Device approval exposes political pressure on FDA

September 25 2009, By MATTHEW PERRONE , AP Business Writer

(AP) -- The Food and Drug Administration has taken the unprecedented step of acknowledging that it buckled to "extreme" pressure from Capitol Hill in its approval of a knee repair device last year. While FDA officials call the situation an anomaly, experts said Friday there is nothing to stop similar political lobbying from influencing future decisions.

In a sweeping critique Thursday, FDA leadership said the agency failed to protect its scientists from outside pressure after they twice rejected ReGen Biologics' Menaflex device.

The Hackensack, N.J.-based company ultimately won approval last December after enlisting the support of four New Jersey lawmakers, who urged then-FDA Commissioner Andrew von Eschenbach to intervene on the company's behalf.

Approval came despite protests by FDA scientists that Menaflex - which reinforces damaged knee tissue - provided little, if any, benefit to patients.

The report marks the first time FDA has openly criticized its own conduct, as Obama appointees try to restore the agency's credibility following a string of bungled drug and food safety issues.

An FDA official called the pressure from Capitol Hill "the most extreme he had ever seen" and the access granted to the commissioner

"unprecedented." Several staffers at the agency called the ReGen ordeal "the worst experience in their professional careers," according to the report.

ReGen Chief Executive Gerald Bisbee said in a statement Thursday that FDA's review involved "procedural irregularities" and does not reflect on the safety of the company's device.

The New Jersey Democrats - Reps. Frank Pallone and Steve Rothman and Sens. Robert Menendez and Frank Lautenberg - received a combined $26,000 in campaign contributions from ReGen executives, according to OpenSecrets.org, which tracks political spending.

Rothman, who represents Hackensack, said he asked the FDA "to treat ReGen fairly, communicate with them better and to render a decision based solely on the science."

A spokesman for Lautenberg said he simply signed a 2007 letter to the FDA along with Rothman, Menendez and former Rep. Mike Ferguson, R-N.J., who left the House in early 2009.

Spokesmen for Pallone and Menendez said the lawmakers called the FDA on ReGen's behalf.

WBB Securities analyst Steve Brozak said there are probably other examples of FDA decisions influenced by politics, but since the agency controls the paper trail, they probably won't come to light.

"I would like to think this was an extreme example, but the better part of me knows it was not," said Brozak, who covers the drug and device industries. "To think FDA isn't influenced by political activism is to not understand the system."

Analyst Ira Loss said federal lawmakers send letters on behalf of companies every day.

"The question is how does the regulator react to the letter," said Loss, who has covered the FDA for over 30 years at Washington Analysis, an investment firm. "In this instance, Dr. Von Eschenbach got very interested."

After lawmakers began contacting the FDA on ReGen's behalf, von Eschenbach became unusually involved in the review of Menaflex, according to the probe. Typically such matters are handled by the agency's lower-level scientific staff.

According to the report, von Eschenbach agreed to a 90-minute meeting with company executives, some of whom "appeared to want the commissioner to personally review" the device.

After the meeting, however, von Eschenbach instructed staffers to "follow the science" in issuing a decision.

A spokesman for von Eschenbach said Friday that he is not commenting on the FDA report.

While the report describes how it handled the Menaflex approval as "unprecedented," the FDA showed itself vulnerable to political pressure only a few years ago.

A federal judge ruled earlier this year that the agency let politics cloud its judgment in 2006 when it denied teenage girls access to the over-the-counter Plan B morning-after pill. The judge said the FDA deliberately delayed making a decision on the birth control pill at the behest of the Bush administration.

When asked Thursday how the FDA would prevent politics from influencing future reviews, agency leaders offered few details. Instead, they said the FDA must develop a clearer system for handling disputes with companies and among staffers.

"The stronger our underlying process is, the less likely it will be interfered with," said Dr. Joshua Sharfstein, FDA's principal deputy commissioner.

The FDA will re-evaluate the decision to approve Menaflex, but currently has no plans to pull it off the market, he said.

Menaflex is ReGen's only FDA-approved product and has generated over $700,000 in sales this year, according to the company.