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Bill calls for FDA to end all conflicts of interest
Agency faces pressure on advisers who have financial ties to firms

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WASHINGTON - The **Food and Drug Administration** could face a tough new assignment from Congress: Eliminate all **conflicts of interest** on outside advisory panels whose votes heavily guide the agency's decision-making.

US Representative Maurice Hinchey, Democrat of New York, attached such language to an agriculture appropriations bill passed by the House last week. The funding measure next moves to the Senate, where the **FDA** conflicts section faces a tough fight; opponents include Senator Edward M. Kennedy, Democrat of Massachusetts.

Regardless of the Hinchey proposal's fate, such congressional chatter might trigger the **FDA** to act forcefully on its own.

Under congressional pressure, the agency said earlier this year that it intends to bar advisers with financial ties to drug and medical device companies that exceed $50,000. Even researchers whose grants or consulting fees amount to less than $50,000 during the previous 12 months would be affected

under the draft guidance; they would be allowed to serve as **FDA** advisers but could not vote on the meeting's outcome. The **FDA** is still sifting public comments and has not issued a final proposal.

The moves come amid unprecedented attention to the billions of dollars in drug industry funding that flow through academia and the nation's top hospitals. Because so many leading researchers accept drug and device company funding, the **FDA** has said it has a difficult time eliminating all traces of financial ties among its advisers. Often it can't find enough scientists free of conflicts within the **FDA** or other federal health agencies, such as the National Institutes of Health and the Centers for Disease Control and Prevention. The **FDA** has argued that it must retain the latitude to grant waivers so the nation's finest scientific talent will be able to serve on advisory panels.

That's a viewpoint endorsed by Kennedy, who noted that doctors Craig Mello and Phillip Sharp, Nobel-Prize-winning Massachusetts scientists, would face limits on their participation on **FDA** panels if Senate proponents of the stricter rules were successful.

"Many of the nation's best scientists wear both hats - working in an academic lab one day and consulting for a start-up biotech firm the next," Kennedy said in May, rejecting a move to impose an "inflexible" cap on the number of waivers the **FDA** can grant.

Last week, for example, five researchers on the 26-member panel that decided to keep the diabetes drug Avandia on the market had financial ties to GlaxoSmithKline PLC, its manufacturer, or to rival companies.

Dr. John R. Teerlink, director of the heart-failure clinic at the

San Francisco Veterans Affairs Medical Center, reported receiving the highest level of funding - between $10,001 and $50,000 as a reviewer for a drug company that competes with Glaxo and $50,001 to $100,000 in stock held in a health sector mutual fund. Teerlink, permitted to vote by the **FDA,** agreed with the majority that Avandia's emerging heart attack risks are real, but he also voted to keep the drug on the market.

Dr. Curt Furberg, who also served on the Avandia panel, expects congressional interest will lead the **FDA** to further refine what it considers to be a **conflict of interest.** Furberg is paid $200 annually to consult for the NIH on a diabetes study that includes Avandia. The **FDA** permitted him to serve as a temporary adviser for the Avandia panel but barred him from voting.

Furberg, a drug safety expert at Wake Forest University School of Medicine, and others have argued that the **FDA** packs panels with clinicians more apt to keep questionable products on the market to help their patients but includes fewer drug safety proponents who argue for restrictions and market withdrawals.

"My assumption is it is going to be tougher to stack the committee with people who have conflicts," Furberg said. "The first step is to limit the number of people with potential conflicts. The other is to define conflict more explicitly."

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