

# Congressional report reveals FDA "conflict of interest"

A House Government Reform Committee staff report has criticized the Food & Drug Administration (FDA) and the Centers for Disease Control (CDC) for routinely allowing scientists with conflicts of interest to serve on two influential advisory committees that make recommendations on vaccine policy.

The report concluded that, "conflict-of-interest rules employed by the FDA and the CDC have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings."

In a letter to Health and Human Services Secretary Donna Shalala, Chairman Burton called for reforms to crack down on conflicts of interest on the two committees. The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) makes recommendations on the approval of new vaccines. The CDC's Advisory Committee on Immunizations Practices (ACIP) makes recommendations on guidelines for the administration of vaccines.

The Government Reform Committee staff report found that the majority of members of both committees have financial ties to vaccine manufacturers or hold patents on vaccines under development.

The report focuses on the advisory committees' review of the controversial rotavirus vaccine in 1997 and 1998.

Despite concerns about potentially serious side effects of the drug, it won unanimous votes of support in both committees. Within one year, the vaccine, made by Wyeth Lederle, had to be pulled from the market because it was causing severe bowel obstructions in infants that required surgery to correct. One baby died.

The Committee found that three out of the five full-time FDA advisory committee members who voted for the vaccine had financial ties to Wyeth Lederle or two companies developing rival rotavirus vaccines -- Merck and SmithKline Beecham. Four out of eight CDC advisory committee members who supported the vaccine had conflicts with the same companies.

The staff report concluded that the committees demonstrated a "lack of vigilance" in their review of the rotavirus vaccine known as "Rotashield," with the CDC's committee rushing to approve guidelines for the vaccine even before the FDA had licensed it.

Other highlights from the staff report include:

\*\*\* One physician who voted to recommend the rotavirus vaccine on the FDA's advisory committee received \$255,000 per year in research funds from the maker of the vaccine, Wyeth Lederle. She received a waiver from the FDA to vote on the issue because her research for Wyeth focused on other vaccines.

\*\*\* One member of the CDC's advisory committee who was not allowed to vote on the rotavirus vaccine because of a conflict was allowed to participate in closed-door working group meetings that drafted the committee's recommendations for the vaccine. He was also allowed to make an impassioned plea for approval of the vaccine at the full committee meeting.

\*\*\* Another member of the CDC's advisory committee held a lucrative patent on a rival rotavirus vaccine under development by Merck. Despite this conflict, the doctor voted three times on recommendations regarding Wyeth's vaccine. It was not until the committee voted to rescind its recommendation of the rotashield that he recused himself because of a "perception of conflict."

\*\*\* The staff report took issue with the FDA's lax guidelines for conflicts of interest. For instance, under the FDA's rules, ownership of up to \$25,000 of stock in a vaccine sponsor is considered a "low-involvement" conflict that is routinely waived. Ownership of up to \$100,000 in stock is considered a "medium involvement" conflict that is also eligible for waiver. Until some time in 1999, the chairman of the CDC's advisory committee owned 600 shares of stock in Merck, one of the world's largest vaccine manufacturers. The chairwoman of the FDA's advisory committee also owned Merck stock.

\*\*\* The staff report found that the CDC's practice of automatically granting annual waivers to all members of its committee for one-year periods "does not lend itself to a healthy respect for the conflict-of-interest rules." (Members who have direct conflicts with the sponsor of a vaccine are generally not allowed to vote on that company's products, but they are free to participate in working groups that draft the recommendations and in committee deliberations leading up to the vote.)

In his letter to Secretary Shalala, Chairman Burton stated:

"For the public to have confidence in the decisions made by their government, they must be assured that those decisions are not being affected by conflict of interest. ... It has become clear over the course of this investigation that the VRBPAC and the ACIP are dominated by individuals with close working relationships with the vaccine producers. This was never the intent of the Federal Advisory Committee Act, which requires that a diversity of views be represented on advisory committees."

**SOURCE:** U.S. House of Representatives Committee on Government Reform, August 2000.