OOPS, FDA approved knee injury device in error

By ACSH Staff — October 15, 2010

The FDA admitted Thursday [1] that it erroneously approved the knee injury device known as Menaflex in response to political pressure from four New Jersey federal legislators and a former FDA commissioner. Menaflex, manufactured by ReGen Biologics Inc., is a dissolvable collagen implant inserted into the knee of patients with an irreparable meniscus tear or tissue loss; it was said to facilitate the growth of new tissue that can support and repair the meniscus, the cartilage that cushions the ends of the bones that form the knee joint. The FDA scientists assigned to evaluate Menaflex for accelerated approval approached Sen. Charles E. Grassley (R-Iowa) and told him that their agency superiors approved the device despite their conclusion that contrary to ReGen s claims the device is significantly different from already approved devices and therefore required further testing. Sen. Grassley subsequently pushed the FDA to admit to the error and reverse Menaflex s approval. As reported in The Wall Street Journal, this is the first time the FDA has reversed an approval without scientific data contradicting a drug or device s safety and admitted to approving a drug in error.

This is a radioactive story, says shocked ACSH President Dr. Elizabeth Whelan. ACSH's Dr. Gilbert Ross adds, The sad truth is that this is going to further undercut the general public s trust in the FDA doing a scientific job, as opposed to being a politically-influenced body.

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