Headlines

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FDA's Lobbying Questioned

by Brody Mullins

In a rare lobbying campaign by a federal agency, the Food and Drug Administration has formed an unofficial alliance with the pharmaceutical industry to urge House Members to vote today against a bill that could flood the nation with cheap prescription drugs from Canada and overseas.

The FDA's extraordinary moves to kill the bill — and the informal lobbying partnership between a federal regulator and the industry it oversees — has come under fire from several Members who support the legislation.

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In the last week, Administrator Mark McClellan and other FDA officials have spoken with key Republicans and Democrats to highlight the agency's opposition to a bill sponsored by Rep. Gil Gutknecht (R-Minn.) that would allow "reimportation" of less expensive drugs sold abroad.

Meanwhile, a pair of officials in the FDA's Congressional affairs office spent last week calling key lawmakers in both parties to say, among other things, that the bill would cost the industry $2 billion a year because of new packaging to guard against counterfeits.

The FDA's lobbying effort against the bill is the latest example of the close ties the Bush administration shares with the pharmaceutical industry, one of the biggest financial backers of President Bush and GOP leaders, who oppose the legislation.

As the House vote on the reimportation bill neared, the FDA ramped up a campaign to defeat Gutknecht's legislation on Capitol Hill by highlighting the alleged flaws in the legislation.

With help from lobbyists in the pharmaceutical industry, McClellan on Friday circulated a letter to lawmakers charging that the bill would make it more difficult for the FDA to ensure the "safety and efficacy" of prescription drugs in the United States.

“The agency has serious public health concerns regarding this legislation,” McClellan said in a letter to House Energy and Commerce Chairman Billy Tauzin (R-La.).

At the same time, lobbyists for U.S. drug-makers — which stand to lose the most if the legislation is approved — have used their resources to help distribute the FDA’s critiques of the measure to nearly every office on Capitol Hill.

After McClellan sent the letter, lobbyists for drugmaker Johnson & Johnson e-mailed it to key Congressional offices.

Separately, FDA officials called Members to outline the agency’s concerns with the bill.

“The FDA has longstanding concerns about the importation of drugs and believes that this bill would severely compromise the safety of consumers,” said one such message left by Diane Prince, who works in the agency’s legislative affairs office.

Prince went on to say that the bill would “cost consumers $2 billion per year because it requires manufacturers to incorporate anti-counterfeiting technology into their packaging.”

The letters and phone calls against the bill echo calls by pharmaceutical companies, which believe the bill will undercut the industry’s incentive to invest in the research and production of future drugs.

Earlier this month, a lobbyist for drugmaker Johnson & Johnson sent House offices a list of more than a dozen health and safety protections undermined by the importation bill.

“It’s dishonest and hypocritical,” Rep. Bart Stupak (D-Mich.) said of the lobbying effort.

Executive branch agencies are permitted to lobby Congress as long as the efforts do not balloon into “costly letter-writing or similar publicity campaigns” designed to urge the public to contact Members of Congress about legislation, according to a report by the Congressional Research Service.

The 1919 measure that bars pricey grassroots efforts caps the cost of such campaigns at $7,500 — or about $75,000 in today’s terms.

Still, federal agencies come under attack from time to time on Capitol Hill for their moves to advocate for or against legislation.

Several years ago, House Members threatened to eliminate funding for the Federal Communications Commission’s Congressional affairs office after lobbyists for the agency pressed Members to block legislation sponsored by Rep. Mike Oxley (R-Ohio) to pull the plug on low-power radio operators.

Before that, the Environmental Protection Agency found itself sullied by charges that it improperly influenced Congress.

Both efforts caused controversy on Capitol Hill but ultimately did not result in

legislation. Lawmakers involved in the most recent lobbying effort say they are still determining if they will try to take action against the FDA.

A spokesman for the FDA said it is perfectly legal — and common — for the agency to contact Members to highlight its position on bills under consideration.

“It’s standard practice for the Office of Legislative Affairs to educate Congress about an issue,” said FDA spokesman Jason Brodsky. “The whole purpose of that office is to educate Members and their staffs about public health legislation.”

Brodsky added that the phone calls to lawmakers were routine contacts to follow up on a June 24 Energy and Commerce Committee hearing in which a pair of FDA officials, William Hubbard and John Taylor, testified about the dangers of the legislation.

Still, several health care staffers who received calls from the FDA found them highly unusual.

“In my years doing health care issues I have never gotten a call from an agency on a piece of legislation,” said one staffer. “What really put off a red flag was when [the FDA official] mentioned the specific bill number and asked how my boss was going to vote. I thought, ‘Oh my gosh, this is lobbying.’”

She added: “I felt like I was being lobbied. Period. It’s one thing to talk about a bill — it’s another thing to ask how we are voting and to talk about a specific bill number.”

But not all heath care aides who received phone calls from the FDA found them unusual.

“I don’t feel like we have been improperly pressured by the FDA,” said an aide to one Member who supports the FDA’s stance. “Agencies write letters about legislation all the time. Usually we want to know what the agency’s positions are on a bill.”

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