



Volume 4, Number 1

# Countering Vaccine Misinformation

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*This issue does not contain a discussion of unapproved/investigative use of a commercial product/device.*

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## Learning Objectives

- To discern the factors that contribute to vaccine hesitancy.
- To understand that valid scientific information is needed but not sufficient to reassure immunization-hesitant parents about vaccine safety.
- To formulate a tailored response to parental immunization concerns.
- To explore the vaccine safety monitoring system in the United States and the role of pediatricians in it.
- To identify reliable sources of vaccine safety information for concerned parents.

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# Transcript of the Panel Discussion

as recorded on the Audio CD

Numbers indicate CD Track

## <sup>1</sup> Introduction

<sup>2</sup> **Dr. Myers:** I'm Marty Myers. I'm a Professor of Pediatrics and Preventative Medicine at the University of Texas in Galveston and I'm Director of the National Network for Immunization Information.

**Dr. Orenstein:** I'm Walt Orenstein. I'm a Professor of Medicine and Pediatrics at Emory University and Associate Director of the Emory Vaccine Center.

**Dr. Marcuse:** I'm Ed Marcuse. I'm a Professor of Pediatrics and Adjunct Professor of Epidemiology at the University of Washington and Associate Medical Director at Seattle Children's.

**Dr. Myers:** All three of us are involved with the National Network for Immunization Information (NNii), which has many affiliates, but the primary ones are the American Academy of Pediatrics, Pediatric Infectious Diseases Society, and the Infectious Diseases Society of America. Our whole purpose for existing is to provide reliable information about vaccines.

Eighty percent of Americans look for health information on the Internet and most of them use a search engine like Google or Yahoo. The trouble with a search engine is, 50% of what you find is misinformation and it's much better to start with a reliable source.

**Dr. Orenstein:** And it's worth pointing out that NNii is independent of either the manufacturers or the government.

**Dr. Myers:** It gives us some financial struggle sometime, but keeps us free of any perceived conflicts of interest. And our Website is [www.nnii.org](http://www.nnii.org).

<sup>3</sup> So let's talk about vaccine safety and some of the systems that are in place. We know that when a vaccine is licensed by the Food and Drug Administration (FDA) that it's been tested generally in about 10,000 children, looking for common adverse events. But, of course, looking at that number won't find a less common adverse event, like intussusception after the RotaShield (Wyeth, Laboratories, Inc., Marietta, PA), the initial rotavirus vaccine, which occurred in about 1 in 10,000 children. The new vaccines were tested in more than 60,000 children for this reason. But the real vaccine safety observa-

tions come after a new vaccine is licensed and it's recommended for use. Walt, why don't you tell us about what the Centers of Disease Control and Prevention (CDC) and the FDA do to monitor for vaccine safety concerns?

**Dr. Orenstein:** Vaccine development is a long process. It starts in the preclinical phases with pathogen discovery, determination of what are the key immune responses to be induced, evaluation in animal models if possible, both for effectiveness and any safety-related efforts. And then there are a series of clinical trials that are conducted to look for dose, scheduling, age groups — and in those groups, they look for not only immune responses, but for frequent vaccine safety problems. These are known as phase I, phase II, and phase III trials. Phase I trials are often 20 to 80 people, and they're the first human trials. Phase II trials are a little bit bigger, looking again for safety and immunogenicity. And phase III trials, which Marty was talking about, about 10,000 children or more, are the pivotal trials for vaccine licensure.

But the process doesn't stop there. Once vaccines are licensed, there's a series of steps that are taken. The FDA usually requires manufacturers to do phase IV studies. These are post-licensure studies often conducted in managed care databases to look, in a prospective fashion, at a large number of children to see if any unusual adverse events occurred.

<sup>4</sup> There are several mechanisms in which we monitor the entire population post-vaccine licensure. The first is the vaccine adverse event reporting system, or VAERS. Every person who gets a recommended vaccine for routine immunization should get a vaccine information statement. On that statement is a number to report to VAERS. We rely on pediatricians to pick up potential associations. And this was probably no better demonstrated than in 1999 when the original rhesus rotavirus vaccine, or RotaShield, was associated with intussusception. It was reports from 14 cases of intussusception by pediatricians that helped to trigger an entire major investigation that documented that the rhesus vaccine could cause intussusception, and it was withdrawn from the market.

Once VAERS generates a signal, as it did with intussusception, there are a variety of mechanisms evaluated. One of the biggest is the Vaccine Safety Data Link, which consists of multiple health maintenance organizations (HMOs), about 3% of the U.S. population, and it allows you to calculate the incidence of the adverse event after vaccination and compare it with the incidence of the adverse event in the absence of vaccination. If the rate is higher in vaccinees, it would be compatible with causation. Other modalities include the Clinical Immu-

nization Safety Assessment Network, which looks at clinical patterns and is available to you to help in answering clinical questions. The CDC and FDA monitor vaccine safety closely and, when necessary, make changes such as warnings or, as in the case of rotavirus, the withdrawal of the recommendation.

**Dr. Myers:** VAERS is really important for reporting. It's [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or 800-822-7967.

**Dr. Marcuse:** I think it's important to emphasize to physicians that they don't have to know whether or not it was vaccine related. If there's any question, they can report. In addition, anyone can report, so that a parent who has a concern that the pediatrician may not regard as being related in any way to the vaccine can simply encourage the parents to report it themselves.

**Dr. Orenstein:** That's important. I think physicians should allow people at CDC and FDA to make decisions about causation. If there's something bad that happens following vaccination, it's better to report it and let someone else sort it out than just to assume it's not causally related.

- <sup>5</sup> **Dr. Myers:** An adverse event is a term that all three of us have used, and it's important that people understand that that's just something that occurred after. It doesn't necessarily have anything to do with causation. Although sometimes, in common use, the public uses the term equivalent to a side effect. It's important to report adverse events and then you can't evaluate causation with the VAERS data. Anything that goes into the VAERS database stays there.

There's a wonderful anecdote about that. A person who reported that after getting an influenza immunization that he became the Hulk, and it got actually put into the database. When he was contacted by the VAERS investigators, they requested whether they could remove that from the database. He allowed them to do it; but if he had said no, then we would have a Hulk report in the database.

**Dr. Orenstein:** I think there are two issues. One is, one of the reasons we've changed terminology from adverse reactions to adverse events is the word *reactions* implies causation, and adverse events is a far more neutral term.

The other key thing about VAERS is it lacks a control group. We need to remember that if we're immunizing 90% of children, that 90% of the bad things that were going to happen anyway will happen coincidentally after vaccination.

- <sup>6</sup> But there are things in VAERS that can help in generating a signal. For example, there is a bias in reporting to VAERS of things that occur shortly after vaccination. So if you look at VAERS reports and you see a cluster, as we did with intussusception, 3 to 5 days after vaccination but not in the first couple of days after vaccination, this was suggestive that there was a problem going on. There are other patterns one uses in VAERS to evaluate safety. For example, if you look at other vaccines and you look at different kinds of events that are reported, and you compare it with the vaccine in question and they're a different pattern or distribution, that again generates a signal. And when those signals are generated, you could either go to the Vaccine Safety Data Link and look at the incidence of that event with vaccination versus in the absence of vaccination, or do special kinds of case control or other kinds of epidemiologic studies.

- <sup>7</sup> **Dr. Marcuse:** The Vaccine Safety Data Link has come a long way. Marty, can you say something about what a rapid cycle analysis is and how that's used?

**Dr. Myers:** It's an interesting use of the Vaccine Safety Data Link. When a new vaccine is licensed, there are certain adverse events that you want to look for. So instead of data mining, like we do with VAERS for trying to find signals that we aren't expecting, the Vaccine Safety Data Link has been refined enough that they're able to say, okay, I'm worried about intussusception after a particular vaccine, and so let's look for a signal. And they can look every week as children are being immunized with a new vaccine. If they find a signal, then they can go back and do a case control study where they refine the cases that they're counting and look and see whether the signal is valid or not.

**Dr. Marcuse:** I think it's important to differentiate between a signal in VAERS and a signal in the Vaccine Safety Data Link, because in the Vaccine Safety Data Link you are comparing something that occurred in vaccinated kids to something that occurred in unvaccinated kids.

**Dr. Myers:** The way they look for a signal is, of course, they're using the administrative database, which has all sorts of problems built into it, but it allows them to find the signal fairly quickly. So after the meningococcal conjugate vaccine was licensed, there was concern about whether Guillain-Barré syndrome was occurring at an increased rate. And, in fact, they looked and they found the signal. But when they went and did it as a case control, looking at medical records and defining the cases

properly and who got vaccine from the medical records and who didn't, they found that there was no increase in risk. It was an incorrect signal.

**Dr. Marcuse:** What's the timeframe?

**Dr. Myers:** About 6 to 9 months.

**8 Dr. Orenstein:** The other thing that can be done through the Vaccine Safety Data Link and other kinds of studies is, sometimes so many kids are vaccinated that there really isn't a good completely unvaccinated control group for comparison. And what can be done at that point is to look at risk intervals. So to look at the incidence of an adverse event, let's say in the 3 weeks post-vaccination, you could have children serve as their own controls, looking at the incidence of the event, let's say, in the 3 weeks before immunization or the incidence of the event 4 or more weeks after vaccination. So you can use the Vaccine Safety Data Link, even when you have very high immunization coverage, to begin focusing down on likely risk periods, since most adverse events would be expected to occur during a specific risk period following vaccination, if they're causally related.

**Dr. Myers:** There is a robust system in place between CDC and the FDA and these partner organizations, the Vaccine Safety Data Link and so on, seeking causal relationships between adverse events or trying to establish whether they're coincidence or not.

**Dr. Orenstein:** And to reemphasize your role in this whole system, because so much of it is dependent upon your reporting to VAERS as the initial trigger for evaluation and setting up other kinds of studies. So it's really critical for you to report to VAERS if you're suspicious.

**9 Dr. Myers:** Now, let's talk about countering misinformation — misinformation being erroneous information about vaccine safety. Where do vaccine safety concerns come from in the first place? Our mothers taught us very well: "after that, therefore, because that." Our mothers taught us not to put our hands on the top of a hot stove or to put our hands in the flame, because we would get burned. So, unfortunately, when we talk about coincidence, it's really counterintuitive to people. People really understand you do something and something else happens, and they think that means causation.

And I think most vaccine safety concerns come from that logical fallacy. People make intuitive decisions: they see a child gets immunized and something adverse happens,

and they make that association. I think that's one of the core issues. Most vaccine safety concerns are raised by case reports; people making that type of an association. And that then requires a collection of the type of data that Walt was talking about in the Vaccine Safety Data Link, to do the case control studies to show whether there's causation or not.

Of course it's really easy to define causation when there's a cause. When there isn't, it takes years and multiple studies in multiple populations to assure yourself that it is probably a coincidence. As Walt often says, you can't prove the null hypothesis. You can only disprove it. So it's accumulation of information.

During that period of time after a vaccine safety concern is raised, there's a period where there are no data; the data have to be collected and it may take years to collect the data. So we call that the *vaccine safety concern du jour*, and they certainly do seem to evolve and appear frequently. Some of them have taken on a life of their own despite the robust data to suggest that it's coincidental.

**10 Walt's** been in the interesting position of having to make public health policy in the circumstances when you have misinformation and how to manage. No matter whether you think there might be causation or might not be causation, you still have to make a public health decision for the best protection of children. Walt, why don't you tell us a little about some of your experiences on that.

**Dr. Orenstein:** Thanks, Marty. I think that's the real advantage of historians; they can look back and see whether the decision made was correct. The problem clearly is what happens when a safety concern is raised and you don't have immediately available the kinds of detailed, scientific information to help you put it in perspective. Things that are considered are: 1) Biologic plausibility: is there something that makes sense with regard to this allegation. 2) What data are available that might weigh one way or the other? 3) Are there any animal models or any other kinds of models that might be similar to this? So, for example, if you have something associated with a wild virus and you are using an attenuated virus vaccine, and you get the same adverse event, that might add to the biologic plausibility even if it turns out later it's not causal.

These theoretical risks then have to be weighed in terms of the risks of not vaccinating. And one needs to think about where there is clearly a known harm, and that is the resurgence or perpetuation of vaccine-preventable diseases. And I think there's a good example of this decision making that occurred with the rhesus rotavirus

vaccine in 1999, when it became apparent through 14 reports from physicians and another one picked up in the Vaccine Safety Data Link — 15 cases in total of intussusception — that occurred within the 3- to 5-day interval after vaccination, after the first dose, and supported by other information from an HMO and some data from Minnesota. What happened with rotavirus was: 1) it had not yet been implemented in terms of vaccination; 2) while the morbidity was appreciated, there were alternative treatments and that was oral rehydration or parenteral rehydration; 3) we had a season with rotavirus. The season was about 4 to 6 months after this concern was raised, so we had some luxury of time.

And so what was done with the rhesus rotavirus vaccine was to put implementation on hold in order to do the studies. Those studies later confirmed intussusception as an adverse event at an attributable risk of roughly 1 in 10,000. And given the magnitude of that event, the vaccine recommendation was withdrawn. Our current rotavirus vaccines were tested in over 60,000 children each to assure that there was no risk of intussusception in that range.

- 11 Dr. Myers:** That July of 1999 was a busy time. It was also the time that the joint statement was published, within a week of the rotavirus. Why don't you talk about some of the issues of decision making at that time when there was no information about thimerosal.

**Dr. Orenstein:** I think that's a good case in point. With rotavirus, there was a clear clinical syndrome and there was this data signal that there potentially was harm. With thimerosal, we were talking about a theoretical problem that the amount of ethyl mercury in the schedule could be greater than one of three federal guidelines for methyl mercury, a compound known to be more neurotoxic. So there was exceedingly little information on ethyl mercury, which is the form in thimerosal, to make an evaluation.

On the other hand, we knew that there was great harm from not giving *Haemophilus influenzae* type b vaccine, from not giving diphtheria and tetanus toxoids with acellular pertussis (DtaP) vaccines, and from not giving hepatitis B vaccines; all of which contained thimerosal at the time. What was done at that time, therefore, was to recommend to manufacturers to get thimerosal out of their vaccines as soon as feasible, to continue vaccination as it was occurring, and to do studies.

With that process we learned that the precautionary principle, which was thinking we were doing no harm, wound up in doing some harm. It was a decision to

move the hepatitis B birth dose out of the birth period, because that was the biggest concern theoretically with thimerosal. It was thought at the time that it would be simple because those infants born to surface antigen-positive mothers would get vaccinated and the rest could wait till their 2-month visit. As it turned out, a lot of unforeseen things happened; some hospitals actually stopped all newborn vaccination, and kids who should have been getting the vaccine didn't get it.

We also saw problems occur that none of us anticipated. No one ever thought at the time that autism was a potential problem related to thimerosal. The biggest concern was more subtle neurodevelopmental defects that had been seen with low-level exposures to methyl mercury. The big focus on autism and thimerosal really was a surprise; it was championed by a group that later became SafeMinds ([www.safeminds.org](http://www.safeminds.org)), and virtually the entire focus on thimerosal has been on autism.

- 12 Dr. Myers:** It's interesting that at the start of all this, the concern was developmental problems, but not autism. It wasn't associated with methyl mercury or ethyl mercury poisoning; no symptoms of that type. And in fact, it's a case study in the evolution of misinformation. Sally Bernard misinterpreted the symptoms of autism to be similar to the symptoms of organomercury poisoning, which in fact they are not. Both the Institute of Medicine looked at that and a group of neuroscientists looked at that, and it's just a hypothesis that doesn't hold water.

But they promulgated that their children had autism as a consequence of thimerosal. It wasn't until about a year after the joint statement that the whole issue of autism started to be discussed. And so it's really a case study of a concern that was raised. In 1999, we didn't have any good epidemiologic data about developmental disorders of any kind or autism with ethyl mercury. And 2001, when the Institute of Medicine looked at the issue, we didn't have enough data for them to feel comfortable in saying that it favored rejection of the hypothesis.

By 2004, there were sufficient good epidemiologic studies from multiple centers, from multiple populations that said that there was no association with autism, that the Institute of Medicine felt quite comfortable in saying that the data favored rejection of the hypothesis. So, I sort of set my clock by about 2004 when they made their statement, and that's when missing information really became misinformation. Since then, what we've been dealing with is the misinformation about thimerosal in this country.

In Great Britain and Europe, it's been measles and autism, a very similar evolution of case reports of measles

and association with autism. Robust data now show that measles vaccine is not associated with autism, but the most unfortunate thing is that outbreaks of measles in Great Britain when immunization levels fell, one child died. And then an outbreak of mumps because many parents withheld the measles-mumps-rubella (MMR) vaccine; they had 63,000 cases of mumps in Great Britain, which were the source of the outbreaks of mumps in the United States and the Maritimes of Canada.

**Dr. Orenstein:** With the United Kingdom problem, it actually became even more theoretical, because I don't think they attributed it purely to measles. It was the MMR, and somehow the three together were felt to be a problem. There was never any good data, but the media really picked up on it and scared people, in a sense, because you had these autism cases and you had people who got MMR. And as I said, if you get high levels of coverage, high proportions will have autism after vaccines.

- <sup>13</sup> And I think another critical point that you made, Marty, that I'd like to reinforce, and because it deals with the null hypothesis issue, which actually Ed has raised multiple times before: if you look at the Institute of Medicine reviews, they have five categories of evidence. No evidence at all. They have a category of the evidence as insufficient to say whether or not there's a causal relationship. They have two categories of causation. One is the evidence favors causation, and the other is the evidence establishes causation. On the negative side, they only have a category that the evidence favors rejection of causation. Because you can never prove the negative, there is no category that the evidence establishes no causation.

**Dr. Marcuse:** So, the hypothesis was that measles or measles-mumps-rubella or thimerosal causes autism. That's the hypothesis. All science can do is say there is no evidence of an association between measles, mumps, rubella, thimerosal, and autism. Science can never say measles does not cause autism. When we say "the null hypothesis," that's a statement that you can't make with scientific accuracy even though you believe it to be true.

**Dr. Myers:** The measles story in Great Britain is worth emphasizing. On the day that a series of case reports was published, a press briefing was held. There was a press video and the media picked up on it immediately. Even though it was just case reports, there were no data establishing any relationship — but the major press carried headlines that said "vaccines linked to autism." That began the media intensity, propelled a hypothesis very vividly into the minds of families. And the ultimate con-

sequence of that was a reduction of immunization levels and disease outbreaks.

**Dr. Marcuse:** Well, that's a wonderful segue into the climate in which all this was occurring.

- <sup>14</sup> About a decade ago in 2000, about 20% of parents of kids in the United States had vaccine safety concerns. Today, about 20% actually decline or defer some vaccines. So over the last 8 years, we've moved from worry to action. And it varies around the country and within states. In my own state of Washington, in various counties, the folks opting out of school entry vaccines, claiming exemptions against one or more vaccines, varies from a low of 1.4% to a high in some counties of 30%. So today, practitioners are encountering parents who want to decline or defer a vaccine almost every half day that they're in the office.

The reasons for this, I think, are many. Clearly, the success of vaccines in decreasing vaccine-preventable diseases: measles is just not a common experience for families today. I think there's been a general recognition of the limits of medicine technology and science. There's a growth of consumerism that affects our whole society. There's a background of product liability and malpractice litigation. And then there's this distortion of the scientific process, which you just illustrated in the measles/autism example. When Jenner developed his smallpox vaccine, he presented it to the Royal Society, who argued about it. So it was initial discussion among scientific peers, then it got published in a scientific journal.

Today, when there's a hypothesis, it's very likely to be immediately in the press, picked up around the world, and it gets validated by repetition before it has ever been tested. There are different criteria for causation in the scientific world and in the legal world. So a legal decision to compensate this or that may be quite different than scientific evidence that something caused this or that.

And clearly, for the media, controversy is what sells. It is not necessarily a search for truth. And case reports are extraordinarily powerful.

- <sup>15</sup> **Dr. Myers:** In the few studies on how people in the public find out about vaccine safety concerns and how they answer their questions, a trusted health professional is the most usual source. But the studies as they have been reported over the last few years have been increasingly talking about the role of media and the Internet for information acquisition. And part of the culture for journalists is that to show that they're not biased, they need to balance a story. And of course that often means the less informed media person balancing science with a

person who has a different opinion. And the unfortunate part of that is it gives them credibility. So I think the media is an important piece of what we as pediatricians need to do. We need to be educating people about a balance that isn't equal and what they're hearing. We need to be able to respond to that.

We need to understand that people use the Internet, they use it frequently, and we need to be giving them guidance as to how to use the Internet to get their reliable information.

Going back to the media, one of the other issues is what makes a good story. Well, secrets, cover-ups attract a lot of attention. A story always has heroes and villains. We always think of the villains being the diseases, the heroes being the vaccines — although in the misinformation attacks that have been occurring recently, you don't hear about the villains being vaccines. High-profile personalities attract attention. Having conflict within a story makes it even more powerful. And signal value, what's coming next, what's the next shoe that's going to hit the floor; if there are lots of people perhaps involved and, of course, all the children get vaccines, the implication in the media story could be your child. And, of course the suffering child and mother who's convinced that the vaccine caused the problem.

- 16 **Dr. Marcuse:** The safety concerns are often framed as plausible scientifically and they're not quickly refuted by science. As you and Walt pointed out, it takes time to get the information.

I think that underlying some of the hesitancy is a fear of environmental toxins, a fear or distrust of government or of industry, and then faith in things like alternative medicine or faith in a trusted spokesperson like Oprah. It's not easy to quickly refute with scientific information concerns that are fundamentally based on fear or faith. We can't treat that kind of reservation as ignorance that we can beat back with good data. It's not just rational science that's needed, but it's absolutely essential. But we need a dialogue.

**Dr. Myers:** I think one of the great frustrations for all of us and any pediatrician is the fact that science is being discounted as part of the discussion and pseudoscience is given equal weight. I think it carries an enormous frustrating message as to how to respond to the talk show hosts.

**Dr. Marcuse:** But in all fairness, Western medicine is not good at answering the existential questions: why me, why my child, why now, what's next? Science doesn't help it.

It tends to give you a rather cold answer to those kinds of questions.

- 17 **Dr. Orenstein:** I think another potential problem is some of the most problematic syndromes we deal with are those without known cause. And so people are groping to find the cause for something, because we don't know exactly what is causing a syndrome like autism.

**Dr. Myers:** And if we think back about some of the major vaccine safety concerns over the past few years — sudden infant death, asthma, diabetes, encephalopathy and so on — often cases of things that we don't really understand in their entirety.

**Dr. Marcuse:** I think it's important to differentiate between the tactics and strategies that are appropriate when you're trying to sustain society's support for immunization and public health, and you're trying to refute advocates who are spreading misinformation, versus the tactics and strategies that are appropriate when you're dealing with a concerned individual parent. I think those are two rather different approaches.

- 18 **Dr. Myers:** There's a very interesting study recently looking at how you present information as well. And the study was looking at one of the CDC's information sheets about the facts and myths around influenza vaccine administration where they were trying to address the concerns, as a myth and then giving the facts. And when a group of people were given this fact and myth sheet, they read it and at the end of having read it, they tested quite well understanding the facts. But a half an hour later, 16% of them had now picked up on the myth — that rapidly. And so it's important to give the factual information, but not to repeat the myth because very quickly it's familiar. It's called the *familiarity bias*: the more it's repeated, these misinformation attacks that you were talking about, the repetition makes it seem like it may be real.
- 19 We've been talking a lot about the origins of misinformation and the science, but let's talk about vaccine safety concerns.

**Dr. Marcuse:** And I think here the key point is, it's about the dialogue, not just the science.

**Dr. Myers:** I couldn't agree more. And you used a word a few moments ago about something being *plausible*, and that's a good word to talk about, the same thing we spoke about before with the adverse event. We've all

been trained that plausible means that it's theoretically possible. But to the general public, it means it's worthy of belief or that it's factual. And there are a lot of expressions that we use in talking about vaccine safety that we assume parents mean the same thing that we do.

Significant — well, we think of that as this may not be a chanced difference, but to the public that means it's important. And not significant — we mean it's probably due to chance, and the public thinks that's not important.

**Dr. Marcuse:** As you talk with families, you've got to use language that they understand. You have to tailor your response to the individual family. First, you really need to understand what the basis of their concern is. You need to understand a bit of how they make decisions, what kind of evidence counts for them. And you really want to focus more on their behavior than necessarily just their knowledge. You want to maximize the benefits of immunization for their child and their circumstance, and you want to minimize the barriers to getting their child immunized — whether that means talking about common side effects or whatever it is that's a chief concern to them. The point is, you want to ally with the family and try to make this a collaborative discussion. It's not a battle to be won or lost.

20 There are some key points that you want to make; there's some key messages you want to get across in talking with any family. I think you want to make clear that you understand that they want to do what's best for their child and to emphasize that so do you. You want to let them know that you know that they're being bombarded by information that's conflicting and that it's complex. And that you understand that science can't provide all the answers to all the questions that are concerning them, but science is the best method we have to get reliable answers.

I think you want to make clear to the family that you wish you could make the world completely safe for them and their child, but you can't. There are threats that you can't eliminate, but you can help them protect their child. You can help them to get the information they need to make an informed decision. But ultimately it is their decision. And it's important that you give them time to make that decision, that you revisit the issue repeatedly if you encounter resistance.

I think the dialogue is more important than the immediate outcome in any one visit. Research has shown that when you're dealing with an issue where there's relatively low emotional investment, people tend to rely on experts. But that when you deal with an issue where

there's a lot of emotional investment, a lot of concern, in fact trust becomes much more important than expert opinion. So I think it's maintaining the dialogue that's really important.

There's been a lot of discussion about when is it appropriate to fire a family from your practice because they don't accept your recommendations. I'm very reluctant to see physicians fire families around issues of immunization concern. First, most families who wish to decline or defer a vaccine do not decline or defer all vaccines. I'm very concerned about where those families will go. And I think the sense of being treated with respect is important.

21 **Dr. Myers:** We observed that, in one of the misinformation attacks that occurred a couple of years ago, that there was a sudden surge in interest in that topic on our Web site. The essays on the topic were archived, so they actually had to get to our Web site and search the archives to find the articles. And very interestingly, in addition to that, they would link from there to essays on how to evaluate the information. So in addition to looking for reliable information, people are looking for guidance on how to find reliable information. And I think it's a great opportunity, when somebody has concerns about vaccine safety, for us to be able to not only do the types of conversation that you're talking about, but also to give them guidance as to where they can get reliable, factual information, because there is so much misinformation available.

**Dr. Marcuse:** And vaccines are one of so many things that a new parent is struggling with: phthalates in the plastic bottles, environmental contaminants and the effects on the child.

22 But I think it's important maybe we come back to what do you do specifically about the family who doesn't want all the vaccines at once and really wants them spread out, one at a time. Walt, do you want to talk a bit about that?

**Dr. Orenstein:** I think it's important that it is not without risk to spread them out over time. Part of the reason we give vaccinations early in life is potential exposures early in life. That's why we recommend rotavirus at an early age. Pertussis can be particularly severe the younger the child. Pneumococcal disease can cause very severe disease in very young children. There's not an arbitrary reason that the vaccines are given early. It's a reason that many of the exposures to the disease or many of the outcomes of disease are more severe in the youngest of children.

I think it's also important to point out that, in essence, the number of proteins that are in the immunization schedules today, even though there are more shots in the schedule today, is actually reduced because the vaccines are substantially more pure. Whole cell pertussis vaccine had about 3,000 proteins in it. If you add all of the other vaccines we've added to the schedule since we substituted acellular pertussis for whole cell, it doesn't add up anything near what children were being exposed to before. Also, children are exposed every day to many different organisms through their own oral and fecal flora and other kinds of exposures. But there is clearly a risk toward postponing immunization.

But if I could come back to what Ed was saying, that doesn't mean that you should fire the family who requests it, because if you do, then there's the potential that that child will get no immunizations and that's probably the worst of all consequences. And Paul Offit, Bob Davis, and Deborah Gust wrote, in a chapter in the fifth edition of *Vaccines*, six points that physicians should use to deal with parents to keep parental confidence in vaccines high. Be respectful, solicit questions. Number two, be empathetic if parents have concerns. Number three, educate the parent before the day of the immunization. If you have brochures, vaccine information statements, information on Web sites, get that to them early so that they're not trying to come to grips with it on the day the vaccination is due. Give information tailored to the parents concerns, if possible. Be informed about current vaccine allegations. And lastly, strongly recommend vaccines. And some of the words they use are, say to them, "I believe in immunizations. My children are immunized" or, "my nieces or nephews," to show that this is not just something for them; that you're a real human being, and you're a parent too or you have people in your family, to get that message across.

**23 Dr. Myers:** I'd like to pick up on one point you both made and that is, when you delay vaccines, the parent needs to understand they're taking a risk. One pediatrician told me about a child who came in who was behind on immunizations at about 20 months of age, and the family said it's alright to immunize him, but he could only have four shots. And the decision was to omit the varicella vaccine. And, of course, as luck would have it, 3 weeks later the child developed chickenpox caught from a classmate, then developed staphylococcal infection of the lesions, and required hospitalization for 5 days. So there's a risk on any vaccine being delayed. And as you said, you don't want to delay pertussis. Mothers need to be immune to tetanus before the baby is born. And there are some vaccines that it's important to emphasize to

parents just what risks they are actually taking.

**Dr. Marcuse:** The burden of all of this communication cannot rest solely on the shoulders of the clinician confronting the parent over immunizing the specific child. I think a number of the organizations we all are involved with and our public health community really have to affect the public dialogue about vaccines so that the individual parent decisions are more likely to be informed.

**24 Dr. Orenstein:** I certainly cannot forget a big resurgence of measles between 1989 and 1991 where 123 people died, primarily children, young children; over 55,000 cases occurred and over 11,000 hospitalizations. The cause was not getting children their measles-mumps-rubella vaccine on time, which was a major problem.

**Dr. Myers:** And now that we're almost two decades away from that, we know there was another problem with the resurgence of measles: the rare complication of subacute sclerosing panencephalitis (SSPE) as a complication of measles. It's rare, but it occurs. And there was also a resurgence from that time period of cases of SSPE. The measles identified in their brains was the strain that was circulating, and it was not the vaccine strain. So, measles epidemics: we all know about the one in four per thousand that die, and the one in four per thousand who develop encephalitis, but it's an ugly disease, both acutely and has profound long-term risk factors.

**Dr. Marcuse:** The United States is seeing a larger number of measles cases than we have seen in a long time, and they've been coming from developed countries: Switzerland, Israel. Many of the people who are affected are, in this country, people who have opted out of immunization.

**Dr. Myers:** Sixty-three out of sixty-four.

**Dr. Marcuse:** So it may well be that, in fact, the system has to break a bit for it to get fixed, for people to actually perceive that their children are at risk from these diseases. It would be nice to be able to protect the country as a whole from that experience, but I don't know that we're going to be able to.

**25 Dr. Myers:** The misinformation about measles vaccine from Great Britain, of course, spread widely throughout Europe, and there have been outbreaks of measles in a number of countries, presumably because of reduced immunization coverage. And several of the introductions in the United States recently have come from Switzerland,

which is one of the countries that's had resurgent measles associated with Great Britain. So misinformation crosses borders and has impacts. The introductions of measles that are occurring now, many of them can be traced back to the misinformation outbreaks in Great Britain.

26 One thing we ought to also talk about is the Vaccine Injury Compensation Program, which was created in 1986 because of the problem of manufacturers dropping out of the marketplace because of the large settlements and lawsuits for vaccine injury. And what the Vaccine Injury Compensation Program is, is a tax on each dose of vaccine goes into a trust fund. There is a no-fault system established where, if a family has, their child has been injured by a vaccine or reasonably thought to have been injured by a vaccine, the court can compensate the family for the medical expenses. The best example might be a vaccine-associated paralytic polio. It's not the child or the family's fault, but it is a big financial issue for them.

This program has really changed the dynamics of the vaccine industry.

**Dr. Orenstein:** And can I say, one of the issues is a recognition that certain vaccines, as designed, cannot be designed to be 100% safe. So your example of the oral polio vaccine is one where there was no way of avoiding a very rare, albeit tragic, consequence - roughly one in 750,000 first doses associated with the oral vaccine causing polio itself. And so the compensation program was designed as no-fault to say this is society's obligation, because a child who gets vaccinated is not only getting individual protection, but protecting all of society.

**Dr. Myers:** There are specific guidelines for how the Vaccine Injury Compensation Program deals with issues that are brought to it. And there's a table that people have agreed to, that if a child falls into that and the timeframe is appropriate and so on, the case is conceded. Conceding a case, of course, does not say anything about causation. It's just a legal procedure to try and make it a much simpler system to compensate families whose child may have been injured by a vaccine. And as Walt says, vaccines are not 100% safe. We know of serious complications, albeit they are rare, with most vaccines.

27 There's been one case recently that is probably worth our talking about because of the misinformation circus that we've had surrounding it. A child with an underlying medical condition, a mitochondrial defect, a defect in oxidative phosphorylation, received a series of vaccines and developed encephalopathy afterwards. In mitochondrial defects, when a child is stressed and needs more

energy, of course the brain is the place that is usually injured because of such high energy needs. And this particular child developed opisthotonos and a high-pitched screaming, refused to walk. As it got away from the encephalopathy, then the child ultimately, over months, developed some behaviors that children with autism spectrum disorders have.

The Vaccine Injury Compensation Program is set up and, by law, specifies that once a case has been conceded because it met the criteria of the program, they can't talk about it. And so we don't really have all the facts in this case. But looking at it myself, it looks to me as if this child had an underlying defect, at least temporally associated with receiving vaccines had developed encephalopathy and brain injury; part of the behavioral manifestations were similar to autism. But the system is set up that you don't have to establish scientific causality, and it's just a legal term that the child should receive and the family should receive compensation.

This was leaked by the anti-vaccine group and made into a media circus. It was a child with an underlying defect, which Health and Human Services conceded might have been made worse. We don't know whether it was, in fact, the vaccine or whether the child had another illness. But we do know that these children get high fevers when they get measles; when they get these other diseases, these children are at risk of encephalopathy. We don't have a means of screening for mitochondrial disorders at this time. And this child did not have autism, even though that's been the case that's been made in the media talk shows and by advocacy groups and so on.

28 **Dr. Marcuse:** The objective of the Vaccine Injury Compensation system is, in fact, social justice. But nonetheless, pediatricians are now faced with this dilemma. Since some vaccines can cause fever and since fever can be associated with neurologic symptoms in children with some rare disorders, what's to be done? I think it's important to point out that the Mitochondrial Disease Association has come out in favor of immunization of children with those diseases, according to the recommended schedule. It's important that pediatricians make a clear recommendation that it's in a given child's interest to get all the recommended vaccines on schedule. However, some families are going to continue to be anxious based on this and are going to press to have those vaccines spaced out.

Walt, what do you have to say about that?

**Dr. Orenstein:** I think it's the obligation of the pediatrician to explain the schedule, why the rationale for the

schedule, and to strongly encourage the parent to get the child immunized on schedule. But I also feel, after going through all of that, if the parent still wishes to get less than the full complement of vaccines at any one time, it is better to provide some than none. It's in the best interest of the child to have at least some immunizations and to try and work with that parent to gain the trust and perhaps — hopefully — catch up at a later date on some of the other vaccinations. If not, having to give them multiple visits over time. But I think the child needs to be immunized to protect against all of these vaccine-preventable diseases.

**Dr. Marcuse:** And this is not a unique situation in clinical medicine. All of our patients who are obese don't lose weight. They don't adopt exercise regimens. It's not unusual for families not to accept all recommendations. So a strong recommendation is absolutely necessary to make clear what you believe is in the child's best interest. But it shouldn't have a sense of defeat if the family has been made so anxious by what they have heard, that you need to modify the schedule in order to get the vaccines delivered.

**Dr. Myers:** I had a nonmedical colleague who pointed out to me about advocacy that the older the pediatrician is, the harder they advocate for vaccines. I'm not sure if that's a valid observation or not, but those of us of a certain age have had a vivid experience of measles encephalitis, Haemophilus influenzae meningitis and its consequences, and so on. One of the disadvantages is that's part of our culture of being in pediatrics: we believe in vaccines, we don't want to see the vaccine-preventable diseases anymore, and many of them are not satisfactorily treatable. And so we tend to be very, very strong advocates for vaccine.

I think that's good, but I think your point is right — that sometimes people need to make their own decisions about losing weight or about vaccines.

**Dr. Marcuse:** In my own community, families who have ties to countries where vaccine-preventable diseases are still common tend to be the highest acceptors of immunization. A young mother will go home and check with grandma or granddad who has, in fact, experienced the measles or whooping cough or any of these diseases in the old country, and they readily recognize the benefits of immunization. I think our cultural experience of some of these diseases has faded due to the success of immunization.

**Dr. Myers:** For families, some of the diseases like autism

and asthma are much more recognizable and familiar than are diseases like measles and congenital rubella and so on.

29 I think one of the critical factors in responding to, countering misinformation is to provide good information; how to access good information and reliable information, and how to evaluate the information that people receive. Walt.

**Dr. Orenstein:** The point I'd like to make is, pediatricians have a major role in our vaccine safety monitoring system. And to encourage pediatricians to, one, use vaccine information statements as legally required. Give them to the parents, discuss it with them. And also, when there are significant adverse events, to report them to VAERS. The Web site is [www.VAERS.hhs.gov](http://www.VAERS.hhs.gov), or call 800-822-7967. It's those reports that form the foundation for the overall vaccine monitoring system.

**Dr. Marcuse:** It's about the dialogue as much as it is about the science. Parents who are vaccine hesitant need to be approached with compassion for their distress in sorting out what is best for their child. There are some advocates among them but, for the most part, they are simply worried, concerned parents who are looking for your clear recommendation, but may have trouble accepting it. The dialogue is what counts.

30 **Dr. Myers:** There's Web sites that I think it's important for people to know about for health information in general. I find the most useful one being the National Library of Medicine, [www.nih.nlm.gov](http://www.nih.nlm.gov), which has two portals. One is for health professionals and the other is for the public. For the public, PubMed Plus (<http://medlineplus.gov>), has a lot of information that is very useful. It's a good place to start a search.

We have a bunch of other sources: the Children's Hospital of Philadelphia ([www.vaccine.chop.edu](http://www.vaccine.chop.edu)); the Hopkins site ([www.vaccinesafety.edu](http://www.vaccinesafety.edu)); Immunization Action Coalition ([www.immunize.org](http://www.immunize.org)), and the Academy's Web site for pediatric information ([www.aap.org](http://www.aap.org)).

**Dr. Orenstein:** Another one, Marty, I think that's very helpful is the CDC Web site, which is [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines).

**Dr. Myers:** Yes, that's a very good one. And the other site at CDC, which I think is very useful, is [www.CDC.gov/travel](http://www.CDC.gov/travel), where you can look up any country, any region of a country, and find out immunization as well as chemoprophylaxis recommendations.

**Dr. Marcuse:** There are a couple of books that I think are also very useful. There's a new one, *Do Vaccines Cause That?* from NNii, which is excellent and has reliable information about vaccine safety. And Paul Offit's book, *Vaccines: What You Should Know*, which is in its third edition, is an excellent overview of vaccine-preventable disease.

**31 Dr. Myers:** That concludes our recording. And I want to thank Ed Marcuse and Walt Orenstein for participating. I'm Martin Myers. And we'd like to thank the American Academy of Pediatrics for giving us the opportunity to have this conversation.

**32 Narration Close**

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