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Client Alert

FDA & Life Sciences Practice Group

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FDA 510(k) Rescission Authority Upheld
U.S. District Court Finds for FDA in ReGen Litigation

The United States District Court for the District of Columbia issued an opinion in *Ivy Sports Medicine, Inc. v. Sebelius*, a lawsuit filed in May 2011 by ReGen Biologics, Inc. ("ReGen") against the Food and Drug Administration (FDA or "the Agency") and decided on April 10, 2013. (Ivy Sports Medicine, Inc. ("Ivy") acquired ReGen in June 2011.) The recent ruling is the latest event in ReGen's attempt to reinstate the December 18, 2008, 510(k) clearance for its Menaflex collagen scaffold device that FDA rescinded on March 30, 2011. Although the ruling appears limited in its precedential value, it provides support for FDA's long-held position that it has the inherent authority to rescind 510(k) clearances.

Background

FDA rejected ReGen's first two 510(k) notices for the Menaflex device, filed in July and December 2006, when the Agency determined that the device was not substantially equivalent to the claimed predicate devices. ReGen submitted a third 510(k) for the device in July 2008 and spoke with FDA officials in August 2008 following the lead reviewer's recommendation that the Menaflex be found not substantially equivalent. Following a meeting of the Advisory Panel, ReGen's Menaflex device finally gained FDA clearance in December 2008 as a Class II medical device. The device's indications for use statement noted that the Menaflex was "intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the meniscus" in the knee.

Soon after clearing the device, FDA was criticized for clearing the Menaflex and the Agency began to reconsider its decision. In March 2009, the Wall Street Journal published an article claiming that political lobbying influenced FDA's decision to clear the device. Congress soon began to question FDA about the clearance decision. FDA undertook an internal review in April 2009 and publicly released a preliminary report in September 2009, noting "procedural irregularities" in the review and clearance of the third ReGen 510(k) submission.[1]

During an October 7, 2009 meeting with ReGen, FDA informed the Company that the Agency was reconsidering the Menaflex clearance. In March 2010, FDA convened a meeting of the Orthopedic Advisory Panel. Following further internal review, FDA informed ReGen on October 14,

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2010 that the Agency intended to rescind the 510(k) and the Menaflex's Class II designation, which would reclassify the product as a Class III device. After ReGen declined the opportunity for a hearing on the issue, FDA informed ReGen on March 30, 2011 that it was rescinding the Menaflex 510(k). ReGen filed suit against FDA in May 2011, seeking a judgment that the rescission was illegal and that the December 18, 2008 510(k) clearance be reinstated. ReGen contended that the rescission was unlawful because FDA did not follow the statutory procedure for reclassifying a device contained in 21 U.S.C. § 360(c). Following summary judgment motions by both parties and a hearing on the motions, the court issued its opinion on April 10, 2013.

District Court Opinion

The District Court sided with FDA and found that, given circumstances specific to the history of Menaflex's clearance, the Agency did not unlawfully rescind the Menaflex 510(k). The Court considered three sub-issues in reaching its decision:

Did FDA have the inherent authority to rescind the 510(k)?

The Court first addressed whether FDA was required to follow the statutory reclassification procedure to reclassify the Menaflex as a Class III device and rescind its 510(k), or whether the Agency could simply rescind the 510(k) clearance as an exercise of FDA's "inherent authority." The Court first distinguished *American Methyl Corp. v. EPA*,[2] the case relied upon by ReGen, by finding that the precedent did not apply because of multiple instances of "misconduct affecting the integrity of the [Menaflex's] 2008 substantial equivalence determination." These instances of misconduct included: scheduling an advisory panel meeting with only one, rather than the customary three to five weeks' notice; permitting ReGen to exclude the CDRH review division from speaking at the advisory panel; and inappropriately responding to pressure from Senators and Representatives lobbying FDA on behalf of ReGen. FDA's own September 2009 report also admitted that there was "excessive reliance" on the opinions of the advisory panel when deciding to grant 510(k) clearance.

Because *American Methyl* specifically excluded situations in which misconduct is present from its holding that agencies must use statutory mechanisms to reverse their decisions, rather than acting on their inherent authority, the Court found that it did not apply. This distinction -- while not helpful to ReGen's case -- suggests that misconduct must be present for FDA to use its inherent authority, rather than the statutory reclassification procedure, to reverse 510(k) decisions. Relying on several cases that support agencies' inherent authority to reconsider their decisions and correct their mistakes, the Court found that FDA had the authority to rescind the Menaflex 510(k) without formally reclassifying the device.

Did FDA timely rescind the 510(k)?

The Court next addressed the issue of whether FDA rescinded the Menaflex 510(k) in a sufficiently timely manner. FDA originally cleared the Menaflex on December 18, 2008, began investigating Menaflex clearance decision in April 2009, published the preliminary results of that investigation in September 2009, and finally, informed ReGen in early October 2009 that FDA planned to reconsider the Menaflex 510(k) -- a period of ten months. Applying a reasonableness standard, the District Court found that FDA did act in a reasonably timely manner, putting emphasis on the facts that the reconsideration of the 510(k) required considerable time and attention and was a complicated

process, and that there was no evidence that FDA acted in bad faith. The Court found support in a Sixth Circuit case[3] that found that "the public interest in achieving the correct result tipped the scales in favor of a finding that reconsideration was timely."

Did FDA act properly and within its statutory authority?

The final issue that the Court considered was ReGen's contention that "the FDA acted arbitrarily and capriciously because it failed properly to limit its review of [Menaflex] to the description provided in the device's Indications for Use statement." ReGen contended that the Menaflex device was 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." FDA, however, looked beyond the explicit Indications for Use statement and referred to other labeling including the device's Instructions for Use, finding that the device was in fact intended to replace damaged tissue. Because the predicate devices claimed by ReGen were not intended to replace tissue and were only intended for reinforcement and repair, FDA determined the Menaflex device was not substantially equivalent to the claimed predicates. The Court found that FDA's decision was not arbitrary or capricious and that the Agency was entitled to look to labeling other than the Indications for Use statement to determine the device's true intended use. This finding suggests that although there will always be a marketing incentive to stretch the intended use beyond that of the predicate device through claims in product labeling, doing so may result in adverse consequences, including FDA finding that the product is not substantially equivalent to its claimed predicate.

Implications

In our view, there is a serious question as to whether FDA has the authority to rescind a 510(k) under any circumstances. Indeed, the Federal Food, Drug, and Cosmetic Act does not explicitly confer this power on the Agency. We note that FDA itself has acknowledged the uncertainty regarding its authority to rescind a 510(k). For example, the Agency's own 510(k) Working Group recommended in its 2010 report[4] that FDA "consider issuing a regulation to "define the scope, grounds, and appropriate procedures, including notice and an opportunity for a hearing, for the exercise of its authority to fully or partially rescind a 510(k) clearance." Moreover, the Working Group suggested that FDA also "consider whether additional [statutory] authority is needed" to rescind 510(k) clearances.

Despite the decision in *Ivy Sports Medicine v. Sebelius* permitting FDA to rescind the Menaflex 510(k), it is not settled that FDA has the authority to rescind other 510(k)s using its purported inherent authority. The Court relied heavily on the many examples of misconduct found in the Menaflex 510(k) decision and so the Court carefully limited its decision to instances in which there is demonstrated misconduct in the original 510(k) clearance process. The Court does not expect that FDA will often be able to lawfully rescind 510(k)s: "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 [Menaflex]." (emphasis added)

Finally, the decision's precedential value is also limited to the District of Columbia. Although decisions from the U.S. District Court for the District of Columbia often receive deference from other District Courts in administrative law cases, the decision is nevertheless not binding on any other federal courts.

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[1] Food and Drug Administration, Review of the ReGen Menaflex®: Departures from Processes, Procedures, and Practices Leave the Basis for a Review Decision in Question: Preliminary Repot (Sept. 2009), *available at* http://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM183642.pdf.
[2] 749 F.2d 826 (D.C. Cir. 1984).
[3] *Belville Mining Co. v. United States*, 999 F.2d 989 (6th Cir. 1993).
[4] Center for Devices and Radiological Health, Food and Drug Administration, *510(k) Working Group: Preliminary Report and Recommendations* (Aug. 2010), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220784.pdf.