

Washington, DC - Congressman Maurice Hinchey (D-NY) today demanded answers from the Food and Drug Administration (FDA) over the agency's recent dismissal of an advisory board panelist at the apparent request of the pharmaceutical company whose drug was under review. According to news reports, the FDA withdrew Dr. Sanjay Kaul's invitation to serve as an advisory panel member for the agency's review of the blood thinner drug, prasugrel, after Eli Lilly, the drug's manufacturer, complained to the FDA about critical comments Dr. Kaul previously made about the drug.

The congressman today sent a letter to Dr. Janet Woodcock, who is the director of the FDA's Center for Drug Evaluation and Research, which dismissed Dr. Kaul, asking her for an explanation of the agency's actions, what it defines as intellectual conflicts of interest, and a list of other similar incidences. Hinchey, who is a member of the House Appropriations Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, which allocates the FDA's budget, noted that Eli Lilly had a direct financial conflict of interest when it urged the agency to disinvite Dr. Kaul.

Hinchey has led the effort in Congress to end the FDA's practice of granting waivers to advisory panel members who have financial conflicts of interest with the drugs and devices they review. The congressman has successfully authored legislation in the House over the past several years that would forbid any such waivers.

The full text of Hinchey's letter to Woodcock follows:

February 26, 2009

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Building 51, Room 6133
Silver Spring, MD 20993

Dear Dr. Woodcock:

I am writing to express my concern with the Food and Drug Administration's decision to withdraw Dr. Sanjay Kaul's invitation to participate in the agency's Drug Safety and Risk Management Advisory Committee review of the drug prasugrel. As you know, several news reports have suggested that the FDA withdrew Dr. Kaul's invitation at the behest of Eli Lilly, the manufacturer of prasugrel, because the company was upset over critical comments he had previously made about the drug.

Eli Lilly has claimed that Dr. Kaul had an intellectual bias towards prasugrel, which the company argued should disqualify him from lending his opinion to the advisory committee reviewing the drug. While I understand that the FDA has a formal process to evaluate claims of intellectual conflicts of interest to ensure fairness in the evaluation of a drug, it does not appear to have followed its own rules in the case of Dr. Kaul. My understanding is that agency staff made the decision to disinvite Dr. Kaul after conferring with representatives from Eli Lilly just days before the committee meeting. It has been reported that the staff did not bring this matter to your attention, which I understand is required under agency rules. In fact, you have been quoted as saying that "we didn't go through our ordinary procedures" in making the decision to not include Dr. Kaul in the approval process. While I appreciate the FDA's admittance of fault, I am much more concerned about the fact that the agency removed a panelist at the request of the company whose drug was under review.

As a longtime critic and author of successful House legislation that would end the FDA's repeated practice of issuing waivers to advisory panel members with financial conflicts of interest, I have long been concerned that the FDA is too closely tied to the drug industry and has lost its way as a regulator whose primary concern is public safety. This situation does not instill policymakers with confidence that the FDA is capable of objectively overseeing the drug industry. How can we trust the FDA if a drug maker like Eli Lilly can get a potential agency advisor that it doesn't like disqualified from submitting an opinion? It seems to me that the real conflict of interest in this matter rests with Eli Lilly, which stands to profit greatly from the approval of its drug. The FDA needs to be able to withstand the pressure coming from a manufacturer whose primary interest is recovering costs and making profits and make objective decisions. Unfortunately, this situation raises serious doubts as to your agency's ability to do that.

There is no room for easily preventable errors or mistakes in the drug-approval process. Americans need to be able to trust that the FDA is not taking orders from the drug industry and unjustly excluding the views of medical experts during the drug approval process. The FDA

was created to protect the public interest, not the interests of the drug industry. It is time for the FDA to once again start doing its job and protect the American people.

Given the serious nature of this incident, I request that you provide me with the information and answers to the questions below:

- A detailed description of the FDA's process for determining an intellectual bias in a candidate selected to serve on an advisory panel.
- A list of other candidates from this and other advisory panels deemed by the FDA to have an intellectual bias who have had their invitations to serve as advisors withdrawn. Please also include the FDA's justification of their dismissals.
- Looking ahead, what will the agency do differently to ensure this breakdown in communication never happens again between agency staff and senior FDA officials?
- In retrospect, if the correct procedure was followed and you had been alerted to this situation by agency staff, would you have also decided to exclude Dr. Kaul from the advisory meeting?

Thank you for your prompt attention to my request. I look forward to hearing from you.

Sincerely,
Maurice D. Hinchey