

Testimony of Mark H. Sawyer, MD
**Concerning the Reemergence of Vaccine-Preventable Diseases: Exploring the Public Health
Successes and Challenges**

Submitted for the Record to the Senate Health, Education, Labor and Pensions Committee

February 10, 2015

Submitted by: Mark Sawyer, MD, FAAP, American Academy of Pediatrics

Chairman Alexander and Ranking Member Murray, thank you for holding today's hearing on such an important topic – the reemergence of vaccine preventable diseases and what we can do to prevent further outbreaks. My name is Dr. Mark Sawyer, and I am a Professor of Clinical Pediatrics, in the Division of Infectious Diseases at the University of California San Diego and Rady Children's Hospital in San Diego, California. I have been in the clinical practice of infectious disease for more than 30 years and have worked in the area of vaccine delivery in my community for the last 20 years. I am also a member of the Committee on Infectious Diseases with the American Academy of Pediatrics. My testimony today has the strong endorsement of the AAP, a non-profit professional organization of 62,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

The Success of Vaccines

It is undeniable that vaccinations are one of the greatest public health achievements in medicine. Vaccines are the safest and most cost-effective way of preventing disease, disability and death, particularly in children. Prior to the introduction of vaccines children were regularly afflicted with deadly diseases like measles, mumps, rubella, polio, and bacterial meningitis. The development and widespread use of vaccines has led to the reduction or eradication of these once common childhood diseases. As a pediatrician, I have never seen a case of polio, diphtheria or tetanus. I lived through the era when the most common form of bacterial meningitis was essentially eliminated through vaccination. In a teaching session I held last month with about 20 pediatric residents in training I asked them if they had ever seen measles--none of them had. I'm afraid that is changing. As we have seen in headlines across the country announcing the recent measles outbreak, and earlier stories about the eruption of pertussis in various areas of the country, we are witnessing the reemergence of vaccine preventable diseases here in the United States. Pediatricians are concerned that this reemergence of disease is only a signal of future, wider-scale outbreaks yet to come.

The Disneyland Measles Outbreak

Currently, the United States is experiencing a large, multi-state outbreak of measles linked in part to exposures at Disneyland in California. From January 1 to January 30, 2015, 102 people from 14 states have been reported to the Centers for Disease Control and Prevention (CDC) as having measles, many of them related to this outbreak. Most of the cases (92) are from California, and 13 cases are from my community. Most of those infected were intentionally unvaccinated, some of them did not know their vaccination status, and a minority of them were vaccinated. Once outbreaks get started even vaccinated people can be affected because no vaccine is 100 percent effective. The outbreak likely started from a traveler who became infected with measles and then visited the amusement park while infectious. The source, however, has not yet been identified. Given our current immunization rates this will happen again.

Measles is one of the most highly contagious infections we know, much more contagious than Ebola virus that we have read so much about recently. It is one of the few infections that can literally fly through the air and you can become infected simply by walking into a room where someone with measles has been in the recent past. Measles can also be transmitted before it can be diagnosed - four days before the characteristic rash appears. Measles starts with a fever, and soon after it causes a cough, runny nose, and

red eyes. Then a rash of tiny red spots breaks out. The rash starts at the head and spreads to the rest of the body, lasting for up to a week. Measles can lead to serious health complications such as pneumonia, encephalitis, and even death--about 1 in 1000 may die.

As a pediatrician that specializes in infectious diseases, I am alarmed by this recent outbreak. It illustrates the problem created by the rising number of unimmunized children in the United States. A simple trip to Disneyland has triggered an outbreak of measles in close to 100 people. It is completely predictable that such outbreaks will occur again if immunization rates stay where they are or get worse.

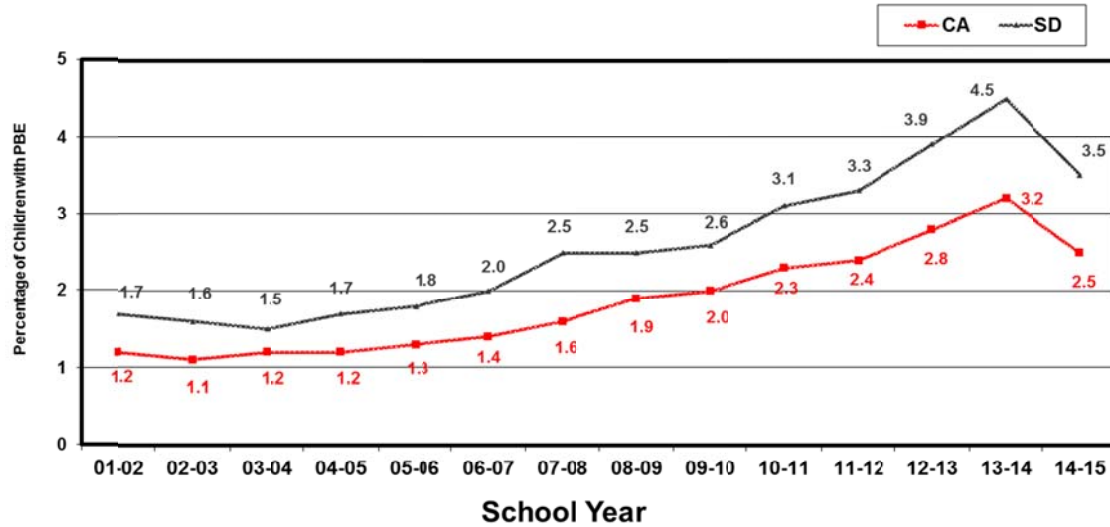
Why is this happening?

The primary reason for this measles outbreak, and all other measles outbreaks we have seen in recent years, is that we have too many people who are intentionally not immunized. The measles vaccine works extremely well and creates long-lasting immunity, but too many children are not receiving the vaccine. We need to increase vaccination rates in the United States in order to reduce the number of outbreaks that we will see in the future. I think we can do that, but it is a big challenge.

Before discussing vaccine hesitancy or refusal, it is important to note that most parents do choose to vaccinate their children, as vaccination is the best choice for a parent to adequately protect his or her child from very serious, contagious diseases. Every year the CDC analyzes school immunization data collected by states to see how many kindergartners have received their vaccinations and the latest results from October of last year showed that for the 2013-2014 school year median vaccination coverage was 94.7 percent for the measles, mumps, and rubella (MMR) vaccine; 95 percent for diphtheria, tetanus toxoid, and acellular pertussis (DTaP) vaccine; and 93.3 percent for varicella vaccine. The median total exemption rate was 1.8 percent. However, vaccination rates vary greatly by region and from school to school and lower vaccination coverage and high rates of exemption from school vaccine requirements cluster within communities, often times in wealthier and higher educated locales.

We see this in San Diego County. First, our overall rate of exemptions from school vaccine requirements for the 2014-15 school year is 3.5 percent, which is higher than the national average and higher than California as a whole. Second, and more importantly, those obtaining an exemption from vaccine requirements are not evenly distributed throughout our community. We have individual schools in which 30-50 percent of the students are not fully immunized. These are the schools at highest risk for outbreaks. This clustering of unvaccinated children occurs all over the country. The graph below shows the rates of exemption from school-required vaccines in San Diego County (black line) and California (red line) over the past 14 years. The trend is very concerning. The drop in exemption rates for 2014-2015 can be attributed to a new State law that requires parents who choose to exempt their children from vaccines at school entry have a form signed by a healthcare provider that they have at least been educated on the risks and benefits of their decision. The drop tells us that when many parents receive accurate, scientifically valid information about vaccines, they choose to immunize. But, we are left with some who still decline.

Personal Belief Exemptions (PBE) Kindergarten Entrance Assessment 2001-2014



2014-15 California kindergartners= 535,234(13,592 students with PBE status) among 8,170 schools
San Diego kindergartners=43,827 (1,518 students with PBE status) among 609 schools

An AAP survey of its pediatrician members found that 7 out of 10 pediatricians reported that they had a parent refuse an immunization on behalf of a child in the 12 months preceding the survey. Most frequently refused was the measles-mumps-rubella (MMR) vaccine, followed by varicella (chicken-pox), pneumococcal conjugate, hepatitis B, and diphtheria and tetanus toxoids and pertussis (whooping cough) vaccine.¹

Since most infectious diseases can still be just a touch or a sneeze away, and unvaccinated children are at greater risk for contracting these diseases, a large cluster of unvaccinated children has a negative impact on an important benefit of vaccinations known as “herd immunity.”

The Importance of Herd Immunity

The reason that many infectious diseases have been on the decline or eradicated is because of the public health concept of “herd immunity.” Herd immunity occurs when a significant portion of the population vaccinates against a disease, thereby protecting those who cannot yet get vaccinated, or who are otherwise unable to get vaccinated. Herd immunity is extremely important for infants who are too young to receive vaccinations, people with weakened immune systems, people with allergies to ingredients in vaccines, and those who may be undergoing treatment for other diseases, like cancer, who cannot receive vaccines. When the rest of the population is vaccinated, disease transmission is disrupted and these at-risk populations are unlikely to be exposed to the disease.

Herd immunity is crucial to protecting our population from disease threats. Though measles is relatively uncommon in the United States, it is still prevalent in other countries. An estimated 20 million people are infected, and 122,000 die each year from measles. In today’s global society, people travel rapidly and frequently to many parts of the world. This means that every day, our population is coming into contact with diseases our own country has eradicated or severely limited.

Unfortunately, the complex concept of herd immunity is not easily understood by the general population. Though vaccination rates remain relatively high, many parents are taking advantage of a “free-rider” system. They are relying on the vaccination of everyone else to protect their own child from getting sick. But what they don’t understand is that herd immunity depends on what herd you are in. Schools with high rates of unimmunized students do not have herd immunity. Once a disease is introduced into such a school, everyone can get infected. And once an outbreak starts it can spread outside that school to the general community. We are seeing that with the current measles outbreak.

Herd immunity, or the lack thereof, illustrates an important fact about infectious diseases—they are a shared, public health problem. When one person is infected, people around them, people they don’t even know, can become infected. The decision of a parent to leave their child unimmunized, however well meaning, is a decision that doesn’t just affect their family, it affects all of us. Two years ago I saw a child with leukemia who was just finishing his chemotherapy, and who was cured of his cancer, die of chicken pox. Despite the parents best efforts he was exposed and because of his weakened immune system he died from it. We all share infectious diseases.

Why do parents decide not to immunize?

All parents want what is best for their children and so it is important to examine why we are observing an increase in families who believe choosing not to vaccinate their children is the best choice for them. While we have witnessed the number of vaccine refusals and exemptions increase over the past decade there is not one distinct cause for this refusal – there are multiple factors that influence a parent’s decision but they usually start with an anecdote. Something happens to a child in the period of time following routine vaccines and it is human nature to conclude that the vaccines were responsible. But an association in timing of two events does not prove cause and effect. It takes careful science to decide if one event caused the other. Parents who decide not to immunize are not being exposed to or are not believing the science that supports the safety of vaccines.

Ultimately, there are three main reasons why parents are choosing not to vaccinate their children:

1. Fear of severe side effects
2. Mistrust of the recommended vaccine schedule
3. Religious and philosophical objections

I have held a number of community forums in San Diego specifically designed to engage vaccine hesitant parents, to hear their concerns, and address them one-on-one. One common reason for refusal that I continue to hear is the belief in the myths that vaccines cause autism, brain damage, or other neurologic maladies. Although autism does typically present clinically at an age when we give many routine vaccines, any link between the two has been repeatedly disproven through solid scientific research. Coupled with this myth is the assertion that vaccines contain ingredients, such as mercury that can be harmful to children. Once used commonly as a preservative in vaccine, ethyl mercury (thimerosal), not to be confused with its toxic counterpart methyl mercury, used to be added to vaccines. This allowed for vaccines packaged in multiple dose vials to avoid contamination. Out of an abundance of caution, thimerosal has been removed from almost all vaccines, yet we have not seen a drop in the rates of autism. Clearly the two were not related, yet people still hold to the idea that vaccines contain mercury and that it causes autism. In fact, two years ago the AAP retracted a position it took in 1999 to support the removal of thimerosal as a preservative as a precautionary measure. The AAP reversed its decision in December of 2012 because the evidence collected over the past 15 years has failed to yield any evidence of significant harm, including serious neurodevelopmental disorders, from the use of thimerosal in vaccines.

Another common reason I hear for refusal is the notion that the vaccine schedule is too rigorous for an infant or child, that somehow the number of vaccines given will overwhelm the child’s immune system. If

this were true, as an infectious disease specialist, I would be seeing children with increased rates of infections at 2, 4, and 6 months of age following routine vaccines because their immune systems were weakened. I don't. But as a result of this vague concern, some parents want their children to follow a nonstandard vaccine schedule that introduces vaccines at a slower pace. Unfortunately, this approach leaves children at risk for serious diseases at a time when they are most vulnerable. The vaccine schedule as recommended by the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics has been developed with strong scientific standards and has been proven to be both safe and effective. The main principle behind the schedule is to protect children as early as we can for as many diseases as we can. To have parents decide to delay protection makes no sense and puts our community at risk.

There are also parents who refuse vaccinations for their children based on religious beliefs. Although there are very few religions that actually advise against the use of vaccines, every state except for Mississippi and West Virginia allow parents to opt out of required vaccines for religious reasons. This is not the problem. The problem is States that have allowed people to refuse vaccines for non-religious philosophical exemptions, like California. In California a parent can just read something on the Internet, decide they don't want to have their children immunized, and send them to school without vaccines. Unfortunately, parents get ahold of inaccurate information and make a poorly informed decision which then affects the public's health. I have had parents tell me they are not immunizing their 5-year-old child because they are afraid their child will get autism. If a child is going to have autism, it happens before 3 years of age, so that parent clearly was making a decision based on incorrect information. I have had parents tell me that their child can't get the measles because it doesn't exist in the United States anymore. Well, our current situation tells us otherwise. The Internet can be a dangerous place for parents looking for information about vaccines.

What can be done to get more people immunized?

There are four ways to begin to spur more parents to vaccinate their children:

1. Emphasize the safety and effectiveness of vaccines
2. Limit the type of exemptions allowed for vaccine requirements for school entry
3. Improve communication with families about vaccines
4. Improve science literacy

The best way to reverse the number of families refusing to vaccinate their children is to improve communication with families about the safety and effectiveness of vaccines, explain the concept of herd immunity, improve the way the medical community talks to families about their concerns and questions regarding vaccines, and increase the science literacy of our population.

Parents need to know that the benefits of vaccines far outweigh any risks. The inclusion of a vaccine on the recommended schedule and the age it is recommended is based on careful review of the science that leads to the conclusion, in every single case, that the risk from disease far exceeds any risks associated with the vaccine.

No vaccine can be administered to a child unless it has been carefully tested, researched, and approved. After a vaccine is approved by vaccine experts within the Food and Drug Administration the safety of the vaccine is carefully reviewed by the Centers for Disease Control and Prevention, the American Academy of Pediatrics, and the American Academy of Family Physicians, before that vaccine is routinely recommended for use. The safety of all vaccines is carefully evaluated after doctors begin giving vaccines as well. There are a number of systems in place to make sure all vaccines continue to have a safe track

record. In fact, vaccine safety research has been and still is a top priority, including working to eliminate even the very rare cases of adverse reactions.

In compliance with the *National Childhood Vaccine Injury Act* of 1986, health professionals and vaccine manufacturers must report specific adverse reactions to vaccines to the Vaccine Adverse Event Reporting System (VAERS). VAERS is a national vaccine surveillance system sponsored by the Centers for Disease Control and Prevention and the Food and Drug Administration that collects reports on possible reactions to vaccines and uses it to identify vaccine safety concerns for study. VAERS receives about 30,000 reports of possible adverse reactions each year. Among those, 13 percent are classified as serious, meaning that they are associated with disability, hospitalization, life-threatening illness, or even death. These reports are carefully investigated using sound scientific methods to determine if there is a real vaccine safety concern. VAERS is an important tool for continually monitoring the safety of vaccines, and ensures that any potentially unsafe patterns are quickly recognized.

The bottom line is that vaccines are extremely effective, and have kept children healthy and largely disease-free for more than 50 years. Most childhood vaccines are 90 to 99% effective in preventing disease. Additionally, even in the rare case that a child who has been vaccinated does get the disease, the child will often have a less serious case.

Exemptions from school entry vaccine requirements

In addition to improving communication with parents about the benefits of vaccines, another option to help improve vaccination rates is to limit the exemptions that are offered by states to opt out of school vaccine requirements. While most states require students to be vaccinated before attending school, many states have relatively permissive exemption laws for vaccinating children, like the religious and philosophical exemptions mentioned earlier. Parents are taking advantage of these “personal belief” exemption laws on a much more frequent basis than in the past. This is a concern for pediatricians and the AAP believes that vaccine exemptions should be available but with rigorous criteria and include the involvement of health professionals. School entry requirements can be strengthened further and help boost herd immunity by limiting exemptions from vaccine requirements.

Improved communication can help reduce fears

As a result of vaccine hesitancy, pediatricians have taken it upon themselves to try to better educate parents about the benefits of vaccination. Unfortunately, many parents are reading misinformation on the Internet and through other unreliable sources and are skeptical of the facts. Pediatricians can do their part by personally engaging with families to answer their questions and concerns and to explain the safety and effectiveness of vaccines. That means really listening to parents and taking their fears seriously. It is important that health care providers discuss these fears and lay out the benefits and importance of vaccinations without seeming to talk down to parents. The AAP has put together training materials to help pediatricians communicate more effectively with parents about vaccines and recommends that pediatricians take the time to thoroughly discuss each of the vaccines that a parent may be hesitant about. It helps to have evidence-based literature available to share with parents and have a list of evidence-based websites that parents could go to and look up more information on their own.

Public Health Support

In the meantime, it is essential that public health agencies around the country receive adequate funding to do the hard work of controlling outbreaks when they occur. Without that combined effort, the Disneyland outbreak would have been much bigger. On the Federal level, it is imperative that the CDC receive adequate funding so that they can continue the important work that they do in partnership with State and local health departments. We have recently seen how important CDC was to help control the outbreak of Ebola and we need to prioritize new resources to the CDC and its National Center for Immunization and Respiratory Diseases (NCIRD), as they play such an important role in the prevention of disease, disability

and death. Whether it is a rare outbreak of Ebola, or reemerging diseases that were once considered eliminated, we need to support our public health system which is crucial in keeping our country safe from diseases that we know we can protect ourselves from.

Issues unrelated to parents

Outside of parents actively choosing not to vaccinate, there are also some barriers that can affect the ability of some children to get vaccines they need on time.

At times, there are shortages in the vaccine supply that affect appropriate delivery of vaccines. Since 2003, there have been increasingly disruptive shortages in vital vaccines. When health care providers are unable to keep a steady supply of vaccines in their offices, they miss the opportunity to vaccinate a child. In addition to missed opportunities, these shortages may lead to increased administrative burden on health care providers who must then track these children down at a later date to ensure vaccination.

In addition, many newer vaccines are expensive. The Centers for Disease Control and Prevention estimates that the acquisition cost for immunizing an otherwise healthy child through the age of 18 years is more than \$900 for boys, and more than \$1200 for girls. This is a more than six fold increase from 1995. These costs primarily result from the addition of newer vaccines to the schedule, or from substitution of newer vaccines over the older ones.

Payment for almost all vaccines is available through private or public sources. However, the cost of buying, storing, and administering these vaccines has soared, straining the finances of many pediatric practices. In addition to these acquisition costs, payment is an issue. Payment levels vary between private insurance, Medicaid, and third-party payers. As the costs of vaccines increases, these payments have not followed suit.

The federal Vaccines for Children (VFC) program, Section 317 federal grants, and state funds now purchase more than half of vaccines administered in the United States. These programs do excellent work in providing vaccines for children who are in need, but they also require a large administrative and record-keeping effort from practices. Additionally, in many states, VFC payments are lower than the cost of administering the vaccines, thus causing many practices to leave the program. Finally, Medicaid payments for giving vaccinations are far less than what Medicare pays, despite the fact that administering vaccines to a child is more labor intensive than administering vaccines to an adult. It is imperative that the acquisition costs and payment systems around vaccines be remedied in order to ensure that we are vaccinating the maximum number of children that we can.

Many parents today are not aware of how dramatically vaccines have improved the health of children. Before the U.S. measles vaccination program started in 1963, about 3-4 million people in the United States contracted measles each year, 48,000 were hospitalized, and 4,000 developed encephalitis because of measles. As mentioned earlier, measles was declared eliminated from the U.S. in 2000, but since then, there has been a rise in the number of cases.

Summary

It is clear that vaccines have dramatically improved the health of our society. What were once extremely morbid and mortal threats to children and society have now been abated. Most parents today did not grow up in a world where they were confronted with these deadly, and very visible diseases. Many parents believe that their own decision not to vaccinate is an isolated one, and that it only affects their child. Unfortunately, this is not true. Every vaccine refusal weakens herd immunity, and it is imperative that the public health aspect of vaccination is emphasized. The reemergence of vaccine preventable diseases is alarming and must be confronted if we are going to sustain our past successes. While it will take a

renewed focus and effort, if we continue to educate the public on the safety and effectiveness of vaccines, improve communication and dialogue with those who harbor fears of vaccines, and eliminate non-medical exemptions allowing parents opt out of vaccinating their children, we can shrink the clusters with lower immunization rates that threaten herd immunity and reduce the risk of more outbreaks of vaccine preventable diseases like we are experiencing with today's measles outbreak.

Thank you for allowing me to testify before the committee today. I look forward to your questions.

ⁱ <http://pediatrics.aappublications.org/content/115/5/1428.full.pdf+html?sid=f4d4ccaf-c087-4854-8c99-2ce33ab197ad>