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Food, Drug & Device Law Alert - Federal Court Of Appeals Holds FDA Lacks Authority To Rescind 510(k) Clearance

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The U.S. Court of Appeals for the District of Columbia recently held that the FDA lacks the authority to rescind a 510(k) clearance. In *Ivy Sports Medicine, LLC v. Burwell*, Case No. 13-5139 (Sept. 26, 2014 D.C. Cir), the court reversed a contrary decision by the district court and ordered the district court to vacate the FDA's decision and remand to the FDA for further proceedings.

The case originally involved a company named ReGen Biologics. In 1993 (twenty years ago!), ReGen began research on a new device for use in certain knee-repair surgeries and eventually developed a product called the Collagen Scaffold. The Collagen Scaffold is a crescent-shaped surgical mesh made of bovine collagen. According to ReGen, the Collagen Scaffold was intended to reinforce and repair the knee cartilage remaining after knee surgery and to provide a scaffold on which new tissue could grow.

ReGen originally submitted a pre-market approval (PMA) application for the Collagen Scaffold, but withdrew it. ReGen submitted two 510(k) applications for the Collagen Scaffold, both of which resulted in a "not substantially equivalent" determination. Some Congressmen wrote the FDA Commissioner on behalf of ReGen, and ReGen then had a meeting with the FDA's Center for Devices and Radiological Health (CDRH), who recommended that ReGen file another 510(k) application with some revisions. FDA's staff again recommended a "not substantially equivalent" decision, but the CDRH Director convened an expert panel instead. The panel voted in favor of the scaffold, and eventually it was cleared and classified in Class II. At this point, other members of Congress complained the scaffold should not have been approved, and FDA launched an investigation. The investigation concluded that there were irregularities in the review process and ultimately the FDA issued an order "rescinding" the approval, forcing ReGen to take the product off the market.

ReGen filed suit in the U.S. District Court for the District of Columbia to challenge the FDA's action. ReGen filed bankruptcy and Ivy Sports Medicine purchased its assets and became a party to the case. As noted above, the district court ruled for FDA and Ivy appealed.

Early in its opinion, the D.C. Circuit noted that the Food, Drug & Cosmetic Act includes a procedure that allows FDA to reclassify a device. According to the court, Section 360c(e) allows FDA to change the classification given to a device. During the time period relevant to the case, that provision stated: "Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an

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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."

This statutory re-classification procedure was dispositive of the issue in the court's opinion. Although the Court agreed that in general administrative agencies have inherent authority to reconsider their decisions, it further concluded:

> [W]e have also recognized that any inherent reconsideration authority does not apply in cases where Congress has spoken. In *American Methyl Corp. v. EPA*, 749 F.2d 826 (D.C. Cir. 1984), we held that an agency may not rely on inherent reconsideration authority "when Congress has provided a mechanism capable of rectifying mistaken actions." 749 F.2d at 835. In such circumstances, we concluded, "it is not reasonable to infer authority to reconsider agency action." Id.; see also *New Jersey v. EPA*, 517 F.3d 574, 583 (D.C. Cir. 2008) ("Congress . . . undoubtedly can limit an agency's discretion to reverse itself"). Put more simply, our cases assume that Congress intends to displace an administrative agency's inherent reconsideration authority when it provides statutory authority to rectify the agency's mistakes.

In short, because the FD&C Act includes the procedure for FDA to reclassify devices, FDA lacked authority to rescind its decision classifying the Collagen Scaffold into Class II and the related marketing clearance. Thus, if FDA still wants to remove the product from the market, it will have to invoke the reclassification procedure and reclassify the product into Class III.

There was a lengthy dissenting opinion, so it will be interesting to see if FDA seeks reconsideration of the panel's decision by the entire Court of Appeals and/or seeks Supreme Court review.

A copy of the court's opinion can be found here.

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