News 8 Investigates: Prevnar

Reporter: Valeri Williams

Updated: Feb 23, 2001 at 01:26PM

http://www.wfaa.com/wfaa/articledisplay/0,1002,20489,00.html

Part 1

DALLAS — By the time our children are old enough to go to school in this country we have given them nearly 40 doses of vaccines.

In 1940, children received just nine doses of vaccines.

News 8 Investigates has been looking into the questionable science behind the federal government's vaccine approval process and what parents should know about the latest vaccine on the market, Prevnar.

This is not a report about vaccines being bad. In the past 50 years, they have helped us to eradicate polio, smallpox and whooping cough, just to name a few dreaded childhood diseases.

But as the number of vaccines grows in this country, so do the profits for the pharmaceutical companies who manufacture them.

"The vaccine manufacturer of a new vaccine that's added to the universal use list has an assured stable market of three-and-a-half to four million babies born in this country every year," said Barbara Loe Fisher of the National Vaccine Information Center. "As of 1986, the manufacturer has virtually no liability for adverse events that may occur, as do the doctors who administer the vaccine as of 1986. No liability. Stable, made market. No liability. A stockholder's dream."

Prevnar is one of the latest vaccines to be licensed by the Food and Drug Administration. Since last March, 10 million doses have been distributed.

Prevnar is administered in a series of four shots, each priced about $60. It is one of the most expensive vaccines in history.

Hayley Graves was nine months old when she received her second dose of Prevnar.

"I had a baby that was perfectly healthy, happy, okay until she got a shot, until she got her vaccine," said her father, Ray Graves. "Thirty, forty hours later, she's in the hospital having seizures that they can't stop. You're not going to tell me it's not related to the vaccine somehow."

Hayley slipped in and out of a coma for 45 days until she died in September. Tremors shook her little body almost the entire time.

"It's hard, it's very hard," Graves said.

Like many parents, Ray and Lisa Graves were told by their pediatrician that Prevnar would help to prevent "otitis media" -- ear infections.

During a four-month investigation, however, News 8 discovered that Prevnar was never licensed for that use.

In fact, clinical trials showed that overall Prevnar decreased a child's chance of getting an ear infection by only 6 percent as compared to children who did not get the vaccine.

"I don't think anybody believes the vaccine was developed to prevent otitis," said Dr. John Modlin, chairman of the Centers for Disease Control Vaccine Advisory Committee.

Dr. Modlin confirmed that he knew this to be the case during an interview last week.

Last March, however, the CDC issued a fact sheet telling parents that "children who have frequent or serious earaches" are among those who benefit most from Prevnar.

"I think you're creating basically a tempest in a teapot here," Dr. Modlin said.

But the misinformation from federal regulators doesn't stop there.

Doctors who log onto the CDC's website for Continuing Education Credit are given this test question which asks:

"Which type of pneumococcal disease is the Prevnar vaccine effective in preventing?

The correct answer, according to the CDC, is "all of the above" -- including "acute otitis media."

Dr. Erdem Cantekin, a medical researcher, is one of the nation's leading experts on earaches. "It [Prevnar] is an ineffective and toxic vaccine," he said.

According to Cantekin, not only are federal regulators issuing bad information, they are also not revealing some of Prevnar's dangerous side effects.

Cantekin says a study by the vaccine's manufacturer shows seizures happened four times more often in infants given vaccines with Prevnar than children in a control group.

"I think the FDA approval of this vaccine is an act of irresponsibility,"Dr. Cantekin said. "I think the FDA is following their regular course. They ignore the warnings until many people die, and then it becomes such a public outrage and public problem, they say, 'Oops, we will take this thing off the market.'"

Before licensing Prevnar last year, vaccine committees from both the FDA and the CDC dismissed the data on seizures as insignficant.

However, as part of our investigation, News 8 reviewed nearly 800 adverse reaction reports filed with the FDA during past nine months. We found that one of out 10 children who had suspected side effects suffered some sort of seizure.

"I'm not angry, I'm mad," Graves said. "I guess I'm a little bitter about losing a child. I'm not a little... I'm a lot bitter."

The Graves have no absolute proof that Prevnar killed their daughter -- just a string of medical coincidences.

Wyeth-Ayerst Laboratories, which makes Prevnar, says it has received a small number of reports about seizures among patients who've received the vaccine.

The company declined to interview with News 8, but it did fax us this letter, which says in part:

"These reports are consistent with data from clinical trials documenting seizures in children who did not receive Prevnar. While there have also been a small number of deaths coincident with Prevnar administration, there is no reason to conclude that there is any association between these deaths and the administration of Prevnar. Prevnar... was tested in hundreds of thousands of children prior to its approval by the FDA."

"Once you assume that a certain number of children are expendible, it is a very slippery slope," Fisher said. "How many can you sacrifice? Is it five? Is it 100? Is it 5,000? It's very dangerous to employ that kind of utilitarian rationale."

So if Prevnar was not licensed for ear infections, exactly what was it approved for?

To fight some strains of pneumococcal meningitis, pneumonia, and bacterimia.

But last year, there were only 1,500 cases of pneumococcal meningitis in infants in this country.

Critics say that's not enough of a threat to scare parents into getting the vaccine, but because there are five million cases of ear infections each year, recommending Prevnar for that purpose can generate a lot more interest.

Our next report will focus on the stocks, grants or contracts that the people who sit on the vaccine committees have with the pharmaceutical industry.

It's called "conflict of interest."

http://www.wfaa.com/wfaa/articledisplay/0,1002,20550,00.html

Vaccine Safety Part 2
Reporter: Valeri Williams
Updated: Feb 23, 2001 at 12:57AM

DALLAS - Most parents trust the government to ensure that the vaccines we inject into our children are safe.

A News 8 Investigation focused on what some call the questionable science behind getting vaccines licensed in this country.

As we've said before and we want to stress again: traditional childhood vaccinations have been a good thing.

But what we've chosen to do with this is take a closer look at how some of the newer vaccines are coming on to the market, and to ask why parents aren't being told more.

"I feel like I took him to the doctor's office and I paid them to poison my son -- and I didn't know any better," said Melynda Slay.

In June 1999, Slay had her newborn son inoculated with the new RotaShield vaccine.

Vaccine ads from that time promised that RotoShield would help prevent childhood diarrhea. But within days, Harrison's bowels were dangerously obstructed to the point of possibly rupturing.

"That probably was the worst week I've ever had in my life because I wasn't sure if my son was going to live or die," Slay recalled.

Federal regulators from the Centers for Disease Control soon discovered that more than 100 other infants had suffered the same problem.

RotoShield was pulled off the U.S. market in less than 15 months and some are now questioning how the drug ever received government approval.

"These committees have become the rubber stamp committees for the drug companies to push their product in the market," said Dr. Erdem Cantekin, a medical researcher.

Cantekin has long been concerned about the financial links between the pharmaceutical industry and many doctors and scientists who sit on vaccine approval

committees.

He is not alone.

Last summer Rep. Dan Burton (R-Ind.) held Congressional hearings which revealed that at least half the members of vaccine committees at both the Food and Drug Administration and the Centers for Disease Control had financial ties to drug companies developing different versions of the Rotavirus vaccine.

"We have had people who are head of advisory panels who own stock in pharmaceutical companies," Burton said.

The report found others who received grants or contracts worth hundreds of thousands of dollars, yet all were granted waivers which let them vote on the vaccine's approval.

"If you own stock in a pharmaceutical company, and you are on an advisory panel that will be approving or disapproving a vaccine by that pharmaceutical company and you know it could have an adverse impact on the stock that you hold in that company, it just might taint your judgment," Burton said.

On the very same day that the CDC's Vaccine Advisory Committee pulled the plug on RotoShield, it drafted a recommendation for another vaccine called Prevnar.

News 8's investigation found that out of 12 committee members, four had financial ties to the drug company making Prevnar.

At the FDA, three out of 12 committee members received waivers for conflicts of interest so they could vote on Prevnar's license.

Among them was Dr. Robert Daum, the newly-elected chairman of the committee. He said his conflict amounted to research on another vaccine for children at another company.

"You have to understand I still drive my 1989 Toyota, and the door on the right side still doesn't open. Nothing good happened to me," Dr. Daum said. "They're still selling God-knows how many million doses a year now for American Home Products. I don't benefit from that. Nothing has changed in my life."

Daum admitted, however, that his role is "a very fine line."

Daum and others argue that there is a very limited list of experts within the world of

vaccine research. They say that in order to have the best professionals on the committees, there must be acceptance of conflicts of interest.

"No man can serve two masters," Cantekin countered. "I could find 100 competent scientists and doctors to put on these committees which are better than they have. All of whom don't have any conflict of interest and have not taken a single dollar from anybody."

He and others claim all this chumminess has made government committees unwilling to challenge poor testing procedures in studies of a proposed vaccine's safety.

For example, here are the results of a clinical trial of Prevnar in 38,000 California children:

According to the drug company's own documentation, children receiving Prevnar with other vaccines had more seizures, more rashes, higher fevers and other side effects than children who received the control vaccine.

And the real surprise? The control vaccine in the testing was not a placebo, but another experimental vaccine that was still being tested.

Dr. Daum defended the testing procedure. "I think it makes for better parent compliance and more willingness to participate to have a control that would actually benefit from receiving something, and not saline. I wouldn't want to submit my child to an experimental protocol where there was a chance he just going to get a dummy shot."

Barbara Fisher is the only member of the FDA's Vaccine Committee who is not a doctor or a scientist; she's a consumer advocate and the only committee member to have voted against issuing a license for Prevnar.

Fisher said the study leading up to the license fails to measure up -- ethically, morally or scientifically.

"What's scientific about that? That every time something bad happens after vaccination it's 'coincidence'? That's not science, that's politics," said Fisher.

Prevnar was licensed to vaccinate infants against certain strains of meningitis, pneumonia and bacteremia -- horrible diseases which combined affect fewer than 150,000 children each year.

Weighing the risks of vaccination versus the risks of disease is a tough decision for any parent, but what many parents have told us upsets them is that they were surprised -- and scared -- by how much information they did not know.

Rep. Burton said he is calling for another Congressional hearing on the approval of Prevnar this spring.