)." *Id.* at 830 (footnote omitted). The D.C. Circuit found that EPA could not invoke inherent authority under 211(f), because section 211(c) was the only authority by which the agency could rescind the waiver. The court stated that because "Congress has provided a mechanism capable of rectifying mistaken actions . . . it is not reasonable to infer authority to reconsider agency action." *Id.* at 835. To Ivy, in a sense, this ends the debate: they argue that the statutory framework in *American Methyl* is sufficiently analogous to the one at issue here, and therefore the FDA must use the framework in place rather than claim inherent authority.

But *American Methyl* is distinguishable in several critical ways. One is that in *American Methyl*, the parties did not dispute the validity of the initial waiver. The court stressed this at least five times. *See id.* at 837-38 ("Because there is no issue now before us as to the original administrative record justifying the Petrocoal waiver, however . . . ."; "Whatever the validity of this concern, it in no way impugns the validity of the original waiver . . . ."; "no issue before us as to the adequacy of the original waiver"; "EPA's primary reason for revoking American Methyl's waiver does not relate to a defect in the original grant; thus, under EPA's own interpretation of its powers, a revocation proceeding is not warranted in this case."; "Because the Administrator points to no defects in his original approval of the Petrocoal waiver, he may not . .

. reopen that waiver."). The present litigation is clearly distinguishable from *American Methyl* in this respect. This case is fundamentally about defects in the approval process of the CS device in December 2008 and the record before the agency at the time.

Another key difference between this case and *American Methyl* is clarified by what the D.C. Circuit said that case was *not* about. The *American Methyl* panel stated:

> We of course intimate no view as to EPA's power to revoke a waiver obtained through fraud, ex parte contacts, or other misconduct tainting the original record and *thereby affecting the integrity of an agency's proceedings*. . . . EPA alleges no misconduct in American Methyl's securing of the Petrocoal waiver . . . .

Id. at 834 n.51 (emphasis added). Therefore in a situation in which the integrity of an approval process can reasonably be challenged, *American Methyl* does not necessarily apply to an agency exercising its inherent authority. While Ivy argues that the "FDA's efforts to shoehorn this case into the fraud category must fail," (Dkt. No. 62, at 26), clearly fraud is not the only "category" discussed by *American Methyl*. The key point is whether some form of misconduct "taint[ed] the original record" and "affect[ed] the integrity" of the FDA proceedings. *American Methyl*, 749 F.2d at 834 n.51.

In this case, the FDA internal review concluded that there were multiple "procedural irregularities" that called into question the basis of the agency's decision, (AR 3497), and Dr. Shuren said "the integrity of our process for reaching a decision was compromised in this case . . . ." (Dkt. No. 24-9, at 4). These rather damning conclusions are entirely consistent with the key point of *American Methyl*'s footnote 51, and Ivy's attempts to distinguish these consistencies are simply a bridge too far.

One of the reasons for an agency to invoke inherent authority, about which *American Methyl* expressed no opinion, is ex parte contacts, and the Administrative Record in this case includes several communications that fit into this category. For example, the FDA found that the

agency violated its "usual practice" when it met with Ivy "without members of the review team present." (AR 3525). The FDA allowed Ivy to have "unusual access to the Commissioner and his Principal Deputy." (AR 3526). The FDA violated their "[t]ypical[]" procedures and allowed members of Congress to speak "directly to both the FDA Commissioner and the Principal Deputy Commissioner." (*Id.*). Generally, "[n]o rules or practices limiting the access of ReGen officials or its consultants to agency officials appear to have been observed." (*Id.*). For these reasons alone, this case is not controlled by *American Methyl*.

Significantly, the *American Methyl* court also noted that it was not expressing a view about whether an agency can invoke its inherent authority when "other misconduct" occurred that "taint[ed] the original record." 749 F.2d at 834 n.51. Ivy purports to describe this category by misquoting the case in a way that substantially changes the meaning of the opinion. Multiple times, Ivy inaccurately quotes *American Methyl* as granting an agency authority to revoke an action based on "fraud, ex parte contacts, or other *similar* misconduct." (Dkt. No. 62, at 26 & 31) (emphasis added). But the word "similar" does not appear in footnote 51 of *American Methyl*. It is hard to credit these multiple misquotes as an accident; one of the times Ivy misquotes the case they are citing to Defendants' brief, where the quote appears correctly. (*See* Dkt. No. 62, at 31 (citing Dkt. No. 33, at 30-31)). Adding the word "similar" narrows the list of acceptable reasons for an agency to invoke its inherent authority to act, as opposed to the more broad formulation that actually appears in *American Methyl*. While the language manufactured by Ivy may be what the company wishes the D.C. Circuit had said on the issue, this Court is bound by the actual language of the opinion, which is that misconduct affecting the integrity of an agency's approval can take that approval out of the *American Methyl* context.

In this case, the Administrative Record contains several examples of misconduct affecting the integrity of the CS device's 2008 substantial equivalence determination. The September 2009 preliminary report prepared by the FDA noted "multiple departures from processes, procedures, and practices." (AR 3487). This includes "the agency's failure to respond appropriately to external pressure on decision-makers; the exclusion of individuals, if not viewpoints, from parts of the scientific debate; and the excessive reliance on advisory panel deliberations in reaching the final decision to clear the CS device for marketing." (AR 3488). Decision makers failed "to sufficiently explain and document the bases for their decisions in an administrative record." (AR 3487). The "haste" with which Dr. Schultz convened the panel "resulted in a panel inexperienced not only with the substantial equivalence standard, which is novel even to standing panel members, but also in FDA's usual panel procedures." (AR 3499). Ivy "succeeded in excluding the Review Division from speaking at the Panel meeting," which "may have skewed the discussion by precluding adequate consideration by the Panel of key Review Division concerns." (*Id.*). The review "constitute[d] a clear deviation from processes needed to support scientific integrity." (AR 3509). The compressed timeframe in convening the panel meant key members could not participate, and gave people less time to prepare. (AR 3528). And the agency relied on the panel "excessively." (*Id.*). The September 2009 report states that "basing a decision entirely or almost entirely on the views of an outside Panel, particularly when those views conflict with the views of FDA reviewers and the reviewers' concerns are not addressed in the decision-making documents, is not a standard part of the process." (AR 3508). All of this raises "[t]roubling questions," (AR 3509), and it shows that the agency had a valid reason to invoke its inherent authority to review the CS substantial

equivalence determination, and that its reason was one about which the *American Methyl* court "intimate[d] no view." 749 F.2d at 834 n.51.

Because *American Methyl* carves out the situation present in this case, where misconduct impacted the agency's initial decision, the fact that the FDA concedes it could have used 21 U.S.C. § 360c(e), (*see* Tr. 42:12-17 Mar. 14, 2013), does not change the determination that the agency properly invoked its inherent authority. Although no "new information" led to the agency's decision to reconsider the classification of the CS device, Ivy claims that because the FDA relied on "new information" to reclassify the CS device, "the overall circumstances of this case are no different from those in *American Methyl*." (Dkt. No. 62, at 32). But as discussed above, the circumstances here are distinctly different from the facts of *American Methyl*, and that case expressed no view about whether an agency can invoke its inherent authority to review a ruling tainted by misconduct, even if a statutory provision could also be used. Such is the situation here. In sum, numerous and substantive differences between *American Methyl* and this case are present, and therefore the case does not control here.

Several cases offer support for the agency's position that it properly exercised its inherent authority in this case. In *Boesche v. Udall*, 373 U.S. 472 (1963), the Supreme Court endorsed the Secretary of the Interior's decision to cancel a lease for invalidity at its inception "under his general powers of management over the public lands . . . unless such authority was withdrawn by" statute. *Id.* at 476. The Secretary, the Supreme Court continued, "should have the power, in a proper case, to correct his own errors." *Id.* at 478. In *Belville Mining Co. v. United States*, 999 F.2d 989 (6th Cir. 1993), the Department of the Interior identified errors leading to its initial decision to grant strip mining rights for four tracts of land, and a new agency official reevaluated the decision and reversed it. The district court had decided that, "because a Congressional

investigation prompted reconsideration, and there was a contemporaneous change in directors at [a Department Office], reconsideration impermissibly had been motivated by policy changes." *Id.* at 998. The Sixth Circuit reversed, finding that "[t]he authority of an agency to reconsider an earlier determination may be expressly conferred by statute. Even where there is no express reconsideration authority for an agency, however, the general rule is that an agency has inherent authority to reconsider its decision, provided that reconsideration occurs within a reasonable time after the first decision." *Id.* at 997 (citations omitted). Because of the facts and holding of *Belville*, the case is relevant here, and it is hard to square with Ivy's claim that *Belville* does not "involve circumstances remotely comparable to the facts of this case." (Dkt. No. 62, at 34).

Other cases also stand for the proposition that "[e]mbedded in an agency's power to make a decision is its power to reconsider that decision," *ConocoPhillips Co. v. EPA*, 612 F.3d 822, 832 (5th Cir. 2010), or as stated by the D.C. Circuit: "The power to reconsider is inherent in the power to decide," *Albertson v. FCC*, 182 F.2d 397, 399 (D.C. Cir. 1950). For example, in *American Therapeutics, Inc. v. Sullivan*, 755 F. Supp. 1 (D.D.C. 1990), the FDA approved a drug, but the approving official was unaware of facts indicating that the applicant "could not satisfy the approval requirements." The FDA discovered the mistake and rescinded approval. Judge Gesell of this court found that the agency in correcting a good faith mistake "is entitled to some deference when its actions are examined" and "[t]here is authority that suggests an agency must be given some leeway to remedy mistakes." *Id.* at 2. Because of the procedural irregularities present in this case detailed above, this too is a proper case to allow invocation of inherent agency authority.

Ivy relies almost exclusively on *American Methyl* for its inherent authority argument, and essentially cites only two other cases for support: *New Jersey v. EPA*, 517 F.3d 574 (D.C. Cir.

2008), and *Douglas Timber Operators, Inc. v. Salazar*, 774 F. Supp. 2d 245 (D.D.C. 2011). Both cases are readily distinguishable. In *New Jersey v. EPA*, despite the EPA previously determining that emission regulations were necessary for certain sources, the agency nonetheless then purported to delist sources from oversight without making any findings despite a statute specifically requiring such findings. The court rejected EPA's actions under step one of *Chevron*, stating that although an agency "can normally change its position and reverse a decision," 517 F.3d at 582, Congress had spoken directly to the issue and "unambiguously limit[ed] EPA's discretion," *id.* at 583. Unlike in *New Jersey v. EPA*, where the court agreed that the agency "violated [the law]'s plain text and structure," *id.* at 581, no such argument is at issue here. There is no claim that the FDA acted in direct contravention to a statute, but only that it used its inherent authority when Congress provided another avenue that the agency could have used if "new information" was the basis for reclassification. Similarly, in *Douglas Timber* the court found that "specific administrative procedures exist . . . [for the agency] to amend its own decision by following procedures that require public participation." 774 F.2d at 258. Both *New Jersey v. EPA* and *Douglas Timber* deal with statutory provisions providing clear and limiting guidance to the agency about its ability to use inherent authority. Such language is not present here.

Because of the numerous departures from normal agency practice, the circumstances of this case present the rare situation where the FDA was justified in exercising its inherent authority to reevaluate the approval of the CS device. The Court now turns to the issue of whether the agency did so in a timely manner.[5]

[5] The FDA also cites 21 C.F.R. § 10.33 as justification for rescission, which reads in part: "The Commissioner may at any time reconsider a matter, on the Commissioner's own initiative or on the petition of an interested person." *Id.* § 10.33(a). Because the Court decides on the

B. Whether the FDA acted in a timely manner to reclassify the CS

1. Appropriate Standard to Apply

Although the Court finds that in this case the FDA properly relied on its inherent authority to reevaluate the CS device, that inherent authority is not without limit. The next question is whether the agency acted within a timely manner. The parties look to different D.C. Circuit precedent to support their positions. For Ivy, the key case is *Albertson v. FCC*, 182 F.2d 397 (D.C. Cir. 1950). For the FDA, the key case is *Mazaleski v. Treusdell*, 562 F.2d 701 (D.C. Cir. 1977).

In *Mazaleski*, the D.C. Circuit set out the test that governs this case. There the D.C. Circuit, approvingly quoting *Gratehouse v. United States*, 512 F.2d 1104, 1009 (Ct. Cl. 1975) as "applicable to this case as well," stated:

> We have many times held that an agency has the inherent power to reconsider and change a decision *if it does so within a reasonable period of time*.

562 F.2d at 720 (emphasis added). The Court finds the *Mazaleski* standard applicable here too. The reasonableness approach, rather than a fixed time limit, has also been frequently applied in other circuits. *See, e.g.*, *ConocoPhillips Co.*, 612 F.3d at 832; *Saqr v. Holder*, 580 F.3d 414, 420 (6th Cir. 2009); *Glass, Molders, Pottery, Plastics & Allied Workers Int'l Union v. Excelsior Foundry Co.*, 56 F.3d 844, 847 (7th Cir. 1995); *Dun & Bradstreet Corp. Found. v. U.S. Postal Serv.*, 946 F.2d 189, 194 (2d Cir. 1991).[6]

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alternate grounds described above, the Court expresses no opinion as to whether 21 C.F.R. § 10.33 provides the FDA inherent authority to act in all cases at any time.

[6] Ivy simultaneously claims that *Mazaleski* is "[t]he only D.C. Circuit case that FDA cites in support of the 'short and reasonable time period' standard," (Dkt. No. 62, at 32), but then in a footnote concedes that the FDA also cites *National Ass'n of Trailer Owners v. Day*, 299 F.2d 137 (D.C. Cir. 1962). (Dkt. No. 62, at 39 n.23). Ivy tries to distinguish *Day* in part because it did not explicitly use the phrase "short and reasonable," but *Day* did endorse such a formulation by referring to the appropriate use of inherent authority "both within a reasonable time . . . and

There are important differences between *Albertson*, the case relied on most heavily by Ivy, and this case. According to Ivy, *Albertson* stands for the proposition that agency reconsideration is only permissible "within the period for taking an appeal," 182 F.2d at 399, after which the agency has no jurisdiction to reconsider. Here, according to Ivy, that would be 30 days. *See* 21 U.S.C. § 360g(a)(8). This understanding, however, does not clearly derive from *Albertson*, due to that case's procedural posture. In *Albertson*, the plaintiff, a radio station holder, applied for a rehearing of an FCC order granting another person a license for a new radio station. The FCC dismissed the application. Albertson then filed what the court referred to as a motion to reconsider within the twenty day period for noting an appeal then required by statute. The FCC denied that motion, and Albertson noted his appeal within twenty days of the denial of his motion to reconsider. 182 F.2d at 399. The FCC and an intervenor claimed that the appeal was untimely because the motion to reconsider did not toll the twenty day limitation to file an appeal. The D.C. Circuit disagreed. "We conclude that the Commission did have authority to entertain the motion [to reconsider]; that consideration thereof on the merits suspended running of the period for taking an appeal from the order dismissing Albertson's application for rehearing, and that the twenty day period for noting the appeal commenced from the effective date of the order denying the motion to reconsider. Therefore, we hold that the appeal was taken in time." *Id.* at 400. Thus, *Albertson* decided an appeal to the D.C. Circuit was timely, so long as the appeal was noted within the statutory period following the denial of a motion for reconsideration. It was not really necessary for the court to decide by when a motion for reconsideration must be filed. The language relied upon by Ivy is dictum.

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without subjecting the parties affected to any undue or unnecessary hardships." 299 F.2d at 139-40.

Ivy offers inconsistent interpretations of the import of *Albertson*. At one point the company claims that *Albertson* "made clear that reconsideration is only permissible within the time period for taking an appeal, after which the agency has no jurisdiction to reconsider." (Dkt. No. 69, at 45). But elsewhere Ivy admits that *Albertson* does not establish an unassailable rule, stating that it does "not mean to suggest that an agency can never reconsider its initial decision after the time period for an appeal has passed." (Dkt. No. 69, at 47). *Albertson* held that during the statutory period that aggrieved parties are able to make appeals, there twenty days, a motion to reconsider tolled the appeal period. This was because the FCC's own rule limited the agency's ability to reconsider actions to twenty days. *See* 182 F.2d at 400. Thus, the *Albertson* court's decision was intended in part to equalize the playing field for reconsideration on the agency's own motion with reconsideration on the motion of an interested party. The FDA is correct when it states that "[i]f a statute or regulation states that an appeal deadline applies to an agency as well as others, an agency's inherent authority would be time-limited . . . ." (Dkt. No. 67, at 16 n.8). But there is no such limitation at issue in this case, and *Albertson* therefore is inapposite. By the same logic, Ivy's suggestion that *Albertson* trumps *Mazaleski* because the two are in conflict is rejected. (*See* Dkt. No. 62, at 39 n.24).

American Methyl, citing *Albertson* and other authorities, states that "agencies have an inherent power to correct their mistakes by reconsidering their decisions within the period available for taking an appeal." 749 F.2d at 835. This is true, but *American Methyl* also concedes there may be "further inherent or implicit authority" for an agency to reconsider its actions beyond the time period for appeal where Congress has not specified a mechanism for correcting agency error. *Id.* As described above, the numerous procedural irregularities present in this case lend additional support for finding such authority in this case. Also, because the

authorities cited by the court in *American Methyl* relate to other agencies limited by statutory deadlines, the Court finds the "reasonable period of time" standard to be the proper one for this case. *See Greater Boston Television Corp. v. FCC*, 463 F.2d 268, 287 (D.C. Cir. 1971) (stressing that "precedents pertaining to other agencies are not necessarily fungible, and each case calls for analysis of the statutory system governing the agency in order to ascertain how Congress has balanced the interests of flexibility and finality.").

Even more sui generis is *Prieto v. United States*, 655 F. Supp. 1187 (D.D.C. 1987), which Ivy also relies on for support. At issue in *Prieto* was an appeal for reconsideration initiated by a third party, not the agency acting on its own, and the government had reclassified the challenge from a "notice of appeal"—which was limited by regulation to 30 days—to a complaint—which apparently was not so burdened. *See id.* at 1189-90, 1192. Unlike here, the initial review involved no readily identifiable procedural defects—the court called the reconsideration "a most questionable exertion of an agency's adjudicatory powers." *Id.* at 1191. *Prieto* is also inapplicable because it only dealt with the impact on one individual, "an American Indian who comes under the special protection of this nation's laws and this particular Department's regulations." *Id.* at 1193. *See also Belville*, 999 F.2d at 1002 n.14 (distinguishing *Prieto* based on its effects on "a single individual"). And even *Prieto*, which cites *Albertson*, also approvingly cites to cases that, for example, allow reconsideration when sought "reasonably promptly." 655 F. Supp. at 1192 (citing *Duvin v. Dep't of Treasury, Public Employees' Retirement System*, 386 A.2d 842 (N.J. 1978)).

Given the issues involved in the approval of the CS device described earlier, the Court finds that *Mazaleski* supplies the appropriate standard for this case and that application of the reasonable period of time standard to the FDA's reconsideration in this case is appropriate.

2. How to Determine What is a Reasonable Period of Time

Although application of the reasonableness standard is appropriate, that does not end the timeliness inquiry. The *Mazaleski* court stated that the inherent power to reconsider could be exercised, absent unusual circumstances, "in weeks, not years." 562 F.2d at 720. The FDA argues that under the facts of this case they acted within a reasonable period of time, while Ivy argues that the agency took far too long to act and therefore the reconsideration is outside the bounds of reasonableness.

To determine what is reasonably timely, various factors have been considered by courts. For example, courts have considered: the complexity of the decision; whether the decision was based on fact or law; whether the agency acted according to its general procedures for review; the express time limit for appeals set forth in agency regulations; whether legally cognizable property interests had arisen through the initial decision; whether parties had relied upon the initial decision; whether the agency acted in bad faith by advancing a pretextual explanation to justify reconsideration; whether the agency provided notice of its intent to reconsider the initial decision; and the probable impact of an erroneous agency decision absent reconsideration. *See Macktal v. Chao*, 286 F.3d 822, 826 (5th Cir. 2002); *Belville*, 999 F.2d at 1001; *Dun & Bradstreet Corp. Found. v. USPS*, 946 F.2d 189, 194 (2d Cir. 1991); *Prieto*, 655 F. Supp. at 1192-93. Of those factors listed, the fact that Ivy invested time and money in reliance upon the FDA's substantial equivalence determination weighs in favor of the company, but most factors, notably that the reevaluation involved considerable time and attention to a complicated review, and that there is no evidence of bad faith on the part of the agency, favor the agency.

Courts have varied regarding the determination as to what a reasonable amount of time is. For example, courts have rejected reconsiderations begun more than a year after the initial

adjudication, *see, e.g.*, *Gabbs Exploration Co. v. Udall*, 315 F.2d 37, 41 (D.C. Cir. 1963), and upheld reconsiderations made within a short period, *see, e.g.*, *Mazaleski*, 562 F.2d at 720-21. In *Belville*, 999 F.2d at 1000, the court used the "short and reasonable time period" standard, and found an eight month period to be timely. In *Belville*, pursuant to the Surface Mining Control and Reclamation Act ("SMCRA"), the Interior Department's Office of Surface Mining, Reclamation, and Enforcement suspended and reversed its determination that plaintiffs possessed a valid existing right that would exempt their tracts of land from SMCRA. The court examined eight factors listed above, relying particularly on the complexity of the valid existing right determination, the lack of agency bad faith, the potential impact of an erroneous decision, and the lack of reliance by plaintiff as the state had yet to issue a strip mining permit. *Id.* at 1001-02. The court further noted that the public interest in achieving the correct result tipped the scales in favor of a finding that reconsideration was timely. *Id.* at 1002. Although the FDA cites other cases suggesting an even longer time period may be appropriate, *see Elkem Metals Co. v. United States*, 193 F. Supp. 2d 1314, 1322-23 (Ct. Int'l Trade 2002), the Court finds *Belville* to offer more useful guidance as to the proper time frame.

The next question is how to calculate the relevant time period. Ivy argues that the time period at issue here is twenty-two months, and that the clock stopped running when ReGen received "formal notice" of suspension of the CS device. (Dkt. No. 62, at 39-40 n.26). The FDA argues that *Belville* supports a different time period. The agency construes the language in *Belville* to mean that in this case the time frame is the eight to ten months between the FDA's initial determination and the FDA's notice to ReGen that the agency was reconsidering its determination. (Dkt. No. 67, at 16-17). The Court finds that the agency's reading of *Belville* is the correct one. In *Belville*, the "relevant time period" ran from the initial agency determination

to when the affected party received notice that the determination was "actively under reconsideration," not when the agency made its final decision. *See* 999 F.2d at 1001 n.12. That is, the time period measured was from the determination of Belville's valid existing rights in December 1988 and its receipt of notice of suspension in August 1989, not the later agency reversal of its determination of valid existing claims. This understanding accords with other cases as well. *See, e.g., Dun & Bradstreet*, 946 F.2d at 194 (evaluating period between when Dun & Bradstreet first learned that the Postal Service had approved their request and when they received notice of reconsideration). In this case, the FDA initially classified the CS device in December 2008, began its investigation on April 29, 2009, published its preliminary report in September 2009, and met with ReGen in October 2009. This is the same timeframe at issue in *Belville*. There is an argument to be made that the timeframe here was even shorter, given the evidence in the Administrative Record that ReGen was aware that the agency had begun its reevaluation at the latest as of June 9, 2009. (*See* AR 3300). Either way, the time period falls comfortably within the reasonableness standard. *See Belville*, 999 F.2d at 1002 ("[T]he public interest in achieving a correct result . . . especially tips the scales in favor of a finding that reconsideration was timely.").

C. The FDA Acted Properly and Within its Statutory Authority

1. The FDA evaluated the CS based on its intended use

The agency's substantial equivalence determination of a 510(k) submission is limited to the "intended use" of a device set forth in "the proposed labeling submitted in a report for the device under section 510(k)." 21 U.S.C. § 360c(i)(1)(E)(i). Ivy argues that the FDA acted arbitrarily and capriciously because it failed properly to limit its review of the CS device to the description provided in the device's Indications for Use statement, which states its use "is

intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the medial meniscus . . . and is not intended to replace normal body structure." (AR 3242). The agency counters that Dr. Shuren properly based his decision on "the labeled description of the device," including material outside the Indications for Use statement.[7]

The FDA properly analyzed the Indications for Use statement and looked beyond it as well. In comparing the CS device to predicate devices based on the Indications for Use statement, Dr. Shuren found differences "in two primary respects: none of the predicates are indicated for use in an intra-articular joint space, nor do they contain such explicit directions for preparation of the surgical site." (AR 5467) (footnote omitted). As a result, Dr. Shuren looked at other labeling, including the CS's Instructions for Use. The FDA broadly defines labeling to include "all labels and other written, printed, or graphic matter . . . accompanying such article." 21 U.S.C. § 321(m). This definition indicates Dr. Shuren acted appropriately, and by failing to address the FDA's argument on this point, (*see* Dkt. No. 33, at 44; Dkt. No. 67, at 19-20), Ivy concedes it, *see Newton v. Office of the Architect of the Capitol*, 840 F. Supp. 2d 384, 397 (D.D.C. 2012) ("When a party files an opposition addressing only certain arguments raised in a dispositive motion, a court may treat those arguments that the non-moving party failed to address as conceded."). Ivy also conceded the point when it listed its Instructions for Use under "Proposed Labeling, Packaging." (*See* AR 2663).[8] Based upon his examination, Dr. Shuren

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[7] Ivy also argues that if the FDA thought that the CS device had a replacement function, its proper course was to require an additional labeling statement. But, as explained below, this argument is rejected because the agency can only require additional labeling when an intended use "is not identified in the proposed labeling," 21 U.S.C. § 360c(i)(1)(E), whereas here the agency found the CS device to have a new intended use identified in the proposed labeling.

[8] Ivy suggests that the FDA should have limited itself only to the Indications for Use, "which is the only document that is actually attached to the substantial equivalence determination." (Dkt. No. 62, at 43). But the company failed to address Supreme Court precedent contradicting this argument and cited by the agency. *See Kordel v. United States*, 335

found that "the Instructions for Use make clear that upon implantation the CS device is intended to replace damaged meniscal tissue that has been removed." (AR 5468). Simply because Ivy stated that the CS device is "not intended to replace normal body structure" does not mean it is not intended to replace anything. As Dr. Shuren noted, "this disclaimer does not counter plain statements in both the Indications for Use statement and in the instructions for use that the device is intended to replace *something*, namely, damaged meniscal tissue that has been surgically removed." (AR 5471) (emphasis in original). He later added: "The indications for use statement purporting to indicate the device for use in repair and reinforcement seems to be an attempt to manipulate language to conform the indications for the CS device to those of predicate meshes." (AR 5475). Whether Ivy is correct that looking beyond the Indications for Use Statement is not "[t]ypically" what is done, (Dkt. No. 62, at 43), is irrelevant: there is nothing improper about doing so, *see* 21 U.S.C. § 321(m).

Others at the FDA besides Dr. Shuren shared the view that the CS device was intended to replace tissue rather than simply reinforce and repair damaged tissue. For example, the FDA's lead reviewer noted "that the device was used to replace significant amounts of meniscal tissue that were removed during partial meniscectomy, and NOT to augment tissue that had otherwise been adequately repaired." (AR 2952) (emphasis in original). As Dr. Shuren noted, this was not the opinion of one person, but the review team generally. (AR 5474). Dr. Shuren also noted that "[m]embers of the November 2008 Panel conceded that they were 'having trouble with comparing [the CS device] with predicate devices because [the devices] really aren't used in the same way.'" (AR 5462) (footnote omitted). "Further, the March 2010 Panel in particular expressed uncertainty about what the CS device is intended to do." (AR 5465). While Ivy is

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U.S. 345, 349 (1948) (holding that, for material accompanying a device, "[n]o physical attachment is necessary. It is the textual relationship that is significant.").

correct that the FDA's Donna-Bea Tillman found that Ivy "had provided a plausible explanation for why a 'repair and reinforce' indication was different than a 'replace' indication," (AR 2951),[9] Dr. Tillman finding Ivy's explanation "plausible" does not mean Dr. Shuren's conclusion is not also "plausible."

Dr. Shuren's examination of predicate devices adequately explains why their differences from the CS device indicate the agency did not treat the CS device unfairly. For example, Ivy claims that the DuPuy Restore device "performs the same type of function in the shoulder that the CS is intended to perform in the knee." (Dkt. No. 62, at 45). But Dr. Shuren analyzed the device, and rationally reached a different conclusion: "Though both devices are intended for orthopedic indications, the two devices function differently, are in different anatomical locations, and have different intended uses." (AR 5472). This accords with the remarks of the March 2010 panel member who remarked that "the mechanical requirements of the knee are different than the predicate devices." (*See* AR 5471). Dr. Shuren examined other devices as well, and concluded that

> [n]one of these devices in any of their iterations have an intended use of replacing tissue in the knee that has been surgically excised. The review team considered all predicates indicated by ReGen in its 510(k) submission and concluded that none were suitable predicates for the CS device. I agree with that conclusion.

(AR 5474). Ivy disagrees with this conclusion, but mere disagreement is not enough to overturn an agency's considered analysis. Dr. Shuren gathered and examined the relevant information, and explained his analysis of that information. Thus, the Court finds the agency satisfies the test of establishing a "rational connection between the facts found and the choice made." *Motor*

[9] Ivy claims that Dr. Shuren came to his conclusion "without ever addressing Dr. Tillman's prior memoranda." (Dkt. No. 62, at 42). Not so. Dr. Shuren directly addressed her opinions, and found them too heavily reliant on the November 2008 panel. (AR 5463-64).

Vehicles Mfrs. Ass'n v. State Farm, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).

"[T]he function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Cottage Health Sys. v. Sebelius*, 631 F. Supp. 2d 80, 90 (D.D.C. 2009) (citation omitted). The district court must "review the administrative record to determine whether the agency's decision was arbitrary and capricious, and whether its findings were based on substantial evidence." *Forsyth Mem'l Hosp., Inc. v. Sebelius*, 639 F.3d 534, 537 (D.C. Cir. 2011) (citing *Troy Corp. v. Browner*, 120 F.3d 277, 281 (D.C. Cir. 1997)). A court must "perform a searching and careful inquiry into the facts underlying the agency's decision," but "will presume the validity of agency action as long as a rational basis for it is presented." *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 519 (D.C. Cir. 2009) (citations and quotation marks omitted). "The Court is not empowered to substitute its judgment for that of the agency." *Davis v. Latschar*, 202 F.3d 359, 365 (D.C. Cir. 2000) (citations omitted). This is especially so, as here, in the context of matters involving complex scientific issues. *See Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 378 (1989).

Dr. Shuren's Memorandum to the File contains argument that cannot reasonably be called arbitrary or capricious, which is the standard at issue here. He based his decision on a review of the relevant material, including an examination of both panels, meetings with the review team, and the overall record. (*See* AR 5461). He properly based his conclusion on the CS device's proposed labeling. (*See* AR 5466-67, 5470-76). And while Ivy is correct that not every single person in the entire agency agreed with him, that is not the standard of review. *See Serono Labs, Inc. v. Shalala*, 158 F.3d 1313 (D.C. Cir. 1998) (holding deference "is owed to the

decisionmaker authorized to speak on behalf of the agency, not to each individual agency employee").

2. The FDA Identified Technological Differences Between the CS and Proposed Predicate Devices

The FDCA also states that whether a new device is substantially equivalent to a predicate depends on the device's "technological characteristics"—they need to either be the same or, if different, the manufacturer must demonstrate that the device is as safe and effective as a predicate. 21 U.S.C. § 360c(i)(1)(A). The agency argues, independently from its argument about intended use, that it found the device not substantially equivalent to a predicate because "differences between the technological characteristics of the CS device and each of the predicate devices raise different questions of safety and effectiveness." (AR 5458). Although the agency's argument about differences in device thickness appears weak, Dr. Shuren does properly present concerns about differences in shape.

Dr. Shuren found that the "CS device has different technological characteristics from other [predicate devices] because of differences in shape," (AR 5476), and that these different characteristics "raise new types of safety and effectiveness questions," (AR 5477). Ivy states that Dr. Shuren offered "no reason" for his concerns about the shape of the CS device. (Dkt. No. 62, at 50). But Dr. Shuren stated that "new types of safety and effectiveness questions are raised based on the shape of the CS device in terms of biomechanical properties, composition, and possible chondral changes in the knee joint from the presence of the device." (AR 5477). Again, Dr. Shuren is not alone: the review team also found "different technological characteristics from other meshes because of differences in shape." (AR 5476).

Because of the technological differences, Ivy needed to submit data demonstrating the CS device was as safe and effective as the proposed predicates. A number of people, including Dr. Shuren, found the company failed to do so. For example, in presentations at the March 2010 panel meeting, Srinidhi Nagaraja, Ph.D., noted "inadequacies in the data comparing tensile strength of [the] CS device to other meshes [and] inadequacies in animal data," Dr. Elizabeth Adegboyeha-Panox noted "inadequacies in the clinical data, including the use of the unvalidated Tegner index, missing follow up data, and follow up conducted at different time points," and Scott Miller, Ph.D., noted "inadequacies in feasibility and major clinical study, including potential bias and failure to meet primary and secondary endpoints." (AR 5477). Dr. Shuren concluded that "limitations in the data supporting the effectiveness of predicate devices does not support a finding of substantial equivalence for the CS device because ReGen has provided no valid scientific evidence supporting effectiveness." (AR 5479). Based on his analysis and the analysis of others, Dr. Shuren properly concluded the device is not substantially equivalent. *See* 21 U.S.C. § 360c(i)(1)(A), Again, this satisfies the test of establishing a "rational connection between the facts found and the choice made." *Motor Vehicles Mfrs. Ass'n*, 463 U.S. at 43 (quoting *Burlington Truck Lines*, 371 U.S. at 168).

CONCLUSION

For the foregoing reasons, Defendants' Motion for Summary Judgment (Dkt. No. 28) is **GRANTED** and Plaintiff's Motion for Summary Judgment (Dkt. No. 22) is **DENIED**. An Order accompanies this Memorandum.

Date: April 10, 2013

Digitally signed by Judge Robert L. Wilkins
DN: cn=Judge Robert L. Wilkins, o=U.S. District Court, ou=Chambers of Honorable Robert L. Wilkins, email=RW@dc.uscourt.gov, c=US
Date: 2013.04.10 19:03:31 -04'00'

ROBERT L. WILKINS
United States District Judge