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Feds' conflict of interest over vaccines?

Committee eyes 'incestuous' ties between drug-makers, FDA, CDC

by Jon E. Dougherty

The House Committee on Government Reform has pledged to examine complaints that some pharmaceutical companies have been exerting undue influence over key federal advisory committees tasked with approving vaccines for mandated health-care programs.

Yesterday, the committee, chaired by Rep. Dan Burton, R-Ind., held hearings into what some have called an "incestuous" relationship between drug-makers and those charged with approving them for use in mandatory child vaccine programs.

Last August, the committee launched an investigation into charges that some drug companies had a conflict of interest with federal policymakers who decide which vaccines would be mandated or approved for the general public.

Rep. Dan Burton, R-Ind., chairman of the House Government Reform Committee

According to a statement, the committee conducted an extensive review of financial disclosure forms and related documents, and interviewed key officials from the Food and Drug Administration and the Centers for Disease Control and Prevention.

"In the course of the investigation, the committee has discovered that many individuals serving on two key advisory committees have financial ties to the pharmaceutical companies that manufacture vaccines," said a committee report on Wednesday. "Often, these individuals were granted waivers to fully participate in the discussions that led to recommendations on vaccine licensing and adding vaccines to the Childhood Immunization Schedule."

Under federal law, advisory committee members must recuse themselves from making decisions about vaccines in which they may have a financial interest. Also, advisory members are required to disclose any financial conflicts of

interest.

However, the committee's investigation found 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."

Specifically, Burton's investigation found:

- The CDC routinely grants waivers from conflict of interest rules to every member of its advisory committee.
- CDC advisory committee members who are not allowed to vote on certain recommendations due to financial conflicts of interest are allowed to participate actively in committee deliberations and advocate specific positions.
- The chairman of the CDC's advisory committee until recently owned 600 shares of stock in Merck, a pharmaceutical company with an active vaccine division.
- Members of the CDC's advisory committee often leave key details out of their financial disclosure statements and are not required to provide the missing information by CDC ethics officials.

Yesterday's hearing focused specifically on the FDA's and CDC's approval of the controversial rotavirus vaccine in 1998 and 1999. The committee's report said that three out of the five FDA advisory committee members who voted to approve the rotavirus vaccine in December 1997 had financial ties to the pharmaceutical companies that were developing different versions of the vaccine. And, investigators said, four out of the eight CDC advisory committee members who voted to approve guidelines for the rotavirus vaccine in June 1998 had financial ties to pharmaceutical companies that were developing different versions of the vaccine.

The vaccine was pulled from the market a year after its approval because it caused severe bowel obstructions.

However, CDC and FDA officials defended their decision to launch the vaccine, saying that studies showed virtually all U.S. children were susceptible to the rotavirus.

Dr. Dixie Snider, assistant surgeon general and executive secretary of the CDC, testified that the rotavirus vaccine was approved for a number of reasons.

"The vaccine could prevent 50 to 75 percent of all rotavirus cases, and it was found to be effective against 80 percent of the most serious cases, where

dehydration and death were involved," Snider said.

"The rotavirus does not respect race or gender," he added, noting that all children could contract it regardless of "social or gender" status.

Snider also said he knew of no financial conflicts of interest among advisory panel members. Furthermore, he said a drug-maker's vaccine revenue only averaged about 1.5 percent of total revenues, "so nobody's stock was going to rise too much" by the advisory panel's approval of the rotavirus vaccine.

Critics of the government's approval process, however, have also charged that the CDC and FDA may also have ignored key life-threatening information about the rotavirus vaccine.

According to the Association of American Physicians and Surgeons, the rotavirus vaccine was pulled after at least 15 infants suffered life-threatening intestinal obstructions (intussusception) after receiving the vaccine.

But, the group said, "what may be even more alarming is the rate of intussusception in the clinical trials that were the basis for the vaccine's approval.

"A search of the records by AAPS reveals that it was 30 times the expected rate," said a report published April 6. "But neither physicians nor parents were warned to watch for symptoms of intussusception. Eight infants have needed surgery, and one lost seven inches of bowel."

"The situation with the rotavirus vaccine may be a clue to a far more serious problem with the vaccine approval process," said Jane Orient, M.D, executive director of AAPS, in a letter written to Burton last August.

Though official reporting methods eventually alerted federal health officials to the rotavirus side effects, Orient asked why the vaccine was approved "in the first place when the incidence of the serious complication of intussusception was far higher in pre-licensure trials" than those reported through official channels after it was in use.

"We must ask, what did they know, and when they know it?" she wrote. "AAPS has been studying the reports and has concluded that the FDA and CDC may have ignored or concealed data that showed the problems from the outset."

Despite the AAPS findings, on its website the CDC said of the rotavirus in March 1999: "In studies that have been done so far, [it] has been associated only with mild problems."

Orient called for public disclosure of the approval process and independent review of data, and supports a Senate measure that would require public access

to all federally-funded research.

"Sunshine is a disinfectant, and public access to such data minimizes the opportunity for corruption, mistakes and fraud concerning such data," she said.

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