

[World](#)[U.S.](#)[New York](#)[Business](#)[Markets](#)[Tech](#)[Personal Finance](#)[Life & Culture](#)[Opinion](#)[Careers](#)[Real Estate](#)[Small Business](#)

THE WALL STREET JOURNAL
Small Business WSJ.com

Essential Tools
Smart Reads
Best Advice

Visit
WSJ.com/smallbusiness
today

Dow Jones Reprints: This copy is for your personal, non-commercial use only. To order presentation-ready copies for distribution to your colleagues, clients or customers, use the Order Reprints tool at the bottom of any article or visit www.djreprints.com

[Bajjit Grewal: Ex-budget chief differs with Obama on U.S. tax cuts](#)

[See a sample reprint in PDF format.](#)

[Order a reprint of this article now](#)

THE WALL STREET JOURNAL

WSJ.com

POLITICS | APRIL 7, 2009

Donations Preceded FDA Shift

By [ALICIA MUNDY](#)

Executives of a small medical-device company donated \$50,000 in the 2008 election campaign to New Jersey Democrats who went to bat for the company's knee implant at the Food and Drug Administration, according to campaign donation records.

Three top executives of ReGen Biologics Inc., based in Hackensack, N.J., began the donations in the fall of 2007, about a month after the FDA's second rejection of the medical device. The three together made only two other political donations totaling \$6,000 this decade, according to the Center for Responsive Politics, a nonpartisan watchdog group.

The New Jersey recipients were Sen. Robert Menendez, Sen. Frank Lautenberg, Rep. Frank Pallone and Rep. Steve Rothman, as well as related political action committees. Rep. Pallone is chairman of the Health Subcommittee of the House Energy and Commerce Committee, which oversees the FDA. Sen. Menendez, who was not up for re-election in 2008, received \$18,300, the highest sum.

ReGen spent \$200,000 on lobbyist Michael Hutton, Sen. Menendez's former chief of staff, according to House records. It didn't retain lobbyists before 2007, the records show.

The New Jersey Democrats began pressing then-FDA Commissioner Andrew von Eschenbach to become involved in the ReGen case in late 2007. Three of the lawmakers sent Dr. von Eschenbach a letter, and Sen. Menendez called the commissioner, according to ReGen's lobbyist.

Through 2008, ReGen's executives strove to get the FDA to approve the knee-surgery device called Menaflex. In October 2008, an aide to Rep. Pallone called FDA officials to discuss ReGen's desire for input on the membership and agenda of an agency advisory panel, according to an internal FDA memo. The FDA's top device regulator cleared Menaflex in December 2008.

ReGen said through a spokeswoman that it turned to politicians to prevent FDA scientists from applying what the company considered illegal standards of safety and efficacy. "In contacting members of Congress, ReGen's goal was to obtain fair process and a timely decision" at the FDA, the spokeswoman said. She declined to comment about the donations.

All four New Jersey politicians have said through representatives that their involvement in the ReGen case was aimed at ensuring the company received fair treatment at the FDA.

ReGen Chief Executive Gerald Bisbee and his wife, who live in Connecticut, contributed \$32,100 to the New Jersey candidates and the Democratic Senatorial Campaign Committee between October 2007 and October 2008. John Dichiara, ReGen's government-relations director, gave \$20,800. The company's chief financial officer contributed \$2,500 to Mr. Menendez.

The approval of Menaflex is under investigation in the Senate Finance Committee. In addition, Rep. Michael Burgess (R., Texas) has asked the House Energy and Commerce Committee's investigations panel to review it.

"I am particularly troubled by the allegations" that normal procedures weren't followed in the FDA's approval process, Rep. Burgess wrote in a letter to Rep. Bart Stupak (D., Mich.), head of that panel. Mr. Burgess cited FDA documents in ReGen's case.

Write to Alicia Mundy at alicia.mundy@wsj.com

Printed in The Wall Street Journal, page A6

Copyright 2009 Dow Jones & Company, Inc. All Rights Reserved

This copy is for your personal, non-commercial use only. Distribution and use of this material are governed by our [Subscriber Agreement](#) and by copyright law. For non-personal use or to order multiple copies, please contact Dow Jones Reprints at 1-800-843-0008 or visit

 [Bajjit Grewal: Argentina Government: GDP Seen Growing At Least 5.9% In 2010](#)
www.djreprints.com