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E-ALERT | Food & Drug

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D.C. DISTRICT COURT RULES FDA HAS INHERENT AUTHORITY TO RESCIND 510(K) CLEARANCE IN "RARE SITUATION"

In a closely watched case, *Ivy Sports Medicine v. Sebelius, et al.*, the United States District Court for the District of Columbia recently upheld FDA's rescission of the clearance of ReGen's[1] 510(k) for the Menaflex Collagen Scaffold device.[2] The court held that FDA has inherent authority to rescind a 510(k) clearance order in "rare situations" so long as FDA acts within a "reasonable time." In upholding FDA's actions, the court focused heavily on the "procedural irregularities" that occurred throughout the process that led to FDA's clearance of ReGen's device.

BACKGROUND

Most Class II devices enter the market pursuant to a premarket notification (commonly known as a "510(k)") submitted to FDA under Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDCA"). To obtain clearance of a 510(k), a manufacturer must show that the proposed device is "substantially equivalent" to a "predicate device."[3] Under FDCA Section 513(i), to be considered substantially equivalent, a device must (1) have "the same intended use as the predicate device," and (2) be the subject of an order by FDA determining that (a) the device has "the same technological characteristics as the predicate device," or (b) if the device has different technological characteristics, it is "as safe and effective as a legally marketed device" and "does not raise different questions of safety and effectiveness than the predicate device."[4] If FDA determines that the device is substantially equivalent to the predicate, the agency issues an order clearing the device for marketing.

Although Congress has expressly granted FDA authority to withdraw or revoke other types of marketing authorizations, the FDCA does not expressly authorize the agency to "rescind" a 510(k) clearance order. FDA has nonetheless asserted that it has authority to rescind 510(k)s in the past, most notably in its responses to a 1994 citizen petition,[5] and in a 2001 proposed rule on rescission. The 2001 proposed rule would have established six grounds for rescinding a 510(k) clearance order, which FDA characterized as situations where "information in the 510(k) is incorrect, incomplete, unreliable, or not evaluated properly by FDA in accordance with section 513(f) and (i) of the act."[6] To support the agency's position that it has 510(k) rescission authority, FDA relied on case law holding that federal agencies have implicit authority to reconsider their decisions and correct mistakes, as

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[1] After the litigation began, Ivy Sports Medicine, LLC became the successor in interest to ReGen, and the court granted the company's motion to substitute for ReGen. For continuity, we will refer to ReGen rather than Ivy Sports Medicine throughout this client alert.
[2] *Ivy Sports Medicine, LLC v. Sebelius, et al.*, No. 11-cv-1006, slip op. (D.D.C. Apr. 10, 2013) (Slip Op.).
[3] 21 U.S.C. § 360c(f)(1)(A)(ii).
[4] 21 U.S.C. § 360c(i)(A)(i)-(ii).
[5] *See* Joseph A. Levitt, Deputy Director for Regulations and Policy, CDRH, Final Response to Citizen Petition, Docket 94A-0388 (Sept. 22, 1997); Joseph A. Levitt, Deputy Director for Regulations and Policy, CDRH, Interim Response to Citizen Petition, Docket 94A-0388 (Sept. 11, 1995).
[6] 66 Fed. Reg. 3523, 3525 (Jan. 16, 2001).

well as on its own regulations. FDA never finalized the 2001 proposed rule, and no agency action has been taken to formalize the agency's claimed rescission authority.

FDA'S CLEARANCE OF REGEN'S MENAFLEX COLLAGEN SCAFFOLD AND THE AGENCY'S SUBSEQUENT DECISION TO RESCIND ITS CLEARANCE ORDER

The regulatory history leading up to FDA's ultimate clearance of ReGen's Menaflex Collagen Scaffold in December 2008 is complicated. ReGen submitted its first 510(k) notification in 2005, wherein the company described the device as a "resorbable collagen-based surgical mesh" that "serves to reinforce and repair soft tissue." FDA refused to clear the 510(k), concluding that the device was not substantially equivalent to a predicate surgical mesh because ReGen had failed to demonstrate that the device was as safe and effective as a legally marketed device.[7] After the company requested reconsideration of this decision, FDA again refused to clear the 510(k) notification, this time reasoning that the device had a new intended use.[8]

About six months later, ReGen submitted a second 510(k) notification, which described the device's use as "repairing and reinforcing meniscal defects." FDA again refused to clear the 510(k) notification. A few months later, both of New Jersey's Senators, as well as two members of the State's House of Representatives delegation, wrote to FDA on ReGen's behalf, requesting FDA's review of ReGen's most recent 510(k) submission and a meeting "to discuss the situation."[9]

Following the suggestion of the then Director of FDA's Center for Devices and Radiological Health, ReGen submitted a third 510(k) notification in July 2008. In September 2008, multiple FDA staff, including the Director of the Office of Device Evaluation, recommended that the Menaflex Collagen Scaffold be found not substantially equivalent. Nonetheless, FDA enlisted its Orthopedic Advisory Panel to review the 510(k). Although the propriety of the procedures used in the advisory panel review was later questioned and many of FDA's staff continued to conclude that the device was not substantially equivalent, FDA relied on the Panel's recommendation and in December 2008, cleared the Menaflex Collagen Scaffold as a Class II device.[10] ReGen began commercial distribution of the device shortly thereafter.

In October 2009, FDA informed ReGen that the agency was reconsidering its decision to clear the Menaflex Collagen Scaffold. A new FDA review team concluded that the device was not substantially equivalent to a predicate device. FDA notified ReGen in March 2011 that it was rescinding its clearance of ReGen's 510(k). As a result, the agency reclassified the Menaflex Collagen Scaffold as a Class III device requiring premarket approval before marketing.

REGEN UNSUCCESSFULLY CHALLENGES FDA'S RESCISSION OF ITS 510(K) IN COURT

ReGen challenged FDA's decision to rescind clearance of the Menaflex Collagen Scaffold in the United States District Court for the District of Columbia. ReGen argued that FDA lacked authority to rescind clearance of the Menaflex Collagen Scaffold, and FDA's rescission therefore violated the Administrative Procedure Act.[11] ReGen argued that FDA was bound to follow the statutory process for reclassification in 21 U.S.C. § 360c(e), which the agency unlawfully failed to do. In response, FDA argued that it had acted properly in rescinding clearance of the device in light of serious procedural

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[7] Slip Op. at 5.
[8] *Id.*
[9] *Id.* at 6.
[10] *Id.*
[11] *Id.* at 11.

irregularities in the clearance process and the absence of any statutory limitation on the agency's power to reconsider its clearance decisions.[12]

The court upheld the agency's rescission of ReGen's 510(k). In doing so, the court addressed two main legal issues: (1) whether FDA has inherent authority to rescind its clearance order outside of the reclassification procedure set forth in 21 U.S.C. § 360c(e), and (2) if the agency has this inherent authority, whether the agency exercised it in a timely manner.[13]

With regard to the question of FDA's inherent authority to rescind its clearance of the Menaflex Collagen Scaffold, the court held that "[b]ecause of the numerous departures from normal agency practice, the circumstances of the present case present the rare situation where the FDA was justified in exercising its inherent authority to reevaluate approval of the CS device."[14] Among the procedural irregularities that led to the court's conclusion were the agency's failure to respond appropriately to external pressure on decision-makers, the exclusion of individuals and viewpoints from the scientific debate, and the excessive reliance on advisory panel deliberations in reaching the final clearance decision. As such, although FDA could have chosen to follow the procedures for reclassification in 21 U.S.C. § 360c(e) if its rescission decision was based on "new information," the agency had inherent authority not to do so with respect to the Menaflex Collagen Scaffold.[15]

Although the court concluded that FDA does have authority to rescind its clearance of ReGen's device, the court noted that this authority is limited. The court concluded that to properly exercise its inherent authority, FDA must act within "a reasonable period of time."[16] The court declined to set forth a specific timeframe that constitutes a "reasonable period of time" for reconsidering a 510(k) clearance. Instead, the court considered several factors in determining what constitutes a reasonable time period, including, among others, the complexity of the decision, whether the agency provided notice of its intent to reconsider the initial decision, whether the agency acted in bad faith by advancing a pretextual explanation to justify reconsideration, and the possible impact of an erroneous agency decision absent reconsideration.[17] The court held that the relevant time period in this case began with FDA's clearance of the Menaflex Collagen Scaffold in December 2008 and extended to FDA's October 2009 meeting with ReGen to discuss FDA's decision to reconsider clearance. The court concluded that, when considering the factors listed above, FDA's reconsideration of its clearance decision falls "comfortably within the reasonableness standard."[18]

The impact of the *Ivy Sports Medicine* decision remains to be seen. Under the Federal Rules of Appellate Procedure, Ivy Sports Medicine has 60 days from the date of the judgment to file an appeal in the D.C. Circuit, unless the company files a motion in the district court for an extension of time to file an appeal.

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[12] *Id.* at 13.
[13] The court also evaluated whether FDA properly limited its substantial equivalence determination to the "intended use" of the Menaflex Collagen Scaffold reflected in the proposed labeling submitted by ReGen. The court held that the agency's substantial equivalence review was proper. *See id.* at 27–33.
[14] *Id.* at 20.
[15] *Id.*
[16] *Id.* at 21.
[17] *Id.* at 25.
[18] *Id.* at 27.

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