

*Agency Reportedly Withdrew Dr. Sanjay Kaul's Invitation at Request of Drug Manufacturer*

*Washington, DC* - The Food and Drug Administration (FDA) has formally admitted to Congressman Maurice Hinchey (D-NY) that agency officials wrongly dismissed a doctor who was scheduled to serve on an advisory board earlier this year and that the panelist would have been able to serve on the committee had proper agency protocol been followed. The agency's written admission comes in response to a letter Hinchey sent to the FDA demanding answers as to why agency officials withdrew Dr. Sanjay Kaul's invitation to participate on an advisory board just days before that panel was set to debate the safety of the blood thinner drug, prasugrel.

According to news reports, the FDA decided to remove Kaul after the maker of prasugrel, Eli Lilly, complained to agency officials about past comments made by Kaul that expressed concerns about the drug. The FDA admitted that the decision to remove Kaul was made by agency staff that did not have the authority to unilaterally do so. The agency said that the removal was made without a proper evaluation and without consulting the director of the FDA's Center for Drug Evaluation and Research or the FDA's Commissioner's office as agency protocol states. Nevertheless, the agency did not detail what the motivation was for the agency staff to improperly dismiss Kaul nor does it mention if those staff members were reprimanded in any formal or meaningful way. The agency does not, however, refute Hinchey's argument that the decision was made after FDA officials consulted with Eli Lilly representatives.

"The FDA should not be in the business of picking and choosing advisory panelists based on what a drug company thinks about a particular panel member," Hinchey said. "Rather, the FDA should be solely concerned about picking the best scientists and doctors to serve on their advisory panels so that decisions can be made exclusively in the best interests of the American people, not the shareholders of drug companies. Dr. Kaul's removal from the prasugrel advisory board underscores the underlying problem of FDA officials having inappropriately close ties to drug industry representatives. I appreciate the FDA's candor in admitting that a mistake was made, but that admission begs the question of what steps they are taking to reprimand the staff members who were responsible for preventing a well-respected doctor from participating on an advisory panel and to ensure that a similar situation doesn't happen in the future."

In February, Hinchey sent a letter to Dr. Janet Woodcock, who is the director of the FDA's Center for Drug Evaluation and Research, which dismissed 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 Kaul.

In its response to Hinchey, the FDA acknowledged that instances of intellectual bias "occur very infrequently." In fact, the agency noted that while manually looking into Hinchey's request for a list of other candidates for advisory panels who were dismissed by the FDA because of a perceived intellectual bias, it could only identify "two relevant situations over the past five years."

"The fact that cases of intellectual bias occur so infrequently makes it even more alarming that FDA staff would take such bold action without consulting senior agency officials," Hinchey said. "The FDA is broken and is in need of comprehensive reform that will break the inappropriately close ties between the agency and the drug manufacturers it is supposed to regulate."

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 authored legislation in the House over the past several years that would forbid any such waivers.