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THE REEMERGENCE OF VACCINE-PREVENTABLE DISEASES: EXPLORING THE PUBLIC HEALTH SUCCESSES AND CHALLENGES

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED FOURTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE REEMERGENCE OF VACCINE-PREVENTABLE DISEASES; FOCUSING ON EXPLORING THE PUBLIC HEALTH SUCCESSES AND CHALLENGES

FEBRUARY 10, 2015

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C O N T E N T S

STATEMENTS

TUESDAY, FEBRUARY 10, 2015

THE REEMERGENCE OF VACCINE-PREVENTABLE DISEASES: EXPLORING THE PUBLIC HEALTH SUCCESSES AND CHALLENGES

TUESDAY, FEBRUARY 10, 2015

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10 a.m., in room SD–106, Dirksen Senate Office Building, Hon. Lamar Alexander, chairman of the committee, presiding.

Present: Senators Alexander, Collins, Kirk, Roberts, Cassidy, Murray, Mikulski, Sanders, Casey, Franken, Bennet, Baldwin, Murphy, and Warren.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Senate Committee on Health, Education, Labor, and Pensions will please come to order.

This morning, we're holding a hearing about the reemergence of vaccine-preventable diseases. Senator Murray and I will each have an opening statement. Then we'll introduce our panel of witnesses. After our witness testimony, Senators will each have 5 minutes of questions.

We have two panels today and 2 hours for the hearing. We're going to end about noon. We'll have an hour for each panel, and I will end the first panel at 11 o'clock.

From smallpox to polio, we have learned in the United States that vaccines save lives. Yet a troubling number of parents are not vaccinating their children. Last September, this committee held a hearing about the Ebola virus. Our witnesses included a brave physician, Dr. Kent Brantly, who worked in Liberia and who contracted Ebola, and a brave father in Sierra Leone who came to warn us about how rapidly the virus was spreading there.

The number of people being infected with Ebola was doubling every 3 weeks, and many of those infected were dying, because for Ebola there was and is no cure, and there was and is no vaccine. This produced a near panic in the United States. It changed procedures in nearly every hospital and clinic. I remember one Chattanooga public health officer saying it's all Ebola all the time every day.

In response, Congress appropriated more than $5 billion to fight the spread of the virus. The impact of efforts to fight Ebola is that the number of Ebola cases is declining. At the same time, here in

the United States we are now experiencing a large outbreak of a disease for which we do have a vaccine.

Measles used to sicken up to 4 million Americans each year. Many believed that it was an unpreventable childhood illness. But the introduction of a vaccine in 1963 changed everything. Measles was declared eliminated, meaning absence of continuous disease transmission for greater than 12 months from the United States in 2000.

Then from 2001 to 2012, the median yearly number of measles cases reported in all of our country was 60. Today is February 10, 2015. It is the 41st day of the year, and already we have seen more cases of measles than we would in a typical year.

One measles outbreak in Palatine, IL, a suburb about a half hour from Chicago, has affected at least five babies, all less than 1 year old. Infants and individuals who are immunocompromised are traditionally protected by what is called herd immunity, meaning when more than 9 out of 10 of the people around them are vaccinated, so they don't get sick, and that keeps the babies and others who can't get vaccinated from getting sick. That herd immunity is incredibly important. Measles can cause life threatening complications in children, such as pneumonia or swelling of the brain.

Our witnesses today will talk more not just about what is causing this outbreak, but why some parents are choosing not to vaccinate their children. Measles is only one example. This hearing, which was planned before the measles outbreak, reminds us of the importance of vaccines.

An analysis of immunization rates across 13 States performed by USA Today found the following: Hundreds of thousands of students attend schools, ranging from small private academies in New York City to large public elementary schools outside Boston to Native American reservation schools in Idaho, where vaccination rates have dropped precipitously low, sometimes under 50 percent.

California is 1 of the 20 States that allow parents to claim personal belief exemptions from vaccination requirements. In some areas of Los Angeles, 60 percent to 70 percent of parents at certain schools have filed a personal belief exemption. In those elementary schools, vaccination rates are as low as those in Chad or in South Sudan.

The purpose of this hearing is to examine what is standing between healthy children and deadly diseases. It ought to be vaccinations. Too many parents are turning away from sound science. Sound science is this: Vaccines save lives.

They save the lives of the people who are vaccinated. They protect the lives of the vulnerable around them, like infants and those who are ill. Vaccines save lives.

They protect us from the ravages of awful diseases like polio, which invades the nervous system and can cause paralysis. I can remember as a child how parents were frightened by the prospect of polio for their child. I had classmates who lived in iron lungs. Our majority leader, Senator McConnell, contracted polio as a child.

Whooping cough is another example, which causes thick mucus to accumulate in the airways and can make it difficult for babies to breathe; or diphtheria, a bacterial infection that affects the mu-

cous membranes of your nose and throat and can, in advanced stages, damage your heart, kidneys, and nervous system.

We have learned that vaccines save lives. They take deadly, awful, ravaging diseases from horror to history.

It is troubling to hear that before we've even reached Valentine's Day this year, 121 Americans are sick with measles, a disease eliminated in the United States 15 years ago. It is troubling that a growing number of parents are not following the recommendations of doctors and public health professionals who have been making those recommendations for decades.

At a time when we are standing on the cusp of medical breakthroughs never imagined—cutting-edge personalized medicine tailored to an individual's genome, for example—we find ourselves retreading old ground.

I now turn to Senator Murray for her opening statement.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Thank you very much, Chairman Alexander. Thanks to all of our witnesses for coming and sharing your expertise with us today.

Keeping our children and families healthy could not be more important. I'm glad to have the opportunity to hear from all of you about the threat vaccine-preventable diseases still pose in the United States and to discuss what we should be doing to take these threats off the table.

There's no question we have come a long way when it comes to what were once widespread and extremely dangerous illnesses. Vaccines are truly one of our country's greatest public health successes. Thanks to them, we know how to prevent illnesses that struck so many children as recently as a generation or two ago, like polio and whooping cough and measles.

Recent news about the measles outbreak in many States, including my home State of Washington, made clear that vaccine-preventable diseases are still a threat and that we can't afford to become complacent about protecting the progress that we've made.

Bottom line, this means children across the country need to be vaccinated. It also means we need to be vigilant about breaking down any barriers that families may face when it comes to accessing certain vaccines. We need to ensure that in any cases where take-up rates are low, we're providing information and spreading awareness so that more people can be protected.

The HPV vaccine is a great example. It prevents life threatening cancers, including cervical cancer, which impact thousands of lives in the United States each year.

Despite that, CDC reports that take-up rates for the vaccine are still unacceptably low, meaning people continue to be exposed to deeply harmful illnesses that could have been prevented.

I know several of our witnesses have done a lot of work on this issue. I will certainly have questions about what we can do to encourage broader use of vaccines. We're looking forward to an update from Dr. Schuchat about the recent measles outbreaks and the work the CDC is doing to continue to encourage vaccination.

I'm very eager to hear from Dr. Kelly Moore about the role of States in preventing and responding to outbreaks like this one. I

know that Dr. Sawyer and Dr. Jacks will also be able to provide valuable insight into ongoing, nationwide efforts to increase immunizations rates and keep children and families healthy.

I want to thank again all of our witnesses for the important work you are doing and for taking the time to be here with us today.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray, and thank you to you and your staff for working with us to jointly invite the witnesses today. That always produces a better hearing and a good variety of views.

Each witness will have up to 5 minutes.

We'll ask you, Dr. Schuchat, if you'll summarize your views in 5 minutes so Senators can have a chance to ask questions.

Then we'll take an hour. I said before some of the Senators came in that we'll have to end the first panel at 11 so we can get to the second panel, which will go on to 12. I hope all of us can get questions in to the first panel. If not, you'll be first in line on the second panel.

Dr. Schuchat is the Director of the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention. She has worked at CDC since 1998 on immunization, respiratory, and other infectious diseases. She is a Rear Admiral in the U.S. Public Health Service Commissioned Corps and was named Assistant Surgeon General of the U.S. Public Health Service in 2006.

Dr. Schuchat, welcome.

STATEMENT OF ANNE SCHUCHAT, M.D., (RADM, USPHS), DIRECTOR, NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. SCHUCHAT. Good morning, Mr. Chairman and members of the committee. Thank you for the opportunity to speak with you today.

Our nation's immunization system is strong, protecting the health of Americans, saving lives and money. This year's outbreak of measles demonstrates how interconnected we are. Many threats, including measles, are just an airplane ride away.

Despite high national immunization coverage against measles, last year, we had more cases of measles in the United States than we've had since 1994. Since January 1, we've already had more measles cases this year than we've had in most full years since 2000, when home-grown measles was eliminated in the United States.

From January to February 6 this year, 121 people from 17 States have been reported to have measles. Most are linked to an ongoing outbreak that originated at Disney parks in California during December. Most cases were not vaccinated or didn't know if they had been vaccinated.

Recent patients with measles have exposed others in a variety of settings, including at school, childcare, emergency departments, outpatient clinics, and airplanes. These episodes require a rapid response coordinated across local, State, and Federal jurisdictions. The backbone for such a response comes from the public health im-

munization infrastructure, the systems and people that protect our communities from vaccine-preventable diseases.

Today, we're talking about measles, but we could just as easily be talking about a resurgence of whooping cough, a meningitis outbreak in college, or adapting to a shortage of a popular combination vaccine. We need a strong immunization system that takes care of the everyday prevention and assures the quality of clinical practice but is also robust enough to respond to emergencies and ready to launch mass vaccination for the next pandemic.

Whether a vaccine is given in a private doctor's office or at a community clinic, the public health system plays a critical role in making sure vaccination is accessible, safe, and effective and used in the best way to protect all Americans, and that our immunization policies are based on a strong scientific foundation continually reviewed.

Our priorities for maintaining a strong program include preserving core public health infrastructure at the local, State, and Federal levels; maintaining adequate vaccine purchase to provide a safety net for uninsured adults and for responding to outbreaks and other urgent vaccine needs; and making strategic investments to enhance the immunization infrastructure and evidence base and improve efficiency.

Coverage for many childhood vaccines is above 90 percent, and reported cases for most vaccine-preventable diseases are down by more than 90 percent. Most parents are vaccinating their children with most of the recommended vaccines. Less than 1 percent of toddlers have received no vaccines at all.

Immunization continues to be one of the most cost-effective public health interventions. For each dollar invested in the childhood program, there are $10 of societal savings and $3 of direct medical savings. The past 20 years of U.S. childhood immunization has prevented over 300 million illnesses, 732,000 deaths, and resulted in $1.4 trillion in cost savings.

In many ways, though, we are victims of our own success. Because of our success, fewer and fewer doctors, nurses, and parents have witnessed the serious and sometimes life threatening consequences of these diseases. Because of our success, parents may wonder if vaccines are necessary, and they may worry that the risk or temporary discomfort of vaccinating may outweigh the benefits of protecting their families from vaccine-preventable diseases.

The increase in measles cases should be seen as a wake-up call. Measles is very contagious and quickly uncovers pockets of undervaccination. In the 1980s and early 1990s, measles outbreaks uncovered systemic problems with poor children having access to vaccines, leading to the creation of the Vaccines for Children Program.

Today, measles in the United States is an indicator of how globally interconnected we are. When we see outbreaks associated with importations, measles uncovers those people in areas in the United States that are opting out of immunization. We have indications that some of those unvaccinated micro communities may be getting larger.

Our immunization system has risen to challenges in the past, and CDC will work with partners to keep measles from regaining a foothold in our country again. Working together, we can keep

these numbers down, keep measles from returning and threatening the health of our communities, and sustain the enormous health and societal benefits that our immunization partnership has achieved.

Thank you.

[The prepared statement of Dr. Schuchat follows:]

PREPARED STATEMENT OF ANNE SCHUCHAT, M.D. (RADM, USPHS)

INTRODUCTION

Good morning Chairman Alexander, Ranking Member Murray, and members of the committee. I am Dr. Anne Schuchat, Director of the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to speak with you today.

It has been said many times that vaccines are one of public health's greatest achievements. The immunization of children in the United States has saved millions of lives, contributed to longer life expectancy, reduced health disparities, improved quality of life, and saved trillions of dollars in societal costs. Immunizations have become a routine part of how we care for our children. Less than 1 percent of children in the United States receive no vaccines at all.

However, the success of vaccination means fewer and fewer doctors, other healthcare providers, and parents have witnessed the serious and sometimes life-threatening consequences of vaccine-preventable diseases (VPDs). Illness from vaccine-preventable disease is no longer common, and parents may wonder if vaccines are really necessary or believe that the risks of vaccinating infants or temporary discomfort a vaccine may cause outweigh the benefits of protecting them from infection with VPDs. Yet even small numbers of cases can lead to the re-emergence of VPDs if we have increasing numbers of unvaccinated people.

MEASLES

The recent measles outbreaks in the United States provide an excellent example of our continued vulnerability to VPDs. Measles is a highly contagious respiratory disease caused by a virus. It spreads through the air through coughing and sneezing. After an infected person leaves a location, the virus remains viable for up to 2 hours on surfaces and in the air. It spreads so easily that if one person has it, 90 percent of the people close to that person who are not vaccinated or otherwise immune will also become infected. The good news is that since the 1960s, there has been a highly effective vaccine to prevent measles. One dose is about 93-percent effective at preventing measles; two doses are about 97-percent effective. Before the U.S. measles vaccination program started in 1963, about three to four million people in the United States got measles each year; 400–500 of them died, 48,000 were hospitalized, and 4,000 developed encephalitis because of measles. In the United States, widespread use of the vaccine has led to a 99-percent reduction in measles cases compared with the pre-vaccine era.

Because of a highly effective vaccination program and a strong public health system for detecting and responding to measles cases and outbreaks, measles was declared eliminated from the United States in 2000. However, the story does not end with elimination. While the western hemisphere has eliminated measles, the disease is still endemic in many parts of the world, with 20 million cases occurring worldwide annually. Outbreaks can occur in the United States when unvaccinated groups are exposed to imported measles virus. Between 2000 and 2013, a range of 37 to 220 measles cases per year were reported in the United States with most of these originating outside the country. Importations of measles remain a significant challenge. Unvaccinated U.S. residents traveling overseas are at risk for measles, and returning unvaccinated U.S. residents and foreign visitors to the United States may develop measles and expose unvaccinated people in the United States. When measles gets into communities of unvaccinated people in the United States, such as people who refuse vaccines for religious, philosophical or personal reasons, outbreaks are more likely to occur. New research recently published in the journal *Pediatrics* has found that people who seek personal belief exemptions for their children often live near one another. We think these micro-communities are making it difficult to control the spread of measles and are making us vulnerable to having the virus re-establish itself in our country again. In addition, they put others at risk who cannot get vaccinated because they are too young or they have specific health conditions. CDC works with its partners, such as the American Academy of Pediatrics and the

American Association of Family Physicians, to develop and disseminate evidence-based tools to help health care providers and parents understand the science recommending vaccination.

High measles vaccine coverage and rapid public health response are critical for preventing and controlling measles cases and outbreaks. While overall measles vaccination coverage rates are high at 92 percent, one in 12 children in the United States is not receiving his first dose of measles-mumps-rubella (MMR) vaccine on time, underscoring considerable measles susceptibility across the country. In addition, we see considerable variability in coverage across States. In 2013, there were 17 States where less than 90 percent of toddlers had received at least one dose of MMR. Within States, some counties or communities have much lower vaccination rates than the State average.

From January 1, 2015, until January 30, 2015, a total of 102 people in 14 States have been reported as having measles. Most of these cases are part of an ongoing, large multistate outbreak linked to the Disneyland theme parks in California. CDC is working with State and local health departments to control this outbreak which started in late December. Many of you know that in 2014, the United States experienced the highest number of measles cases we had reported in 20 years, over 600 driven in large part by one large outbreak of 383 cases, occurring primarily among unvaccinated Amish communities in Ohio. Although we aren't sure exactly how this year's outbreak began, we assume that someone got infected overseas, visited the parks and spread the disease to others. Infected people in this outbreak here in the United States this year have exposed others in a variety of settings including school, daycares, emergency departments, outpatient clinics and airplanes. Frontline public health workers and clinicians across the country are following up on suspected measles cases in light of the recent outbreak. They are part of an enormous public-private partnership that protects health and saves lives through the Nation's immunization system.

In response to the current outbreak, CDC issued a Health Advisory on January 23, 2015, to notify public health departments and healthcare facilities about the multi-State outbreak and to provide guidance for healthcare providers nationwide. On January 29, 2015, CDC held a press briefing to inform the public about the outbreak and the importance of appropriate prevention and treatment measures. CDC updates its web page weekly to prominently include information about measles including direct links to fact sheets and continuing education webinars aimed at clinicians regarding measles. CDC also works with many partner organizations including clinician organizations, public health associations, and patient groups to share information, develop tools, and explore new partnership activities to reach the public and health care providers about immunization. In addition, CDC supports State and local health departments in their outbreak investigations by providing technical support for measles prevention and control; testing specimens from patients with suspected measles infection; and, providing rapid assistance on the ground through formal requests from State health departments.

OVERVIEW OF U.S. IMMUNIZATION POLICIES AND PROGRAMS

CDC's national immunization recommendations currently provide guidance for the prevention of 17 VPDs across the lifespan. CDC's immunization program plays a fundamental role in achieving national immunization goals and sustaining high vaccination coverage rates to prevent death and disability from VPDs. CDC's Immunization program includes the Vaccines for Children (VFC) entitlement program, and CDC's 317 Immunization program.

VFC is one of the largest and most successful public-private partnerships. Created by the Omnibus Budget Reconciliation Act of 1993 and implemented in 1994 as a new entitlement program, the VFC program allows eligible children to receive recommended vaccinations free of charge as part of routine care, supporting the reintegration of vaccination and primary care. The VFC program serves children through 18 years of age without insurance, those eligible for Medicaid, American Indian/Alaska Native children, and underinsured children who receive care through federally qualified health centers or rural health clinics. CDC purchases vaccines to distribute to VFC-enrolled providers by funding 61 eligible grantees for VFC-related operations activities. Currently, there are more than 44,000 public and private providers in the VFC program, and VFC distributes over 50 percent of all routinely recommended vaccines for those 18 years and younger. VFC has been instrumental to achieving high vaccination coverage rates and reducing disparities.

In addition, a discretionary immunization program was enacted in 1962 through the Vaccine Assistance Act, or section 317 of the Public Health Service Act. Over its 50-year history, the Program has played a role in helping to achieve national im-

munization goals by supporting the public health workforce and systems at the national, State, and local levels as well as supporting vaccine purchase. These include systems to ensure quality assurance, such as proper vaccine storage, manage vaccine shortages, and educate and promote immunization recommendations across the life span. To implement the discretionary program, CDC works collaboratively with the 64 grantees, including the 50 States, six large cities (including the District of Columbia), five territories, and three Pacific Freely Associated States.

In addition, the discretionary program is responsible for investments that strengthen the evidence base for our immunization policies and practices. It supports disease surveillance, laboratory capacity, and scientific studies to evaluate vaccine effectiveness, safety, and program. The program allows us to maintain public health preparedness for a response to a vaccine-preventable national emergency, such as a pandemic or biologic attack.

Scientifically based vaccine policies are a foundation of the U.S. immunization system. In the United States, the Advisory Committee for Immunization Practices (ACIP) advises the CDC on national vaccine policy for preventing infectious diseases in the civilian population. The immunization systems and expertise that are supported by the national immunization program make substantial contributions to the evidence base upon which the ACIP deliberates in making its recommendations by providing data about the burden of disease, safety and efficacy of the vaccine, economic analyses, including cost-effectiveness data, and information about other factors such as how the recommendation can be implemented by the health care system in conjunction with other recommended vaccines.

Once adopted by CDC, the committee's recommendations establish the standard of practice for preventing VPDs. The Affordable Care Act requires that, as of September 2010, vaccines recommended by ACIP (along with other recommended preventive services) be covered by non-grandfathered private health plans without cost-sharing. In addition to post-market surveillance conducted by the CDC and the Food and Drug Administration (FDA) for FDA-approved vaccines, ACIP continues to review the safety and effectiveness of vaccines even after they are recommended, and updates recommendations as more data become available. New data are reviewed in the context of the risks of adverse effects and the benefits provided by the vaccine.

Coverage for many childhood vaccinations are at, near, or above 90 percent, and reported cases for most VPDs have decreased by 90 percent or more in the United States. Immunization continues to be one of the most cost-effective public health interventions. For each dollar invested in the U.S. childhood immunization program, there are $10 of societal savings and $3 in direct medical savings.[1] The past 20 years of childhood immunization has prevented 322 million illnesses, 732,000 deaths, and nearly $1.4 trillion in societal costs.[2] Our investments have supported national, State and local programs that have dramatically improved access to vaccination for all children and put systems in place to detect and respond to outbreaks of VPDs and to monitor vaccine effectiveness and safety.

CHALLENGES

While overall vaccination rates remain high, we still face several challenges in preventing VPDs. The majority of parents have their children vaccinated, however, we know that some parents delay or refuse vaccinations. CDC has conducted research to better understand why some parents choose not to vaccinate their children. There are many reasons parents give for their vaccine hesitancy despite overwhelming and consistent scientific evidence that vaccines are safe and effective. For some, many VPDs don't have the visibility they once had, and many parents tell researchers that they question whether the vaccines are more dangerous for their child than the disease they prevent. Parents also have access to conflicting and often inaccurate information about vaccines via the internet, and others express concern that there are too many vaccines.

CDC knows that maintaining public confidence in immunizations is critical to preventing declines in vaccination coverage rates and outbreaks of VPDs. CDC supports science-based communication campaigns and other efforts to convey the benefits of vaccines to the public to aid individuals in making informed vaccine decisions to protect themselves and their loved ones. CDC also conducts outreach to educate healthcare providers about current immunization policy and clinical best practices

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[1] Zhou F, Shefer A, Wenger J, et al. Economic evaluation of the routine childhood immunization program in the U.S., 2009. Pediatrics 2014;133:577–85

[2] CDC. Benefits from Immunization During the Vaccines for Children Program Era—United States, 1994–2013. MMWR 2014;63(16):352–55

to help them protect their patients and communities from VPDs. CDC developed and will maintain a dynamic provider toolkit for conversations with parents about vaccination that includes evidence-based strategies, print materials, and web-based tools.

Another challenge we currently face is a low adult vaccination coverage rate. Last week, CDC released the latest non-influenza vaccination coverage rates for adults, and the results were not encouraging. Findings show most coverage rates continue to be below Healthy People 2020 targets with persistent racial and ethnic gaps. We know that to reach adults we will need different strategies than we have used with the childhood program. Unlike children who have scheduled routine visits with their pediatrician, adults may see multiple physicians for specialty care, many of whom do not offer vaccination services. CDC is working to increase awareness of the need for vaccines for adults among the general population and the provider community. We also are looking at increasing access through non-traditional venues, including pharmacies and retail clinics.

Outbreaks of VPDs continue to be an ongoing challenge for the public health system. Measles elimination was declared in the United States in 2000, but we still contend with importations of measles viruses. In addition, there have been recent outbreaks of meningitis and mumps in university settings and other tight knit communities. Measles, however, is a particularly sensitive indicator of the strength of our public health systems as it is very contagious and quickly uncovers pockets of under vaccination. In the 1980s and early 1990s, measles outbreaks uncovered a weakness in access to vaccines, resulting in the creation of the VFC program. Today, it is an indicator of how globally interconnected we are, with measles importations uncovering those communities opting out of immunization, and indicating those communities may be getting larger. Ongoing surveillance is critical to detecting and responding to outbreaks quickly to prevent further spread of the disease and to understanding vaccine effectiveness and safety over time. CDC is committed to a strong evidence base to assure that immunization programs are protecting Americans and based on the best available data, continuously reviewed and updated.

LOOKING FORWARD

The U.S. immunization system has been very successful in reaching high coverage levels and low incidence of most VPDs. As the current outbreak demonstrates, we cannot become complacent to the threat of VPDs as the current increase in measles cases has shown us. CDC's priorities for the coming year focus on keeping the American public prepared to respond to such threats. These include: educating and engaging health care providers and the American public on the science about vaccine safety and effectiveness, preserving core public health immunization infrastructure at the local, State, and Federal levels; maintaining an adequate amount of vaccine purchase to provide a vaccination safety net for uninsured adults and for response to VPD outbreaks and other vaccine urgent needs while recognizing the expanded access to vaccine coverage through the Affordable Care Act; and, making strategic investments to enhance the immunization infrastructure and evidence base and improve efficiency.

The increase in measles cases should be seen as a wake-up call. Our immunization system has risen to challenges in the past, and CDC is committed to keeping measles and other VPDs from regaining a foothold in the United States again. The very large outbreaks we have seen around the world often started with a small number of cases. Working together, we can keep these numbers down, keep measles from returning and threatening the health of our communities, and sustain the enormous health and societal benefits that our immunization partnership has achieved.

The CHAIRMAN. Thanks, Dr. Schuchat. About 10 years ago, Senator Frist, our Senate majority leader, who was also a physician, led a group of us to South Africa, where we found the president of South Africa had rejected the science on HIV/AIDS. He decided it wasn't caused by a virus, and that the cure was the elimination of poverty, setting back South Africa for years in terms of its ability to deal with HIV/AIDS.

Now, today, there's information that's on the internet, which is where we were told the South African president had found his information some years ago, that says there was a study published in *The Lancet* in 1998 by Andrew Wakefield alleging a connection

between the measles, mumps, and rubella vaccine, MMR, and autism.

Let's say you're a physician or pediatrician, and a parent comes in and says, "I've been on the internet, and I'm concerned, because I found that according to this medical journal, there is a relationship between the measles and mumps vaccine and autism." What would you say to that parent?

Dr. SCHUCHAT. Autism is a terrible condition. That paper that you're mentioning has been totally discredited. It was found to be fraudulent and is not the case. There have been dozens of studies of vaccines and the question of autism. Vaccines don't cause autism. They are highly effective and safe and are a good way to protect your children from vaccine-preventable diseases.

The CHAIRMAN. When you say totally discredited, what do you mean by that?

Dr. SCHUCHAT. The information in that particular report was found to be fraudulent by a British investigator. Some of the information wasn't correct in terms of the notes that were submitted.

There have been dozens of studies that were better to try to understand whether there is a link between vaccines and autism. It was sort of a natural question some parents had because of the onset age for autism. Those studies have been incredibly reassuring.

When I talk to the public or I talk to parents, I like to explain that as a physician and as a public health expert, I can tell you that vaccines are very safe and effective. While autism is a terrible condition, one thing we know is that vaccines don't cause autism.

The CHAIRMAN. You would say to the parent that that article was just flat wrong.

Dr. SCHUCHAT. That's right.

The CHAIRMAN. And that numerous studies have shown that it was wrong.

Dr. SCHUCHAT. That's right.

The CHAIRMAN. What happened to the author of the article?

Dr. SCHUCHAT. He lost his medical license.

The CHAIRMAN. Why?

Dr. SCHUCHAT. Because of the fraudulent behavior.

The CHAIRMAN. Because of the fraudulent behavior. We've been talking about a variety of vaccines. It struck me, as we were so worried about Ebola last fall—and we're still worried about it—that many of the public health people from Tennessee would point out to me that we had the flu season coming up. How many Americans die each year from the flu?

Dr. SCHUCHAT. Flu is very variable, but it can be between 3,000 in a really good year to about 50,000 in a severe year. This is a quite severe year for flu.

The CHAIRMAN. Three-thousand to fifty-thousand could die from flu. Is there a vaccine for flu?

Dr. SCHUCHAT. That's right. There are several different vaccines for influenza. Right now, about 46 percent of Americans get a flu vaccine each year. We'd like that to be much higher. We do recommend everybody 6 months and over get a flu vaccine every year.

The CHAIRMAN. Let's go back to measles for a minute. Measles is not just a runny nose, is it? It is a serious disease. What would

you say to a parent who comes in and says, "I'm going to opt not to get the measles vaccine?" What are the risks of that? How many children who contract measles die?

Dr. SCHUCHAT. Before there was a measles vaccine in the United States, 400 to 500 children in this country died. The risk of dying is much higher in countries that are poor, where malnutrition is a problem. We have about 150,000 deaths from measles around the world each year. It used to be millions, and that's actually an improvement because of high uptake of measles vaccine.

The CHAIRMAN. Would it be accurate to say that if your child contracted measles in the United States, the chances of a death would be about 1 in 1,000?

Dr. SCHUCHAT. That's right. But remember there are other problems with measles, not just that rare risk of dying. Even a mild case of measles is a really scary thing for a parent.

My mom was telling me about when I had measles. She was scared to take my temperature because I looked so horrible and it had been so high and she was worried it wasn't coming down. Measles can be pretty scary for parents, even the mild cases.

There are other complications besides death. Children can get pneumonia. They can get dehydration. They can also get a neurologic problem, encephalitis, which can be quite scary and severe.

The CHAIRMAN. Thank you.

Senator Murray.

Senator MURRAY. Dr. Schuchat, thank you so much for being here, and I really thank you for all the work you do to protect our families and children across the country. There is no doubt that challenges remain with regards to immunization rates, and American families' broad access to no-cost vaccines is clearly a key factor in maintaining and improving our vaccination rates.

In my home State of Washington, we have a universal childhood vaccine program which provides recommended vaccines for all children. I know there are a number of important Federal programs that ensure access to free vaccines in our country.

Can you describe CDC's effort to ensure all Americans do have access to the vaccines they need without cost sharing, including through the Vaccines for Children Program, and, particularly why that's so important?

Dr. SCHUCHAT. The CDC administers the Vaccines for Children Program, and we just celebrated 20 years of that program. It's been extraordinarily effective. It provides free vaccines to children who are uninsured, Medicaid eligible, American Indian, Alaskan Native, truly to financially vulnerable children in the country. It actually provides vaccines for almost 50 percent of children in the United States.

This program has greatly overcome racial, ethnic, and financial barriers to vaccination, and we see much higher coverage now in the era of the VFC Program. As I mentioned, we think it has saved over 300 million illnesses—prevented those illnesses in the past 20 years and saved $1.4 trillion.

CDC also supports the States in a discretionary immunization program to try to bridge some of the gaps that are not addressed through the VFC Program, in particular, supporting the public

health infrastructure for immunization. State and local health departments have immunization programs that work with the clinicians in those areas.

They don't just investigate outbreaks like the measles outbreak, but they work day in and day out in supporting provider education, in dealing with vaccine shortages, in distributing vaccines so that they get to the providers' offices. Your own State of Washington has an absolutely fantastic program.

Senator MURRAY. Thank you. For me and for a lot of my colleagues, disease prevention was a key priority when we wrote the Affordable Care Act, and I'm very proud of the fact that health plans now do have to cover recommended vaccines without cost sharing.

As health insurance coverage now is increasing, can you tell me what CDC is doing to help health departments bill insurance providers for vaccines provided to cover individuals?

Dr. SCHUCHAT. That's right. The Affordable Care Act means that more people have insurance, and more insurance is excellent for vaccines, because the ACA requires that insurers provide all recommended vaccines with no co-pays or deductibles when they're given in that work provider.

CDC has been supporting, I believe, 35 States to set up billing practices so that if insured people need to get vaccinated, for instance, in a public health clinic, that health clinic will be able to bill the insurer and recoup the money. We're really trying to make sure that the scarce Federal dollars that are discretionary really go to protect the infrastructure and that the insurers pay their way.

Senator MURRAY. OK. Good. I just wanted to mention I'm really proud of the number of organizations in my home State where they're really truly global leaders in promoting vaccination worldwide. We have the Gates Foundation and PATH, and the reality is we're incredibly lucky in this country to have people who have witnessed deaths by diseases like measles or polio or whooping cough.

I know that you've worked with these issues across the globe. Can you tell us what you perceive as the key challenges to achieving optimal immunization rates here as opposed to developing countries?

Dr. SCHUCHAT. We are so fortunate here to have a strong health system and access to vaccines. In many countries, even with the GAVI Alliance that provides vaccines for free for some of the poorest countries, the infrastructure is very weak. Strengthening health systems overseas so that they really can deliver vaccines is vitally important.

There are a number of public-private partnerships that have been helping in that arena, and I want to just mention the Measles-Rubella Initiative. They're responsible for more than a billion children getting measles vaccines through campaigns and other areas. We think that about 15 million children have been prevented from dying from measles in the last 15 years through the Measles-Rubella Initiative working with governments around the world.

Senator MURRAY. The public health infrastructure that we have here is critical for issues like this.

Dr. SCHUCHAT. Absolutely. Even if every single American was insured, we still need public health to make sure that we are addressing the needs of the communities.

Senator MURRAY. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thanks, Senator Murray.

We'll now move to 5-minute rounds of questions. Senator Collins, Senator Mikulski, Senator Cassidy, Senator Warren will be the first four. For the Senators who just arrived, at 11, we're going to move to the second panel even if we haven't finished the Senators' questions. That will take 15 minutes, and then we'll pick right up where we left off with the Senators who are next in line.

Senator Collins.

STATEMENT OF SENATOR COLLINS

Senator COLLINS. Thank you, Mr. Chairman.

Dr. Schuchat, the president's budget request includes a $50 million cut to the Centers for Disease Control and Prevention Section 317 immunization program. You just responded to a question from Senator Murray about the importance of the State and local public health infrastructure.

More than just paying for vaccines, the section 317 immunization program supports outreach, awareness, surveillance efforts by the State and local public health agencies. It's puzzling to me that the administration would propose to cut this program when we're in the midst of a measles outbreak, when you would think that you would want increased public outreach, awareness, and surveillance.

You've just talked about the importance of the State and local roles. Could you explain to us why this cut has been proposed?

Dr. SCHUCHAT. The public health infrastructure at the State, local, and Federal level is vitally important to protecting Americans. As I mentioned earlier, these threats like measles are an airplane ride away.

The reduction in resources requested through the President's budget will be accounted for through a reduction in vaccine purchase, and the idea is that instead of paying for vaccines for insured people, the health departments will be able to bill the insurer so that they will pay their way. Absolutely, protecting the public health infrastructure at that State and local level is critically important, as is the communication outreach and the provider work that we do.

Senator COLLINS. Well, it just seems to me that this is exactly the wrong time for us to be reducing funding in this area, given the importance that you've just outlined.

Historically, access to healthcare and the cost of vaccines had been the major barriers to achieving high vaccination rates. Increasingly, it's clear that other factors have come to bear as we're seeing declining vaccination rates in some extremely wealthy areas of our country. For example, there was a recent article in *The Atlantic* magazine that recently compared unfavorably the vaccination rates in wealthy areas of Los Angeles to the higher rates in the South Sudan.

How should our public health strategy change to reach those parents? You would not think that that would be the area, since they

obviously can afford the cost of the vaccines and have ample access to healthcare, certainly better than those in the South Sudan.

Dr. SCHUCHAT. Twenty-five years ago, we were dealing with a problem of children not having access to vaccines. What we're seeing more and more these days are parents opting out of the system and not wanting their kids to be vaccinated. I like to start with the premise that every parent wants their child to be healthy and safe, and that's No. 1.

For a number of parents, especially in some of these communities where opting out is common, they really don't realize that the diseases are still around. As we're seeing this year, when measles virus comes into a community, it's those communities where lots of people aren't vaccinated that are at higher risk. I hope parents in those communities are recognizing that the threat is actually real.

Another factor is misinformation, and, of course, in today's world, it's really easy to get information of all types. Much of it isn't very good. We at the CDC try to have the best information possible available and to make sure people see the sources of the information and can really check the facts themselves. We also work closely with clinician groups like the American Academy of Pediatrics, because what our research suggests is that parents want to hear about these things from their own doctor who knows them and their family and their unique circumstances.

A lot of the attitudes out there may be from complacency that these diseases haven't been visible. Unfortunately, this year, the disease is getting more visible.

Senator COLLINS. Thank you. I think that *The Lancet* study also played a huge role. Unfortunately, there are a lot of people who still mistakenly believe there is a link to autism and are unaware that that study has been thoroughly discredited.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Collins.

Senator Mikulski.

STATEMENT OF SENATOR MIKULSKI

Senator MIKULSKI. Thank you, Mr. Chairman.

Doctor, my question was going to be fairly identical to Senator Collins' question on the reduction of $50 million in the 317 grant program, which is to take care of the uninsured as well as vaccine safety outreach and education. Now, you're saying that that reduction of $50 million will have no impact on those services related to vaccine safety outreach and education?

Dr. SCHUCHAT. No, I can't say that those reductions will have no impact. What I actually tried to say is that the way that we would address those changes would be to reduce the discretionary vaccine purchase and try to really increase the billing of insurance. It's, of course, vital that the public health infrastructure be protected.

Senator MIKULSKI. Well, we feel the same way and, particularly, on the issues related to outreach and education. I'd like to join with the gentlelady from Maine, because this is not an appropriations hearing, but when we do move to Labor HHS, this is a valid area of inquiry and bipartisan cooperation.

This then takes me to science and the misinformation. Does CDC track the correlation between vaccine compliance and rates of au-

tism? Specifically, Mississippi, that has almost virtually a 100 percent compliance rate—what is the autism rate in Mississippi?

Dr. SCHUCHAT. I don't have that information. There are a number of ways that we've tried to understand trends in autism and vaccine exposures, and a number of different study designs have really discredited any link between autism and vaccines.

Senator MIKULSKI. Here's my question. See, I believe that the solution to misinformation is more information and that it be science and evidence-based, exactly your whole professional career, Doctor. My question, though, is do you track that? Do you track the correlation?

Dr. SCHUCHAT. We track the trends going on in autism and the trends going on in vaccination around the country. The trends in vaccination are that almost everybody is getting vaccinated with most of the vaccines. State by State, there are differences in particular vaccines.

Mississippi does not allow personal belief exemptions, and many people feel that the only exemptions that ought to be allowed are medical ones, because, of course, some children can't get vaccines because of health reasons.

Senator MIKULSKI. I'm not here trying to get into it. What I'm trying to get into is the epidemiology.

Dr. SCHUCHAT. Right.

Senator MIKULSKI. That where there are high rates of compliance, how does that correlate?

Dr. SCHUCHAT. There's no correlation between vaccination uptake and autism.

Senator MIKULSKI. And you have the epidemiology to support that?

Dr. SCHUCHAT. Right.

Senator MIKULSKI. Which then goes exactly to outreach and education. I want to go to a different—the committee ought to really think about our efforts in the area of autism. I know we've been very focused on issues related to Alzheimer's and others. It really is an epidemic in our country.

Mothers would do anything, and fathers as well, to protect their children. They need good information, they need real science, and for families facing these challenges, they need to have answers. It's another area we should take a look at on a bipartisan basis.

I want to shift gears to immigrant children and their vaccinations, and I know this can get controversial. What are the outreach efforts and how do we deal with this? Because, for example, 60,000 children came to America last year. Many of them are in Maryland, and, hopefully, they're in the sunshine, going to schools and so on.

Has CDC made an effort with States where there are high rates of new immigrants, both legal and not legal, where the immunizations of the children are addressed? Because there's this whole attitude—they shouldn't be in our schools, they shouldn't get our public health infrastructure, and this is exactly what we're talking about.

In my own hometown of America, Central American kids are going to school side by side with the gentry kids. How do we ensure that the needs of those children are addressed and, therefore, the needs of American children to be protected are also addressed?

Dr. SCHUCHAT. Vaccine-preventable diseases don't respect borders, and it's critically important for individuals to be vaccinated for their own health but also to protect the people around them. The State and local health departments work very hard to make sure that people are immunized, regardless of their country of origin.

It's very important in an era where measles has been eliminated from North and South America for us to continue to make sure that there are strong immunization efforts in other parts of the world where measles is still circulating. For vaccine-preventable diseases, it is important to make sure that people have access to vaccines, regardless of where they're from.

Senator MIKULSKI. Thank you.

The CHAIRMAN. Thank you, Senator Mikulski.

Senator Cassidy.

STATEMENT OF SENATOR CASSIDY

Senator CASSIDY. Dr. Schuchat, tell me, of those folks infected in the California epidemic, how many were native-born Americans and how many had immigrated here?

Dr. SCHUCHAT. I don't have that information. What I can say is that most of the importations that we have of measles each year are in Americans who are traveling abroad.

Senator CASSIDY. Now, when you say American, though, an American——

Dr. SCHUCHAT. U.S.-born.

Senator CASSIDY. A U.S.-born American.

Dr. SCHUCHAT. Right.

Senator CASSIDY. We've heard a lot about how the families from the wealthy communities of Santa Monica and the west side of Los Angeles are not vaccinating their children, but is that where we're seeing these cases? Do you follow what I'm saying? I did my residency in Los Angeles, and there are a lot of immigrants, and a lot of those immigrants may have fallen between the cracks. Again, do we have any sense of who is contracting this?

Dr. SCHUCHAT. Right. For the measles outbreak, we are seeing spread in some of the wealthier communities in California, for instance. Years ago, we had a lot of importations of measles from Latin America, which is where we have a lot of immigrants. The Americas really took on the elimination of measles and did major campaigns around all of the countries and had great success.

Senator CASSIDY. Can I ask then—I'm sorry—just because time is limited—when someone immigrates, what is their requirement in terms of immunization? If somebody is coming from the Philippines, what is the requirement now?

Dr. SCHUCHAT. There's a requirement for documentation of vaccination against the vaccine-preventable diseases. For children, the Vaccines for Children Program actually makes sure that the refugees, for instance, would have access to vaccines.

Senator CASSIDY. Now, that would be for VFC. That's for children, by definition, less than 18. What if an adult immigrates from a country like the Philippines?

Dr. SCHUCHAT. Right. That's not the case there, but most of the spread is coming from—most of the risk is in children. If you sur-

vive to adulthood in most countries, you've actually already been exposed to measles.

Senator CASSIDY. Of those adults going to the Philippines and coming back, and they are the ones bringing the cases, is there any—I assume there's a travel advisory—if you go to the Philippines, get immunized. Is there any effort in the Philippines? You've mentioned how the Americas have kind of bucked up their immunization efforts. What about the Philippines?

Dr. SCHUCHAT. Yes, there are efforts there. Unfortunately, the Philippines suffered that horrible hurricane, and after the weather problem, much of their immunization infrastructure was destroyed. They have had a really bad measles outbreak in response and are really—actually CDC and others have helped respond to help them work on their immunization campaigns.

The biggest outbreak we had last year of measles was in travelers—a couple of Amish adults who traveled to the Philippines who had never been vaccinated and brought the virus back to Ohio. It turned out the Amish community really stepped up to be vaccinated, but that was a large community where very few people had been immunized.

Fortunately, in the United States, most communities have high immunization rates, and it's just these newer communities where parents are opting out that we're quite worried about.

Senator CASSIDY. When we travel overseas, oftentimes we need an immunization record. A fellow from my church just went to a mission conference in the Philippines. I should ask him. Was he required to show his vaccination record, et cetera, to go, and is it required—MMR?

Dr. SCHUCHAT. He wasn't, but we hope that we're reaching him through our outreach efforts. We were concerned that with the Ohio outbreak we hadn't reached those travelers. They hadn't realized they should have been immunized. In fact, they were misdiagnosed——

Senator CASSIDY. That seems like an easy thing to do, if you apply for a visa, to put in a note saying, "Listen, you're traveling to a place with endemic measles."

Dr. SCHUCHAT. Yes, there are a lot of electronic prompts and so forth now that do alert you. With our alerts, they're not 100 percent in terms of people following them.

Senator CASSIDY. Is that something that we, when we approve a visa—somehow, it seems like there should be some process by which when somebody is traveling to an endemic country that we would remind them of the risk.

Dr. SCHUCHAT. Yes. Definitely, we could look into that.

Senator CASSIDY. What about immunization rates since 2009? Have they risen or stayed the same?

Dr. SCHUCHAT. They have risen for some of the newer vaccines, and they're stable for the others. As I mentioned, we track very closely the percent of children who receive no vaccines at all by age 2, and that's low.

Senator CASSIDY. Some of it's stable. I just am wondering about Senator Murray's statement—and you seemed to concur—that the Affordable Care Act may have improved immunization rates. We know with the CHIP Program and the Vaccines for Children Pro-

gram—I have done a lot of immunization work among children—that, really, cost has not been a barrier for immunization for children for some time, again, because of VFC as well as for public health units. Would you accept that?

Dr. SCHUCHAT. That's right. It's adults where the vaccination record rates are very low, and then we have some lagging coverage in teenagers, particularly with the HPV vaccine.

Senator CASSIDY. But VFC would not, for example, require hepatitis B coverage in an adult, I presume.

Dr. SCHUCHAT. No, the VFC just covers people through age 18.

Senator CASSIDY. The ACA would not, either?

Dr. SCHUCHAT. No, the ACA would cover vaccination of an adult with hepatitis B if they were in a recommended——

Senator CASSIDY. If they're at risk.

Dr. SCHUCHAT. Yes.

Senator CASSIDY. A gay man or something like that.

Dr. SCHUCHAT. Well——

Senator CASSIDY. I do think it's important for the record that for childhood immunization, the Affordable Care Act has really, not hurt, but it has certainly not augmented that which was previously there.

Dr. SCHUCHAT. The Vaccines for Children Program has had huge impact, and it's really been a wonderful——

Senator CASSIDY. Huge impact, yes, the VFC but not the ACA.

The CHAIRMAN. We need to keep moving.

Senator CASSIDY. I yield back. I'm sorry.

The CHAIRMAN. Thank you, Senator Cassidy.

Senator Warren.

STATEMENT OF SENATOR WARREN

Senator WARREN. Thank you, Mr. Chairman.

When the polio and measles vaccine became available for the first time, parents lined up to make sure their kids would be protected. They lived in a world of infectious diseases that destroyed children's futures, and they desperately wanted to leave that world behind.

These vaccines worked so well that the memory of these diseases has faded and the importance of vaccination has become less obvious. Last month, the Pew Research Center Report found that while nearly 80 percent of baby boomers and seniors believe vaccines should be mandatory, only 59 percent of people under 30 hold that belief, and now measles is back.

Dr. Schuchat, you are the top immunization official in the United States. I just want to walk through the science on this with you. Is there any scientific evidence that vaccines cause autism?

Dr. SCHUCHAT. No.

Senator WARREN. Is there any scientific evidence that vaccines cause profound mental disorders?

Dr. SCHUCHAT. No, but some of the diseases we vaccinate against can.

Senator WARREN. The diseases can, but not the vaccines. Is there any scientific evidence that vaccines have contributed to the rise in allergies or autoimmune disorders among kids?

Dr. SCHUCHAT. No.

Senator WARREN. Are there additives or preservatives in vaccines that can be toxic to kids?

Dr. SCHUCHAT. Not in the amounts that are in vaccines.

Senator WARREN. Is there any scientific evidence that giving kids their vaccines further apart or spacing them differently is healthier for kids?

Dr. SCHUCHAT. No, it actually increases the risk period for children.

Senator WARREN. So it adds to the danger.

Dr. SCHUCHAT. Right.

Senator WARREN. Is there any scientific evidence that kids can develop immunity to these diseases on their own simply by eating nutritious foods or being active?

Dr. SCHUCHAT. No.

Senator WARREN. How do the risks of a child responding negatively to a vaccination compare with the risks of skipping vaccinations and risking exposure to a deadly disease?

Dr. SCHUCHAT. Vaccines are safe and highly effective, and it's important for parents to know they're the best way to protect their kids.

Senator WARREN. Every parent wants to protect their children. Parents should know that all of the credible scientific evidence suggests that modern vaccines are safe, modern vaccines are effective, and modern vaccines are our best chance of protecting our children from diseases that can kill them. Is that right?

Dr. SCHUCHAT. That's right.

Senator WARREN. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren.

Senator Roberts.

STATEMENT OF SENATOR ROBERTS

Senator ROBERTS. Thank you, Mr. Chairman. I appreciate you holding this hearing.

In Kansas, we had 19 cases of vaccine-preventable diseases last year. The most prevalent was measles. We have not had any new measles cases reported yet this year. However, our public health workers are concerned, our parents are concerned, and I am concerned. The problem is that our immunization rates are down. For the 2013 year to the 2014 school year, the percentage of youngsters that have received the necessary vaccinations is now below 90. That's not good.

For the record, I had measles and chicken pox and mumps and everything else that people had back in the day.

What I'm asking, if I can get to it here very quickly—if immunization rates continue to decline, what advice do you give to these youngsters' parents who have to rely on others in their community to choose vaccination to help protect their own?

Dr. SCHUCHAT. The lower the rates are, the more your children are at risk. You want to be making sure your own children are vaccinated, but also it's important to have those around them vaccinated. Some kids can't get vaccines because they have leukemia, for instance. They can't get live viral vaccines. Our best protection is that community level of vaccination.

Senator ROBERTS. Well, you highlight three reasons parents don't vaccinate—the fear of side effects, religious or philosophical objections—and there's a whole bunch of paragraphs here in the background information on which States are easier to get a religious exemption and which are easier to get a philosophical objection—a simple letter signed by a doctor.

How often, however, about the mistrust of the recommended vaccine schedule—how often would you say that is the reason that the vaccine schedule is too rigorous, and what reassurances could you provide to parents on this concern?

Dr. SCHUCHAT. Many parents do mention the number of shots the children get at a particular visit as something that concerns them. We like to let people know that the vaccines are recommended at the times they're recommended because of the way they work and because of the disease risk.

Our advisory committee on immunization practices reviews the science of the vaccines and diseases and updates the schedule every year based on the best information available. I strongly recommend parents get their children vaccinated on time and according to the schedule.

Senator ROBERTS. In answer to the chairman's question, which really nailed the issue right off the bat, there was a major Danish study published in 2002—540,000 children showed definitely there was no relationship between MMR, i.e., measles vaccination, and any kind of problem with autism. An Institute of Medicine report in 2004 did the same.

Along the way, there have been studies from the National Institutes of Health, the Centers for Disease Control, and hundreds of other reliable academic groups. All of these examinations point to the same conclusion. The body of evidence was firmly established a long time ago.

However, this is a State issue, and that seems to be the problem. CDC is doing the very best that you can to try to convince every State—Mississippi leads. We're at the bottom—not at the bottom, but fairly close to it. I'm very concerned about it. At least the media today realizes that the one study which was totally discredited—that there should be a very strong statement by everybody involved that they should go ahead and get these vaccinations.

I strongly recommend that, and I thank you for your leadership.

The CHAIRMAN. Thank you, Senator Roberts.

We'll now go to Senator Baldwin. I want to mention again to the Senators that at 11 we're going to excuse Dr. Schuchat and call the second panel for 15 minutes. Then any Senator who hasn't had a chance to ask a question will be the first one up.

Senator Baldwin.

STATEMENT OF SENATOR BALDWIN

Senator BALDWIN. Thank you, Mr. Chairman. I also want to thank the Ranking Member for holding this hearing.

Our Nation's vaccine program has greatly reduced human suffering and saved lives by preventing and reducing the outbreak of preventable diseases. Thanks to national policies, including the Affordable Care Act, now millions of families have access to free immunizations. It's why I'm so concerned, as I know many of my col-

leagues are, about the recent measles outbreak and the surge in misinformation exacerbated by the media and even some national figures. This misinformation, of course, is surrounding vaccine safety.

To prevent against future outbreaks, it's vital that we continue to invest in our Nation's vaccine production capacity, support cutting edge science, and enhance public education surrounding vaccine safety. I have a number of questions, especially around our production.

Over 20 years ago, partially in response to a measles outbreak, Congress recognized the critically important roles of vaccines by passing and creating the CDC's Vaccine for Children Program, which provides recommended pediatric vaccines to low-income children. The CDC also maintains a stockpile for pediatric vaccines.

Dr. Schuchat, could you tell us the current state of our national pediatric vaccine stockpile, and is the measles vaccine included in that supply? Can you elaborate on the role of the stockpile in addressing outbreaks as well as how CDC works to maintain it?

Dr. SCHUCHAT. Yes. The Vaccines for Children Program includes a stockpile that is approximately 50 percent of—enough vaccine for 50 percent of the pediatric population to be vaccinated for a year. We currently have over 3 million doses of MMR vaccine.

The vaccine stockpile has been used both for outbreak response, but it's also been used for vaccine shortages. Even with a robust vaccine manufacturing industry, there are many vaccines where there's only one or two manufacturers that produce them, and when there are interruptions in supply, we'll have to go to our stockpile to make sure that there's not an interruption in use. It's really been a critical safety net for the vaccine security.

Senator BALDWIN. I want to explore a little further this issue of production and interruptions in production, both with diseases that are prevented by vaccines but also with the influenza vaccine, where there may not be 100 percent match to the strain that's prevalent in a given flu season.

Three issues—first, domestic manufacture versus overseas manufacture in the case of an epidemic that's particularly lethal has long been an issue. I understand we've improved domestic production. Anything you could elaborate on that would be helpful.

Second, production is usually still slow and based on chicken eggs, and there have been many efforts to transition to a cell-based production in the influenza vaccine. Where are we on that?

And, third, with regard to diseases that are preventable by vaccine, we have had drug manufacturers who have decided to exit that area and oftentimes with little notice to the medical profession. I've heard from front line pediatricians who say, "We don't have enough in our clinic, and we have people coming in, and we can't meet the demand."

Is there better notice given to the CDC? Do we have more safeguards in place to make sure that we don't have an alarming shortage?

Dr. SCHUCHAT. We had a big wakeup call about 10 years ago in October 2004 where, overnight, half of the expected influenza vaccine supply wasn't coming through. That really prompted an enormous amount of reevaluation on the different parts of government.

We're in much better shape now. That year, we eventually had about 58 million doses of flu vaccine.

This year, we have nearly 150 million doses of flu vaccine that have been distributed. There are multiple new manufacturers or additional manufacturers producing for the U.S. market. We also have a number of formulations besides the egg-based that have been approved by the FDA and are being used. Cell-based and recombinant-based influenza vaccines are included among this year's seasonal flu vaccine supply.

Looking toward the future, there's a lot of enthusiasm across the government and across academia around investments toward a universal influenza vaccine that might give us broader, better and longer lasting protection than the annual flu vaccines that we use today. There's a lot of progress in the past decade. But, there's more work to be done.

In terms of the communication with the industry——

The CHAIRMAN. Dr. Schuchat, I'd like to try to get Senator Franken in before you leave, if we may.

Senator BALDWIN. We're good.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Franken.

STATEMENT OF SENATOR FRANKEN

Senator FRANKEN. Thank you, Mr. Chairman, for that.

I'm thinking that maybe this outbreak in measles is a bit of a wakeup call. As Senator Warren said, there are a lot of baby boomers and some of us who are—some of the Senators who are older had measles and remember it. Maybe this is a really good time for people, especially some educated people who were foregoing this for their children, to understand things like herd immunity, and that if you get a critical mass of people not getting immunized, you have outbreaks like this.

What the costs are—just like the financial costs—there was a 2005 NIH article that attempted to quantify the economic impact on health infrastructure, and researchers estimated that one case of measles costs the Federal, State, and local health departments more than $140,000 to respond to just one case.

You talked about the return on investment for all of these immunizations, and it's one of the most—it's obviously cost-effective and also prevents a lot of suffering. We live in a global world, and I just wanted to ask you about that investment that we put into global public health and what the importance of that is, in terms of our investing in this in Africa and other places. Can you respond to that?

Dr. SCHUCHAT. Yes. Measles has been eliminated from the Americas, but it's still circulating around the world with about 20 million cases a year. In some of the countries that have had major outbreaks, it's really investing in their health infrastructure and supporting their ability to have strong immunization systems that will protect Americans as well as strengthen their health.

We're really keen to be partners in the wholly eradication initiative and the measles-rubella initiative in the GAVI Alliance and in ways that we can help protect children everywhere with vaccines that are safe and effective. It really strengthens our communities'

protection here at home and it's really the right thing to do overseas as well.

Senator FRANKEN. Because measles, in particular, is highly contagious, and you're one plane ride away from an American getting infected, speaking of which, what other infectious diseases may be on the horizon? What might be the next measles, and what might come from abroad, like MERS or—what else are we looking for in the near future, possibly?

Dr. SCHUCHAT. With infectious diseases, you really have to be ready for the idea that the microbes are changing faster than we are as people. This past year, we dealt with the Enterovirus D68 problem, a severe respiratory illness in children that we really hadn't seen. The last 2 years, we've been dealing with the Middle East Respiratory Syndrome, a new virus that was causing very severe disease in the Middle East and in some travelers returning from there, with two cases here in the United States.

Senator FRANKEN. And that's the MERS?

Dr. SCHUCHAT. MERS, right. We really think it's critical to be strengthening public health infrastructure and capacity for global health security in countries around the world so that we don't let an epidemic like Ebola get as bad as it got but can jump on it right away. We don't see importations of MERS, but we recognize that these diseases are overseas and help the countries that are battling them deal with them swiftly.

Senator FRANKEN. That's why the CDC is so important. I really want to thank you for your service to this Nation and to the world. Thank you, Doctor.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Franken.

Dr. Schuchat, maybe I misheard something. The State Department website says that U.S. immigration law requires immigrant visa applicants to obtain certain vaccinations prior to the issuance of an immigrant visa. An adult immigrant to the United States who obtains a visa is required to obtain certain vaccinations, correct?

Dr. SCHUCHAT. Yes, I think that's right. I can double check. We can confirm that for the record.

The CHAIRMAN. I'm reading it off of the State Department website.

Dr. SCHUCHAT. Oh.

The CHAIRMAN. I didn't want to leave a different impression if a different impression was untrue.

Dr. SCHUCHAT. Thank you.

The CHAIRMAN. Dr. Schuchat, thank you so much for your time. There are a couple of Senators who haven't had a chance to ask questions. I hope they will understand that we want to invite the second panel to come up now, and they will be the first ones up after the next 15 minutes of testimony.

I'll now move ahead and introduce the second panel to save time, if I may. First, we'll hear from Dr. Kelly Moore. Dr. Moore is director of the Immunization Program at the Tennessee Department of Health. In this role, she is responsible for promoting proper use of recommended vaccines, as well as overseeing the response to outbreaks of vaccine-preventable disease.

She has her undergraduate and medical degrees from Vanderbilt, and a master's of public health from Harvard School of Public Health. I'm completely objective, but the Tennessee Department of Public Health is one of the finest in the country.

Dr. Mark Sawyer is professor of Clinical Pediatrics and a pediatric infectious disease specialist at the University of California San Diego and Rady Children's Hospital in San Diego. He's also the medical director at San Diego Immunization Partnership and involved in a variety of immunization projects.

Dr. Tim Jacks is a pediatrician and the father of two children who recently were exposed to measles in Arizona. He's an Every Child By Two immunization champion. Every Child By Two is a nonprofit dedicated to increasing vaccination rates among children. His wife is in Arizona caring for their two children. I'm grateful he could be here to tell their story.

Dr. Moore, let's begin with you. If the three of you could summarize your comments in 5 minutes, we would appreciate it, and then the Senators will continue questioning.

STATEMENT OF KELLY L. MOORE, M.D., MPH, DIRECTOR, IMMUNIZATION PROGRAM, TENNESSEE DEPARTMENT OF HEALTH, NASHVILLE, TN

Dr. MOORE. Thank you, Chairman Alexander and Senator Murray, for holding this hearing on the benefits of immunization and for inviting me here to testify about the public health perspective on vaccine-preventable disease. Most people are unaware that even in a State with a strong history of immunization, a single case of measles requires a major public health response.

I'd like to begin by acknowledging Governor Bill Haslam and First Lady Crissy Haslam for their commitment to immunization as an essential step in promoting and protecting the health and prosperity of Tennesseans. You could say Tennessee has a culture of immunization.

For the past two influenza seasons, the majority of Tennesseans age 6 months and up received a flu vaccine. In 2013, 95 percent of kindergarteners were immunized with all required vaccines, including both doses of MMR. Just 1 out of 100 claimed a religious exemption, and just over 1 in 1,000 were exempted by a doctor for medical reasons.

The Federal Vaccines for Children Program has removed barriers to access for eligible children since 1994. Our State's online immunization information system, supported by section 317 Federal funds, ensures that authorized users such as clinics and schools have access to immunization records to see what vaccines a child may need or to verify that they're protected.

We have more work to do to reach high immunization rates with vaccines designed for teens and adults that prevent diseases such as meningitis, cancer, pneumonia, and shingles. Public health partners with our clinical and pharmacy colleagues to address misinformation and concerns about safety, health benefits, and affordability.

To improve access, our department is using Federal prevention and public health funds to help local public health clinics become in-network providers for commercial insurance plans so we can pro-

vide recommended vaccines to their beneficiaries with no out-of-pocket cost.

When it comes to disease outbreaks, few realize how much public health work goes into one case of measles. I vividly recall each of the nine cases Tennessee has had in the decade I've directed our immunization program. Our most recent experience is a good example.

On a Friday afternoon last April, a doctor called his regional public health office about an adult with an uncertain immunization history and recent overseas travel who was in the ER with classic symptoms of measles. The diagnosis was not in question.

A game plan was quickly developed in a call with the State immunization program to identify those who may have been exposed in the 4 days the unsuspecting patient was highly infectious. One hundred twenty-four people were identified. The MMR vaccine could protect the most recently exposed susceptible contacts if local public health could find them quickly enough.

Twenty-five contacts with uncertain immunity were vaccinated on Saturday. Others were counseled about what to do if symptoms developed. Among the 124 contacts, just three cases among other adults developed. For these, the same isolation, contact tracing, and notification process was practiced, but faster. No additional cases occurred. In total, 406 contacts were evaluated.

TDH worked with the media statewide to educate the public and prepared clinicians through State health alerts and an educational webinar. CDC measles experts provided consultation and specialized testing that helped us optimize our outbreak management tactics.

A great deal of credit in this story goes to the hard work of public health at all levels. This result, however, could only have been achieved in a community where a very high percentage of the population was already immune. Had this imported case landed among those who were unimmunized and susceptible, there would have been a very different outcome.

Congress' sustained commitment to immunization and a strong public health infrastructure through the VFC Program and section 317 funding will continue to equip us to meet the educational and operational challenges of keeping individuals and communities healthy and safe through affordable, accessible, and effective immunization services.

Thank you for the opportunity to testify here today. I've provided a more detailed written testimony for the record, and I'm glad to answer your questions.

[The prepared statement of Dr. Moore follows:]

PREPARED STATEMENT OF KELLY L. MOORE, M.D., MPH

SUMMARY

State and local public health fosters a culture of immunization in Tennessee through close working relationships and partnerships with pediatricians, family doctors, nurses, coordinated school health programs and pharmacists. Public health supports this network in several ways. The Federal Vaccines for Children Program has removed the barrier of cost and access to immunization for any child without insurance coverage. We use Federal section 317 funds to track immunization coverage rates among young children and use these data to educate healthcare providers to target our specific vulnerabilities. We work closely with schools to help

them properly enforce State school immunization requirements in order to keep schools a safe and healthy learning environment. Our section 317-funded State immunization information system helps clinicians provide quality immunization services and issue school immunization certificates. Public health clinics are successfully working to become in-network providers for commercial insurance plans so they can vaccinate beneficiaries without deductible or copay.

Tennessee does well in immunizing our young children: about 93 percent have their first MMR before their first birthday. In the past two influenza seasons, the majority of Tennesseans aged 6 months and up were vaccinated against influenza, but there is room for improvement. Our school-located influenza immunization clinics are one strategy we are using. Our 2013–14 kindergarten entry data showed 95 percent had all required vaccines, including two doses of measles, mumps and rubella (MMR) vaccine; just 1 in 100 claimed a religious exemption and just over 1 in 1,000 were exempted from one or more requirements by a medical doctor for health reasons.

One overlooked element of the recent measles outbreak is the amount of public health work needed to contain even a single case of measles in a community. In April 2014, an adult with an uncertain immunization history developed measles shortly after returning to Tennessee from travel overseas. Public health investigators determined that the patient had exposed 124 identified contacts in the days before diagnosis. Swift action to reach these contacts and immunize those who could benefit from a dose of MMR resulted in only three confirmed secondary cases among other adults; no cases occurred among their contacts. In total, 406 contacts were identified and evaluated. Such strong outbreak response can only achieve this type of result in a setting with a high level of immunity among the population. Our ability to respond has been made more possible by increased emergency preparedness funding since 2001, yet sustained support of the public health immunization infrastructure is essential to keep the threat of vaccine-preventable diseases at bay.

I would like to thank Chairman Alexander, Ranking Member Murray and the committee for holding this hearing on the benefits of immunization and inviting me here today to testify about the perspective and role of State and local public health in the promotion of immunization and the response to vaccine-preventable disease outbreaks.

I would like to begin by acknowledging Governor Bill Haslam and First Lady Crissy Haslam for their commitment to immunization as an essential step in promoting and protecting the health and prosperity of Tennesseans. Whether getting an annual flu shot with a smile for the cameras or championing the creation of KidCentralTN.com to help parents access services to help them raise healthy children, the Governor and First Lady have been steadfast champions of our immunization activities.

You could say that Tennessee has a culture of immunization. For the past two influenza seasons, the majority of Tennesseans age 6 months and up were vaccinated against influenza. Three out of four Tennessee toddlers are fully immunized on time by their second birthday, and most that fall short could be caught up with just one more immunization visit. Over 93 percent of them have had their first MMR. By the time Tennessee children start kindergarten, 95 percent have a record of immunization with all required vaccines, including both doses of MMR needed to protect them from measles, mumps and rubella. Just 1 out of 100 had filed a religious exemption with the school and just over 1 in 1,000 were exempted from one or more vaccines by a doctor for medical reasons. Our school nurses and administrators take their commitment to enforcement of immunization requirements seriously, working closely with public health, families and medical offices to identify and catch up children who are behind on immunizations to keep our schools a safe and healthy learning environment.

The Tennessee Department of Health (TDH) fosters our culture of immunization by cultivating strong, supportive relationships with healthcare providers, schools, parents and the public to promote and provide immunizations needed across the lifespan. TDH programs focus on promoting access, affordability, awareness and demand for vaccines. The Federal Vaccines for Children (VFC) Program is critical to our success. VFC-eligible children in our State can be vaccinated with federally funded vaccine in any local health department and at over 500 other participating clinics and hospitals statewide. Our section 317 Federal immunization funds support the effective operation of our VFC Program, including our educational programs for doctors and nurses, and regular site visits to participating clinics by local public health staff to promote compliance with the strong accountability and quality standards expected of all participants in the VFC Program. Resources, training and peo-

ple are in place to enable every doctor and nurse serving VFC-eligible children to provide the highest quality of immunization care for all of the children they serve. These section 317 funds also help us improve lagging adolescent immunization rates by addressing awareness and educational needs among clinicians and families.

In addition to supporting the work necessary to keep the VFC Program strong, a small quantity of Federal section 317 funds are available to purchase and provide certain routine immunizations to uninsured adults in Tennessee who seek care at our local health departments. We use these same 317-funded vaccines to protect people who may be at risk of contracting a vaccine-preventable disease during an outbreak. These section 317 vaccines also are available to us today should we need them to protect anyone who may be at risk after a measles exposure.

Tennessee has recently used Federal section 317 funds to implement a new, secure immunization information system, known as TennIIS, to replace a legacy system with limited functionality. The State first created its IIS, or Immunization Registry, in 1996, as a repository of immunizations administered by health departments and by any other immunization providers who chose to report them and accessible only to authorized users. Today, TennIIS is fast becoming the heart of Tennessee's immunization activities. All authorized users, such as Vanderbilt's network of clinics in middle Tennessee, can look up immunization records on their patients. For example, the health records system used by Vanderbilt University clinics electronically updates TennIIS with the immunizations they give and pulls down information from TennIIS about immunizations given to their patients by other users who report to the system. TennIIS provides decision support for busy clinicians by instantly displaying what vaccines are due or overdue for a child, based on the current CDC schedule. This simple tool helps clinicians follow the complex current immunization schedule for optimal patient care.

Our IIS, implemented and operated with our Federal section 317 funding, is an increasingly important tool in the prevention and control of vaccine preventable diseases. Several months ago, the New York City Department of Health notified the Immunization Program that two young Tennesseans had been exposed to measles while visiting there. A call such as this is a small public health emergency because of the threat of measles. The State vaccine-preventable disease epidemiologist normally alerts local public health to reach the affected people without delay to find out if they are sick and to ask their immunization status, which they rarely know with certainty. However, a quick check of the IIS confirmed that both were up to date with MMR vaccine and almost certainly protected from disease. The typical scramble became a brief and reassuring call to the exposed individuals because the needed immunization history was readily accessible to public health.

In Tennessee, local school nurses and coordinated school health directors are among our most important champions of immunization. These men and women are responsible for enforcing immunization requirements for the children in their schools to ensure that schools remain a safe and healthy learning environment. They take this responsibility very seriously and are often the ones to catch problems and alert the parents and healthcare provider so they can be corrected. In 2013, the Department of Health developed and launched a function in TennIIS to simplify and improve the quality of immunization certificates for school and daycare. A simple click of the button can produce a complete, accurate immunization certificate based on a child's age and grade. If the record is incomplete, a failed validation report pinpoints exactly what is missing. Any TennIIS user can produce these, including school administrators and immunizing pharmacists. Someday, we envision that parents will be able to produce their own, further simplifying this rite of school entry.

In many counties in Tennessee, schools partner with local public health to offer influenza vaccine at school each fall. Such programs are far more complicated to organize today than in the time many people recall when children simply lined up for their sugar cubes and polio vaccine. With more expensive vaccines, consent forms, private insurance billing, VFC eligibility documentation and separate vaccine inventories for different funding sources, these programs are not easy. Despite the logistical hurdles, these partnerships strengthen the bonds between educators and public health and raise awareness about the importance of influenza vaccination for the whole community, as our statewide influenza vaccination rates show.

When it comes to immunization, local public health departments long ago ceased to be the primary providers of childhood immunizations as children's primary care medical homes have taken over this role, but we are relationship-builders and resources and we provide a safety net of access for all routine immunizations. Tennessee public health departments carry all routinely recommended vaccines for people of all ages. When it comes to concerns about vaccine safety, the Immunization Program is where the public and healthcare providers bring those questions and the

Program facilitates in depth consultation when necessary with vaccine safety experts at the CDC and at Vanderbilt's Vaccine Research Program.

What I hear when I visit local clinics is that one of the most frustrating challenge to our front line public health nurses is keeping up with which people qualify for vaccines from which sources and how much they must pay. Years ago, with fewer, less expensive vaccines available, the nurses were simply focused on ensuring that no child or adult in need of vaccination left without being immunized. Today, we have Federal VFC vaccine for eligible children, section 317 vaccine for uninsured adults and State-purchased vaccines for insured children and adults ineligible for Federal vaccines. Each inventory must be managed and accounted separately. Once they have finished answering questions about the vaccines themselves, explaining the differences in costs for different groups is frustrating. They spend extra time to avoid making a mistake and using vaccine from the wrong funding source. They long for simpler days, but they work very hard to immunize everyone they can and to properly account for every dose they use.

Challenging work is ahead to achieve these same high rates of immunization for vaccines designed for the preteens, teens and adults who are difficult to reach. Several of the vaccines recommended for people in these age groups are relatively new, designed to prevent diseases such as meningitis, cancer and shingles. Public health works to inform and educate the public about these vaccines, addressing misinformation and concerns about safety, affordability and health benefits.

Until recently, our local health departments did not participate in commercial insurance plans as in-network providers; a major effort is underway using Federal Prevention and Public Health Funds to help local public health clinics become in-network providers in order to provide routine recommended vaccines to commercial insurance beneficiaries of any age with no out-of-pocket cost. Currently, patients insured by a plan we have not yet joined are asked to pay out-of-pocket for vaccinations at our clinics, meaning that they often leave unimmunized to try to locate an in-network provider to serve them. Some have found this challenging in areas where the public health department may be the nearest provider with the vaccine in stock. We are making progress in obtaining in-network status with major plans to help close this gap.

The dedicated and creative people who work in local and State public health, including our public health nurses, are the quiet heroes who protect the public from vaccine-preventable diseases by promoting immunization and by responding without hesitation when cases occur. In recent discussions about the ongoing measles epidemic, few have addressed how much tightly coordinated work is being done among local, State and Federal public health officials in the public health response to a single case. The story of Tennessee's 2014 measles outbreak illustrates this point.

On a Friday afternoon in April 2014, an infectious diseases doctor contacted the west Tennessee regional public health office about a recently returned international traveler who had come to their hospital emergency room with classic signs and symptoms of measles. Even without laboratory results, the diagnosis was not in question. A game plan was quickly developed among the regional public health team, the State immunization program and partners in neighboring public health jurisdictions to initiate laboratory testing and to identify those who may have been exposed in the 4 days leading up to the diagnosis when the unsuspecting patient was highly infectious while working and visiting a primary care clinic. One hundred twenty-four people were identified as contacts. Because the doctor contacted public health immediately, we gained the advantage of a small window of time to administer the MMR vaccine and protect some of the potentially susceptible contacts, if the local public health team could find and vaccinate them quickly enough. A clinic was arranged for Saturday morning and 25 contacts with uncertain immunizations were vaccinated. Those exposed more than 72 hours earlier were counseled about the illness and what to do if symptoms developed. To expedite testing, staff drove clinical specimens to the State lab for testing and shipping onward to the CDC, where CDC later confirmed the diagnosis and linked it to a large epidemic in the country recently visited by our traveler who, like the others he infected, had simply been unaware of his susceptibility.

Among the 124 people exposed to measles by our index case, just three secondary cases among other adults occurred. For these three, the same isolation, contact tracing and notification process was practiced, only faster. No additional cases developed and the outbreak was officially declared over in June. A total of 406 contacts were evaluated in multiple local public health jurisdictions with State communicable disease staff providing coordination and technical support. Front line staff worked with patients and contacts. The Tennessee Department of Health educated the public through the media and kept our health care community informed through our State health alert notices and a live webinar with subject matter experts. The CDC

measles epidemiologists and laboratory team provided specialized laboratory testing and technical consultation to help optimize our outbreak management tactics.

Despite how well this collaboration worked, the swift resolution was achievable because of the already very high level of immunity in the general population. No one in this situation opposed or refused immunization. While prompt immunization after exposure likely prevented some cases, the fact is that the vast majority of people exposed were already immune. Increased emergency preparedness funding since 2001 has helped public health become more effective at responding to outbreaks, yet had this imported case landed among those who were unimmunized and susceptible, there would have been a very different outcome. Importations are not completely preventable, but by sustaining a highly immunized population, such events can be managed by motivated and well-trained public health responders.

Our public health professionals, along with our clinical partners, schools and each immunized person in our community together hold back the tide of vaccine-preventable diseases that washed over past generations. Regular investments in training, support, technology, vaccines and immunization services maintain this protective infrastructure and allow us to live in health with these threats held at bay. These outbreaks of vaccine-preventable diseases are like small breaches that warn us of the threat we face should this infrastructure break down. Should it be allowed to crumble, the breaches will become larger and the consequences to our communities could be far greater.

I want to close by thanking you again for the opportunity to speak to this committee on behalf of the dedicated State and local public health professionals of Tennessee. We are justly proud of our culture of immunization in Tennessee and the health and prosperity our residents derive from it, but we have much more work to do. Our immunization culture is promoted by public health and sustained by our close, trusting working relationships with schools, healthcare providers and parents. We all work hard to prevent fear and misinformation from misguiding people about vaccines, their safety and effectiveness. People need to be able to make well-informed decisions about vaccines, and such decisions can only be made with clear and reliable information from trusted sources. Our public health system continues to work to extend the benefits of high immunization rates among young children to reach preteens, teens and adults with vaccines designed to protect them. Congress's sustained commitment to our immunization programs, immunization information systems and public health will strengthen our defense against the tide of vaccine-preventable diseases that continue to threaten the vulnerable among us.

The CHAIRMAN. Thank you, Dr. Moore.

Dr. Sawyer.

STATEMENT OF MARK H. SAWYER, M.D., FAAP, PROFESSOR OF CLINICAL PEDIATRICS, DIVISION OF INFECTIOUS DISEASES, UNIVERSITY OF CALIFORNIA SAN DIEGO AND RADY CHILDREN'S HOSPITAL, SAN DIEGO, CA

Dr. SAWYER. Chairman Alexander and Ranking Member Murray, thanks very much for holding this hearing on a very important topic, the reemergence of vaccine-preventable disease and what we can do together to prevent further outbreaks.

As you've heard, I'm a pediatric infectious disease specialist at the University of California San Diego and Rady Children's Hospital in San Diego. I'm also a member of the Committee on Infectious Diseases of the American Academy of Pediatrics, and my testimony today has the strong endorsement of AAP.

Vaccines are one of the greatest public health achievements, as has been pointed out by Dr. Schuchat and several of the Senators. Prior to the introduction of vaccines, children suffered regularly from serious illnesses like measles, diphtheria, polio, even bacterial meningitis.

The development and widespread use of vaccines has led to a reduction or eradication of these once common childhood illnesses. Because of the success of vaccines, I have never seen a case of

polio, diphtheria, or tetanus in my 30 years of practice in pediatric infectious disease.

In a teaching session I held last week with 20 pediatric residents in training, I asked them if any of them had seen the measles. None of them had. However, as we have seen from our current measles outbreak and continued outbreaks of pertussis or whooping cough around the country, we are witnessing a reemergence of vaccine-preventable diseases here in the United States.

Unfortunately, my residents are going to get a chance to see the measles. Pediatricians are concerned that the reemergence of disease is a signal that bigger outbreaks are yet to come.

Most of the cases in this current measles outbreak are from California, and 13 are from my own community. Outbreaks like this are increasing in frequency and size. This measles outbreak, like all other measles outbreaks, is occurring because we have too many intentionally unimmunized children in the United States, and it illustrates the problem created by unimmunized populations. A simple trip to Disneyland has led to a multistate outbreak of measles involving more than 100 people.

Measles is one of the very few infectious diseases that literally flies through the air. It is completely predictable that such outbreaks will occur again if immunization rates stay where they are or get worse.

While most parents do choose to vaccinate their children, there are pockets of unimmunized children all over the country. In San Diego, we have 1,500 kindergarten students who are not fully immunized, and that number has been increasing steadily over the last decade.

The current measles outbreak reminds us of an important fact about infectious diseases. They are a shared public health problem. When 1 percent is infected, people around them, people they don't even know, become infected. The decision of a parent to leave their child unimmunized, however well meaning, is a decision that affects us all.

Although our public health community has done an excellent job of controlling this current measles outbreak, when too many people make the decision not to vaccinate their children, outbreaks will no longer be controlled. Why is this happening? All parents want what is best for their children, but many parents are choosing to not have their children immunized because they have received inaccurate information about the risks and benefits of vaccines and the diseases they prevent.

I have held a number of forums in San Diego County, meeting with vaccine hesitant parents to hear their concerns. Based on what I've heard in these discussions, I conclude that the internet can be a dangerous place for parents looking for information about vaccines. The internet is replete with anecdotes and misinformation that leads parents to think that vaccines have caused harm.

What is overlooked by parents is the fact that just because an adverse health outcome occurs in the time after a vaccine doesn't mean that the vaccine caused the problem. It takes science to prove or disprove a linkage between two events, and our parents are not hearing the science.

The vaccine schedule recommended by CDC and AAP has been developed with strong scientific standards and has been proven to be both safe and effective. In every case, for every vaccine, the risk from the disease outweighs any risk from the vaccine.

In my opinion, the best way to decrease the number of families refusing to vaccinate their children is to improve communication about vaccine safety and effectiveness, to increase the science literacy of our population, to limit the philosophical exemptions from school entry requirements for vaccination, and to continue to carefully monitor the safety of all of the vaccines we use. Taking these steps can ultimately help reduce the number of parents who choose not to vaccinate their children.

The reemergence of vaccine-preventable diseases is alarming and must be confronted if we are going to prevent further outbreaks like the one we're currently experiencing.

Thank you for allowing me to testify, and I look forward to your questions.

[The prepared statement of Dr. Sawyer follows:]

PREPARED STATEMENT OF MARK H. SAWYER, M.D., FAAP

SUMMARY

My name is 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, CA. I am also a member of the Committee on Infectious Diseases with the American Academy of Pediatrics (AAP). My comments today have the strong endorsement of AAP.

The Great Success of Vaccines: Vaccines are the safest and most cost-effective way of preventing disease, disability and death. 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. However, as we have seen from our recent measles outbreak and continued outbreaks of pertussis in various areas of the country, we are witnessing the reemergence of vaccine preventable diseases here in the United States. I am concerned that this reemergence of disease is only a signal of future, wider-scale outbreaks yet to come.

The Measles Outbreak at Disneyland: Currently, the United States is experiencing a large, multistate outbreak of measles linked to Disneyland in California. Most of the cases are from California and 13 cases are from my community. This measles outbreak occurred because we have a rising number of unimmunized children in the United States and illustrates the problem created by unimmunized populations. A simple trip to Disneyland has triggered a multistate outbreak of measles involving close to 100 people. It is completely predictable that such outbreaks will occur again if immunization rates stay where they are or get worse.

The Problem of Low Immunization Rates: Although most parents immunize their children, pockets of unvaccinated children exist all over the country and the number of unimmunized children has been increasing steadily for more than a decade. The current measles outbreak 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 affects all of us.

Why is This Happening? Many parents are choosing to not have their children immunized because they have received inaccurate information about the risks and benefits of vaccines and the diseases they prevent. The Internet can be a dangerous place for parents looking for information about vaccines because it is replete with anecdotes that lead them to think vaccines have caused harm. What is overlooked is the fact that just because one event follows another does not mean the first event caused the second. It takes science to prove or disprove a linkage between two events. The vaccine schedule as recommended by the Centers for Disease Control and Prevention and the American Academy of Pediatrics has been developed with strong scientific standards and has been proven to be both safe and effective.

What Can We Do? 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, increase the science literacy of our population, limit exemptions from school entry requirements for vaccination, and continue to carefully monitor the safety of all the vaccines we use. In the meantime we need to maintain our Public Health infrastructure to control the outbreaks that will inevitably happen.

The reemergence of vaccine preventable diseases is alarming and must be confronted if we are to prevent the further outbreaks of disease. Thank you for allowing me to testify before the committee today.

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, CA. 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, multistate 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—4 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 1,000 may die.

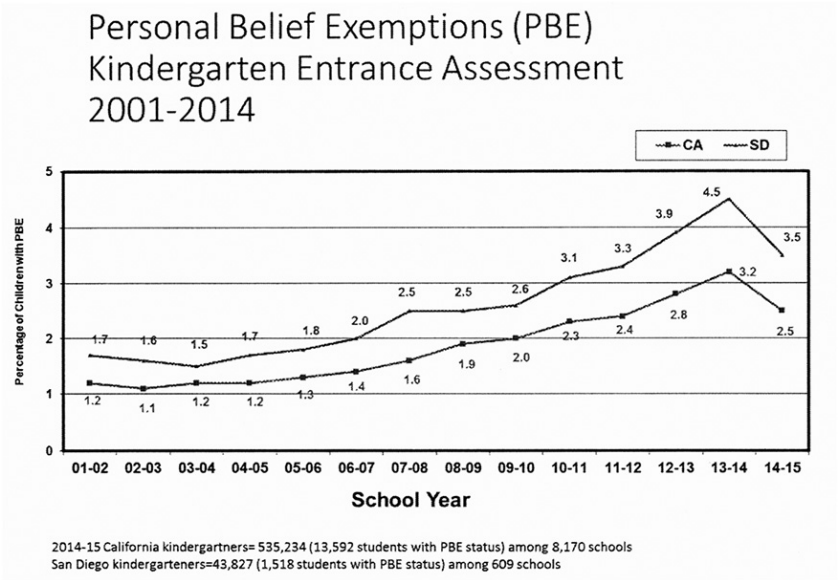
As a pediatrician that specializes in infectious diseases, I am alarmed by this recent outbreak. It illustrates the problem created by the rising number of unimmunized children in the United States. A simple trip to Disneyland has triggered an outbreak of measles in close to 100 people. It is completely 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. 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 2013–14 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, vaccinations 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 2014–15 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.



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. 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. Once an outbreak starts

[1] *http://pediatrics.aappublications.org/content/115/5/1428.full.pdf+html?sid=f4d4ccaf-c087-4854-8c99-2ce33ab197ad.*

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. 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, 2 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 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. 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 philo-

sophical 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 a hold 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 percent 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 Web sites 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 $1,200 for girls. This is a more than sixfold 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 recordkeeping 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 United States 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 dialog with those who harbor fears of vaccines, and eliminate non-medical exemptions allowing parents to 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.

The CHAIRMAN. Thank you, Dr. Sawyer.

Dr. Jacks.

STATEMENT OF TIM JACKS, M.D., DO, FAAP, PARENT, PEDIATRICIAN, AND EVERY CHILD BY TWO IMMUNIZATION CHAMPION, GILBERT, AZ

Dr. JACKS. Senator Alexander, Senator Murray, esteemed Members of Congress, my name is Tim Jacks. I'm a board certified pediatrician, and I'm on the front line of this vaccination issue. I daily recommend vaccinations to my patients and address concerns and questions they have regarding immunizations. Lately, I've also been addressing many questions over the ongoing measles outbreak.

I'm not here today as a medical professional. I'm here today as a father. Three weeks ago, my infant son and daughter, Magdalene, who is battling leukemia, were exposed to measles. Since her diagnosis with leukemia 6 months ago, our home life has revolved around my daughter Maggie's care. She has been admitted to the hospital six times and spent nearly a month there.

She's on a very regimented schedule of treatments, and she takes medications three times a day, up to six medications at a time. We have weekly visits to an outpatient clinic where she has procedures, she has blood work drawn, and she gets her chemotherapy infusions.

At one such clinic visit, my children were exposed to measles. We were informed of this exposure and instructed to return for shots of the measles antibodies, which we did. Now, these antibodies are not perfect protection, but in the case of my children, it's the only thing we can do to prevent them from actually coming down with measles.

Right now, my two children are at home under quarantine. While we are waiting the 3-weeks to see if they develop measles or if they exit quarantine without any symptoms, I typed an entry into Maggie's blog. This blog is something I use to update family and

friends to her treatment progress and just to let people know how she's doing.

Typically, I get 100 people reading this blog. Needless to say, it has gone viral. The title of this blog entry was "To the Parents of the Unvaccinated Child Who Exposed My Family to Measles." In this blog, I vented my frustrations, my anger at the situation, and I explained and, hopefully, educated some people as to why my children and many other children like them are at risk.

Eli, my 10-month-old son, has received all of his immunizations on schedule, but is too young to receive his first dose of MMR. My daughter, Maggie, who was also previously fully immunized, is at extra risk right now because of her weakened immune system due to her leukemia as well as her treatments.

The blog went viral. In over 2 weeks, it received over 1.3 million shares on Facebook and has been read countless times. I have been contacted and interviewed by CNN, Fox News, and many other local and national media outlets. I have taken these opportunities to share our story and, hopefully, raise awareness to this issue.

My hope is that we can prevent some families from going through the same thing that we've gone through these last 3 weeks. I also hope that we can prevent more families from getting measles altogether. Prevention is simple—vaccinate.

As immunization rates drop, the herd immunity starts to break down, and this herd immunity is the only thing protecting my two young children from being exposed to measles or whatever the next outbreak is. I urge a strong unified bipartisan voice supporting the scientific evidence that vaccines are safe and that they save lives.

We need a consistent message from the presidency to Capitol Hill down to our local and State legislators, schools, and even daycares. I urge Congress to take action supporting the programs and infrastructure already in place to get these vaccines to those that need them most and contain outbreaks such as we are seeing today.

I will care for my family. I will work to promote health among my patients, and through partnerships with organizations like Every Child By Two and the Arizona Partnership for Immunization, I will advocate for timely vaccinations for children.

Thank you for your commitment to this issue. With your help, we can stop the spread of vaccine-preventable diseases and protect the innocent. We can protect our children. We can protect my children.

Thank you.

[The prepared statement of Dr. Jacks follows:]

PREPARED STATEMENT OF TIMOTHY JACKS, M.D., DO, FAAP

SUMMARY

Because of the decline in vaccination rates, the United States is seeing a resurgence of vaccine preventable illnesses.

Those most at risk from the current measles outbreak are children too young to receive the MMR vaccine and those with medical conditions (like leukemia) which compromise their immune system. Their only protection is from the "herd immunity" of people around them.

Last month, my healthy infant son and 3-year-old daughter, who has leukemia (blood cancer), were exposed to measles.

In response, I wrote a blog entry venting my emotions and educating readers about our situation. The blog went viral, and I was approached by the media.

As a pediatrician, I have engaged this wider audience. I have taken this chance to educate and hopefully cleared up some of the confusion regarding immunizations.

I stand with the scientific community and recommend that all children be vaccinated—and not just against measles.

When considering immunizations, families need to understand the risk of disease exposure and the seriousness of infection—especially to the young and medically fragile among us.

I urge you to take a strong, unified, bi-partisan stand supporting the scientific evidence that vaccines are safe and they save lives. Finally, I urge Congress to take action in support of programs that get vaccines to those who need them most and help contain disease outbreaks.

Thank you.

Esteemed Members of Congress, Chairman Alexander and Senator Murray, my name is Tim Jacks, DO. I am a board certified pediatrician and fellow of the American Academy of Pediatrics. I work in Gilbert, AZ and encourage on-schedule vaccinations for all my patients. Parents regularly come with questions regarding routine immunizations. Unfortunately, not every parent decides to follow the recommended CDC vaccination schedule.

Because of these refusals, the United States has recently seen a resurgence in measles cases, and we are struggling to contain this outbreak. My job is on the frontline of this outbreak. The clinics and urgent cares where I work are seeing many concerned families with possible exposures.

I am not here today for professional reasons. The circumstances that have brought me here today are deeply personal ones.

Last month, my two young children, one battling leukemia and the other who is below the recommended age for MMR vaccination, were both exposed to measles.

Our current journey began 6 months ago. Our daughter Maggie had been looking a little pale and had more bruising than a rambunctious 2-year-old should have. Labs were ordered. Later that evening, we received a call that shook our small family to its core.

Maggie had cancer.

Specifically, she was diagnosed with ALL—acute lymphoblastic leukemia—a form of blood cancer. Over the next week, Maggie was admitted to Phoenix Children's Hospital, had a port placed for infusions and blood draws, had many more tests run, and was started on chemotherapy.

Since then, our family's day-to-day life revolves around Maggie's treatment. She is on a very regimented treatment protocol. She visits an outpatient pediatric specialty clinic at least weekly for blood tests and chemotherapy infusions. She takes medicines three times a day up to six at a time. She has been admitted six times in total and spent nearly a month in the hospital.

The ongoing chemotherapies have put Maggie's leukemia into remission, but they have also weakened her immune system. She is at risk for serious illness from even the most benign exposures. Any fever requires an ER visit, antibiotics, and possible admission. Because of this we stay home most of the time.

Before cancer, Maggie had been fully immunized. Now due to her weakened immune system, her previous immunity is limited, and she is unable to receive further vaccines on schedule. She will remain at risk until her 2½ years of treatment end. Eli, our infant son, has received all recommended vaccines for his age but is still too young for the MMR vaccine (given at 12–15 months of age). Because of this, my children rely on the immunity of others to protect them from measles and other diseases. When enough people are immunized, the spread of disease slows or even stops. This is herd immunity, and it is starting to break down.

Since her diagnosis, I have kept a caring-bridge blog chronicling Maggie's journey through leukemia. This was my post the day after my family's measles exposure.

To the parent of the unvaccinated child who exposed my family to measles, I have a number of strong feelings surging through my body right now. Toward my family, I am feeling extra protective like a papa bear. Toward you, unvaccinating parent, I feel anger and frustration at your choices.

By now we've all heard of the measles outbreak that originated in Disneyland. Or more accurately, originated from an unvaccinated person that infected other similarly minded vacationers. I won't get into a debate about the whole anti-vaccine movement, the thimerosal controversy (no longer even used in childhood vaccines), or the myth that MMR causes autism (there are changes in autistic brain chemistry prior to birth).

Let's talk measles for just a minute. It once was widespread in the United States. It is now considered "eliminated" in the United States (not continually circulating in the population—only contracted through travel out of country). Measles is highly contagious (>90 percent infectious) and can survive airborne in a room and infect

someone *2 hours later*. Another fun fact is that measles is transmittable before it can be diagnosed—4 days before the characteristic rash appears.

> "Measles itself is unpleasant, but the complications are dangerous. Six to twenty percent of the people who get the disease will get an ear infection, diarrhea, or even pneumonia. One out of one-thousand people with measles will develop inflammation of the brain, and about 1 out of 1,000 will die."

(*http://www.cdc.gov/vaccines/vpd-vac/measles/faqs-dis-vac-risks.htm*) That sounds fun!

Ok.

Calm down self.

I assume you love your child just like I love mine. I assume that you are trying to make good choices regarding their care. Please realize that your child does not live in a bubble. When your child gets sick, other children are exposed. My children. *Why would you knowingly expose anyone to your sick unvaccinated child after recently visiting Disneyland?* That was a bone-headed move.

Why does this affect me and mine? Why is my family at risk if we are vaccinating? I'm glad you asked.

Regarding measles, there are four groups of people.

All are represented in my family.

First, the MMR vaccine results in immunity for most who receive it. Two doses provides protection that can be confirmed with blood titers. My wife is in this group.

Second, about 3 percent of fully vaccinated children do not develop a lasting immune response. They have low blood titers and are not protected against measles. If exposed, this group will likely get the illness. I am in this group. I was thankfully not exposed. [Repeat testing has shown myself immune.]

Third, we have the unvaccinated. My son, Eli, is 10 months old. He is too young to have received the MMR vaccine and thus has no protection. Whether by refusal or because they are too young, exposed unvaccinated children have a *90 percent chance* of getting measles.

Fourth, there are children like my Maggie. These are children who can't be vaccinated. Children who have cancer. Children who are immunocompromised. Children who are truly allergic to a vaccine or part of a vaccine (i.e., anaphylaxis to egg). These children remain at risk. They cannot be protected . . . except by vaccinating people around them.

Back to my story. . . .

It was Wednesday. Maggie had just been discharged from Phoenix Children's Hospital after finishing her latest round of chemotherapy. That afternoon she went to the PCH East Valley Specialty Clinic for a lab draw. Everything went fine, and we were feeling good . . . until Sunday evening when we got the call. On Wednesday afternoon, Anna, Maggie, and Eli had been exposed to measles by another patient. Our two kids lacked the immunity to defend against measles. The only protection available was multiple shots of rubeola immune globulin (measles antibodies). There were three shots for Maggie and two shots for Eli. They screamed, but they now have some temporary protection against measles. We pray it is enough.

Unvaccinating parent, thanks for screwing up our 3 week "vacation" from chemotherapy. Instead of a break, we get to watch for measles symptoms and pray for no fevers (or back to the hospital we go). Thanks for making us cancel our trip to the snow this year. Maggie really wanted to see snow, but we will not risk exposing anyone else. On that note, thanks for exposing 195 children to an illness considered "eliminated" from the United States. Your poor choices don't just affect your child. They affect my family and many more like us.

Please forgive my sarcasm. I am upset and just a little bit scared.

Papa bear.

PCH has been great though this whole ordeal. We have done what is physically possible to protect our children. Now we pray. Please pray alongside us.

We are not currently contagious. Rest assured, if measles visits our house, it will not spread to anyone else.

Thank you for your prayers and support.

When I typed this entry, I had no idea it would resound so clearly with so many people. In less than 2 weeks, this post has received over 1.3 million shares on Facebook and reached countless readers. In addition I was featured on CNN as well as other local and national media outlets.

Both online and in my daily practice of medicine, there is a lot of confusion and misinformation resulting in resistance toward vaccinations. Some parents do not understand the wonders of the immune system and how well equipped it is to deal with the immunologic components within vaccines. Instead they believe there are too many shots for a young developing immune system. Some still hold to the de-

bunked theory that the MMR vaccine causes autism. They are concerned about the chemicals in vaccines. They are more afraid of a vaccine reaction than getting the disease itself.

As a result, immunization rates drop. Herd immunity weakens. Outbreaks happen. Children get exposed.

My measles-exposed children have been quarantined at home for nearly 2 weeks now, and we anxiously watch for signs of disease. Every warm forehead, every sign of rash, and every runny nose could be the start of measles, and that brings me back to why I am here.

I don't want any family to repeat what we have gone through these last few weeks.

The solution is simple. Immunize.

We need to get more children protected against these vaccine-preventable diseases. We need families to understand the present danger of exposure and the seriousness of infection—especially to the young and medically fragile among us.

Every family has a decision to make regarding vaccinations. Let's help make it a clear choice.

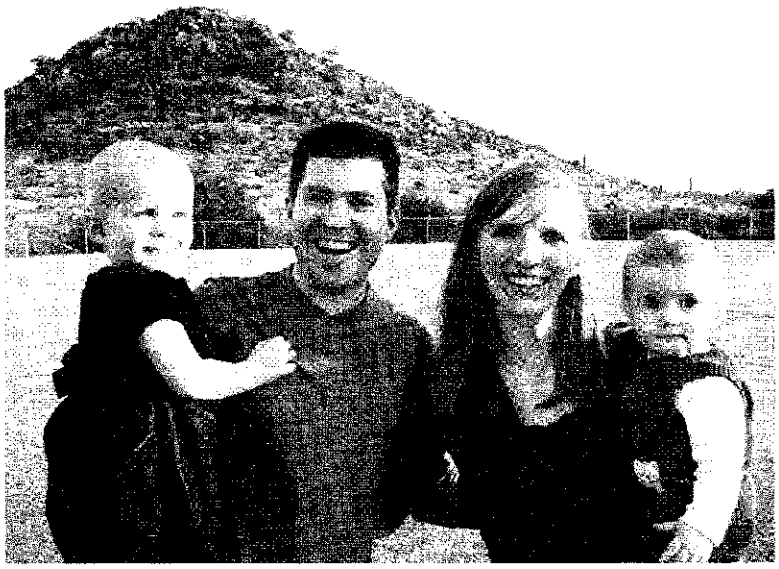
I urge you to have a strong, unified, bi-partisan voice supporting the scientific evidence that vaccines are safe and they save lives. We must maintain a consistent message at every level of society from the presidency, to Capitol Hill, all the way down to our State legislators, schools and even daycares.

While there are instances where it is medically necessary to decline immunizations, State health authorities should make it less convenient to refuse and require families to receive education regarding the dangers of not vaccinating, both for the child and the larger community.

Finally, I urge Congress to take action in supporting the programs and infrastructure that gets vaccines to those that need them most and helps contain outbreaks such as measles. It is important to remember as congressional budgets are negotiated that vaccines offer the greatest cost savings of all medical treatments. We must support the access to and affordability of immunizations.

Back in Arizona, I will care for my family. I will work tirelessly in promoting health in my patients. Through my work with Every Child My Two and The Arizona Partnership for Immunization, I will continue advocating for the timely immunization of our children.

Thank you for your commitment to this issue and for caring about the children of this great nation. This issue is close to my heart as a father and pediatrician. With your help, we can put an end to vaccine-preventable illnesses and protect the innocent. We can protect our children.



From left to right, Maggie, Tim, Anna, and Eli Jacks

The CHAIRMAN. Thank you, Dr. Jacks, for your personal story, and thank you, Dr. Sawyer and Dr. Moore.

Now, we'll go to the Senators who have not yet had a chance to ask questions, and we'll begin with Senator Casey.

STATEMENT OF SENATOR CASEY

Senator CASEY. Mr. Chairman, thank you very much. I appreciate this hearing. We certainly want to thank the witnesses for bringing to this hearing room today your experience, your knowledge, and the significant time that you've dedicated your lives to on these issues.

Dr. Jacks, we're especially grateful that you're bringing your own personal story. These issues are difficult enough, but ever more so when you have a loved one, in your case, a daughter, that is the subject of your own efforts. We're grateful for you bringing that to us.

I'm tempted to ask, but I won't. I'll just refer to it as kind of the why question—why this failure to vaccinate has become so significant. That may be the question that we're all asking. I guess maybe a better question to ask is what we can do to push back against it. We're doing that today, and, obviously, each of your testimonies have referred to that.

I wanted to get to some of the ground level work that has to get done day in and day out, about which I don't know much, and maybe some members of the panel do. What happens in our

schools, what happens in communities, and what happens even in the offices of pediatricians?

Dr. Sawyer, you were talking about the fact that you, in all your years, had never been exposed to this in a direct way as a practitioner. I wanted to ask some specific questions about pediatrics. Do you think we're reaching the point where there has to be pediatric training that speaks to this, in other words, a change in the training that reflects the reluctance that some parents have to vaccinate?

Dr. SAWYER. Yes. That's an excellent question, and there are efforts underway from the American Academy of Pediatrics nationally and, in my case, locally. I have a curriculum for residents about immunization. Three or four years ago, I added a whole section of that curriculum to teach residents in training about how to communicate about vaccine safety and address the concerns of these parents in an open, non-confrontational way with the hope that if we can just educate our families and give them good accurate information, they will make the right decision.

The problem is there's so much inaccurate information circulating, and it's highly educated families who get on the internet and read something and take it to heart before they really critically look at the source of that information. That's what we need to try to address.

I mentioned in my statement to raise the science literacy in the United States. That's a tall task, but without that, we're never going to win this battle.

Senator CASEY. Thank you.

Dr. Moore, referring to your testimony, on page 3, you talk about in the second full paragraph, and I'm quoting, "In Tennessee, local school nurses and coordinated school health directors are among our most important champions of immunization." Can you tell us about that and the importance of that? Because as much as we have an obligation here in Washington to get a message out and try to get the policy right, a lot of the best work will be done in those settings.

Dr. MOORE. That's true. I can't speak highly enough of our local public health nurses and the school nurses and school administrators who work with families, because, truly, these parents often hesitate to vaccinate their children out of fear. They want to do what's best for their child. These bells go off when they hear scary things about vaccines, and it's very hard to un-ring that bell. The people best equipped to do that are the people they trust and are in close relationships with.

When I talk to local public health nurses, they care so deeply about these families that they work with. A lot of this can be overcome with credible information from trusted sources, good relationships, and that's what these folks provided. I'm always a phone call away when they have a question on a technical thing. I can help them with that.

They're the ones with the relationships with the families to help them overcome these fears. Our immunization rates are a testimony to that ability for them to work through this with families.

Senator CASEY. I appreciate that. I'll wrap up with just one statement. I know that in the debate about how to respond to the

Ebola crisis, among the best pieces of advice we all got here was that local validators are a lot better than validators outside of a local area. I won't say Washington, but you know what I'm talking about.

Thank you for your work, and I'm grateful that you're here today.

[The prepared statement of Senator Casey follows.]

PREPARED STATEMENT OF SENATOR CASEY

Chairman Alexander and Ranking Member Murray, thank you for convening this hearing to discuss the reemergence of vaccine-preventable diseases. I am grateful for today's opportunity to shed light on an important public health crisis facing the Nation.

Vaccines are one of the biggest accomplishments of modern medicine, responsible for saving millions of lives and preventing disease and disability around the world. Many people alive in the United States today have never seen the illnesses that vaccines prevent, like measles, smallpox or polio. Globally, we eradicated smallpox entirely, and no longer need to vaccinate against it.

Measles was considered eradicated in the United States as recently as 2000, meaning that it was no longer circulating naturally in the population. Any cases that occurred were imported from countries where the disease is still endemic, such as in many parts of Asia. Yet this year, we have already seen over 120 cases of measles in the United States, mostly linked to a sick child who went to Disneyland and infected other children who had not been vaccinated. At least five of the children to contract measles were too young to be vaccinated, but many of the children who got sick were old enough to be vaccinated.

I am deeply concerned that so many parents in the United States are failing to vaccinate their children. This puts these children in danger, but even more than that, it puts other peoples' children in danger. We must all recognize our personal and collective responsibility to get vaccinated, and to vaccinate our children, in the name of protecting those who are too young or medically unable to be vaccinated.

According to medical experts, the science behind the measles vaccine is clear: the vaccine is one of the most effective vaccines we have; if a child receives the recommended two doses, she has almost total immunity. We saw the panic that erupted around a handful of cases of Ebola last year—yet people refuse to vaccinate their children against measles, which is three times more infectious than Ebola.

I look forward to working together to raise awareness in our communities of the importance of vaccination.

The CHAIRMAN. Thank you, Senator Casey.

Senator Murphy.

STATEMENT OF SENATOR MURPHY

Senator MURPHY. Thank you very much, Mr. Chairman and Ranking Member, for this hearing.

Thank you to all of you, especially you, Dr. Jacks, for taking the time to tell your story.

I wanted to talk for just a minute and ask a few questions about the nuts and bolts of how exemptions work, because we've seen a pretty rapid rise in exemptions in my State, for instance, which has fairly loose rules regarding getting exemptions, a feature we share with California, frankly. We've seen just in the last 3 years, that the number of people who are applying for and getting religious exemptions has doubled—just in 3 years.

I heard in your testimony, Dr. Sawyer, that you're actually proposing eliminating the philosophical objection. Can you just speak for a minute on why you've made that proposal?

Dr. SAWYER. Yes. I made that proposal because, as you pointed out, I live in California, where up until last year, in order to exempt your child from school vaccinations, you simply flipped over a paper at the school registration and signed it that you had a philosophical objection, not a religious exemption, not a medical reason your child couldn't be vaccinated. You just don't believe in vaccines.

Just as you mentioned in your State, we've seen a steady rise in those exemptions in California over the last decade. There are very few religions that specifically advise their followers to not vaccinate. It's this philosophical exemption that's causing the problem, and it's driven by misinformation.

I'm certainly in favor of eliminating such philosophical exemptions. A State Senator in California just introduced a bill last week to do just that, and I'm certainly going to be supporting that effort in California.

Senator MURPHY. Let me suggest an alternative to the elimination of the exemption. As you mentioned, all that you need to do in a State like California or Connecticut is simply sign a piece of paper. You actually get no information about the consequences of not getting a vaccination. Yet the studies are pretty clear that the more information that you give, the less likely it is that people will take the exemption, and, in fact, the less likely it is that you'll have outbreaks.

Here's a pretty stunning one from 2006. In States that had higher bars for exemptions, they were 50 percent less likely to have whooping cough outbreaks. You can recite other literature that says the same thing.

I asked this to Dr. Sawyer, but I'm happy to get comments from the rest of the panel. Let's say we just raise the bar for a philosophical objection, and we say, for instance, that you have to consult with your physician first, or you have to review information about the risk of not getting your kids vaccinated.

Do you think that that would be helpful if we weren't successful in eliminating the exemption? I asked this to Dr. Sawyer, but I'd be glad to hear other panelists' thoughts.

Dr. SAWYER. I'll respond first, because we have just done that in California. Last year, we passed a law that requires parents, in order to exempt their child, to have a form signed by a healthcare provider that at least they've been educated. That led to about a 1 percent drop in the rate of exemptions in California as a whole. It is still at 2.5 percent to 3.5 percent in different communities within California.

We'll see next year whether that form continues to drop the rate. My concern is we've seen the benefit of a one-time drop and we're

going to go back to the steady gradual increase in exemptions, whether people stick to philosophical ones with their doctors' information or whether they, as you pointed out, start to exercise religious exemptions that they didn't before.

Senator MURPHY. Just quick comments from——

Dr. MOORE. Senator, Tennessee is one of the vast majority of States that does not have a philosophical exemption and has no intention of developing one.

Senator MURPHY. Only 20 States have them.

Dr. MOORE. Correct. About 29 or so have no philosophic exemption, including Tennessee. We have to decide, as a community, do we want to protect the most vulnerable among us, or do we want to provide choices and options for protection? We can't do both at the same time with a disease as contagious as measles.

If we're prepared to accept the consequences of outbreaks like this, then personal choice is perfectly fine. If we want to protect the vulnerable, like Dr. Jacks' children, then immunization needs to take place to do that. It's the best way to do it.

Senator MURPHY. Thank you, Mr. Chairman. My office is looking at some proposed legislation that would provide some incentives for States to increase the information that they're giving to parents, not actually dictating what exemptions are used, but to admit that as a national health priority, it probably makes sense to make sure that the best information is given out.

The irony is that if you're getting a medical exemption, in most States, you actually have to have a note signed by a doctor. If you're using a philosophical exemption or a religious exemption, often all you have to do is sign the back of that form. It seems like we should, at the very least, try to marry those two standards together.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murphy.

Senator Bennet.

STATEMENT OF SENATOR BENNET

Senator BENNET. Thank you, Mr. Chairman, and thank you very much to you and the Ranking Member for holding this hearing. It strikes me, listening to the testimony, that we've been victimized by two things.

One is a generation that has not experienced these diseases because of vaccines and have lost sight of what they look like, and, interestingly, to Dr. Sawyer's point, the unedited content on the internet that people—more affluent families, I guess, are reading.

I wonder, Dr. Sawyer, and then I'll ask the other panelists—and let me also say to Dr. Jacks I thank you for your testimony. I hope Maggie's having a chance at least to watch you while you're doing this, or maybe doing something more interesting at home. Thanks for being here.

Dr. Sawyer, maybe I'll start with you. Could you use this opportunity to tell us what the biggest falsehoods are that are being trafficked on the internet and what the answers to those falsehoods are? If the other panelists would like to join in, that would be great as well.

Dr. SAWYER. Well, as has been mentioned here several times today, autism remains one of the major concerns of parents, even though, as Dr. Schuchat pointed out, the science has completely discredited any association between the two. Once you get beyond that, the next thing you hear is that we're overwhelming children's immune system with too many vaccines too soon.

The whole philosophy of the immunization schedule is to protect children as soon as we can for as many things as we can. Delaying vaccines is really counterintuitive to the whole purpose of the vaccination program.

If we were overwhelming children's immune system—I'm an infectious disease doctor—those kids would then be getting unusual infections because their immune system was overwhelmed. We don't see that at 2 months, 4 months, and 6 months when we give routine vaccinations.

The last major theme that you hear about are the ingredients in vaccine and the concern that perhaps some of them are toxic. Once again, that's been discredited and looked at very carefully. FDA approves these vaccines in large part based on their safety record.

Senator BENNET. Dr. Moore.

Dr. MOORE. I will add to Dr. Sawyer's excellent list—that I agree with—that the flu vaccine causes the flu. I hear that every year over and over from well-educated folks, and that's certainly one that we work to counteract because of the benefits of flu vaccine. That's a common one. And then that HPV vaccine might cause promiscuity. We hear that from time to time as well from people concerned about the HPV vaccine given to pre-teens.

Senator BENNET. Just to be clear to anybody listening to this, these are all things that are scientifically demonstrably incorrect.

Dr. Jacks, I wondered—you're a pediatrician. Do you have advice for pediatricians across the country about how to handle the conversation that they have with parents about vaccines?

Dr. JACKS. Yes. With regard to families that do have questions and concerns, it's really just that. It's addressing their questions and concerns. Back in the day, physicians could take somewhat of an authoritative stance, and there was a great deal of respect.

Nowadays, it's really more of a working with families to come to a conclusion of what's best for their children, whether it's immunizations or whether or not we want to treat an ear infection. As a pediatrician, my goal is to, No. 1, develop relationship with my families so that we do have that rapport, and then for me to make my recommendations and address their concerns specifically.

Senator BENNET. Do you have any—and, Dr. Sawyer, you train pediatricians. This question of whether there are things that pediatricians can do——

Dr. SAWYER. Right. The curriculum I mentioned, that we've developed locally in San Diego as well as the Academy's curriculum, basically takes people through the appropriate way to listen attentively to people's issues and be respectful in addressing them, but to continue to convey the science in the most clear way one can so that families reach the right conclusion.

Senator BENNET. Thank you.

Thank you, Mr. Chairman. I surprised the chairman because I finished early.

The CHAIRMAN. That's 43 seconds——

Senator BENNET. Let the record—I'll never get that time back.

The CHAIRMAN. We'll put it in the bank.

[Laughter.]

Senator BENNET. I'll take that.

The CHAIRMAN. We have time, and I'm sure all of us would probably like to have a second round of questions.

Dr. Moore, I believe you said that the case of measles in Tennessee was in Memphis, an adult in Memphis. Is that correct?

Dr. MOORE. It was actually an adult in west Tennessee.

The CHAIRMAN. In west Tennessee.

Dr. MOORE. Right.

The CHAIRMAN. You described how you moved in quickly, and the number of people for just that one case that you had to be in touch with was how many?

Dr. MOORE. One hundred twenty-four people had come into contact with that one case during the 4 days before they were diagnosed.

The CHAIRMAN. This is an area where the vaccination rate for measles is what?

Dr. MOORE. Very good. I don't have the specific number for that region, but it was clear—because 124 people were exposed and only three people got sick—that it was very high.

The CHAIRMAN. So it was high. Well, as Dr. Sawyer was talking earlier, I was thinking about the phrase, going viral, and then Dr. Jacks used it. This generation understands the idea of going viral.

You're talking about measles flying through the air. That's unlike Ebola, that threw the country into a near—well, a complete panic, actually,—last fall, when Congress appropriated over $5 billion for Ebola-related efforts, and hospitals changed procedures. Ebola dominated what was going on in all the public health departments, yet it can only be spread through contact with bodily fluids. Measles flies through the air. This goes viral. This is a disease that goes viral.

We Senators, in a bipartisan way, understand the problem of dealing with highly educated people who get bad information on the internet. That happens to us every day. We deal with that. We know what it is.

Let's go back to the going viral. What if this person in west Tennessee, who Dr. Moore acted on quickly—what if that person had been discovered in a part of Los Angeles where 60 to 70 percent of parents at certain schools have filed a personal belief exemption from immunization requirements. Describe the number of people and the multiplying of people that would have to be contacted to make certain that the disease didn't spread.

Dr. SAWYER. Well, I can share the experience we had in San Diego in 2008, which was our last outbreak. We had 12 cases and over 800 people were exposed to those 12. It quickly goes up exponentially, the number of people you have to track, and unless public health is there to track those people and keep them quarantined, it could easily just get completely out of control.

The CHAIRMAN. You had 800 people, but then each of them might have infected someone else, right?

Dr. SAWYER. Exactly. In that outbreak, we had close to 100 people quarantined for 3 weeks just to prevent that next wave. We're all crossing our fingers here with this Disneyland outbreak that maybe we're near the end. I noticed that the case number went up by 20 just this last week, so I'm not sure we're done with this yet.

The CHAIRMAN. So when you say "flies through the air," we have an example of going viral in modern parlance, I suppose.

Dr. Jacks, this may not be an exact comparison, but people ask me why I continued to play the piano when I was young, and I remember responding that I didn't remember my mother giving me a choice about it. I guess I had a choice. We're not talking about taking choices away today from parents.

We are talking about a conversation between a pediatrician and a parent. How strongly do you recommend to parents that they vaccinate their children? I suppose the most persuasive thing you can do is tell them the story of your own children. Do you just make a neutral observation about it, or do you come to a conclusion and say, "I think you should do it?"

Dr. JACKS. I definitely come to a conclusion of recommending that we do vaccinate. I oftentimes don't approach it quite that way because I want to get their thoughts and opinions and their fears first so I can address those.

Yes, I talk to families—from a couple that's still pregnant that hasn't had their first child yet to that first visit after they're born to the routine visits where we would do vaccinations. Every visit, whether they're 100 percent getting vaccinated or whether they're still trying to decide, I'm talking, and I'm answering questions, and I'm urging them to make a good informed decision. My understanding and my opinion is that, yes, vaccinations are absolutely one of the best things that they can do to protect their young child.

The CHAIRMAN. I'm out of time. I know in our State, years ago, my wife led an effort to establish a medical home for every child about to be born—prenatal healthcare. I assume anything in prenatal healthcare that allows a parent to know more about the value of vaccinations before the child is born is a very effective way to keep the vaccination rate high.

Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman.

Dr. Moore, I wanted to ask about this, because I'm especially interested in learning more about what can be done to increase uptake of the HPV vaccine. We are really fortunate to have a vaccine today that can prevent most forms of cervical cancer, which I'm sure you know is the second leading cause of cancer deaths among women in the United States. About 12,000 women get cervical cancer every year. About 4,000 are expected to die from it, and we know that those are deaths that can now be prevented.

What can State and local health departments do to more effectively promote the HPV vaccine?

Dr. MOORE. That's a wonderful question, and, certainly, we know that a lot of young women and men are not being protected against this virus yet who could be. In Tennessee, our immunization rates are about one in three, and we'd like it to be much higher.

We're working collaboratively with cancer advocates, because they have wonderful experience raising awareness about breast

exams and pap smears. We're collaborating together to try to help families understand that this new vaccine is a cancer prevention tool that can help reduce the risk of an abnormal pap smear for a young lady later in life.

We are also trying to make sure people understand this vaccine is safe, it lasts, and it's very, very effective. We bundle it with other routine vaccines, so it's given at the same time in Tdap vaccine for pertussis protection in middle school and the first meningitis shot, and it's just a part of the routine pre-teen immunization bundle.

We're trying to help people understand that there's nothing exceptional about this except that it is phenomenal cancer prevention, and it's incredibly exciting to have a tool in our hands that the last generation didn't have to protect women and men from cancer for their lifetimes.

Senator MURRAY. Well, thank you. I appreciate that. I also want to mention that in my home State, we have an incredible public-private partnership. It's called VAX Northwest. At a time when my State had the highest vaccine exemption rate in the country, our State health department came together with some key health promoting organizations, including Group Health Foundation, Within Reach, and Seattle Children's Hospital, to create this really innovative partnership which addresses vaccine hesitancy through work with parents and our healthcare providers alike. It has support from the Gates Foundation, which was helpful, and the engagement of a lot of partners.

VAX Northwest is doing some really amazing work, which I should mention also is being rigorously evaluated with the intent of sharing a lot of lessons that they're learning with other States.

I wanted to ask you, Dr. Moore, how can working with private and nonprofit partners help health departments in their efforts with vaccines?

Dr. MOORE. Thank you. Health departments have a major role in promoting immunization. We've long ago stopped being the medical home for most children. They go to their own private doctors' offices for immunizations now, which is providing the best possible holistic care for the upbringing of that child.

We partner with these organizations in order to help support them in doing the right thing, because what I find in clinical practice is that pediatricians are incredibly busy with everything they have to do, and it really helps them if there is a group in public health focused on promoting just the immunizations where we can provide them support, like our immunization information system, that makes their jobs easier.

Our role, when it comes to doing site visits about the quality of their immunization care through the VFC Program, site visits that we do in their offices, educational programs that we provide, promotional materials—we help give them the resources they need for the private sector to do the best possible job for the patients, because they're primarily the ones vaccinating our children. This partnership has been wonderful.

I'm all about relationships, and these relationships have been great at developing strong collaborations and bolstering immunizations in Tennessee, certainly.

Senator MURRAY. Thank you.

Dr. Jacks, thanks for being here today. I really appreciate your willingness to come. Since you started speaking out about your own family situation, have you been surprised to know how many people don't know that some people cannot be vaccinated?

Dr. JACKS. Surprisingly, no, actually. There's been a lot of good support, a lot of positive feedback. There's certainly a small amount of negative feedback from certain populations. It seems like the knowledge is there. I just don't think it's in the public conscience when they're making the decision to vaccinate or not vaccinate, and that's why I'm doing this. I want to raise awareness of that issue so it can be part of the discussion.

Senator MURRAY. I appreciate that. I just wanted to ask you, as a pediatrician, what do you think are the key barriers to vaccine uptake?

Dr. JACKS. Largely education and the misinformation that's out there.

Senator MURRAY. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray.

Senator Cassidy.

Senator CASSIDY. Yes. First, I'd like to request unanimous consent to enter into the record a statement from the March of Dimes.

The CHAIRMAN. It will be done.

Senator CASSIDY. Thank you.

[The information referred to may be found in Additional Material.]

Obviously, we have declining resources on the Federal level. I see that the Administration is cutting the 317 money, Dr. Moore, that you referenced. I will also note, again, as a fellow who used to work in a public hospital system, that we—I wasn't a pediatrician. I just did a lot of pediatric immunization work. There's always a great concern about immunization.

Sometimes I would see people come to speak to our pediatricians about immunization, and it was like coal to New Castle. These folks cared about it. Jacks and Sawyer care about it passionately. Can we use our 317 money more effectively? I ask this not to challenge, but just to suggest.

When I look at that map of California, you can isolate those communities which are not immunizing. We ought to pay Jacks to come in and speak to those families so that they know, if they have a domestic which is helping them in their home—and they're wealthy—whose child was unvaccinated and recently came from another country, their children are at risk. Dr. Jacks could do that very effectively.

I guess I'm going to ask are we still using our 317 money in a paradigm of 20 years ago, before VFC, before we had immunization registries that could pinpoint where we had pockets of the unimmunized, and before we realized that many people are basing their decisions upon emotion and not upon their physician's recommendation? Simple question—317—are our programs rooted in 20 years ago, or are they adapting to our ability to use data to pinpoint where we need intervention?

Dr. Moore.

Dr. MOORE. Thank you for that question. I can say that under Dr. Schuchat's leadership, the 317 program is definitely focused on where we are today with our immunization programs. The 317 funding that we have is going to support our immunization information system that provides, as I mentioned, clinical decision support for clinicians who need to keep up with the complex current immunization schedule to provide optimal care. It can provide that support. It makes it easy to issue an immunization certificate.

We are also using those funds to provide education, not only for clinicians in large conference settings, but also one-on-one education. We will send a public health immunization expert into a clinic to spend half a day with that——

Senator CASSIDY. My point is that those clinicians, again—they don't need a half a day. They just need to have posted online their clinic's results compared to other clinics. The natural competition is going to drive it. We know that from infection disease rates in ORs. If you post a clinic's immunization rate, and they're lacking, they're going to come up.

I suspect if you did that for an elementary school—we're going to post the rate of the children immunized here. Enter but beware, because over 50 percent are not immunized. Do you follow what I'm saying? It's a Petri dish for measles.

Dr. Sawyer, what are your comments on that?

Dr. SAWYER. First, I'd like to agree with your very last comment about posting these rates for schools, because if we want parents to be informed about vaccines in general, we should also want them to be informed about the environment that they're putting their children in. There's no doubt that a school with 40 percent or 50 percent of unimmunized children is where the next outbreaks are going to occur, because once they get going, they'll spread.

Senator CASSIDY. Is there a push to do so? I mean, that really should be something—we should be letting parents know as much as possible about both—because I read the pediatrics article that staff provided. If a pediatrician pushes immunization, she is more likely to convince a mom to vaccinate than if she is a passive—"OK, that's fine. I'll sign the note."

To what degree are we posting individual clinics and/or individual schools? It seems like you should be doing that in Santa Monica.

Dr. SAWYER. Well, I can certainly comment for California. The rates of school vaccinations are public information. They're posted on the State's website. You have to go look for them rather than—putting them right in the face of the parent as they walk in on the first day of school might be more effective.

Senator CASSIDY. Dr. Jacks, any comments?

[No verbal response.]

OK. Well, I will yield back my 43 seconds. Thank you.

The CHAIRMAN. This time bank is getting full. We've got Senator Franken.

Senator FRANKEN. I don't think I'm going to take very long. I appreciate all of your testimony and all your answers to the questions. I just have—it may be too early to know the answer to this. Maybe—all of you are on the front lines of this, obviously.

Dr. Jacks, with your story, you're hearing a lot.

What is the public reaction to this in the last week or so? Because, hopefully, we're disseminating some information here, and the news has been. What do you sense has been the reaction to the outbreak and to all the public information and all the discussion on the news, et cetera? What has been the reaction from those parents who waived the immunization for their child? Is this being helpful? Is this a learning moment for America?

Dr. SAWYER. I would say absolutely. I have certainly heard stories from local pediatricians who have been trying to convince families for years to immunize, and when this measles outbreak happened, they were walking in the door wanting to be immunized. The publicity is very important to raise awareness about the fact that these diseases are still out there. I thank, again, the Senators for organizing this hearing to partly do that.

Dr. MOORE. Yes. I have had great experience getting a lot of good questions from the media and from families, particularly focused on our immunization exemption, which is low.

Notably, the wealthiest county in Tennessee has almost four times as high an exemption rate as the county next door—Davidson County, from Metro Nashville—among kindergarten students. That caught everyone's attention. Hopefully, even though our exemption rates don't compare to California and some other places, it's making people realize the consequences of their choices.

Senator FRANKEN. Dr. Jacks.

Dr. JACKS. I would just echo what they're saying. There's definitely been a lot of good awareness about the issue. A lot of families have come in to get immunized, both against the measles as well as other immunizations. I just had a family this last week, and the parents were kind of split on—do we vaccinate or do we not? I remembered them, and they came in and got all their vaccinations.

Senator FRANKEN. This *Lancet* article from years ago probably did a lot of damage. We've seen a—not an explosion, but a big—maybe a growth in autism, at least in the diagnosis of it, whether it's a genuine increase or just a better diagnosis, and it's a devastating thing, autism. I know that that fear resonated with people.

Again, this is maybe a wakeup moment, a learning moment, and I hope that it is. I want to thank you for being here today, and I want to thank the chairman for calling this hearing.

I'm giving you a minute and 16, but I'm the end.

The CHAIRMAN. Thank you, Senator Franken.

Senator Murray, do you have closing remarks?

Senator MURRAY. I just wanted to thank all of our witnesses today for being here and for all the work you're doing to help keep people safe from vaccine-preventable diseases. I particularly want to thank our chairman, Senator Alexander, for holding this hearing at such an important time. Thank you.

The CHAIRMAN. I thank Senator Murray for her work and her staff's work in putting together such an extraordinary group of witnesses today. This has been very, very helpful, and not just to us, but to anyone who has been listening.

Dr. Moore, we're, again, so proud of our public health department in Tennessee. I think back, not just on this, but on the quick reac-

tion to the fungal meningitis episode, where your department saved lots of lives.

Dr. Sawyer and Dr. Jacks, thank you for your leadership in your field and your testimony. The hope we have is that Dr. Jacks' message goes viral more rapidly than measles does, and that it goes fast.

I have a hard time keeping my old Governor's hat off, and it makes me think of the importance of our State organizations. CDC really works through the States. The medical associations work through their legislatures and associations, and they're in touch with parents every day.

We would like to take some step to solve this problem. The truth is, in my view, most of that reaction has to be with those who are closest to the parents and who see them regularly. The idea of a medical home for every child who is about to be born is probably the surest and best way for States to approach this, because parents who are talking to their pediatricians are going to make sure their children are vaccinated.

I have some closing remarks I'm supposed to make.

The hearing record will remain open for 10 days. Members may submit additional information and questions for the record within that time. The next hearing will occur tomorrow at 9:30 to look at the issue of ambush elections.

Thank you for being here today. The committee will stand adjourned.

[Additional Material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF THE MARCH OF DIMES FOUNDATION

ABOUT MARCH OF DIMES FOUNDATION

The March of Dimes, a unique collaboration of scientists, clinicians, parents, members of the business community and other volunteers affiliated with 51 chapters representing every State, the District of Columbia and Puerto Rico, appreciates this opportunity to submit testimony for the record of this important hearing on the re-emergence of vaccine-preventable diseases. For over 75 years, the March of Dimes has promoted maternal and child health through activities such as funding research and field trials for the eradication of polio, promoting newborn screening, and educating medical professionals and the public about best practices for healthy pregnancy. Today, the Foundation works to improve the health of women, infants and children by preventing birth defects, premature birth and infant mortality through research, community services, education and advocacy.

The March of Dimes is a national voluntary health agency founded in 1938 by President Franklin D. Roosevelt to support research and services related to polio. Over the course of almost two decades, the March of Dimes collected millions of dollars, raised one dime at a time, to fund the ground-breaking research that resulted in the Salk polio vaccine. That vaccine, along with the later Sabin polio vaccine, put to rest the fears of parents everywhere that their children would be stricken, suddenly and inexplicably, by a disease that could paralyze or kill them. This history serves as the foundation for the March of Dimes' passionate support for lifesaving vaccines and our ongoing work to promote their development and use.

BACKGROUND

The March of Dimes shares the concern expressed by many policymakers about the recent outbreak of measles that continues to spread across the Nation, and more generally about the resurgence of dangerous vaccine-preventable conditions. Over the past decades, the United States has seen the virtual elimination of many feared diseases, largely due to the development and effective administration of vaccines. Public awareness about the dangers of these diseases and the benefit of vaccines has been key to their elimination.

Infants are often more vulnerable to vaccine-preventable diseases than any other population, due to the fact that their immune systems are not fully developed enough to fight off infections that might pose less of a threat to older children and adults. In some cases, vaccines cannot be administered to young children until their immune systems have matured sufficiently to mount an effective response. As such, unvaccinated populations—be they children, adults, communities, or health or child care workers—pose an exceptional, and sometimes deadly, risk to infants.

Pertussis, commonly referred to as "whooping cough," provides a timely example. A recent surge in pertussis outbreaks across the country has raised alarms throughout the health community. Prior to the introduction of the pertussis vaccine in the 1940s, this disease was a common cause of death among infants; in 1934, the Centers for Disease Control and Prevention (CDC) reported 265,269 pertussis cases.[1] After introduction of pertussis vaccines, rates dropped dramatically, with CDC reporting only 1,010 cases in 1976.

However, pertussis cases have surged in recent years. In 2012, 48,277 cases of pertussis were reported by CDC, with many more likely unreported or undiagnosed. From 2000 through 2012, there were 255 deaths from whooping cough reported in the United States; 221 of the 255 victims who died were babies younger than 3 months of age.[2] Most of these babies contracted pertussis from older children or adults who carried the infection, most of whom were likely unaware of their carrier status. Tragically, 80 percent of infants who contract pertussis are infected by parents or other caretakers.

Hundreds of thousands of Americans fell ill or died from pertussis over the past decades, even though we had not long ago nearly eradicated the infection in the United States. This resurgence was not due to stronger pathogens or a lack of health care resources; it was due to misinformation and a lack of understanding of the importance and safety of being vaccinated.

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[1] *http://www.cdc.gov/pertussis/surv-reporting/cases-by-year.html*.
[2] *http://www.cdc.gov/vaccines/vpd-vac/pertussis/fs-parents.html*.

VACCINES, INFANTS, AND PREGNANT WOMEN

Like pertussis, measles has re-emerged, despite having been declared eradicated in 2000. The measles vaccine became available in 1963, and less than 40 years later, the United States was declared free of endemic measles due to widespread vaccination. Vaccination rates dropped, and new cases started to emerge. In 2011, the highest number of measles cases since 1996 was reported. 2015 is on track to record a higher number yet.

As discussed above, declining vaccination rates are causing a resurgence of pertussis as well. In 2010, California saw the largest outbreak of pertussis cases since 1947. A study in *Pediatrics* evaluated the association between non-medical exemptions from immunization requirements and outbreaks. It found that the California outbreak was associated with clusters of unvaccinated children with non-medical exemptions.

The proliferation of non-medical exemptions erodes the overall effectiveness of immunizing the U.S. population against dangerous conditions. A single child who is not vaccinated can place at risk not only themselves but many others, including some who cannot be vaccinated for medical reasons. According to the CDC, nonmedical exemptions are on the rise with a national rate of 1.8 percent, but much higher rates in certain communities.[3]

Although the lack of immunization among the general public and clustered in various communities is dangerous, certain populations are especially critical to vaccinate in order to protect infants. Health care workers such as NICU nurses, orderlies, and doctors are often in close contact with both families and extremely vulnerable populations.

Child care workers are also often in regular contact with children and youth who may be carriers, and also with infants who have not yet developed strong immune systems. For those who are more likely to bridge contact between the vulnerable and the infected, vaccinations should be prioritized, and when appropriate, required.

Pregnant woman are also a priority population for influenza and pertussis (tetanus-reduced diphtheria toxoid-acellular pertussis booster, or "Tdap") vaccinations. Despite the proven benefits of certain immunizations for pregnant women and their infants, maternal immunization rates in the United States remain low. Influenza immunization is known to benefit pregnant women, conferring lower and less severe flu incidence,[4] [5] and flu shots are associated with reducing preterm birth in women immunized while pregnant.[6]

Similarly, studies indicate that vaccination with the Tdap vaccine during the final trimester of pregnancy could reduce hospitalizations due to pertussis during an infant's first months of life, when the infant cannot be immunized directly.[7] Nevertheless, maternal influenza immunization rates have hovered just above 50 percent for the past few years after increasing during the H1N1 epidemic,[8] [9] [10] and Tdap immunization rates are only about 29 percent, with some Tdap immunizations taking place outside the time range recommended for optimal efficacy.

POLICY RECOMMENDATIONS

The United States has shown that we can defeat diseases like polio, measles and pertussis. In order to do so, however, a concerted, long-term effort is crucial. Any lapse in our vigilance and commitment can allow these deadly diseases to return and spread unabated. For that reason, the March of Dimes urges Congress to main-

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[3] *http://www.cdc.gov/mmwr/preview/mmwrhtmi/mm6341a1.htm*.

[4] Jackson LA, Patel SM, Swamy GK, et al. Immunogenicity of an inactivated monovalent 2009 H1NI influenza vaccine in pregnant women. *The Journal of Infectious Diseases, 204*(6), 854–63.

[5] Jamieson DJ. Kissin DM, Bridges CB, Rasmussen SA. Benefits of influenza vaccination during pregnancy for pregnant women. *American Journal of Obstetrics and Gynecology, 207*(3 Suppl), S17–20.

[6] Omer SB, Goodman D, Steinhoff, MC, et al. Maternal influenza immunization and reduced likelihood of prematurity, and small for gestational age births: a retrospective cohort study. *PLoS Medicine. 8*(5), el000441.

[7] Peters TR, Banks GC, Snively BM, Poehling KA. Potential impact of parental Tdap immunization on infant pertussis hospitalizations. *Vaccine, 30*(37), 5527–32.

[8] Centers for Disease Control and Prevention. Influenza vaccination coverage among pregnant women—United States. 2010–11 influenza season. *MMWR, 60*(32), 1078–82. Retrieved from *http://www.ncbi.nlm.nih.gov/pubmed/21849964*.

[9] Centers for Disease Control and Prevention. Influenza vaccination coverage among pregnant women: 2011–12 influenza season, United States. *MMWR*, 61, 758–63. Retrieved from *http://www.ncbi.nlm.nih.gov/pubmed/23013721*.

[10] Bridges CB. Preliminary Results Tdap Vaccination Coverage Among Pregnant Women—September 2013 presentation to NVAC. Washington, DC. Retrieved from *http://www.hhs.gov/nypo/nvac/meetings/pastmeetings/2013/tdap__vaccination__women__coverage__sept2013*.

tain and strengthen our commitment to the multi-faceted national strategy required to keep infectious diseases in check. This can be achieved through appropriate funding for a wide array of programs, including the Vaccines for Children program, Section 317 Immunization Grant Program for States, CDC and State surveillance and reporting, and similar efforts.

In addition to these vital Federal programs, the March of Dimes strongly supports actions at the State and local levels to promote universal childhood immunization.

School immunization requirements are a vital public health tool to promote the health of all children and to protect those schoolchildren who cannot be vaccinated for medical reasons. The March of Dimes opposes non-medical immunizations and works to educate parents and caregivers about the importance of vaccinating their children on time in accordance with the CDC's recommendations. The March of Dimes also supports State-based programs that increase access to immunizations, such as public health clinics, and that remove cost as a barrier to lifesaving vaccines.

CONCLUSION

Thank you for your attention to this vitally important child and maternal health issue. The March of Dimes is committed to working with Congress and other stakeholders to develop and implement solutions, to provide timely information and education, and to procure and make the investments needed to improve the health of every mother and child.

RESPONSE BY ANNE SCHUCHAT, M.D. (RADM, USPHS) TO QUESTIONS OF SENATOR ROBERTS, SENATOR CASSIDY, SENATOR CASEY, SENATOR BALDWIN AND SENATOR WARREN

SENATOR ROBERTS

Question 1. Given that many of our health care professionals were trained after we thought we had eliminated diseases like measles, what efforts has the CDC undertaken to help providers identify symptoms and take appropriate action when coming across a possible case of measles?

Answer 1. CDC recognizes that early detection of measles cases is critical to limiting further spread of the disease. CDC has and continues to develop and disseminate key information to healthcare providers, partners and the general public to increase awareness of measles and the importance of vaccination. CDC uses social media, Web sites, media briefings and other communication strategies to share information. Specific to direct healthcare provider outreach, CDC issued a Health Alert Network message, a mechanism for sharing information about urgent public health incidents, "U.S. Multi-State Measles Outbreak, December 2014–January 2015" on January 23, 2015. In addition, CDC held a Clinician Outreach and Communication Activity (COCA) call, a mechanism to prepare clinicians for response to emerging public health threats and public health emergencies, on February 19, 2015. The purpose of this call was to discuss the current status of measles outbreaks in the United States; describe the clinical presentation of measles and the guidelines for patient assessment and management; outline CDC vaccination recommendations for the general public, international travelers, and healthcare professionals; and identify CDC measles resources and training materials for clinicians.[1] Additionally, CDC has a dedicated hotline and email account for specific questions from clinicians or the general public regarding measles and measles vaccination.[2]

CDC has collaborated across the Department of Health and Human Services, including partnering with the Health Resources and Services Administration (HRSA) to leverage its networks of providers and organizations that serve vulnerable populations. CDC also works with healthcare organizations, including the American Academy of Pediatrics and the American Academy of Family Physicians, to distribute weekly information through email blasts and newsletters. Together, we also co-branded an infographic to help with communication efforts.[3]

Question 2. What guidance or advice does the CDC give to the parents of kids who cannot be immunized due to allergies or because they are otherwise immunocompromised and must rely on others in their community to choose vaccination to help protect their own?

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[1] The archived webcast and transcript are accessible at *http://emergency.cdc.gov/coca/calls/2015/callinfo_021915.asp*.

[2] 1-800-CDC-INFO or *nipinfo@cdc.gov*.

[3] Available at *http://www.cdc.gov/measles/parent-infographic.html*.

Answer 2. Those who cannot be immunized due to allergies or because they are otherwise immunocompromised rely on "community immunity". Community immunity is achieved when a critical portion of a community is immunized against a contagious disease, allowing for most members of the community to be protected against that disease because there is little opportunity for an outbreak. Even those who are not eligible for certain vaccines—such as infants, pregnant women, or immunocompromised individuals—get some protection because the spread of contagious disease is contained. For this reason, it is critical to maintain high vaccination coverage rates among persons eligible for vaccination. Parents of immunocompromised children should talk with their pediatric healthcare provider about how best to protect their child from vaccine-preventable diseases. Parents should also be encouraged to talk to childcare facilities to learn about their vaccination policies and requirements.

SENATOR CASSIDY

Question 1. The United States conducts screening for communicable diseases in some cases, such as Hepatitis C screening for those entering the United States for adoption. Can you explain why those who emigrate from some countries are not being screened for measles? Why is there a difference in policy?

Answer 1. Immigrants (including adoptees) and refugees are required to receive an overseas medical examination in accordance 42 CFR, Part 34: Medical Examination of Aliens. The requirements focus on the detection of class A conditions, most notably active tuberculosis and syphilis.

(a} Hepatitis C is not a class A condition and screening is not required or performed as part of the overseas medical examination.

(b) Class A conditions include:

1. Tuberculosis
2. Syphilis
3. Chancroid
4. Gonorrhea
5. Granuloma inguinale
6. Lymphogranuloma venereum
7. Hansen's disease (leprosy)
8. Mental Disorders (with Associated Harmful Behavior)
9. Substance Abuse

OVERSEAS VACCINATION

As part of the overseas medical examination, vaccinations are required for immigrants. On November 13, 2009, CDC posted a Federal Register Notice revising the vaccination criteria for U.S. immigration. CDC uses these criteria for vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) to decide which vaccines will be required for U.S. immigration. The criteria are used at regular periods, as needed, by CDC. Measles vaccination has been and continues to be required for all immigrants.[4]

(a) The age-appropriate vaccinations required for the immigration examination based on the above criteria or per 8 U.S.C. 1182(a)(1) are:

1. Diphtheria
2. Tetanus
3. Pertussis
4. Polio
5. Measles
6. Mumps
7. Rubella
8. Rotavirus
9. Haemophilus influenzae type b
10. Hepatitis A
11. Hepatitis B
12. Meningococcal
13. Varicella
14. Pneumococcal
15. Influenza

[4] See *http://www.cdc.gov/immigrantrefugeehealth/exams/ti/panel/vaccination-panel-technical-instructions.html#adoptees.*

(b) Adoptees are one class of immigrant visa holders and therefore fall under the same vaccination requirements as immigrants. However, certain adoptees are eligible for exemption for vaccinations.[5]

1. The vaccination requirements do not apply to adopted children 10 years of age or younger, provided the adoptive parent, prior to the child's admission, signs an affidavit stating that the parent is aware of U.S. vaccination requirements and will ensure that the child will receive all required vaccinations within 30 days of the child's arrival in the United States.[6]

2. The Hague Adoption Convention governs adoptions between the United States and other countries in the convention.[7] For countries both in the convention (Hague) and not in the convention (non-Hague), the vaccination requirements do not apply to adopted children 10 years of age or younger, provided the adoptive parent, prior to the child's admission, signs the affidavit concerning exemption from immigrant vaccination requirements for a foreign adopted child.

3. If the adopted child has a history of vaccinations, the panel physician must complete the DS–3025 form if reliable vaccination documents are available.

(c) Refugees are not required to have vaccinations overseas before arriving in the United States but they are required to have vaccinations when they are eligible to adjust their status 1 year later to legal permanent resident. However, because of the public health benefits of vaccination in reducing the importation of vaccine-preventable diseases and improving the health of U.S.-bound refugees, CDC and the Department of State are currently supporting a program to provide routine vaccinations, including measles, to U.S.-bound refugees resettling from Ethiopia, Kenya, Uganda, Thailand, Malaysia and Nepal.[8]

POST-ARRIVAL HEPATITIS C SCREENING

(a) After arrival in the United States, refugees undergo a voluntary health assessment conducted in their State of resettlement. Hepatitis C screening may be recommended as consistent with guidelines for the general U.S. population.[9]

(b) The same general U.S. guidelines would apply to immigrants and adoptees.[10]

Question 2. Since the measles outbreaks are not widespread, but rather isolated in certain communities, can the CDC and States target prevention and notification strategies to these areas? For example, can you require that schools and clinics be required to post immunization rates especially in areas with low immunization rates, so that parents are aware of the risk to their children or the absence of herd immunity? This strategy would help parents with children whose immune systems are compromised to avoid exposing them to unnecessary risk.

Answer 2. CDC's National Immunization Survey (NIS) is essential to assessing national progress, documenting programmatic achievements, and identifying disparities in immunization coverage rates. This information is used by CDC and State and local immunization programs to target outreach efforts. Each year, to assess State and national vaccination coverage and exemption levels among kindergartners, CDC analyzes school vaccination data collected by federally funded State, local, and territorial immunization programs. CDC and the States also publish exemption rates. Eighteen States provide local-level data online, helping to strengthen immunization programs, guide vaccination policies, and inform the public. Local-level school vaccination and exemption data can be used by health departments and schools to focus vaccine-specific interventions and health communication efforts in a school or local area with documented low vaccination coverage or high exemption rates. Where expanded health communication strategies or other interventions are implemented, continued assessment and reporting can be used to facilitate program improvement. Vaccination requirements are within the purview of State authority. Although CDC does not have regulatory authority over schools or healthcare facili-

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[5] Some information about vaccinations for adoptees is located at: *http://www.cdc.gov/immigrantrefugeehealth/adoption/overseas-exam.html* and *http://www.cdc.gov/immigrantrefugeehealth/exams/ti/panel/vaccination-panel-technical-instructions.html*. General information about adoption is available at: *http://www.cdc.gov/immigrantrefugeehealth/adoption/index.html*.

[6] See *http://www.state.gov/documents/organization/80002.pdf* for the affidavit form.

[7] See *http://adoption.state.gov/hague_convention/overview.php*.

[8] See *http://www.cdc.gov/immigrantrefugeehealth/guidelines/overseas/interventions/immunizations-schedules.html*.

[9] *http://www.cdc.gov/immigrantrefugeehealth/guidelines/domestic/hepatitis-screening-guidelines.html*.

[10] Specific guidelines for adoptees can be found at *http://wwwnc.cdc.gov/travel/yellowbook/2014/chapter-7-international-travel-infants-children/international-adoption*.

ties, it encourages its State and local public health partners to make county-level exemption data available.

SENATOR CASEY

Question 1. In your written testimony, you discussed the first U.S. measles vaccination program, which started in 1963. Did this program encounter any resistance to vaccination, similar to the resistance we are seeing from some individuals today? If so, how did it counter this resistance, and are there any important lessons that we can use for countering public resistance to vaccination in the 21st century?

Answer 1. Before the availability of the measles vaccine, there were an estimated 3–4 million cases of measles annually in the United States. In the years that followed the introduction of the vaccine, measles declined 98 percent in the United States, suggesting widespread public support for the vaccine. The measles resurgence of 1989–91 was largely attributed to lack of access rather than decisions to forgo vaccination, and was the impetus for the Vaccines for Children Program, which provides vaccines to eligible uninsured and underinsured children nationally.

The current outbreak of measles is an indication of how globally connected we are. Measles is still endemic in many parts of the world, with 20 million cases occurring worldwide annually. Even though both CDC and the U.S. Agency for International Development support many countries in building stronger immunization programs to vaccinate more children around the world with multiple vaccines, including measles, importations of measles remain a significant challenge. Unvaccinated U.S. residents traveling overseas are at risk for measles, and returning U.S. residents and foreign visitors to the United States may develop measles and expose unvaccinated people in the United States. When measles gets into communities of unvaccinated people in the United States, such as people who refuse vaccines for religious, philosophical, or personal reasons, outbreaks are more likely to occur. New research recently published in the journal *Pediatrics* has found that people who seek personal-belief exemptions for their children often live near one another. We think these micro-communities are making it difficult to control the spread of measles and are making us vulnerable to having the virus re-establish itself in our country again. In addition, they put others at risk who cannot get vaccinated because they are too young or they have specific health conditions.

Question 2. You stated that 1 in 12 children in the United States is not receiving his first dose of measles-mumps-rubella vaccine on time. Has CDC collected any data on the reasons why this is happening with this specific vaccine? For example is it mostly happening because parents object to vaccines, or is access to vaccines an issue, or is some other reason to blame? If CDC has not collected data on this, do you plan to collect data on this in the future?

Answer 2. Unlike the measles outbreaks in the 1980s and 1990s, access to vaccines does not appear to be the contributing factor to the current outbreak. Coverage levels for many childhood vaccinations are at, near, or above 90 percent, and reported cases for most vaccine-preventable diseases have decreased by 90 percent or more in the United States. The creation of the Vaccines for Children Program (VFC) has been instrumental to achieving these high vaccination coverage rates and reducing disparities. The VFC program serves children through 18 years of age who are uninsured, underinsured, Medicaid-eligible, or American Indian or Alaska Native. CDC purchases and distributes vaccines to VFC-enrolled providers and provides funding to 61 eligible awardees for VFC-related operations activities. Currently, there are more than 44,000 public and private providers in the VFC program, and VFC distributes over 50 percent of all routinely recommended vaccines for those 18 years and younger.

The current measles outbreak is an indicator of how globally interconnected we are, with measles importations uncovering those communities opting out of immunization, and indicating those communities may be getting larger. Although the majority of parents recognize the benefits of immunization and have their children vaccinated, with less than 1 percent of toddlers receiving no vaccines, certain concerns lead some parents to delay or refuse vaccinations. CDC has conducted research to better understand why some parents choose not to vaccinate their children. Parents give many reasons for vaccine hesitancy despite overwhelming and consistent scientific evidence that vaccines are safe and effective. For some, many vaccine-preventable diseases don't have the visibility they once had and many parents question whether vaccines are more dangerous for their child than the diseases they prevent. Parents also have access to conflicting and often inaccurate information about vaccines via the Internet, and others express concern that there are too many vaccines given early in life. Before 1985, the recommended immunization schedule included only seven vaccines. The good news is that today, we can protect children younger

than 2 years of age from 14 potentially serious diseases with vaccines. However, this has created a "crowded" and complex schedule for parents and providers. While some parents express concern about the number of vaccines in the childhood immunization schedule, the scientific evidence has shown that the immunization schedule is safe, and there is no evidence that suggests that the recommended childhood vaccines can "overload" the immune system.

CDC knows that maintaining public confidence in immunizations is critical to maintaining high vaccination coverage rates and preventing outbreaks of vaccine-preventable diseases. CDC supports science-based communication campaigns and other efforts to convey the benefits of vaccines to the public to aid individuals in making informed vaccine decisions to protect themselves and their loved ones. CDC also conducts outreach to educate healthcare providers about current immunization policy and clinical best practices to help them protect their patients and communities from VPDs. CDC developed and will maintain a dynamic provider toolkit for conversations with parents about vaccination that includes evidence-based strategies, print materials, and web-based tools.

Question 3. How do MMR vaccination rates compare to the rates for other early childhood vaccines?

Answer 3. Like most childhood vaccines, the overall measles vaccination coverage rate is high at 92 percent. However, 1 in 12 children in the United States is not receiving his/her first dose of MMR vaccine on time, leaving them unnecessarily vulnerable to vaccine-preventable diseases. This underscores considerable measles susceptibility across the country. In addition, we see variability in coverage across States. In 2013, there were 17 States where fewer than 90 percent of toddlers had received at least one dose of MMR. Within States, some counties or communities have much lower vaccination rates than the State average.[11]

SENATOR BALDWIN

Question 1. In 2004, we saw a dangerous shortage of influenza vaccine in the United States due in part to disruptions in vaccine production overseas and our insufficient domestic production capabilities. Since that time, can you please explain what work the CDC is doing to:

- Ensure that we have a sufficient number of domestic vaccine manufacturers and robust domestic production capabilities;
- Help speed development of vaccines with advanced techniques and technologies such as cell-based manufacturing processes; and
- Increase communication and notice to providers as well as other producers when a vaccine manufacturer exits the market?

Answer 1. CDC works closely with public health and provider organizations to ensure that issues related to vaccine supply are communicated in a timely fashion and that messaging is shared directly with providers. While there has not a been a specific recent issue related to flu-vaccine manufacturers exiting the market, CDC's collaboration with public health and provider organizations, as well as CDC's direct communication with its immunization awardees, provides an important communication channel for sharing information related to influenza vaccine supply and availability.

SENATOR WARREN

Question 1. Because of smart investments over the last several decades, we now have a vaccine for HPV that helps to prevent cancer, and a vaccine for Hepatitis B that can prevent liver cirrhosis and cancer associated with the virus. We also have vaccines that can prevent some types of meningitis and pneumonia. We are still struggling, however, to make sure that everyone has access to all of the vaccines available. What do you see as the greatest challenges to getting people of all ages—kids, teens, and seniors—vaccinated?

Answer 1. While we have achieved high coverage rates for most childhood and adolescent vaccines, we have a long way to go regarding human papilloma virus (HPV) vaccination, which prevents virtually all cervical cancers, as well as other types such as anal, vulvar, and oropharyngeal cancers. HPV vaccination coverage is troublingly low, with only a third of U.S. girls receiving all three recommended doses of HPV vaccine. The yearly national vaccination coverage estimate among female teens for one dose of HPV vaccine has been more than 20 percent lower than the estimate for one dose of Tdap vaccine (a booster given to adolescents to extend

[11] Additional information on vaccine coverage rates, including rates by State can be found at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6334a1.htm's_cid=mm6334a1_w.*

coverage of the childhood diphtheria-tetanus-pertussis vaccine), demonstrating that critical opportunities are being missed to vaccinate young people against HPV with a vaccine known to be safe and effective for cancer prevention.

To reach adults, we need different strategies than we have used with the childhood program. Unlike children, who have scheduled routine visits with their pediatrician, adults may see multiple physicians for specialty care, many of whom may not offer vaccination services. CDC is working to increase awareness of the need for vaccines for adults among the general population and the provider community. We are also looking at increasing access through non-traditional venues, including pharmacies and retail clinics. CDC has developed new educational materials aimed at increasing the public's awareness about vaccines that adults need and is partnering with a wide range of vaccine providers, including medical, pharmacy and nursing organizations, and State and local health departments to increase awareness of the low rates of adult immunization and to increase implementation of the standards of adult immunization practice. These standards include assessing adult patients' vaccination needs on a routine basis, recommending needed vaccines, and then either offering vaccines, or if the provider does not stock the vaccine, referring the patient to a vaccine provider in their area. Providers and patients are both able to find vaccine providers in their areas through use of the healthmap.org website. Patients can also take the CDC vaccine quiz to find out which vaccines might be right for them.[12] Taking the quiz generates a list of vaccines a person might need based on their age, medical conditions, prior vaccinations and other factors. Patients can then take this list to their provider to discuss which vaccines they need. In addition, the National Vaccine Advisory Committee will be releasing a National Adult Vaccine Plan that will help identify strategies for improving adult vaccine coverage.

Immunizations are never complete. Every day, babies are born who will require vaccines to prevent 17 diseases across their lifespan. In addition to addressing barriers to vaccination across the lifespan, public health conducts ongoing monitoring of the safety and efficacy of the Nation's vaccine policies and programs. The critical public health workforce and systems that make this possible must be maintained to continue our success.

RESPONSE TO QUESTIONS OF SENATOR CASEY BY TIM JACKS, M.D., DO, FAAP

Question. As a physician, and as a parent, what response would you have for a parent who says that measles is a more acceptable health risk for their children than what they feel are the potential health risks of vaccines?

Answer. As a physician, I would reference back 52 years before there was a measles vaccine. At that time, there were 500,000 cases of measles per year in the United States. Measles caused severe illness, over 25 percent of cases required hospitalization, about 500 people had encephalitis (brain swelling/damage) and about 500 people died each year from measles. In contrast, the MMR vaccine is extremely safe, and severe allergic reactions occur in less than one per million vaccinated. Measles is extremely contagious (>90 percent unprotected exposed people contract it), and the vaccine is every effective (>99 percent protection after the two recommended doses).

As a father, I would speak from personal experience of my daughter's exposure. Not vaccinating puts not only your child at risk but also the larger community—those too young or unable to be vaccinated for medical reasons. For my leukemia-battling daughter, there was a very real risk of severe illness or death if she had contracted measles.

RESPONSE TO QUESTIONS OF SENATOR CASEY BY MARK H. SAWYER, M.D., FAAP

Question 1. In your written testimony, you discussed the importance of the Vaccine Adverse Event Reporting System (VAERS) for continually monitoring the safety of vaccines and ensuring that any potentially unsafe patterns are quickly recognized. Do you feel this system is adequate to protect the American public? Is there any aspect of it that you would like to see improved?

Answer 1. The VAERS system has been very effective in calling attention to possible vaccine side effects but it is not adequate alone to protect the American public. An association between the administration of a vaccine and an adverse event does not prove causation. It would be a grave error to rely on such associations reported to VAERS to dictate vaccine policy. What is required is a companion system, such as the current Vaccine Safety Datalink (VSD) which is organized and supported by the Centers for Disease Control and Prevention. The VSD allows events reported

[12] The quiz can be accessed at *http://www.cdc.gov/vaccines/adults/index.html*.

in VAERS to be studied epidemiologically to prove cause and effect. By studying possible vaccine side effects in the millions of people covered by the VSD we can tell the public exactly how safe vaccines are. This will never be possible during the initial studies conducted by manufacturers when vaccines are being developed because it is impossible to study enough people. The ongoing support for the VSD or similar system is key to maintaining the public's trust in the safety of vaccines. The current funding of the VSD does not allow every possible vaccine side effect to be researched and in my opinion this program should be expanded so that all possible effects of vaccines can be studied.

Question 2. You stated that none of the pediatric residents during a training session reported ever seeing a case of measles, but that you feel that this may change. In what ways, if any, do you think pediatric training should change in order to account for the reluctance of some parents to vaccinate their children, and the reemergence of vaccine preventable illnesses such as measles?

Answer 2. Clearly we are in an era where parents are challenging the advice of doctors. For example, a study published in Pediatrics on March 2 found that the number of parents who are asking to delay their children's vaccination schedule has increased in the last several years. Doctors need to be trained in effective communication in order to impart sound medical advice in this environment. I believe medical educators have recognized this need and are adding curricular materials to their training programs to prepare future doctors for these conversations. I celebrate the fact that young doctors have never seen measles and some types of bacterial meningitis—this is testimony to the tremendous impact of vaccines.

Question 3. You discuss the need to restrict exemptions from school entry requirements in order to help boost vaccine rates. Many State legislatures are currently dealing with this issue, and often they will hear testimony from parents who are seeking broader, non-religious moral exemptions. What factors would you advise State legislators to consider when they hear testimony from these parents?

Answer 3. Central to this issue is the role of government in protecting the public's health. Legislators need to be current in their understanding of the science that supports the utility and safety of vaccines. They also need to have a firm grasp on the impact of unimmunized populations on the general health of the community. There is ample precedent for creating laws that curb some personal choice in favor of protecting the public's health (e.g., public smoking). Those opposed to vaccination will present legislators anecdotes linking adverse health outcomes to vaccines. Left unchallenged these anecdotes will sound compelling and lead to poor policy decisions. I would encourage legislators to probe those who offer anecdotes for scientific evidence that supports the anecdote. It is human nature to assume that if event B happened after event A then event A caused event B. This obviously is not always the case. Legislators need to access the science that confirms the safety of vaccines.

Question 4. Is there any research being done to develop less invasive vaccinations (e.g., flu nasal mist instead of the flu shot)? Do you think less invasive immunizations would sway more parents to vaccinate their children?

Answer 4. Yes, non-injection methods of vaccine delivery are being evaluated and I do think their availability will help. No parent wants to see their child suffer pain. We currently have some oral vaccines and one nasal spray vaccine. If vaccines can be given orally, nasally, or even through the skin using patch technology then much of the objection to vaccines would vanish. Perhaps there is a role for the Federal Government to fund research toward this end.

Question 5. Dr. Jacks shared his story in which his children were exposed to measles in the hospital. Are there systems in place to limit immunocompromised patients' exposure to patients with infectious disease?

Answer 5. Certainly hospitals have systems in place to minimize exposure to infectious disease. Fortunately there are only a few infections that literally fly through the air so that you can acquire infection simply by breathing the air. Measles is one such infection but most infections require direct contact or at least close exposure to an infectious person. Doctor's offices may not be as effective as hospitals in preventing infections from spreading. They often don't have the luxury of isolation rooms to place potentially contagious individuals. Efforts could be increased to screen for possibly infectious patients in doctor's waiting rooms and at least trying to keep them out of waiting rooms.

RESPONSE TO QUESTIONS OF SENATOR CASEY BY KELLY L. MOORE, M.D., MPH

Question 1. You have described your collaborative immunization efforts with schools, public health departments, and medical offices. The program for Women, Infants, and Children (WIC) is one such public health program that often plays a role in improving immunization rates of infants and young children through screening and referral. WIC visits can be particularly influential in boosting MMR immunization rates because the first dose is given at about 12–15 months of age. Could you describe how your State's WIC programs help achieve high immunization rates?

Answer 1. In Tennessee, the WIC offices are co-located with immunization services at our local health departments. WIC program staff review immunization records and refer children to the immunization clinic if they are behind on immunizations. Immunization and WIC visits can be scheduled at the same time for family convenience. Regular contact with WIC staff who promote and counsel parents about immunization helps keep immunization rates high among infants and toddlers.

Question 2. You mentioned how beneficial your electronic immunization information system, known as TennIIS, has been in providing access to immunization records across medical and non-medical settings. Can you tell us what kinds of steps you've taken to encourage use of the data base by providers, schools, and daycares?

Answer 2. We promote the use of TennIIS through statewide professional meetings of pediatricians and family physicians, as well as with our partners in pharmacies, schools and school nursing. The Department of Health made its first major effort to introduce immunization providers to the States immunization information system (IIS) in preparation for the 2009 H1N1 influenza pandemic vaccination campaign when we expanded the system to function as a lifelong immunization registry not limited to children. All immunization providers who were interested in assisting with national immunization efforts were required to create a free IIS user account for their healthcare facility, including outpatient pediatric and adult clinics, hospitals and pharmacies. Over 5,000 new individual users were added during that time.

Today, the over 700 clinics participating in the Federal Vaccines for Children Program (VFC) are required to use TennIIS to manage online annual enrollment documents and to place vaccine orders. In addition, any TennIIS user (including pharmacists and school staff) can produce a simple, complete and accurate Official Immunization Certificate for children entering daycare or school, based on the child's record in TennIIS. If the record is incomplete, TennIIS produces a failed validation report that pinpoints shortcomings in the child's record of required immunization. This tool, while not mandatory, is so effective at eliminating errors and saving time for families and clinic staff that many immunization providers serving children consider TennIIS so helpful they cannot imagine not participating.

Finally, Tennessee has reaped the benefit of the Center for Medicaid and Medicare Services (CMS) Meaningful Use grants to clinicians and hospitals to promote the implementation of interoperable electronic health record systems (EHRs). As part of that program, participating facilities that administer any immunizations are required to submit immunization data to the State IIS through standard messaging protocols. TennIIS staff are working as quickly as possible to activate channels between EHRs and TennIIS among participants in the Meaningful Use program, which will greatly improve the volume of valuable patient immunization information in our voluntary system.

RESPONSE TO QUESTIONS OF SENATOR ROBERTS BY MARK H. SAWYER, M.D., FAAP

Question. What advice do you give to the parents of kids who cannot be immunized due to allergies or because they are otherwise immunocompromised and must rely on others in their community to choose vaccination to help protect their own?

Answer. Parents of children who cannot be immunized due to allergy or an immunocompromising condition should try to minimize the exposure of their children to unimmunized populations. This begins with the immediate family. Parents should assure that all members of the family are current on their immunizations including an annual influenza vaccine. It would also be prudent for such parents to inquire about the vaccination status of participants in organized group settings such as daycare or school and when feasible only choose to place their at-risk child among highly immunized populations. Toward this end, it would be ideal if daycare facilities and both public and private schools were required to make their immunization coverage rates readily available.

RESPONSE TO QUESTIONS OF SENATOR WARREN BY TIM JACKS, M.D., DO, FAAP

Question. Because of smart investments over the last several decades, we now have a vaccine for HPV that helps to prevent cancer, and a vaccine for Hepatitis B that can prevent liver cirrhosis and cancer associated with the virus. We also have vaccines that can prevent some types of meningitis and pneumonia. We are still struggling, however, to make sure that everyone has access to all of the vaccines available. What do you see as the greatest challenges to getting people of all ages—kids, teens, and seniors—vaccinated?

Answer. While there are numerous hurdles to increasing vaccination rates, the greatest challenge is educating the public. Many people don't realize the dangers that these illnesses pose, and they are more afraid of the prevention (vaccines) than the actual illness.

It has proven challenging to communicate the safety and effectiveness of vaccines. The Nyhan study (published in Pediatrics, March 3, 2014), showed that public health communications may not be effective in reducing misconceptions or increasing vaccine uptake. As a pediatrician, I have found this to be true. We have limited time to evaluate a child and educate the parents about vaccines. Many families are ready to immunize. Some families need just a little nudge to proceed with vaccinations. For others, it takes repeated discussions and exposure to the scientific truth behind vaccines before they reach a decision. A minority of families arrive to my office having already decided against vaccines due to widely prevalent myths and misconceptions on the internet and in popular media. Often these families are not even open to discussing vaccines or their concerns.

Another study, published earlier this month in Pediatrics (March 2, 2015), that found an increasing number of parents asking to delay their children's vaccinations. The timely prevention and proximate risk of disease has been lost to these parents. During the recent measles outbreak, my office saw a great influx of families requesting vaccinations. Many were immunized. Sadly, we have since seen a decline in those coming in for catch-up vaccines.

While education is also important in the elderly population, they face a greater lack of insurance coverage when compared to children. VFC, section 317, Medicaid and CHIP have helped get large numbers of children vaccinated, but adults still lag. The mandated coverage of CDC recommended vaccination through the ACA will help expand coverage.

RESPONSE TO QUESTIONS OF SENATOR WARREN BY MARK H. SAWYER, M.D., FAAP

Question. Because of smart investments over the last several decades, we now have a vaccine for HPV that helps to prevent cancer, and a vaccine for Hepatitis B that can prevent liver cirrhosis and cancer associated with the virus. We also have vaccines that can prevent some types of meningitis and pneumonia. We are still struggling, however, to make sure that everyone has access to all of the vaccines available. What do you see as the greatest challenges to getting people of all ages—kids, teens, and seniors—vaccinated?

Answer. Historically, one of the biggest barriers to adequate immunization in our communities has been insurance coverage for vaccines. Prior to the Vaccines for Children (VFC) program many children went unvaccinated because they either didn't have insurance or because their insurance didn't cover all vaccines. This is no longer a problem and it is imperative that the VFC program remain supported. More recently, the Affordable Care Act assured that all vaccines recommended by CDC would be covered by insurance programs. This has made a huge difference for adults who are not eligible for VFC vaccine. It is equally important that this important legislation remain intact so that vaccines are accessible to all.

Beyond the funding for vaccines the biggest challenge facing us is the education of the public about the benefits of vaccines and the maintenance of the infrastructure to assure vaccine safety. In order to maintain the public's trust, systems such as the joint CDC/FDA Vaccine Adverse Events Reporting System (VAERS) and the CDC-sponsored Vaccine Safety Datalink (VSD) program are extremely important for studying any new vaccine safety concerns that arise.

Finally, we need to raise the science literacy of our communities. The science curricula of our middle and high schools need to include education on the immune system, infectious diseases, and immunizations. We need our next generation of parents to make better decisions about immunizing their children in order to protect our whole community.

RESPONSE TO QUESTIONS OF SENATOR WARREN BY KELLY L. MOORE, M.D., MPH

Question. Because of smart investments over the last several decades, we now have a vaccine for HPV that helps to prevent cancer, and a vaccine for Hepatitis B that can prevent liver cirrhosis and cancer associated with the virus. We also have vaccines that can prevent some types of meningitis and pneumonia. We are still struggling, however, to make sure that everyone has access to all of the vaccines available. What do you see as the greatest challenges to getting people of all ages—kids, teens, and seniors—vaccinated?

Answer. The challenges associated with achieving the potential of vaccines to prevent disease in the United States vary by age group: Among children, the Vaccines for Children Program (VFC) guarantees affordable access to eligible children who represent about 50 percent of all children under 19 years of age. Immunization rates are high among young children; in some ways, immunization programs have been victims of our own success. Many young parents are unfamiliar with the diseases vaccines prevent and have unrealistic perceptions of the risks of vaccines. Our greatest challenge in this age group is to convince parents of the safety and essential importance of timely immunization with all recommended vaccines.

Among teens, parents need to understand that there are important immunizations needed during the teenage years. In many States, like ours, preteens are required to obtain the tetanus-diphtheria-pertussis (Tdap) booster to go to school, which gives us an opportunity to administer all recommended vaccines at that time; however, our greatest challenge is vaccination against HPV to prevent cancer associated with this common virus. There is a misconception that this vaccine should be given "just in time" for sexual activity and that leads many parents and healthcare providers to put off immunization. We know that it is more difficult to complete a vaccine series in an older teen. We know that the vaccine is long-lasting and only works to prevent (not treat) infection, so it is safe and ideal to give it years before sexual activity begins. We also know that the HPV vaccine triggers a better immune response when given to preteens. For these reasons, we are working to convince healthcare providers and parents of the critical importance of completing this vaccine on time during the preteen years to give the next generation of young men and women the best chance at a lifetime of cancer protection.

Among adults, two major challenges we face are awareness of the need for vaccines and affordable access to those needed vaccines. Adults are often unaware of the vaccines recommended for them, including Tdap, shingles vaccine, influenza and two types of pneumococcal vaccine. Insurance plans in compliance with the Affordable Care Act cover all recommended vaccines with no deductible or copay if administered at an in-network provider location; however, if an in-network provider does not offer the recommended vaccine, the adult may have difficulty with access, particularly in rural areas where the local health department clinic or local pharmacy may not be an in-network provider. We are working with adult caregivers and pharmacists to raise awareness about important adult immunizations and to simplify access for adults to the vaccines they need at convenient times and locations. Routine documentation of adult immunizations in a State's immunization information system (IIS) can prevent missed immunizations and excess immunizations that result from missing records for adults, just as the IIS helps children. Efforts are underway to encourage adult immunization providers and pharmacists to participate actively in State IIS in all States that have lifelong immunization information systems, as Tennessee does.

[Whereupon, at 11:53 a.m., the hearing was adjourned.]

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