Congressional Hearing Exposes Conflicts of Interest

June 28, 2000

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When a rotavirus (infant diarrhea) vaccine was suddenly withdrawn from the market last year, the public was led to believe that it was because of new information about harmful side effects. At a hearing last week conducted by Rep. Dan Burton (R-IN), we learned that other factors influenced the 1998 Food and Drug Administration (FDA) licensing and Centers for Disease Control (CDC) recommendation.

The FDA and CDC use outside advisory committees to consider new vaccines, and federal laws are supposed to limit conflicts of interest. It now turns out that half of those on the two key committees voting for the rotavirus vaccine had financial ties to vaccine manufacturers, such as being paid as consultants or lobbyists or owning vaccine patents or stock in pharmaceuticals.

The FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) decides whether vaccines are licensed. The CDC Advisory Committee on Immunizations Practices (ACIP) decides whether a vaccine should be included on the Child Immunization Schedule, i.e., put on the list of mandatory vaccines, a decision that overnight makes the vaccine immensely profitable.

Most of the work of the CDC advisory committee is done in "working groups" behind closed doors without public scrutiny. Six of the ten working groups had financial ties to pharmaceuticals that make rotavirus vaccines.

In pre-licensure trials for the rotavirus vaccine, some babies suffered obstructed bowels a week later, some requiring surgery to remove a portion of the intestine, a painful condition called intussusception. Nevertheless, the committees approved the vaccine for universal use, calling these reports statistically insignificant.

Within months, 1.5 million vaccine doses were given to infants. The Department of Health and Human Services, in its announcement, stated that "the most common adverse reactions included moderate fever, increased irritability, and decreased appetite and activity," with no mention of side effects requiring hospitalization or surgery.

The study data were concealed, and the public did not learn of the problem until more than 100 cases of intussusception were reported, including one death.

The Burton hearings provided some answers to help explain this disaster. When the rotavirus vaccine was approved by the FDA committee, 8 of the 15 members were absent, 2 were excluded, and 4 of the remaining 5 had conflicts of interest that necessitated waivers.

This was not a quorum so they were joined by 5 temporary members, and then all voted to approve the vaccine. The committee's own charter states that temporary members are not normally to exceed 4.

The vaccine was not even considered to be all that effective in preventing diarrhea in infants. In a U.S. multicenter trial, for example, the rotavirus vaccine only had a 49% efficacy rate in preventing rotavirus disease.

The CDC routinely grants conflict-of-interest waivers to every member of its advisory committee a year at a time, and allows full participation in the discussions by all members even if they have a financial stake in the decision. One member who cast three votes to recommend the rotavirus vaccine owned a patent for another rotavirus vaccine and admitted that he was paid by the pharmaceutical industry to travel around the country and teach doctors that vaccines are safe.

The data about side effects were never made available to the public. The public still has no access to the actual data concerning side effects of the rotavirus vaccine or for the controversial chicken pox or hepatitis B vaccines.

If these new vaccines are safe, there should be no objection to releasing the actual data that demonstrate this. The obvious incentive to conceal such data is to hide facts that dispute the public recommendations.

At the June 15 hearing, officials from the FDA and CDC defended the various conflicts of interest because waivers were granted. One CDC official went so far as to suggest that it good to use vaccine industry insiders on official advisory committees because they are able to vote based on secret drug-company information!

That is tantamount to letting vaccine industry lobbyists write their own profitable government mandates, i.e., simply own the process.

It is a great mistake to make vaccine policy based on confidential or trade secret data. Science is most reliable when all data and analyses are subject to public scrutiny, and our political system demands that government policy decisions be subject to democratic checks and balances.

The whole concept of the government forcing experimental health treatment on healthy individuals is disturbing to those who value freedom. Mandatory vaccine policies depend on overwhelming public acceptance, but public confidence is eroded by conflicts of interest and secrecy of deliberations and data.

Government should put all the data, analyses and meeting minutes on a public web site, and this should include a risk-benefit analysis, cost-benefit analysis, and a comparison against alternate policies. Only public data and arguments should be considered.

The CDC should appoint advisory committee members with diverse points of view. Scientists from other fields, consumer advocates, and even vaccine critics would greatly improve the quality of the recommendations because more policy implications would be considered. Congressional Hearing Exposes Conflicts of Interest

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