

## Sound Advice

*This is an edited transcript of a telephone interview recorded in April 2009.*

Dr. Paul Offit is Chief of Infectious Diseases and the Director of the Vaccine Education Center at the Children's Hospital of Philadelphia. He is co-inventor of a vaccine for rotavirus. His most recent book is called "Autism's False Prophets: Bad Science, Risky Medicine and the Search for a Cure." Welcome, Dr. Offit.

**Dr. Offit:** Thank you.

**Q:** Dr. Offit, are vaccines safe?

**Dr. Offit:** Yes, vaccines are very safe, which is to say that their benefits clearly outweigh their risks. The risks of not getting a vaccine is to suffer, you know, the possible hospitalization and death that comes with natural infection. So, vaccines are clearly safe. I think sometimes people get caught up in this dichotomy of safe/not safe and I think that by that they mean that something is absolutely safe. Nothing is absolutely safe; meaning, any medicine or biological like vaccines that have an effect -- in this case, the effect is protecting you against disease -- can have a negative effect. And certainly, vaccines can cause pain and redness at the site of injection.

But, I think that you can say without being contradicted that vaccines are the safest, best-tested things we put into our body. They're held to a very high standard of safety. They're often tested in tens of thousands of children before they're put on the market for general use, and I would argue that they're better tested than certainly vitamins, better tested than anything you're going to find in the general nutrition store. I think they're the safest, best-tested things we put into our bodies, because they would have to be because they're given to healthy children.

**Q:** Does giving several vaccines at once overload a child's immune system?

**Dr. Offit:** Not in any way. When we're in the womb, we're in a sterile environment, but when you're brought into the world, you're not in a sterile environment anymore, and very quickly you have, living on the surface of your body, trillions of bacteria. The food that we eat isn't sterile. The dust that we inhale isn't sterile.

So, you know, when you look at what's in vaccines and the number of immunological components in vaccines, it really is literally a drop in the ocean of what we encounter and manage everyday. For example, if you just take a child and swab their nose, a baby, and then put it on a microscope slide, you'll see that the child has living on the surface of their nose, bacteria. I mean it's- it's those bacteria sort of swimming in front of you on the microscope slide. Vaccines are, frankly, pretty wimpy in the scheme of things.

**Q:** Are there toxins in vaccines?

**Dr Offit:** No. There is nothing in vaccine that is at toxic levels. I think people get hung up on this sort of zero tolerance notion. Certainly, for example, there is in some doses of multi-dose

preparations of influenza vaccine, which wouldn't be given to anybody less than six months of age, but could be given to a child at six months of age, there are very, very low levels of a preservative called ethyl mercury.

Now, the quantity of ethyl mercury that's in those vaccines is trivial. It's frankly less than one is typically exposed to during the day if you're breastfed or if you're formula-fed or if you drink water because mercury is part of our environment and therefore, it's in the water we drink and the breast milk and infant formula we give our children. So, it's that small that it's even less than one typically encounters during the day. I think people have the notion that they should have zero tolerance for sort of any exposure to mercury. That's just simply not possible because we live on the planet earth. There is no zero tolerance for mercury unless you want to move to another planet.

The same thing is true, for example, for formaldehyde. There are trace quantities of formaldehyde in vaccines because that's a chemical that's used to inactivate certain viral vaccines like the hepatitis A vaccine or the polio vaccine. But again, ever since we crawled out of the oceans and on to land, we have used something in our body that has the fancy name of single carbon metabolism. Formaldehyde is a product, a natural product. We produce formaldehyde in our bodies every day and we do it at a level far greater than that that's contained in vaccine.

So, I guess the answer to the question is there is nothing in vaccines that is present at toxic levels, no.

**Q:** Besides the flu vaccine, is there a trace amount of ethyl mercury in other vaccines, and is this something parents should worry about?

**Dr. Offit:** Yes, there are trace amounts of ethyl mercury in some vaccines. That's just as a residual to the manufacturing process because those who manufacture vaccines want to make sure that they're sterile at different point of the manufacturing process. But, you have to remember that first of all, ethyl mercury is a manmade product. When people say "mercury in the environment," they're actually talking about something called methyl mercury not ethyl mercury, and ethyl mercury is a much bigger molecule and therefore is eliminated from the body much more quickly, 10 times more quickly than the mercury found in the environment. Therefore, it's much less likely to accumulate.

So, it's trace quantities that are very quickly eliminated. I mean you get certainly far more mercury exposure in just, say, having a tuna fish sandwich than you would ever get from vaccine. And mercury is just very much part of our environment and our everyday existence. The good news is it's at levels that are well below those that are considered toxic, and it's true, frankly, of many heavy metals in the environment. I mean beryllium, cadmium, thallium, lead are all in our environment. We're all exposed to it every day if we drink water, [and] in the case of children, if they drink infant formula or breast milk.

I think one can safely say that, you know, the quantities of things like ethyl mercury that one can find in vaccines -- trace levels, which are tiny, tiny, meaning less than two micrograms per dose,

and a microgram is a millionth of a gram. It's trivial and it's less than what you're exposed to assuming you live on the planet and drink its water or eat its food.

**Q:** Dr. Offit, what about aluminum?

**Dr. Offit:** No, aluminum shouldn't be concerning to parents because the quantities of aluminum that are in vaccines, again, are trivial. Aluminum salts are used in vaccines and frankly, have been used in vaccines since the 1940s as something called an adjuvant, and what an adjuvant means is it actually enhances the immune response.

By adding aluminum salts as an adjuvant to some vaccines, what it means is that you give less of the actual, active ingredient in the vaccine than you would have to, and also it means that you can have fewer booster doses. So, it lessens the number of booster doses and also lessens the quantity of the active ingredient, whether it's a bacterial protein or a bacterial polysaccharide, which is just the complex sugar coating of a bacteria, or a viral protein that you would give in a vaccine.

Aluminum at very high levels can be toxic, but when it is toxic, it's toxic really only in two circumstances. It's in children whose kidneys don't work well or don't work at all, who also are receiving very high quantities of aluminum from another source, such as either in fluids that they're getting intravenously, or in antacids. You have to have two things that happen. One is a child whose kidneys don't work who is also receiving high quantities of aluminum in the intravenous fluids that they're receiving or in antacids. and- and um..- and that's it and aluminum is toxic only in those settings.

But the quantity of aluminum in vaccines is trivial and the amount that children are exposed to is, again, less than one is typically exposed to during the day. Aluminum is actually very commonly found in foods. People tend to generally ingest between five to 10 milligrams of aluminum a day, which is five to ten thousandths of a gram, and the quantity that's in vaccines is measured in the microgram level, meaning millionths of a gram. So again, just in terms of scale, the quantity of aluminum that you're exposed to in vaccines is much, much less than you would be exposed to if you, for example, ate a pancake.

**Q:** Are vaccines tested in combination with the other vaccines that children receive at the same time?

**Dr. Offit:** Yes. The current vaccine schedule that's recommended by the American Academy of Pediatrics and the Centers for Disease Control and Prevention is a very well-tested schedule. Again, it would have to be, because these vaccines are being given to healthy children.

So for example, when a new vaccine comes onto the market or is submitted to the Food and Drug Administration for licensure, there are two requirements that have to be met by the pharmaceutical company who has developed that vaccine. They have to show that their vaccine doesn't interfere with existing vaccines that could be given at the same time on the schedule. By "interfere" what I mean is, is change the immune response to those other vaccines or change the safety profile of those other vaccines. And conversely, one has to show that those existing

vaccines that are part of the schedule don't change either the immune response or the safety profile of the new vaccine. Those studies are called concomitant use studies. If you look in the medical literature, you can probably find roughly 800 concomitant use studies because it's a requirement by the FDA.

So, when people choose a different schedule, choose to delay or withhold or separate vaccines, they're choosing an untested schedule. I mean one can say comfortably is that the current schedule is very well tested and has a tremendous record of safety.

**Q:** How serious are these diseases that vaccines prevent? Should we really worry about preventing diarrhea or chicken pox?

**Dr. Offit:** There's two rotavirus vaccines. That's a virus, rotavirus, which causes diarrhea. It causes fever and vomiting and diarrhea in young children, although primarily it's actually much more a vomiting illness interestingly than a diarrhea illness. And in this country, it caused about 55,000 to 70,000 hospitalizations a year and it caused about 60 children to die every year. I think that if you look at the developing world or in the world in general, what you find is that about 2,000 children die a day from this particular virus and roughly 500,000 a year. So, it's certainly not the killer in this country as it is in the developing world, but it does kill 60 children in the United States every year and causes, 55,000 to 70,000 to be hospitalized and frankly, a couple million every year to suffer the disease of fever and vomiting and then diarrhea. If that can be prevented safely and if that can be prevented effectively, then I think it should be prevented. Why not prevent suffering if you can do it safely and effectively as we have done.

Chicken pox also is a disease which caused about 10,000 hospitalizations a year and between 70 to 100 deaths a year. So again, it's not the killer that, say, measles was, or the killer that polio was or thecrippler that polio was. But, you know, again, 70 to 100 children died every year, 10,000 were admitted to the hospital because they had infections with so-called flesh-eating bacteria, which doctors call group A Strep. Or the chicken pox virus infected their lungs and caused pneumonia or it infected their brain and caused encephalitis. We've seen a few children in our hospital who had a natural chicken pox infection and then the chicken pox infections were reawakened. We've had a few cases of children who had permanent strokes because of a reawakening of a chicken pox infection. Again, if that can be prevented safely, it's certainly worth doing.

**Q:** Dr. Offit, do vaccines cause autism?

**Dr. Offit:** No, vaccines don't cause autism. This question was raised in the late 1990s actually, interestingly, by a British researcher who felt that the combination measles, mumps, rubella vaccine caused autism. I think from a parent's standpoint, again, it's perfectly reasonable to raise the question. "My child was fine. They got this vaccine. Then, they're not fine. Could the vaccine have done it?"

The way that you answer that question is that you look at hundreds of thousands of children who got the vaccine, compare them to hundreds of thousands who didn't get the vaccine, make sure that those two groups are alike in all other aspects with the exception of receiving the vaccine so

you can isolate the effect of that vaccine, and then see whether the risk of autism is greater in the vaccinated group. And this study has been done again and again and again -- now 12 times -- and has clearly shown that you're not at greater risk if you if you got this MMR vaccine than if you didn't. And so, a choice not to get an MMR vaccine is not a choice to lessen your risk of autism; it's frankly just a choice to increase your risk for, in this case, measles or mumps or German measles.

Then, the hypothesis changed to a fear that thimerosal or an ethyl mercury-containing preservative in vaccines caused autism. Again, the same studies were done, looking at children who received thimerosal-containing vaccines or the same vaccines that contained lesser quantities of thimerosal or no thimerosal, and again, the risk was not greater in the group that received thimerosal.

Frankly, with all the science now that's been done on autism, and knowing now what genes seem to be involved and what proteins those genes make and frankly, it drives one to events that probably occur early in utero, meaning when the baby is in the mother's womb. I think that it didn't make sense that vaccines would be a cause of autism and now we have all these studies showing that it hasn't.

But, you know, I think the problem here is that fear -- it's hard to unscare people. I think once you've scared them, it's hard to unscare them. And so, you can do all these studies and spend tens of millions of dollars looking at vaccinated or unvaccinated groups, that received MMR with thimerosal or didn't. That's certainly reassuring to look at these studies, but I think from a parent standpoint, they're still thinking, "You know, maybe even if this is a possibility, I just want to avoid this vaccine." But that choice can be dangerous, as was seen last year when we had the biggest measles epidemic we've had in more than a decade. One hundred and forty children got measles. About 15 of those children were hospitalized with severe dehydration or pneumonia caused by that virus. You know, if we start to get up to a few hundred cases of hospitalization, you're going to start seeing measles deaths again in this country, and this was a virus that before vaccine, you know, killed around 500 children a year. We figured out a way to avoid it and avoid it safely.

It's, frankly, hard as a scientist to watch these hypotheses like "MMR causes like autism" get raised, watch them be frankly refuted by the science, and watch the fear that was created just not go away. I think it's been an enormous disservice to our children and it's caused a lot of suffering that didn't need to be caused.

**Q:** Is it possible that vaccines cause autism in a subset of vulnerable children?

**Dr. Offit:** Well, let me put it to you this way. Given the strength and power of those epidemiological studies, I think you can safely say that if vaccines caused autism in 10 children a year, you would have been able to pick it up with these studies, and we have not been able to find it. So, I mean is it possible that vaccines cause autism in one or two children every year? One can say that that's possible, but it doesn't make biological sense, and you could say that about anything.

You could say it's possible that peanut butter sandwiches cause leukemia in a small group of genetically susceptible individuals and it would be hard to prove that didn't happen to one or two children every year. But again, that doesn't make biological sense, and I think that we can safely say that given all we know about autism, that there's far more information about the cause or causes of this disorder that tell us it has nothing to do with vaccines, and that really is where we should focus our attention.

**Q:** Why doesn't someone do a study of vaccinated versus unvaccinated children?

**Dr. Offit:** Right, and so, one could say, let's just do the definitive study of children who receive all the recommended vaccines -- and there are vaccines now recommend for young children to prevent 14 different diseases -- and compare them to people who've received no vaccines -- and about .5 percent of the population of children in this country's parents choose not to give them any vaccines.

It's a study one could possibly do. There's a couple problems with doing this study. If you do it retrospectively, meaning look just back at the medical records of groups that receive vaccines fully or didn't receive any vaccines, you have to make sure those two groups are alike in all other aspects -- meaning socioeconomic background, medical background and most importantly, health seeking behavior. Are those two groups exactly identical in terms of their health care seeking behavior?

That's going to be hard to control for because you could argue that someone who gets no vaccines believes that they have a healthier child and may be less likely to take their child to the physician if they suspect, let's say, mild autism disorder. And then the question is, "Well, so why not just do it prospectively?" That way, you can control for that because you would be evaluating those children every six months or a year to see whether or not they develop any symptoms of chronic illness, autism, allergies, hyperactivity disorder, asthma.

The problem with doing a prospective control study where you have a group of children who are unimmunized is that if you do the study and it's big enough -- and it would have to be big enough to look for these chronic illnesses -- there will be definitely be children who will get vaccine-preventable disease and who will suffer that choice.

Right now, in this country, parents are allowed to make that decision for their child, but investigators aren't. I don't think an investigator can say, "I'm going to study a group of children prospectively who are not immunized," because there will be some of those children who could get pneumococcal disease, which could cause meningitis and death. Some of those children could get Hib meningitis, and that's certainly happening now in this country where children whose parents are choosing not to vaccinate them are suffering hospitalizations and death from a form of bacterial meningitis which was basically eliminated from this country but is now starting to come back. I just don't see how you can conscience that. I don't see how any institutional review board could allow that kind of study to go on, knowing that there will be children who will suffer that choice. I don't think it's conscionable.

**Q:** Dr. Offit, what advice do you give young parents who hear scary things about vaccines?

**Dr. Offit:** I think it's important for parents to participate in the health of their children, obviously, and the best way to participate in that decision is to be as informed as one can be. The best places to get information are reputable sources such as the American Academy of Pediatrics, the Centers for Disease Control and Prevention, our group, the Vaccination Education Center here at Children's Hospital of Philadelphia. All of those sites, as well as many more, all of which can be, frankly linked from those sites are groups of academic or professional organizations who have looked at all of these studies and then have tried to put together, often in a Q&A format, how to explain those studies so that parents can understand them best and I think thus participate in the care.

The problem is, however, if you look on the Internet and just search the term "vaccine," a lot of "vaccine sites" that come up give information that's terribly misleading, that's not science-based, that's not accurate and will only lead to a misinformed and thus bad decision. Because quite frankly, if you really are informed about the science behind vaccines, you'll get them every time. I mean assuming that you're not in a group of children who can't receive vaccines. If for example, you have a highly allergic reaction to egg proteins, you wouldn't be able to get the flu vaccine. But for people who otherwise don't have those contraindications to vaccines, I think that you would get them every time.

So when a parent makes a choice not to get a vaccine or delay a vaccine or withhold a vaccine or separate vaccines, I think they put their children at unnecessary risk and that risk is not theoretical any more. We're starting to see whooping cough outbreaks, measles outbreaks, Hib -- also called Haemophilus influenza type b -- outbreaks, and children are suffering these bad choices.

I think the job of a parent; probably the principal job of a parent -- I'm a parent of two children -- is to put your child in the safest position possible, to make sure that they are the least likely to be put in harm's way, and that's what vaccines do. I think vaccines put children in the safest position as possible and it's hard, frankly, as a scientist and a doctor to watch parents, based largely on unfounded or certainly not science-based fears of vaccines, make decisions that put their children in harm's way unnecessarily.

I mean we've had -- in Philadelphia in the last couple of months -- we've had six cases of Hib meningitis and three deaths because parents were afraid that vaccines were doing more harm than good. And I think they found out the hard way that the opposite is true, that certainly these natural infections are far more likely to do harm than any vaccine. It's an awesome responsibility being a parent and you need to be fully informed to help your doctor make the decision that's best for you and your child. But to be fully informed, I mean to really be fully informed about vaccines means that you'll get them every time.