UPI Investigates: The vaccine conflict

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Published 7/20/2003 8:45 AM

WASHINGTON, July 20 (UPI) -- The screaming started four hours after 8-month-old Chaise Irons received a vaccination against rotavirus, recommended in June 1998 by the Centers for Disease Control and Prevention for every infant to prevent serious diarrhea.

Within a day he was vomiting and eliminating blood. Doctors performed emergency surgery, saving him by repairing his intestines, which were folding in on one another. A doctor later figured out the vaccine caused Chaise's problem.

In October 1999, after 15 reports of such incidents, the CDC withdrew its recommendation for the vaccination -- not because of the problem, the agency claims, but because bad publicity might give vaccines in general a bad name.

But a four-month investigation by United Press International found a pattern of serious problems linked to vaccines recommended by the CDC -- and a web of close ties between the agency and the companies that make vaccines.

Critics say those ties are an unholy alliance in a war against disease where vaccine side effects have damaged, hurt or killed people, mostly children.

"The CDC is a disgrace. It is a corrupt organization," said Stephen A. Sheller, a Philadelphia attorney who has sued vaccine makers for what he says were bad vaccines. "The drug companies have them on their payroll."

The CDC, based in Atlanta, said it is committed to fighting disease and balancing vaccine side effects.

"Our goal is to protect the public health from both disease and from serious adverse events," said Dr. Walter Orenstein, director of the CDC's National Immunization Program.

The agency sets the U.S. childhood immunization schedule, or the list of shots pediatricians give children. Some states say kids can't go to public school unless they have had CDC-endorsed vaccines.

Since the mid-1980s the agency has doubled the number of vaccines children get, up to nearly 40 doses before age 2. The CDC also tracks possible side effects, along with the Food and Drug Administration. This puts the agency in the awkward position of evaluating the safety of its own recommendations.

An advisory committee of outside experts helps the CDC make vaccine recommendations. UPI found:

-- In two cases in the past four years, vaccines endorsed by the CDC were pulled off the market after a number of infants and adults appear to have suffered devastating side effects, and some died. Critics now worry about a possible link between vaccines and autism, diabetes, asthma and sudden infant death syndrome, among other ailments.

-- Members of the CDC's Vaccine Advisory Committee get money from vaccine manufacturers. Relationships have included: sharing a vaccine patent; owning stock in a vaccine company; payments for research; getting money to monitor manufacturer vaccine tests; and funding academic departments.

-- The CDC is in the vaccine business. Under a 1980 law, the CDC currently has 28 licensing agreements with companies and one university for vaccines or vaccine-related products. It has eight ongoing projects to collaborate on new vaccines.

The situation, while legal, gives critics plenty of reason to worry that vaccine side effects are worse than CDC officials say.

"When you take a look at the ever-increasing numbers of doses of vaccines babies have gotten over the past two decades and you see this corresponding rise in chronic disease and disability in our children, it is out of control," said Barbara Loe Fisher, president of the National Vaccine Information Center, which does not accept money from vaccine manufacturers.

She worries that vaccines might be linked to ballooning rates of chronic illness like autism, which has increased tenfold since the mid-1980s, and asthma, which has more than doubled since 1980.

Fisher's group wants to overhaul the mass vaccination system.

"The CDC has a very hard time investigating in an unbiased way what is happening to our children because of ideological and financial conflicts of interest," she said. Fisher believes a vaccine injured her son in the 1980s.

Developing a vaccine can cost a half a billion dollars. A recommendation by the CDC guarantees a market and a 1986 law limits manufacturers' liability for side effects.

The annual global market for vaccines is expected to go from $6 billion today to $10 billion by 2006.

The CDC said the best vaccine advisers often have ties to the industry, making potential conflicts unavoidable. Agency officials review possible conflicts.

"The issue of safety is critical and you need people extremely knowledgeable about safety to develop the best policy formulations," said Orenstein. The agency has to weigh possible side effects against dangerous disease. "We need to put safety data in context with risk-of-disease data," he said.

The agency said ethics officials also review partnerships with companies to make new vaccines.

"Each one of those proposed activities is reviewed by the CDC's ethics officials, by our office of general counsel, and by me to make sure that there are no conflicts of interest," said Dixie Snider, CDC associate director for science.

Andrew Watkins, director of the CDC's Technology Transfer Office, negotiates licensing agreements with outside companies. He said agency scientists routinely leave to work with vaccine manufacturers.

"It does happen that some of our inventors end up working for a manufacturer," Watkins said. "In fact, we consider that a wonderful tool of technology transfer, although we do lose a good scientist."

But Watkins said very little money actually changes hands, making it unlikely to influence the CDC. He said companies, including vaccine makers, only gave the CDC around $1 million last year to work on collaborative projects and the agency only got $150,000 last year in licensing fees.

"We are a real cheap date," Watkins said.

Rep. Dan Burton, R-Ind., who has been investigating vaccines for four years, said conflicts at the CDC are a problem, particularly on the vaccine advisory panel. He believes vaccines triggered his grandson's autism.

"This presents a real paradox when the CDC routinely allows scientists with blatant conflicts of interest to serve on influential advisory committees that make

recommendations on new vaccines, as well as policy matters," Burton told UPI. "All the while these same scientists have financial ties, academic affiliations, and other vested interests in the products and companies for which they are supposed to be providing unbiased oversight."

Because of concern over vaccine side effects, Congress in 1986 passed a law setting up a database at the CDC to track reports from doctors, manufacturers and the public of possible side effects from vaccines that started in 1991.

As of the end of last year, the system contained 244,424 total reports of possible reactions to vaccines, including 99,145 emergency room visits, 5,149 life-threatening reactions, 27,925 hospitalizations, 5,775 disabilities, and 5,309 deaths, according to data compiled by Dr. Mark Geier, a vaccine researcher in Silver Spring, Md. The data represents roughly 1 billion doses of vaccines, according to Geier.

The reports do not necessarily show that a vaccine caused a problem.

The pain of Rotashield

The CDC's Advisory Committee on Immunization Practices, ACIP, helps the agency decide what vaccines are safe enough to recommend. It is made up of 12 experts from hospitals, universities and state health departments.

In June 1998, the committee recommended that all infants be vaccinated against rotavirus. The virus causes bad diarrhea that can be fatal.

At the time, vaccine maker Wyeth had a vaccine called Rotashield. Merck hoped to soon follow with its own version.

Wyeth ended up pulling its vaccine off the U.S. market in October 1999 after it was suspected of causing an excruciating contortion where a child's large intestine folds over the small one.

Emergency surgery is sometimes required to prevent death. That was the case with 8-month-old Chaise Irons.

"Chaise was vomiting blood and blood was coming out of his stool," said his mother, Jayne Irons, from her home in Malibu, Calif. Doctors performed emergency surgery to repair Chaise's intestines, saving his life.

Jayne said she never questioned her doctor's advice to give Chaise the vaccine. "I had no reason to doubt anybody. I am such a believer in vaccinations," Irons said.

The Irons' will get $25,000 for Chaise's injuries from a government compensation program.

For Rotashield, the CDC's public database contains 664 total reports possibly caused by the vaccine, including 288 emergency room visits, 63 life-threatening reactions, 232 hospitalizations, 10 disabilities and eight deaths.

"Eight deaths," said Jayne Irons. "You just have to thank God that you are not one of the deaths."

Republican staff on the House Government Reform Committee looked into the CDC panel that recommended the vaccination. Their August 2001 report found that "four out of 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."

A transcript from that June 1998 meeting shows the committee voted down an effort by one member to phase in the vaccine because of concern over possible bad side effects. "I'm still a little concerned about the safety issues," Marie Griffin from Vanderbilt University said before that vote.

When asked, members of the committee told UPI their potential conflicts do not affect their judgment.

"I am probably just the kind of person you are talking about," said Paul Offit, chief of infectious diseases at the Children's Hospital of Philadelphia, who was a committee member until last month. At the same time, he shared a patent for another rotavirus vaccine. Merck has funded Offit's research for 13 years.

"I am a co-holder of a patent for a (rotavirus) vaccine. If this vaccine were to become a routinely recommended vaccine, I would make money off of that," Offit said. "When I review safety data, am I biased? That answer is really easy: absolutely not."

"Is there an unholy alliance between the people who make recommendations about vaccines and the vaccine manufacturers? The answer is no."

Merck bought and delivers copies of Offit's book, "What Every Parent Should Know About Vaccines," to American doctors. The book has a list price of $14.95.

"Merck Vaccine Division is pleased to present you with a copy of the recent publication, 'What Every Parent Should Know About Vaccines,'" says a Dear Doctor letter from Merck. "The authors designed the book to answer questions parents have

about vaccines and to dispel misinformation about vaccines that sometimes appears in the public media."

Offit said he does not know how many copies of his book Merck purchased. "I don't have any control over that," he said.

The 2001 Government Reform Committee's investigation noted potential conflicts with another committee member. The chairman of the CDC's Vaccine Advisory Committee, Dartmouth Medical School Professor Dr. John Modlin, owned $26,000 in Merck stock.

In a telephone interview with UPI, Modlin said he had sold that stock, but that he had recently agreed to chair a committee to oversee Merck vaccine clinical trials. Modlin, who was the committee chairman until last month, said he does not know how much compensation he receives from that post, but that Merck "pays my expenses" to attend meetings.

In October 1999, the committee reversed its recommendation that all infants should get rotavirus vaccinations. Modlin said the vaccine was safe enough, but the committee reversed itself out of concern that bad press over Rotashield might make some people stop getting vaccinated altogether.

"There could be some spill-over effects that would have a net negative effect," Modlin said. "I thought that was the committee's finest hour."

Meeting transcripts over the past decade showed that at some meetings, half of the members present had potential conflicts with vaccine manufacturers.

The CDC said that in October 2002 it adopted new guidelines for participating on that advisory committee that in the future will preclude people with conflicts like Offit's from sitting on the committee.

"We learned from that experience (with rotavirus) and have now put in force more stringent criteria recently so we do not nominate people with those kinds of conflicts," said the CDC's Snider.

At the June 2002 committee meeting -- the last meeting for which minutes are available -- four of the 11 members present acknowledged conflicts with Wyeth, GlaxoSmithKline, Merck, Pfizer, Bayer and Aventis Pasteur. Two of the four did research or vaccine trials for manufacturers. One of the four was a co-holder of a vaccine patent as well as a consultant to Merck.

At odds over autism

At 8:05 a.m. on Monday, July 16, 2001, a vaccine safety committee of the influential Institute of Medicine convened a public meeting at the Charles Hotel in Cambridge, Mass.

The purpose: to discuss whether CDC-recommended vaccines might be responsible for a wave of autism and neurological problems in tens of thousands of American children during the 1990s.

The concern: most vaccines contained a mercury-based preservative called thimerosal. Too much mercury has known toxic effects on the brain.

Since the mid 1980s, the number of childhood vaccinations recommended by the CDC had nearly doubled. The agency recommends nearly 40 doses of vaccines for children today. Also since the mid-1980s the autism rate in the United States had soared by 10 times to an astonishing one child in every 300.

Cause and effect or coincidence?

The vaccine manufacturers deny any connection, but the Institute of Medicine -- part of the National Academy of Sciences and a key adviser to the federal government on medical concerns -- wanted to hear from Dr. Thomas Verstraeten, a CDC expert on the issue.

When Verstraeten appeared before the committee, he made a surprise opening statement.

"First, I should mention that as of 8 a.m. European time I have been employed by a vaccine manufacturer," Verstraeten told the panel, according to a transcript. "That means since 2 a.m. American time," just hours before he spoke on behalf of the CDC.

Verstraeten had been working at the CDC on a study of 76,659 children to determine if thimerosal might be causing neurological problems like autism.

Signs of autism usually show up around age 2. Sometimes children who had previously appeared to interact normally will suddenly regress, become withdrawn and stop responding to their parents and the outside world. They may perform repetitive motions, like spinning or flapping their arms, have seizures, scream uncontrollably and resist physical touch.

Manufacturers had used thimerosal, which contains ethyl-mercury, as a preservative in multi-dose vials of vaccine. The vials allow needles to be inserted repeatedly and the vaccine drawn out. The vials are cheaper than packaging doses of vaccine separately, without thimerosal.

Depending on what vaccines a child got during that period, a visit to the doctor during the 1990's may have exposed some children to 125 times the limit on mercury set by the Environmental Protection Agency.

A February 2000 draft of Verstraeten's study, obtained by United Press International, appears to show that thimerosal might cause brain problems.

That draft cites "increasing risks of neurological developmental disorders with increasing cumulative exposure to thimerosal."

"We can state that this analysis does not rule out that receipt of thimerosal-containing vaccine in children under 3 months of age may be related to an increased risk of neurologic developmental disorders," the study said.

To discuss the findings in Verstraeten's study, the CDC convened a meeting at the Simpsonwood Retreat Center in Norcross, Ga., on June 7-8, 2000. The agency invited vaccine experts and representatives of four vaccine manufacturers.

After discussing that study, Dr. David Johnson, a Michigan state public health officer advising the CDC on vaccines, said that the findings were troubling, according to a transcript.

"My gut feeling? It worries me enough," said Johnson. "I do not want (my) grandson to get a thimerosal-containing vaccine until we know better what is going on."

Later in the same conversation, CDC officials agreed to keep the study private.

"We have been privileged so far that given the sensitivity of information, we have been able to manage to keep it out of, let's say, less responsible hands," said Bob Chen, head of CDC's Vaccine Safety and Development unit.

Dr. Roger Bernier, who was then CDC's associate director for science, responded, "I think if we will all just consider this embargoed information, if I can use that term."

The CDC's Walter Orenstein said the agency wanted to look hard at the study before discussing it in public, not cover it up. The CDC never published a study based on the data, but said it would soon.

GlaxoSmithKline declined UPI's request to interview Verstraeten from Rixensart, Belgium, but Orenstein said Verstraeten left the CDC to move back to Europe.

For Lara Bono of Durham, N.C., the connection between vaccines with thimerosal and her son's autism is obvious.

Bono said her son Jackson began to change drastically within days of receiving a group of thimerosal-containing vaccinations.

Bono says that on Aug. 14, 1990, four days after receiving the last of a group of shots, 16-month-old Jackson was becoming withdrawn. Within two weeks he stopped responding or acknowledging his parents. Two weeks after that Jackson no longer would make eye contact. It soon became difficult to get Jackson to eat or sleep. He has had bouts of spinning uncontrollably and seizures.

"Fast forward another couple of months and he was gone. The mercury was in his brain," Bono said.

Years later, Bono discovered that at one point, Jackson's mercury exposure may have been more than 40 times the limit set by the EPA. Nine years later, Bono says, Jackson was diagnosed with mercury poisoning she says came from the vaccines.

Boyd Haley, chairman of the Chemistry Department at the University of Kentucky, has done studies that he says show some children with autism do not excrete harmful mercury from vaccines, but keep it in their bodies. He says the CDC knows the vaccines the agency recommended may have harmed a generation of children.

"I know that they know and that is what bothers me more than anything else," Haley said. "You can't do a study showing it (thimerosal) is safe. It is just too damn toxic."

In June of 2000, the agency's Vaccine Advisory Committee signed on to a statement calling for the removal of thimerosal from vaccines "because any potential risk from mercury is of concern."

"However, there remains no convincing evidence of harm caused by low levels of thimerosal in vaccines," the statement said.

In October 2001, the Institute of Medicine panel that heard from Verstraeten found that it is "biologically plausible" that thimerosal causes autism, but that, "current scientific evidence neither proves nor disproves a link."

To avoid any conflict of interest, that panel specifically excludes "anyone who had participated in research on vaccine safety, received funding from vaccine manufacturers or their parent companies, or served on Vaccine Advisory Committees."

Laid low by Lyme vaccine

The rotavirus recommendation is not the only controversial call made by the CDC. Another involves a vaccine to fight Lyme disease, a tick-borne illness that can cause profound fatigue, headache, fever and severe muscle pain.

"It was after the booster shot that I absolutely collapsed," said Lewis Bull, a farmer from East Lyme, Conn. Bull, now 49, volunteered in 1996 to take shots during a clinical study for a new vaccine to prevent Lyme disease developed by SmithKline Beecham, now GlaxoSmithKline. Clinical studies are tests on humans to make sure vaccines are safe and work before going on the market.

In the study, Bull first received placebo shots containing no vaccine and felt fine.

But soon after his second shot of the real vaccine he began to suffer from debilitating arthritis, memory loss and fatigue. Some doctors believe the Lyme vaccine side effects mirror the disease itself.

"For the first six months I could not get out of bed. The memory loss was incredible. I've played guitar all my life and I could not remember how to play guitar. I could not find the town hall and I used to go there four times a week," he said in a recent telephone interview.

Bull said his fatigue was so severe he would sleep for stretches of 22 hours or more. Without medical insurance, Bull was forced to sell his farm.

On Feb. 18, 1999, the CDC endorsed Lyme disease vaccine for people age 15-70 who work or recreate in possible tick-infested areas.

By October of 2000, more than 1.4 million people had received the vaccine, according to the CDC.

But 19 months later, in February 2002, SmithKline Beecham pulled the vaccine off the market because "sales of LYMERIX are insufficient to justify the continued investment."

The company also faced hundreds lawsuits by people who said they suffered side effects, many similar to Lewis Bull's.

Although he never sued, Bull said he complained to the CDC to report what he says were obvious side effects from the vaccine, called LYMERIX.

The government's database of possible side effects for LYMERIX lists 640 emergency room visits, 34 life-threatening reactions, 77 hospitalizations, 198 disabilities and six deaths after people took the shots since the CDC endorsed it.

According to CDC meeting transcripts where the advisory committee weighed its recommendation, five of 10 committee members disclosed their financial conflicts of interest with vaccine manufactures. Three of the five had conflicts of interest with SmithKlineBeecham.

The committee ignored a plea from a consumer advocate to delay a recommendation on LYMERIX because it might not be safe, according to a February 1999 transcript.

"We are just saying there is a wealth of information out there that is different than the information you have been provided. I think the honorable thing to do would be to wait," said Karen Vanderhoof-Forschner, founder of the Lyme Disease Foundation, a patient's advocacy group that eventually opposed the vaccine.

UPI found that the CDC and SmithKline Beecham worked together on a Lyme vaccine. A 1992 CDC activity report obtained by UPI says the agency had an agreement "with SmithKline Beecham that currently funds three positions at (the CDC) for the purpose of providing information of use in developing advanced test methods and vaccine candidates."

In June 2001, the General Accounting Office delivered a report to Sen. Chris Dodd, D-Conn., on this issue. It says that CDC employees "are listed on two Lyme-disease related patents" including "a 1993 joint patent between CDC and SmithKline Beecham Corporation." The report also said that six of 12 consultants working for the CDC on Lyme vaccines "reported at least one interest related to a vaccine firm."

Do babies need Hep B?

In 1991 the CDC recommended that all infants get their first Hepatitis B vaccination just hours after birth. The disease is mostly spread from dirty needles and unprotected sex. It can create deadly liver disease.

The vaccine has been blamed for mysterious deaths following the shots, sometimes filed as sudden infant death syndrome.

One is the Sept. 16, 1998, death of Lyla Rose Belkin at age 5 weeks. She died 15 hours after getting her second Hepatitis B vaccine booster shot.

Michael Belkin said in a telephone interview from Seattle that his daughter was lively and alert prior to receiving the shot. She became agitated and noisy, suddenly fell asleep, and died 15 hours later. Belkin said the coroner indicated that his daughter's brain was swollen; a reaction some researchers believe could be caused by the vaccine.

"So in the CDC and (the Vaccine Advisory Committee's) own words, almost every newborn U.S. baby is now greeted on its entry into the world by a vaccine injection against a sexually transmitted disease for which the baby is not at risk -- because they couldn't get the junkies, prostitutes, homosexuals and promiscuous heterosexuals to take the vaccine," Belkin told a congressional panel on May 18, 1999.

"Parents need to understand that the system providing the vaccines injected into their children's veins is corrupt and scientifically flawed," Belkin told UPI. "Parents should do their own homework and investigate this question: What is the risk of getting a severe neurological vaccine adverse reaction versus the risk of getting neurological complications from the disease?"

The CDC's files contain 32,731 total reports of possible reactions following Hepatitis B vaccinations since 1991, including 10,915 emergency room visits, 685 life-threatening reactions, 3,700 hospitalizations, 1,200 disabilities and 618 deaths.

In October 2002, the Institute of Medicine reported that the "evidence is inadequate" to prove or disprove that some vaccines might be behind some cases of SIDS, and called for more research.

The CDC says, "There is no confirmed evidence which indicates that hepatitis B vaccine can cause chronic illnesses."

Some of the officials involved in the agency's 1991 decision to recommend that all infants receive the Hepatitis B vaccine also had close ties to vaccine manufacturers.

Dr. Sam Katz was the advisory committee chairman at the time. A professor at Duke, Katz said 30 percent of children who get the disease get it from unknown causes, possibly in daycare.

He said the CDC tried to give the shots to teens, but it was hard to get them to show up for all three doses.

"So they said, 'Well, we've got a captive audience and we want to give it to the newborns anyways.'"

Katz developed a measles vaccine now manufactured by Merck, which also manufactures a Hepatitis B vaccine. Katz said when he was chairman of the committee in 1991 he also worked as a paid consultant for Merck, Wyeth and most major vaccine manufacturers.

He said conflicts do not pose a real problem.

"I think it has increasingly become a problem, but it is a perceived problem, not a real problem," Katz said.

Another member of the committee in 1991 was Dr. Neal Halsey, director of the division of disease control at Johns Hopkins University. He continued to advise the committee throughout the rest of that decade, as did Katz.

Halsey is a former CDC employee who has done research paid for by most of the major vaccine manufacturers. When he testified before the House Government Reform Committee in 1999, he disclosed a salary at that time for work on a Lyme vaccine.

He also established the Johns Hopkins Institute for Vaccine Safety, started in part with "unrestricted educational grants in 1997 from several vaccine manufacturers and some private donations," according to Halsey. Congressional investigators said that support included $50,000 in start-up funds from Merck and a payment from Wyeth. Halsey said vaccine manufacturers do not fund the center's vaccine education activities.

Halsey said the CDC needs experts like him to get the best advice.

"In order to get the people with experience, you need people who have done the research," Halsey said in a telephone interview. "To do that, you have to have people who have done research for vaccine manufacturers."

Halsey said, however, that the CDC should not recommend vaccines and evaluate safety at the same time.

"I think it is a problem and I think it would be better if an independent body evaluated safety," Halsey said.

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