TRANSCRIPT

Nancy Gibbs:

Hello, I am Nancy Gibbs, the director of the Shorenstein Center on Media, Politics and Public Policy at Harvard's Kennedy School, and this is Unlocked. Today we are exploring how the government determines what vaccines are approved, and recommended, and for whom, and the processes before, during, and after immunization recommendations happen. We are lucky to have as our guest, Dr. Paul Offit. He's a pediatrician, an expert in infectious diseases, immunology, virology, director of the Vaccine Education Center at Children's Hospital in Philadelphia. And importantly, has served on federal advisory committees that play a critical role in shaping vaccination protocols. The CDC's advisory committee has undergone significant upheaval in recent months, including with the replacement of all of its members. So let's start there. Dr. Offit, thank you for joining us. Can you explain to us the role that federal advisory committees play?

Dr. Paul Offit:

Sure. So the way it works is that a vaccine maker will submit a vaccine initially to the Food and Drug Administration. So now they've done their studies looking, at this point, tens of thousands of people either did or didn't get the vaccine to prove that the vaccine is safe or to prove the vaccine is effective. And that goes before then a federal advisory committee to the FDA. So the FDA is a regulatory body. So that group then looks at the data and makes a recommendation to the FDA to either license or not license the product. And then the FDA makes that decision. Invariably, they go along with that advisory committee.

Then it goes to the CDC, which is not a regulatory body, it's a recommending body. They have their own advisory committee, the so-called Advisory Committee for Immunization Practices, which is typically composed as is true of the FDA Vaccine Advisory Committee of experts in the field of virology, immunology, microbiology, statistics, epidemiology. Many often are clinicians who advise patients about vaccines who have seen vaccine preventable diseases. They then too make a recommendation in terms of who they think should get this vaccine and when. And that recommendation then goes to the CDC who typically accepts that recommendation. So that's the process.

Nancy Gibbs:

What happens after that process? Over time, what are the systems that are in place that monitor vaccine safety, side effects over time after those initial approvals and recommendations?

Dr. Paul Offit:

Right. So I'll use COVID as an example because I think it's a good one. I was on the FDA Vaccine Advisory Committee in December of 2020 when both Pfizer and Moderna submitted their data on authorization,

emergency use authorization for their vaccine. So Pfizer had done a 40,000-person trial in adults. It was one-to-one placebo-controlled. So 20,000 people had gotten Pfizer's mRNA COVID vaccine. Moderna similarly had done a 30,000-person trial, one-to-one placebo-controlled. So 15,000 people had gotten their vaccine. So basically we were looking in that month, 35,000 adults that had gotten that vaccine, knowing that we were going to be making a recommendation for hundreds and hundreds of millions of people. And because historically it's always true that there is some human price to pay for knowledge, you know that there is going to be some rare side effect and arguably serious side effect. The only question is how rare and how serious and that happened.

So within weeks of that vaccines getting out there in January, February of 2021, you saw that in boys and men between 16 and 29 years of age, that they could have within four days of getting their second dose, myocarditis, inflammation of the heart muscle. Now fortunately, it was transient, self-resolving, short-lived, so it was a small price to pay. And actually, in the last three years we haven't seen any myocarditis associated with that vaccine. So the price to pay for the mRNA vaccine was small. But the vaccine that came out in February of 2021, the Johnson & Johnson vaccine, the so-called vectored virus vaccine that was tested also in tens of thousands of people and then was given to hundreds and hundreds of thousands of people where it was found to be a rare cause of clotting, including clotting of the brain, including fatal clotting of the brain. And that was associated with maybe 1 per 250,000 people who got that vaccine.

Eventually, it drove that vaccine off the market because the mRNA vaccine was a safer vaccine. But what I think is reassuring is there's a system in place, two systems. One is the Vaccine Adverse Events Reporting System. So anybody who feels that there was an adverse event following the vaccine can report it, anybody. And then there's a Vaccine Safety Datalink, which is a linked computerized medical record system of anybody who either did or didn't get the vaccine. So what the VAERS or Vaccine Adverse Events Reporting System does is it raises a hypothesis. So for example, myocarditis was reported in boys and young men following that vaccine, but was that greater than one would've expected from background rates? The only way to know that is through the Vaccine Safety Datalink because there you look at people who got the vaccine or didn't get the vaccine.

So you can see whether or not there really was a risk associated with the vaccine, and that was picked up quickly as was clotting. Something as rare as 1 in 250,000 was picked up quickly by this Vaccine Safety Datalink. So I think people should be reassured that those systems are in place. I mean, people will often say to me, "I don't trust pharmaceutical companies because it's a profit making business." And I understand that. I think you should be skeptical of any profit making business. But you don't have to trust pharmaceutical companies because if they misrepresented data or they omitted data that was submitted to the FDA and ultimately the CDC, this will be picked up in the Vaccine Safety Datalink. There is no hiding.

Nancy Gibbs:

Is the word safe and safety, which you've used itself sometimes a problem because it suggests a binary, something is either safe or unsafe as though there are no side effects or costs? As opposed to our considered judgment is that the benefits far outweigh the risks, which still allows that there are some risks, there are some side effects, but it's not a binary, safe versus not safe. Is that an issue?

Dr. Paul Offit:

No, I think any medical product that has a positive effect will have a negative effect. If there's no negative effect, there probably never was a positive effect. So I think it's always in the medical world, a

matter of risks and benefits. Something is considered safe if it benefits dramatically and clearly outweigh its risks, but there's really pretty much no medical product that is absolutely free of risk.

Nancy Gibbs:

Are there common misperceptions that you come across about vaccines that journalists should be mindful of if they are reporting on this question?

Dr. Paul Offit:

I think that we ask a lot of parents in this country, we ask them to, in the first few years of life, give vaccines to prevent 14 different diseases. That can mean as many as 25 inoculations during that time. That can mean as many as five shots at one time to prevent diseases. Most people don't see using biological fluids. Most people don't understand. So it's not at all surprising that there's pushback. But I think that what people should realize is that we've had major advances in technology over the last 200 years. So for example, what matters is not the number of shots you get, it's what's in the shot that matters, i.e., or meaning the number of immunological components. And by immunological component, I mean something in that vaccine that induces an immune response.

So a viral protein will induce an immune response. A bacterial protein will induce an immune response. The complex sugar coating on a bacteria also called polysaccharide can induce an immune response. So if you add up all the number of immunological components in the, say, 17 vaccines that children get today through adolescence, it adds up to about 170 immunological components. That's less than the one vaccine we got 100 years ago, which was a smallpox vaccine, which was the largest of the mammalian viruses. Actually, you can see that virus under light microscopy, which is amazing. But that had about 200 immunological components. So actually the number of immunological challenges 100 years ago was more than the challenges that we get today due to advances in things like protein chemistry, protein purification, recombinant DNA technology. So that's the most common question I get asked.

Nancy Gibbs:

You may be getting a new question this fall because the American Academy of Pediatrics recently released COVID vaccination guidelines for children that are different from the CDC's guidelines. How unusual is that and what is a parent to do when you have the Academy of Pediatrics saying one thing and the CDC saying another thing?

Dr. Paul Offit:

It's very unusual. Usually those recommendations that are made are invariably in concert with each other. So I'll put this in perspective. In April of this year, the CDC was presented data on the impact of COVID over the past year, and what they found was that in terms of children, about thousands of children were hospitalized with COVID. Of those were hospitalized, about one in five were admitted to the intensive care unit. Virtually all were unvaccinated, half were previously healthy. And about 152 children died. So this was a disease worth preventing in children. Most of those children were less than four years of age. And for that reason then, months ago, we had a recommendation for all children to receive a vaccine if they'd never been naturally infected or never vaccinated because they could be one of these thousands of children who were hospitalized or sent to the intensive care unit or the more than 150 who died.

Then what happened is at the end of May of this year, Robert F. Kennedy Jr. stood up and in a one-minute video on X said that he, Health and Human Services, was no longer recommending this vaccine

for healthy children, which was not in line with the data. Because the data clearly showed that children did benefit. The American Academy of Pediatrics immediately stood up and issued their own black letter recommendations that children should receive this vaccine. And so now you have this variance between what the CDC is recommending according to Robert F. Kennedy Jr.'s unilateral, behind closed doors, science-averse recommendation, and then you have the recommendation by the American Academy of Pediatrics. So who should you believe? You should believe the American Academy of Pediatrics.

The good news is I think that this American Academy of Pediatrics recommendation will be covered by insurance. So I don't think that's going to be an issue. I just think that unfortunately, Robert F. Kennedy Jr. because he has for 20 years been an anti-vaccine propagandist, science denialist, and conspiracy theorist has made it harder, I think, for us in the public health world to do what's best for public health.

Nancy Gibbs:

He has raised questions about liability protection for doctors and hospitals if they don't follow CDC guidelines. How serious a threat is that and is there a scenario where parents can't get their kids vaccinated because healthcare providers fear being sued?

Dr. Paul Offit:

So there was in 1986, an act passed by the Reagan administration called the National Childhood Vaccine Injury Act, which included the Vaccine Injury Compensation Program. This really, if there was a CDC recommendation, this then protected physicians for any sort of liability issues that came up because that would always go through this program. Now, COVID vaccines aren't on that program, but the COVID vaccines are part of a separate program, the so-called PrEP program. So physicians are definitely protected here. I'm a little worried about pharmacists who aren't necessarily part of that. So I do think he's made it a little harder. When he threatened basically clinicians, pediatricians, and hospitals, that was an empty threat because there's no threat there. He never mentioned pharmacists, but I think they may be at some risk, but usually young children aren't vaccinated by the pharmacist.

Nancy Gibbs:

Are there mechanisms of oversight that Congress has over health and human services, over agencies involved in the process along the way of approval and recommendations?

Dr. Paul Offit:

You mean back in the days when Congress actually exercised their oversight? Yes, it's there. But it really, sure, the Congress could very much limit the kinds of harms that are being advanced by Robert F. Kennedy Jr. but they have chosen to stand back.

Nancy Gibbs:

Are there other things finally that you think reporters need to know of, either best practices, things that might be easy to miss in covering evolving vaccine access issues and protocols, and how they can avoid amplifying rumors in the course of coverage?

Dr. Paul Offit:

I think the biggest problem is the, quote, unquote, "scientific study" that proves a point that doesn't make a lot of sense. So taking a step back, there are about 8,000 articles published a day in the medical and scientific literature in the world, 8,000 a day. And not surprisingly, they follow what you would

imagine, which is a bell shaped curve. Some of them are excellent, some of them are awful. Most are more or less mediocre. But there's a lot of bad science that's published every day in the medical literature. And anti-vaccine activists can very quickly glom onto a study and say, "See, the mRNA vaccines do cause depression. The mRNA vaccines do cause suicide. The mRNA vaccines do cause heart attacks." And you can always find some paper that will say that. Actually there's hundreds of papers that are published that the earth is flat. Andrew Wakefield published a paper in 1998 claiming that the measles/mumps/rubella vaccine caused autism. That was in one of the oldest and best respected medical journals in the world, the Lancet. It was wrong.

24 studies have been done since then looking at whether children were at greater risk of getting autism if they got the measles/mumps/rubella vaccine, or if they didn't. But nonetheless, it's very hard to unring the bell. It's very hard to unscare people when you've scared them. And I think that's where we're living right now is a age of misinformation, where it's very easy to get misinformation out there and have it circulate around the world. I think that's the old Jonathan Swift line, which is falsehood flies, and the truth comes limping after.

Nancy Gibbs:

Dr. Paul Offit, thank you very much for helping unlock our understanding of the practices around immunization, vaccine approval, government oversight, and for parents everywhere as well as journalists. I know how valuable it is to hear from an expert. Thank you so much.

Dr. Paul Offit:

Thank you.