

FDA admits mistake in approving knee device

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(AP) -- The Food and Drug Administration says it made a mistake in approving a controversial knee implant against the advice of its scientific reviewers.

The unprecedented announcement comes a year after the agency first acknowledged that its decision to approve ReGen Biologics' Menaflex implant was influenced by outside pressure, including lobbying by four lawmakers from the company's home state of New Jersey.

The 2008 decision to approve the device was made despite protests by FDA scientists that Menaflex - which reinforces damaged knee tissue - provides little, if any, benefit to patients.

The FDA says it is taking steps to revoke Menaflex's approval, although it also plans to meet with the company to discuss what data would be needed to prove the device is actually safe and effective.

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