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Does danger lurk in that vaccine?

Childhood immunizations no longer contain mercury. Flu shots do. But as you take your children for theirs, you have a choice.

By JUDY L. THOMAS, KANSAS CITY STAR

Millions of America's health-conscious parents are lining up their children for this year's flu shot. But many are unaware that some doses contain mercury, a potent poison. Even more do not know that a mercury-free flu shot exists. That lack of understanding has driven down demand and reduced the availability of mercury-free vaccine this year.

The federal Centers for Disease Control and Prevention recommends that all children ages 6 months to 23 months get a flu shot. Citing many studies, the agency insists that flu shots containing mercury are safe.

CDC officials also recommend that parents who want a mercury-free shot for their children, only to find none is available, should still get them vaccinated.

"We want to protect people against influenza, and vaccination is the very best way to do that," said Jeanne Santoli of the CDC's Immunization Services Division.

Critics disagree, saying that mercury - which is used to prevent contamination in multidose flu vaccines - is causing an alarming rise in autism and other neurodevelopmental disorders.

"I think it's absolutely criminal to give mercury to an infant," said Boyd Haley, an expert on mercury toxicity and a vocal critic of the CDC.

As the debate continues, the company that makes most flu vaccines says there is a waiting list this year for health agencies that want vaccines that contain mercury. Meanwhile, the company is scaling back production of its mercury-free vaccine, The Kansas City Star has learned.

Only Sanofi Pasteur is approved to market a new mercury-free pediatric flu vaccine. Spokesman Len Lavenda said the company had planned to make 8 million doses of the mercury-free version of its Fluzone vaccine for this flu season but has cut back to 6 million doses.

The CDC estimates it would take about 12 million doses to vaccinate all children ages 6 months to 23 months.

"We were prepared to more than double the quantity this year, but demand for the product didn't warrant producing that much," Lavenda said. "While we have on several occasions sold out all of our preservative-containing (mercury) vaccine in the last several years, we have never sold out all of our preservative-free vaccine." Lavenda said he had no idea why health officials were not ordering more mercury-free vaccine.

In 1999, the CDC, the U.S. Public Health Service and the American Academy of Pediatrics recommended removing mercury from other childhood vaccines as a precaution after concerns were raised that children may be receiving too much mercury in their shots.

The CDC is adamant there is no risk.

"The preponderance of evidence consistently does not reveal an association between thimerosal (mercury) and autism," Julie Gerberding, the CDC's director, said at a recent news conference.

But The Star's examination found that:

Lower prices appear to be a major factor in the continuing use of flu vaccines that contain mercury - yet mercury-free vaccines cost only about \$2.50 a dose more. The small amount of mercury in flu vaccine still exceeds the U.S. Environmental Protection Agency's daily safety threshold, even though the cumulative amount children now receive from all vaccines is much lower than it was in 1999.

A massive government database that could be used to study the safety of flu vaccines and other vaccines containing mercury has been kept off-limits to some researchers, a move that an independent advisory body has criticized.

At least six states have restricted the amount of mercury allowed in vaccines. A dozen others are considering it, and a similar bill is pending in Congress. Many European countries and Japan already restrict mercury in vaccines.

A law passed earlier this year in Missouri requires that any immunization given to knowingly pregnant women or children younger than 3 contain no more than 1 microgram of mercury per 0.5-milliliter dose. But the law won't take effect until April 1, 2007.

Efforts are just getting under way in Kansas to regulate mercury in vaccines. Pharmaceutical companies, however, insist that flu vaccines containing mercury are safe.

Chiron Corp., for example, is making 18 million to 26 million doses of vaccine this season for people ages 4 and older. Most of the doses contain mercury.

"There have been a number of studies that have not found a link" to autism, said Alison Marquiss, a Chiron spokeswoman. "But at the same time, we're following government guidelines. It's been an ongoing discussion between government and industry, and everybody is working toward the same goal of removing it."

Cost a consideration

If mercury is a health concern, why is it still in some childhood flu vaccines? The reason government officials cite most is money.

Mercury-free vaccine must be made in single-dose packages, which is more expensive than making multidose vials. Single-dose vaccines also take up more refrigerated storage space in doctor's offices and health clinics.

Sue Denny, a spokeswoman for the Missouri Department of Health and Senior Services, said the CDC's cost per dose for a 10-dose vial of flu vaccine is \$9.71. A single-dose package costs the CDC \$12.02.

"So if you're buying a lot of it, it makes a difference," Denny said. Regardless, many parents complain they have been in the dark about what is in their children's flu vaccine.

Laurie LaTessa of Lenexa has been diligent the past two years about getting flu shots for her five children. She was surprised to learn that many of the shots still contain mercury.

"I did it thinking it was protecting them," LaTessa said. "But any protection they would be getting I don't think can compare to the fact that they're getting mercury." LaTessa said that this year she will check first to find out whether the vaccine contains mercury.

The Kansas City Health Department said all of its flu vaccine this year for its "Vaccines for Children" program will be mercury-free. "I think that's because there's a public perception that it's best," said Judy Moore-Nichols, the department's child health and immunization program manager.

The Missouri Department of Health and Senior Services ordered about 90,000 doses for its "Vaccines for Children" program. Denny said some doses were mercury-free, but she did not know how many.

The Kansas Department of Health and Environment ordered 31,000 doses for the program, spokeswoman Sharon Watson said. Of those, 5,000 are mercury-free and 3,000 are a nasal mist that does not contain mercury but is only for people ages 5 and older.

If mercury-free vaccine is not available, the CDC recommends that children still get flu shots because of the risk of becoming sick.

But critics complain that in promoting vaccinations, the CDC exaggerates the number of flu deaths. Before 2003, the agency said that about 20,000 people a year died from the flu.

The CDC's National Center for Health Statistics, however, reports that 727 persons died of influenza in 2002, according to the most recent information available from death certificates. The number of deaths for children ages 4 and younger was 12. In 2003, the CDC raised the total flu deaths to 36,000. Yet Santoli acknowledged the 36,000 figure was only an estimate.

"The way they try to look at the deaths associated with influenza is they look at

deaths during a certain time of year and due to certain causes and how it exceeds the deaths that occurred from those causes during the noninfluenza time of year," Santoli said. "So they look at the excess and estimate those are the number of deaths."

Over safety threshold?

The flu vaccines in question contain thimerosal, a compound that is 49.6 percent mercury by weight. Thimerosal has been used for decades in other vaccines and medical products as a preservative and to prevent contamination from multiple needle punctures into the vials.

But in the 1990s, health officials increased the number of recommended childhood vaccines. That meant many babies went from getting 25 micrograms of mercury in one day to up to 62.5 micrograms in one day.

After it was found that infants were receiving amounts of mercury above the limits considered safe by the Environmental Protection Agency, government and private health agencies in 1999 recommended removing mercury from such childhood vaccines as hepatitis B, DTP and Hib.

The CDC says that because mercury has been removed from all other childhood vaccines, it is not a problem that it remains in flu vaccines because the cumulative exposure now is much lower.

But the flu shot given many babies today contains 12.5 micrograms of mercury - 14 times the daily amount considered safe by the EPA for a child weighing 20 pounds. Young children routinely are given a second 12.5-microgram dose a month later. Other health agencies have limits for mercury exposure, but the EPA's are considered "a scientifically justifiable level for the protection of human health" by the National Academy of Sciences.

"The vaccine has 12.5 micrograms of mercury, which means a baby would have to weigh 275 pounds for it to be considered safe, according to the EPA standard," said Haley, a biochemist at the University of Kentucky.

CDC officials said that because the EPA's guidelines cover an extended period and not a one-time flu shot, it is unfair to assume the vaccine could be dangerous. Still, Richard Deth, an expert on drugs that affect the brain, said that "it does make a difference when it's all given in one day." Deth said his studies at Northeastern University in Boston have found that even low concentrations of thimerosal can hurt the development of brain cells.

"The one time is important because the driving force for going into the brain is the concentration at any one time," Deth said. "So when you get a (large) dose like that, it more or less drives it into the brain based on that higher, even temporary, concentration."

Some lawmakers are concerned that government and industry are not moving quickly enough to remove mercury from all vaccines.

"The fact is there should not be any mercury in any vaccine," said U.S. Rep. Dan Burton, an Indiana Republican who led a congressional committee that researched the issue for several years. Burton has a grandson who is autistic.

But a professor of pediatrics at the University of Missouri-Columbia said her research has found nothing to link mercury in vaccines with autism.

"Obviously, it's worrisome to families, and it seems reasonable to conclude that a relationship exists," said Judith Miles, the director of MU's medical genetics division. "However, if you look at the data, there is simply no relationship between them."
Secret database?

The CDC's Vaccine Safety Datalink, which tracks the medical records of more than 7 million patients, could show what effects vaccines have had on human health. But the database has not been made publicly available for closer examination, which upsets some researchers. The CDC says that because the database contains health information, making it public would violate patient privacy.

Critics, however, think that the lack of access stems in part from a private meeting convened by the CDC in June 2000. At the meeting, dozens of health officials and scientists discussed research from the database. Those studies showed a possible connection between thimerosal and neurological impairment such as tics, attention deficit disorder and speech disorders, but not autism.

Despite the questions, most of those attending the meeting found the results inconclusive.

Since then, those who have tried to examine the Vaccine Safety Datalink have hit CDC roadblocks.

"We subpoenaed stuff like that, and they have jumped through every hoop they could to keep the public from knowing what was in those reports," Burton said. But in February, a committee of medical experts assembled by the Institute of Medicine criticized how the CDC and its National Immunization Program have handled the database.

"There are legitimate reasons for public concern about the independence and fairness of the review of VSD data-sharing proposals ... ," the committee stated. "The lack of transparency of some of those processes affects the trust relationship between the National Immunization Program and some members of the general public."
The committee recommended that the CDC ease restrictions on researchers and said that an independent review of how the database is used "is integral to public trust in the use of the VSD to answer questions about vaccine safety."

Researchers David and Mark Geier have spent years trying to get a complete set of data. They were given access to some of it after a congressman intervened, but they said the process has been difficult.

Documents obtained by the Geiers under a Freedom of Information Act request show that in 2002, the CDC awarded a 10-year, \$191 million contract to the company now called America's Health Insurance Plans to oversee the database and other vaccine safety projects.

Because America's Health Insurance Plans is a private company, the public does not have access to the information.

"You and I paid millions for a database that nobody can see," said Mark Geier, a geneticist from Silver Spring, Md.

Glen Nowak, the CDC's director of media relations, said the agency is trying to accommodate independent researchers.

"We've worked really hard to make these records available to external researchers, but because they're medical records, there are certain steps that need to be taken to ensure people's privacy is protected," Nowak said.

Mercury bans growing

State legislatures are not waiting for Congress to restrict mercury in vaccines. Iowa was the first to do so, followed by California, Missouri, Delaware, Illinois and New York. Legislation is pending in more than a dozen other states. U.S. Rep. Dave Weldon, who also is a doctor, has introduced federal legislation to remove mercury from all childhood vaccines.

"Mercury should be out of all pharmaceuticals and all biologicals," said Weldon, a Florida Republican. "I don't think there's any way you can justify this." Weldon introduced the bill with U.S. Rep. Carolyn Maloney, a New York Democrat. A similar measure is pending in the Senate. So far, neither bill has had a hearing. The fact that mercury remains in many flu shots outrages Kelly Kerns of Lenexa, who has three autistic children - 7-year-old twin boys and a 9-year-old daughter. Although her children's conditions have improved, the emotional and financial drain of dealing with them has been enormous, Kerns said.

The Kerns are among thousands of families who have filed claims with the National Vaccine Injury Compensation Program since 2001. The families allege that their children suffered autism or other neurological disorders because of mercury in their vaccines.

Congress created the program in 1986 to encourage drug companies to keep making vaccines despite increasing liability costs from lawsuits. The program requires families to resolve their claims through the "vaccine court" before filing civil lawsuits. To date, about 1,900 families have received \$1.5 billion for claims that did not involve mercury - but none of the 4,900 claims linked to autism and mercury has been resolved.

For the CDC and many health officials, the debate over whether mercury causes autism is settled. But critics such as Weldon are not convinced. If it is shown that mercury in vaccines has hurt children, Weldon said, it will go down as "one of the biggest blunders in modern medical history."

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Flu vaccine tips

What does the government recommend?

Last year, the Centers for Disease Control and Prevention began recommending that all children ages 6 months to 23 months and all pregnant women get a flu

vaccination.

The CDC says the best time to get a vaccination is October or November. Flu activity generally peaks between late December and early March.

What if I'm concerned about mercury?

Call your doctor or clinic and ask whether thimerosal-free vaccines are available. Even if none is available, health officials recommend getting the vaccine that contains thimerosal (mercury), saying that the benefits of the shot outweigh the theoretical risk of exposure to mercury. Critics disagree, saying they would not give their children any vaccine containing thimerosal.

How can I tell if the flu vaccine I'm getting is mercury-free?

Generally you can tell if flu vaccine contains mercury if it is in a vial that contains multiple doses. Mercury-free vaccine generally is packaged in a single-dose, pre-filled syringe. But this year it also can come in a single-dose vial.