**VACCINE SAFETY & CONCERNS RAISE BY PARENTS***October 2014*

The following recommendations regarding concerns about vaccine safety are based on support provided by Dr. Paul Offit, Director of the Vaccine Education Center at the Children’s Hospital of Philadelphia, and the Maurice R. Hilleman Professor of Vaccinology and professor of pediatrics at the University of Pennsylvania, also in Philadelphia.

**Dr. Paul Offit**

Parents may ask: How do you know vaccines are safe? I researched them on the Internet and learned they’re not.

“When people say they’ve done their research on a vaccine and have decided not to get it, what they really mean is they’ve read other people’s opinions on the Internet,” Dr. Offit said. Parents need to understand that not all information sources are equivalent, and that a vaccine must undergo extensive testing before the Food and Drug Administration licenses it or the American Academy of Pediatrics and the Centers for Disease Control and Prevention recommend it, he said. “The phase III trials invariably involve thousands of children,” he added.

**But the package insert for the vaccine lists a lot of adverse events.**

Any adverse event reported before the vaccine is licensed will be listed on the package insert, whether or not the vaccine caused the event, Dr. Offit said. For example, the original package insert for the chicken pox (varicella) vaccine listed fractured leg as an adverse event, because one recipient of the varicella vaccine broke his or her leg within 42 days after receiving the vaccine, he said. “Package inserts are not a medical communication document,” he added. “They are a legal communication document.”

**Why are people being compensated for vaccine harm if it isn’t a problem?**

The question refers to the [National Vaccine Injury Compensation Program](http://www.hrsa.gov/vaccinecompensation/data.html), which has paid more than $2.8 billion in compensation awards to petitioners since 1989. The program is “a large and tempting pool of money for personal injury lawyers to file compensatory injury suits on behalf of their clients,” Dr. Offit said. But just because a court awarded damages for harm does not mean the vaccine actually caused harm, he said. “The courts are never a place to determine scientific truths. The place you do that is in the scientific venue, by studies.”

Vaccines can contain potential allergens, primarily gelatin (a stabilizer) and [latex](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/latex-table.pdf) (in vials or syringes that contain natural rubber), Dr. Offit noted. However, the rate of truly severe reactions to vaccines is extremely low – about one case per 1-2 million doses of vaccine, he said. An exception is [yellow fever vaccine](http://www.cdc.gov/yellowfever/vaccine/) , which has caused fatal anaphylaxis, and oral polio vaccine also “had the potential to revert to wild type, which is why we went to the fully inactivated polio vaccine by the year 2000,” Dr. Offit noted. Thrombocytopenia is a potential adverse reaction of some vaccines, but is rare, and there are no compelling data associating measles vaccine with encephalopathy, he said.

**The fact of the matter is that vaccines are a product of pharmaceutical companies. Why should I trust a product that is from a pharmaceutical company?**

“The fact is you don’t have to trust pharmaceutical companies,” Dr. Offit said. “A reporting system for adverse events is out there – VAERS [Vaccine Adverse Event Reporting System]. The vaccination safety data will show whether or not there is a safety issue.”

As an example, the human papillomavirus (HPV) 4 vaccine was studied in millions of children after it was licensed in the United States, Dr. Offit said. “The only symptom found was [fainting](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6229a4.htm#tab2),” he emphasized.

“It’s also not good business to make a vaccine that will do harm,” Dr. Offit said, adding that prelicensure studies of vaccines have cost up to $600 million.

**I heard that if I am pregnant, I should not get the flu vaccine because it contains mercury, which is neurotoxic and can harm my baby.**

Parents can benefit from understanding the difference between methylmercury – which naturally occurs in the environment and is neurotoxic at high levels of exposure – and ethylmercury, which is formed when the body breaks down the [thimerosal](http://www.cdc.gov/vaccinesafety/concerns/thimerosal/thimerosal_faqs.html) that is found in small amounts in some vaccines, Dr. Offit said. Ethylmercury poses much less risk to humans than methylmercury, because it is excreted from the body about 10 times faster, he added.

“Mercury is in the earth’s crust, and always has been in inorganic form,” Dr. Offit said. “If you live on this planet, if you drink anything made from water on this planet, you will be exposed to methylmercury. The quantity of mercury that you ingest every day is logarithmically greater than anything you would get from vaccines. You are at no greater risk of neurodevelopmental problems, including autism, from being vaccinated than if you did not receive any vaccines containing thimerosal.”

Parents may argue that drinking a substance is different from injecting it, but in fact, “mercury is very well absorbed in organic form,” Dr. Offit said. “If it’s ingested, it will cross cell membranes.”

And while thimerosal-free vaccines are available, “advertising these vaccines as safer is not true,” because the small amounts of thimerosal in current vaccines do not pose a health risk, Dr. Offit said.

**Why is my child getting hepatitis B vaccine at birth? My child won’t be at risk for a long time.**

“The hepatitis B vaccine first came on the market in the early 1980s, and was originally recommended only for high-risk groups,” Dr. Offit said. “For 10 years, the incidence of hepatitis B in this country did not budge. Then it was recommended as a routine vaccination for newborns, because every year, there were 18,000 cases of hepatitis B in kids under 10 years old.” Only half these cases were a result of exposure to hepatitis B virus in the vaginal canal during delivery, he emphasized. The rest resulted from “casual contact with someone who was infected and did not know it, such as a kiss on the lips from an uncle.”

Parents also should understand that chronic hepatitis B infection is associated with a high risk of liver cancer or cirrhosis, Dr. Offit said.

**I’m Catholic, and I see that a number of vaccines contain cells that are from aborted fetuses.**

In the early 1960s, cells from elective abortions in Sweden and England were used to make vaccines such as hepatitis A, varicella, rubella, and rabies, Dr. Offit noted. Some vaccines are still made in cells that have grown or descended independently from these aborted fetuses, he said. The [Catholic Church](http://www.ncbcenter.org/page.aspx?pid=1284) teaches that Catholics should ask for alternatives when available, but are morally free to use vaccines prepared in cells descended from aborted fetuses, because the greater harm is to the unvaccinated child. The National Catholic Bioethics Center, which derives its teachings directly from the Catholic Church, states, “ The risk to public health, if one chooses not to vaccinate, outweighs the legitimate concern about the origins of the vaccine. This is especially important for parents, who have a moral obligation to protect the life and health of their children and those around them.”

**I don’t want my child to receive vaccines because natural infection is better for the immune system.**

The infections against which vaccines protect can be fatal, cause serious illness, and lead to long-term disability, Dr. Offit emphasized. “The fact is that vaccines are good enough,” he emphasized. “The immunity is good enough. You just need it to be good enough to protect you long-term.”