

*News from the*

**U.S. Senate Committee on  
Health, Education, Labor and Pensions**

**Michael B. Enzi (Wyoming), Chairman**



**For Immediate Release  
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## **Enzi, Kennedy, Durbin Request GAO Review of Waivers Granted to FDA Advisory Panelists**

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Washington, D.C. - U.S. Senator Mike Enzi, R-WY, Chairman of the Senate Health, Education, Labor and Pensions Committee (HELP Committee) and Senator Edward M. Kennedy, D-MA, Ranking Member of the Committee, have asked the Government Accountability Office (GAO) to review the Food and Drug Administration's practice of providing conflict of interest waivers to members of its scientific advisory committees, the panels charged with recommending approval of drug and medical devices for public use.

Enzi and Kennedy, joined by Senator Richard J. Durbin, D-IL, the Assistant Democratic Leader, made the request today saying: "We are concerned about the process that supports FDA's decisions to waive conflicts of interest rules for scientists with financial ties to the manufacturers of the products under consideration, or their competitors."

"The scientific advisory committee system at the FDA is meant to provide the agency with unbiased, independent and professional advice on general scientific matters and issues related to particular products or classes of products," the Senators said. "The scientific expertise provided by advisory panels is critical to FDA's ability to fulfill its mission of protecting public health."

The request came in a letter to David M. Walker, Comptroller General of the GAO. It referenced allegations related to the FDA advisory panels that reviewed the safety of Cox-2 inhibitors, such as

the pain reliever Vioxx, as well as panels convened to review the safety of silicone gel breast implants.

“We are concerned about allegations with regard to FDA's use of waivers of the conflict of interest requirements,” the Senators continued. “These practices appear to have undermined the public's faith in the objectivity and fairness of FDA's advisory committees. Further, there are questions about transparency in FDA's procedures for forming advisory committees and granting waivers.”

By law, advisory committee members must be free of conflicts of interests concerning the products they discuss. However, FDA has the authority to grant waivers to the conflict of interest requirements if it determines that an expert's participation is necessary, the financial interests are not so substantial as to affect the integrity of his or her service to the committee, or if the need for the expertise outweighs the potential risk of conflict due to the financial interest.

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