

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Centers for Disease Control and Prevention (CDC)
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Excerpt: Public Comments

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Debra Wexler, MD
Founder/Executive Director
Immunization Action Coalition (IAC)

My name is Dr. Debra Wexler. I am the Founder and Executive Director of the Immunization Action Coalition (IAC), a 30-year-old national non-profit organization focused on immunization education and advocacy. A core part of IAC's mission is keeping our nation's healthcare professionals (HCP) informed about new and updated ACIP vaccination recommendations. The staff members of IAC are listening carefully to the ACIP deliberations today as you determine future recommendations for new vaccines that will prevent COVID-19 infections. COVID-19 infections have caused the deaths of more than 650,000 people globally, with almost one quarter of those deaths occurring in the US. We are all counting on the prospect of safe and effective vaccines to stem the course of this pandemic. On behalf of the entire staff of IAC, I want to thank all the members of the ACIP for the countless hours you have spent evaluating evidence of safety and effectiveness while also considering the public's values and priorities in determining optimal recommendations for our nation's use of life-saving vaccines. Now with COVID-19, please know that the tremendous number of additional hours your work as an ACIP member requires is seen and appreciated. I also want to thank the staff of CDC for your long-standing commitment to protecting the public's health as the most impactful field epidemiologists and public health scientists in the world. At IAC, we hold your expertise in the highest regard in leading the fight against COVID-19, and we look forward to supporting your efforts in educating immunization providers and the public about future national COVID-19 vaccine distribution and vaccination efforts. Finally, I want to express IAC's deep appreciation to the thousands of scientists and other professionals working in governments, medical facilities, and pharmaceutical companies who have pulled together in an unprecedented global mission to develop new vaccines capable of saving hundreds of millions of lives for a virus we first recognized only a few short months ago. Again, thank you members of ACIP, CDC experts, and vaccine developers for your dedication and tireless efforts toward ending this pandemic. Thank you.

Bonnie Feola, MD, FAAP
Medical Director/General Pediatrician
Busy Bee Pediatrics
Bountiful, Utah

This is Dr. Bonnie Feola. I am a General Pediatrician from Salt Lake City, Utah at Busy Bee Pediatrics. I am the Medical Director of this independent pediatric practice. As a pediatrician, I am very familiar with conversations about immunizations. I have daily conversations with parents and caregivers about vaccines, the vaccine schedule, discussing vaccine safety, as well as reassuring my patients that yes, they will feel a little poke, but it is for a very important reason. Because we live in a world of global travel, an epidemic of measles or the reintroduction of polio is essentially a plane ride away. Globally, 1 in 5 children are not receiving life-saving vaccines. Vaccinations help stop the spread of communicable diseases. We are currently waiting on a vaccine for COVID-19. Unfortunately, during this COVID-19 global pandemic, many childhood vaccines have already been missed or delayed. My mother-in-law contracted polio when she was 11 years old before vaccine was available. She shared the following with me, "I got polio in the summer of 1950. The doctor made my parents take me to the city hospital where I was immediately put in an iron lung. I remember the room being filled wall-to-wall with children in iron lungs. It was terribly, terribly frightening. I was lucky that I wasn't in an iron lung very long. My polio was not as severe as others who died or were paralyzed for life, like my aunt who got it

at the age of 37—the mother of three young children.” It was shortly after this time the Dr. Jonas Salk developed the polio vaccine. Having polio influenced her decision to become a nurse, and she made sure that her own 4 children were vaccinated, and she encouraged her patients to get their children vaccinated. She says that now she is 82 years old and has post-polio syndrome (PPS). Polio has affected her her whole life. The messages from my mother-in-law are clear and simple. Diseases cause illness and illnesses make people sick. We are lucky to live in a time of amazing scientific discovery and during the time when vaccines are available to reduce the impact of many scary and harmful diseases. Vaccines are safe. All vaccines are tested in thousands of people before they are licensed and are monitored extensively after being made available to the public. Vaccines are necessary. We live in a global world. We all know that diseases may be brought into the United States by those who travel abroad or from people visiting from areas with current outbreaks. This is what is happening now. COVID-19 is a highly contagious communicable disease. Currently, we are all at risk. Under-immunized children are similarly at risk for all other preventable communicable diseases. Vaccines save lives. Vaccinations work. I wish that my mother-in-law had been protected from polio. Luckily, my children are. My patients are. Vaccines have protected all of my families. I support the scientific community and the CDC in developing and administering life-saving vaccines. Thank you to the CDC, ACIP, and everyone for continuing to keep children and families healthy. Thank you.

Michaela Jackson
Prevention Policy Manager
Hepatitis B Foundation

Thank you. My name is Michaela Jackson and I am the Prevention Policy Manager for the Hepatitis B Foundation, a national nonprofit dedicated to finding a cure and improving the quality of life for those affected by Hepatitis B. An estimated 2.2 million Americans are living with chronic Hepatitis B. While significant progress has been made with childhood vaccinations, adult vaccination rates remain low. Today, only 25% of all adults have completed the HepB vaccine series. We urge ACIP to consider a recommendation for universal Hepatitis B vaccination to help address these low rates and missed opportunities within guidelines. Current risk-based guidelines are difficult to implement. They ask providers to assess 13 different risk factors to determine if an adult should be vaccinated. If you add up all of the factors, that covers up to 84% of the US population. With such a high percentage of adults meeting vaccination recommendations, it makes the most sense to recommend universal adult Hepatitis B vaccination. There are up to 80,000 new cases of Hepatitis B each year. It is essential to note that the HepB vaccine is considered the first anti-cancer vaccine due to its ability to prevent primary liver cancer, the second deadliest cancer in the US. The 5-year survival rate of liver cancer is just 18%. If left unmanaged, 1 in 4 individuals living with chronic Hepatitis B will develop liver damage or liver cancer in their lifetime. Approximately 63% of the US population were born before ACIP's childhood immunization recommendations potentially leaving them susceptible. Within this vulnerable population, the recent rise in incidence of HepB cases has increased the most amongst 30- to 49-year-olds attributed to the opioid epidemic. Although people who use drugs are recommended for vaccination, reported acute HepB cases have ranged from between 56% to 457% in states heavily impacted by the crisis. Such data is concerning in light of COVID-19 where multiple states have reported stopping or limiting their prevention and outreach services for STIs (sexually transmitted infections), including viral hepatitis. The pandemic has also emphasized the need for increased adult Hepatitis B vaccination efforts. Recent reports show that those living with liver diseases like Hepatitis B are more likely to have severe reaction to coronavirus, especially if the condition is uncontrolled. As many people infected with Hepatitis B are unaware due to a lack of symptoms, preventing this infection is critical to not overwhelming providers and hospitals during the pandemic. In closing,

the United States has committed to eliminating viral hepatitis by 2030 but that cannot be done without addressing the low HepB vaccination rates amongst adults. Yesterday was World Hepatitis Day, the date chosen to honor Dr. Baruch S. Blumberg who discovered the Hepatitis B virus and created the first Hepatitis B vaccine. We have the tools to effectively eliminate HepB in the US, but continued support and resources are needed to fully utilize them. Thank you for your time and continuous efforts to protect vulnerable populations.

Ann Lewandowski

Program Manager, Southern Wisconsin Immunization Consortium (SWIC)

Founder, Wisconsin Immunization Network (WIN)

Thank you. My name is Ann Lewandowski and I am the Program Manager for the Southern Wisconsin Immunization Consortium (SWIC) and the Founder of the Wisconsin Immunization Network (WIN). I would like to thank you for your time and effort in reviewing vaccines. Your work as an independent advisory council is something I often point to in my work promoting the safety and efficacy of vaccines. My comments today stem from my personal experience in seeking vaccines as an individual with an autoimmune disorder. I was pleased to hear the question being asked if patients with immunocompromising conditions or medications will be included in the studies during an earlier discussion. However, I was a bit concerned that the answer was not clear-cut. I bring this up due to my experience seeking the SHINGRIX vaccine. I have requested to receive it based on a history of shingles. I have been advised not to receive it due to a theoretical risk of relapse. I have been advised that the studies for those with autoimmune conditions are ongoing and more information will become available at some future point. Data coming in the future was not helpful when I had a shingles outbreak last year. Specific data on immunocompromising treatments would enhance public confidence of those with disorders and the doctors who treat them. Many of those who face autoimmune disorders have had challenges being diagnosed and often become distrustful of "traditional medicine," with many becoming ripe for negative theories about vaccines. In fact, I just had a discussion yesterday about vaccines supposedly causing my disease. Even with the CDC's vaccine myths page, the person continued to point to a vaccine insert as proof that the vaccine caused harm. We must make significant efforts to overcome the distrust of those impacted by these diseases and these groups to ensure that COVID vaccine is widely accepted. Listening to the treatment options, I was also concerned about the suggestion that monoclonal antibodies are a treatment therapy. I actually receive an antibody therapy every 6 months and it is designed to deplete my adult B-cells. There remain significant questions on whether or not I am able to produce an immune response to a vaccine, and if I will have a compromised immune response to the vaccine if I do mount one. Additional study would be important in understanding a good allocation of resources and, again, building public confidence. As we look to a new vaccine for a novel virus circulating the globe, I hope you consider stories like mine when making recommendations to the CDC and even Operation Warp Speed (OWS). Clinical trials must include a broad spectrum of the US and should consider differences in immune status and therapies with biologics. Thank you.

Paul Darden, MD
Pediatrician & Head of General and Community Pediatrics
University of Oklahoma Health Sciences Center

Thank you. I am Paul Darden. I am a Pediatrician and the Head of General and Community Pediatrics at the University of Oklahoma in Oklahoma City. Much of my career has been spent working with clinics in the community to measure and help them deliver preventive services to children. This has actually meant a lot of work on the delivery of routine vaccines, as these are the most effective in preventing illness and death in children. Certainly, early in my career, I cared for many children with vaccine-preventable diseases (meningitis, dehydration from rotavirus gastroenteritis, and even some tetanus). I don't really miss those days and I don't want them to come back. Thanks to vaccinations and other healthcare advances, it is far less common for a pediatrician like me who practices in a tertiary medical care center to see any of these diseases. We are now in the middle of a worldwide pandemic, which is affecting all of healthcare and actually especially preventive care of children. We are also preparing for a new vaccine against COVID-19. One of the things I'm hearing in Oklahoma that really should be addressed is around the safety of the new vaccines, and really, I was thrilled with the conversation today around safety assessments. Those safety assessments need to be communicated. It needs to be layered and emphasize the planned safety assessments, especially with the new technologies. In addition, there really is a need to support practices to safely provide needed routine vaccinations in addition to the COVID-19 vaccine, including influenza vaccine. This might include support for or promoting funding of alternative venues for immunization, including funding to increase local health department direct delivery of vaccines, mobile vans, and pharmacies. One of the clinics I oversee has actually delivered more vaccines and another, because of the constraints of the facility, much less. I do want to say that I applaud the difficult work the ACIP does and actually really appreciate their guidance. I thank you for doing that work. Thank you.

Chief Gary Ludwig
President, International Association of Fire Chiefs (IAFC)

Good afternoon. My name is Chief Gary Ludwig. I am honored to serve as President of the International Association of Fire Chiefs (IAFC). Thank you for the opportunity to speak to you today about the importance of prioritizing firefighters and EMS personnel with respect to the COVID-19 vaccination program. Firefighters and paramedics are part of the health care delivery system. Even though we are in public safety, we are still healthcare workers. We are the warriors at the tip of the spear. When you see all of the outstanding work being done in the hospitals for COVID-19 by doctors, nurses, and others, please do not forget how those patients got there. The vast majority were transported there by ambulance. The fire service is the largest provider of emergency medical services in the United States, transporting some 30 million patients last year. Unfortunately, as of today, we have documented 60 firefighters—that's 60 firefighters and EMS personnel—who have died from coronavirus as a result of being infected on duty. Additionally, over 1,000 firefighters have been infected and over 10,000 have been quarantined after being exposed. Many of these patient encounters did not occur in a sterile environment but were in the patient's home or on the street. This increases the likelihood of infection and exposure. Fire departments are still reeling from earlier decisions to not prioritize first responders for access to PPE and COVID-19 testing. We are seeing shortages occurring again related to PPE and COVID-19 testing. Shortage are so bad that some fire departments are out of disposable PPE and must use ponchos and rain jackets. States are not prioritizing fire departments in opposition to federal guidance to receive PPE. I applaud the federal government for its Operation Warp Speed program; however, it is vital that fire and EMS personnel be

placed at the highest priority tier once a vaccine is available. Fire and EMS personnel often are in close and sustained contact with members of the public and each other due to the unique demands of their jobs. EMS personnel provide hands-on patient care and routinely treat both low-acuity medical emergencies as well as provide advanced life support services such as intubation and resuscitation. Even non-EMS trained firefighters are normally trained in CPR and are in close physical contact with members of the public when providing CPR, rescuing them from car accidents or confined spaces, or are interacting on fire scenes. One New Jersey firefighter even died of COVID-19 that he contracted while responding to a homeowner who reported a gas leak emergency. In closing, the IAFC strongly urges the ACIP to include firefighters and EMS personnel on the highest priority tier for receiving a COVID vaccine when it is available. As we face increases in the number of COVID-19 patients and looming hurricane and wildland fire seasons, it is critically important that we protect our first responders. Thank you for your service for developing answers to these difficult questions. The IAFC stands ready and willing to assist the ACIP in any way possible. Thank you again.

Claire Hannan
Executive Director
Association of Immunization Managers (AIC)

Good afternoon. My name is Claire Hannan. I have the privilege to serve as the Executive Director of the Association of Immunization Managers (AIC), the very individuals and public health agencies that strive daily to ensure the timely immunization of every child, teen, and adult in this nation. My comments are based on 23 years of working in public health where I've had the opportunity to learn from federal, state, and local health officials and to partner with public health advocates. I am grateful to the ACIP for asking the important questions, collecting and analyzing the critical data, and holding open review sessions for the public. As Dr. Messonnier stated, a successful COVID-19 vaccination campaign depends on so much more than clear recommendations from ACIP. Vaccine allocation, distribution, administration, and tracking will not happen without careful planning and coordination between all levels of government. Funding for CDC and state and local public health agencies is urgently needed. Public health departments at all levels are stretched thin. Staff with immunization expertise have been pulled into other aspects of pandemic response and some have been furloughed due to fiscal deficits. Therefore, resources are sorely needed to build and implement the COVID immunization program that will follow from the ACIP guidance. Coordinated planning between CDC, Operation Warp Speed, and state and local public health agencies is needed immediately as Dr. Messonnier stated. There are critical unknowns that must be addressed. Will allocation of vaccine doses and vaccine ordering be conducted through the existing CDC distribution system? Precisely what role will the Department of Defense (DoD) and the military play? Will the vaccine be provided free of charge to all Americans with no out-of-pocket costs regardless of insurance status? What data elements will vaccine providers be required to report to states and what elements will states be required to report to CDC? What kind of public engagement and communication plans are in place to assure the public will accept the vaccine and trust the oversight systems ensuring ongoing safety and effectiveness? These are just a few of the important logistical issues that public health agencies are grappling with as we race to prepare in advance of vaccine implementation. Immunization Program Managers and their partners in public health agencies stand ready to work with representatives from Operation Warp Speed and CDC. I was pleased to hear Dr. Messonnier mention more concrete micro planning and CDC technical assistance. We welcome this. Every awardee needs this collaboration with CDC to begin now with a sense of urgency. We are all in this together. As we face the greatest public health challenge of the century, we will all rise to the occasion. Thank you for the opportunity to comment.

LJ Tan, MS, PhD**Chief Strategy Officer, Immunization Action Coalition (IAC)****Co-Chair, National Adult and Influenza Immunization Summit (NAIIS)**

Thank you very much. Good afternoon. My name is LJ Tan. I am the Chief Strategy Officer for the Immunization Action Coalition. I also serve as a Co-Chair for the National Adult and Influenza Immunization Summit (NAIIS). Thank you for the opportunity to provide public comment to the committee. First, my deepest appreciation to each and every member of this committee for the amazing work that you do to ensure that the vaccines given to our population are extremely safe and effective. As a previous liaison member to this committee, I understand the work that you all do to consider all the data that are available. I am grateful that experts such as yourselves are engaged in these complex discussions that ultimately result in an ACIP recommendation for the use of the vaccine. I believe that as you develop recommendations for use of COVID-19 vaccines, and I have to shout out to today's excellent presentations, you must continue to maintain ACIP's high standards for evidence, clarity, and transparency as your deliberations proceed. In particular, I was pleased to hear Dr. Romero's comment that the National Academy of Medicine's (NAM) COVID-19 panel considering prioritizations of target populations is being collaborative with the ACIP. The importance of unifying the multiple deliberations surrounding the recommendations for use of any COVID-19 vaccine cannot be overestimated. Data should be considered and discussed collaboratively together to arrive at unified, evidence-based recommendations for target populations, administrations of vaccines, and other vaccine utilization recommendations. When we were developing pandemic plans for influenza, the ACIP and the National Vaccine Advisory Committee (NVAC) developed a joint working group precisely for this reason of consistency. Should that not also be considered for developing recommendations for use of the COVID-19 vaccines and include the NAM panel? Your partners at the Immunization Action Coalition and National Adult and Influenza Immunization Summit stand ready to help implement your important recommendations on COVID-19 vaccine. Finally, I would be remiss if I did not mention the importance of #notwinding this fall season. A double, or twin epidemics, of flu on top of COVID-19 disease would be devastating. Couple that with the fact that flu and COVID-19 share multiple overlapping high-risk populations increases the significance that we do our best this fall season to #takefluoffthetable. To that end, it is important that we talk about expanding the influenza vaccination season, not just extending it. This season in particular, we need to start vaccinating people appropriately once vaccine is available and continue talking about and giving flu vaccinations through December and into 2021. We must reassure providers that it is alright to utilize the entire flu vaccination season to advocate for and give flu vaccine. Once again, thanks to this committee for all the incredible work that you do to keep our country safe from vaccine-preventable diseases.

Alicia Stillman, MBA, MPH**The Emily Stillman Foundation**

Hi, my name is Alicia Stillman. I am from the Emily Stillman Foundation and also the Meningitis B Action Project. In February of 2013, I lost my 19-year-old daughter, Emily, to meningitis B just 36 hours after her first symptom. I am not only here today to tell you my sad story. I'm here as a concerned citizen and advocate committed to making sure that this doesn't happen in other families to other children. First, I'd like to comment on the critical importance of immunizations during COVID-19. At the time of Emily's death, the meningitis B vaccine was not yet available to protect her. It is today, but amidst the COVID-19 pandemic, many of the vaccines available for deadly infections like meningitis B are sitting idly on the shelf. Immunization rates among

children have fallen by 60% to 80%. We're seeing states like Pennsylvania that have temporarily suspended requirements for children's immunizations to enter schools. If children and young adults are not receiving these recommended vaccinations, they are now vulnerable to infections, potentially deadly diseases like bacterial meningitis, and so are the communities they live in. Postponing these vaccinations is not the answer. It is irresponsible and dangerous. Preventing vaccine-preventable diseases should be part of our COVID-19 response. I urge the CDC and ACIP to be very public and vocal about the importance of immunizations during COVID-19 and to ensure that states maintain their requirements and schools and colleges revisit their vaccination mandates before any student is allowed to return to campus. Second, I'd also like to comment on the current language used by the ACIP to describe the meningitis B vaccine recommendation. As you know, it changed from a Category B recommendation to a shared clinical decision-maker. First, it is important that you know that this discussion is not happening consistently, making the recommendation obsolete. A recent CDC-funded study found that 49% of pediatricians and 69% of family physicians do not discuss the menB vaccine during routine visits for their 16 to 18-year-olds. Second, providers are not always interpreting this recommendation correctly. For the last 5 years, I have traveled the country talking to doctors and nurses and there's such confusion about what this means. It's not an equitable approach and I urge you to revisit that. In closing, I want to thank every member for your hard work for protecting all of our communities. We at the Emily Stillman Foundation and at the Meningitis B Action Project are ready and proud to work with you.

Alison Singer, BA, MBA
Founder & President
Autism Science Foundation (ASF)

Good afternoon and thank you for the opportunity to speak today. I'm Alison Singer, Founder and President of the Autism Science Foundation. I am the mother of a child with profound autism and legal guardian to my older brother, who also has very severe autism. The Autism Science Foundation's mission is to support research to uncover the causes of autism and develop evidence-based treatments for people with autism. As we all recall, back in the late 1990s, there was concern that autism might be caused by vaccines. At that time, I shared that concern. But dozens of research studies have indicated that this is not the case and that vaccines do not cause autism. Fortunately, the vast majority of our families have been convinced by the weight of this evidence and have vaccinated their children. It took a lot of hard work to reassure the community that vaccines are safe and effective. My concern today is that efforts to fast-track a COVID-19 vaccine could undo all of that work if time isn't spent making sure that any vaccine recommended by this committee is safe and effective. To that end, we must complete Phase 3 trials on a COVID-19 vaccine. We must do the studies to see if the vaccine works and we must do the studies to make sure the vaccine does not cause uncommon side effects. Without full Phase 3 trials, we risk undermining all of the progress we have made over the past 21 years to restore public confidence in our vaccine program. It is critical that we take all actions necessary to continue to build and maintain trust in the science that supports the nation's vaccine and public health recommendations. Thank you very much.

Melody Butler, BSN, RN, CIC
Founding Executive Director/President
Nurses Who Vaccinate (NWW)

My name is Melody Butler. I am the Founding Executive Director for Nurses Who Vaccinate. Our mission is to help nurses become vaccine champions in their workplaces, communities, and on social media. I'd like to thank all the presenters and members of ACIP for very informative presentations and insightful questions and concerns about these life-saving vaccines. I'd like to touch upon Dr. Sarah Mbaeyi's presentation where she addressed the need to prioritize COVID-19 vaccinations among the healthcare personnel populations. As the Executive Director of Nurses Who Vaccinate, our members are quite familiar with the need for resources and education to keep nurses up-to-date with the latest immunizations and medical recommendations. As the most trusted profession in America, nurses have an obligation to honor that trust and to follow evidence-based practices. I'd like to ask the committee and partners for their support in engaging the nursing community to help encourage and increase vaccine confidence not only among patients, but also among the healthcare community as well. A recent WebMD® reader poll found that fewer than half of people plan to get a coronavirus vaccine in the first year it is available. An even smaller group say they will get it in the first 90 days. If immunizations are low, we will not be able to achieve the level of community immunity that we need to protect us from coronavirus. We have raced to develop and test an effective vaccine and people are questioning the ability to create one so quickly that could work well and be safe. When we are dealing with a population that has 30% of adults with low health literacy, it is critical that we provide transparency and adequate patient education to help patients understand the science and development of these vaccines that we are working so hard to promote. There is a need to start working on vaccine confidence and the nursing community now by providing more behind-the-scenes information on the vaccine development process, resources to accompany the final results, and tools to help explain the study of outcomes. Providing more transparency on the hard work and dedication that is going on in the vaccine research centers will help provide those in the frontlines of education opportunities and resources to educate and get ahead of vaccine misinformation. In conclusion, we would like to thank the ACIP members, CDC staff, scientists, and researchers working on these life-saving interventions. We look forward to working with the many organizations and health partners to help advocate and prevent vaccine-preventable diseases. Thank you.

Michelle Fiscus, MD, FAAP
Medical Director
Vaccine-Preventable Diseases and Immunization Program (VPDIP)
Tennessee Department of Health (TDH)

Good afternoon. My name is Dr. Michelle Fiscus. I am a physician, a pediatrician, a mom, and the Medical Director of the Vaccine-Preventable Diseases and Immunization Program (VPDIP) at the Tennessee State Department of Health. Over my 20 years in medicine, I have provided tens of thousands of vaccines to children, including my own children, and not once in those 20 years have I seen a serious adverse event (SAE) caused by a vaccine. What I have seen are children with chronic neurological disease due to chicken pox, infants admitted to intensive care units (ICUs) due to pertussis, and children who have died from influenza. All of these diseases are vaccine-preventable. Yesterday, a study was published in the peer-reviewed journal *Annals of Internal Medicine* that looked at the safety of vaccines approved by the US Food and Drug Administration (FDA). These Israeli researchers looked at every vaccine approved between 1996 and 2015, 57 vaccines in all, examining safety-related changes made to vaccine labels

since a vaccine's release. Most safety-related label changes were triggered by surveillance systems like the Vaccine Adverse Events Reporting System (VAERS). More than 40% of the warning updates were related to latex allergies due to changes in packaging or the increased risk of fainting after certain vaccines. The other 60% were related to restrictions on who should be given some vaccines, such as those with certain immunocompromising or pre-existing medical conditions, some premature infants, and pregnant women. In only one instance was a vaccine removed from the market due to safety concerns, that being the RotaShield® vaccine used to prevent the most common cause of severe dehydrating diarrhea in infants and resulting in 20 to 40 deaths in the United States each year. When more than 20 years ago, VAERS signaled an increase in a type of bowel obstruction after the administration of this oral vaccine, this committee, the ACIP, concluded that the vaccine should no longer be recommended and the manufacturer voluntarily pulled it from the market. That decision was made after 15 infants were found to have this complication. The risk was 10 cases per 100,000 doses of the vaccine or 1/100 of 1%. It took 7 years for a new vaccine to be developed, studied for efficacy and safety, and released. It is estimated that that vaccine prevents as many as 50,000 hospitalizations of babies and young children each year in the United States. If there were no vaccines, approximately 42,000 of the more than 4 million children born in the United States each year would die early deaths as a result of diseases we can currently prevent. This new study adds yet more evidence that vaccines are remarkably safe, that surveillance systems like VAERS and the work of the ACIP ensure that safety and that vaccines are one of the greatest achievements in public health. I thank this committee for its commitment to the health and well-being of all Americans, especially our children, and I encourage every parent to provide their child with the protections provided by vaccines. Thank you.

Stanley Plotkin, MD
Emeritus Professor of Pediatrics
Perelman School of Medicine
University of Pennsylvania

Thank you for giving me the first opportunity in months to speak about something besides COVID-19. What I want to tell you about is an article that will be published shortly in *Clinical Infectious Diseases (CID)*. Cody Meisner and I had a simple idea and that is to look at the vaccine compensation system [National Vaccine Injury Compensation Program (VICP)]. The people compensated by this system have had either real or likely reactions to vaccines, so we have numbers on the number of awards. We also have numbers concerning the doses of each vaccine that have been given over a period of years. We analyzed the number of vaccines given between 2006 until the end of 2018 and compared that with the number of awards. It turns out that something close to 4 billion doses of vaccines have been given and the number of awards works out to 1.3 per million doses. So, that gives you a very concrete idea of what the real reactions are to vaccines. I should add that much of that is due to influenza vaccine awards which are, as you know, the result of misplaced vaccinations in the shoulders. So, if you removed those from the calculation, the number would be 1 or less per million doses. So, that gives you real ideas, real numbers, about reactions to vaccines. That paper will be published in *Clinical Infectious Diseases*. It is already, I think, out in pre-print. I hope that the members of the committee and others will use those figures in talking to parents. I thank you for your attention.

**Jennifer Johnson, RN
Public Health Nurse
Lincoln County Health Department**

Hello. I am very honored to be here speaking today to the committee. I want to thank the ACIP for all of your hard work and research on immunizations. I am a Public Health Nurse, a School Nurse, Nursing Instructor, and a mom. Keeping children healthy is a priority for me in all aspects of my life. I provide recommendations and I assist with helping families get the best evidence-based information to provide immunizations for their families and to help our community be protected against vaccine-preventable diseases. I want to thank you for giving all of your attention to safety and efficacy for the COVID-19 vaccine. I ask that communication tools be provided for our public use to provide confidence and prevent misinformation and mistrust that is rampant in our communities. I combat misinformation daily and I just want to thank you for providing all of your hard work in providing the best information that we can to protect our families and our children. Thank you.

**Dorit Reiss, LLB, PhD
Professor of Law
Hastings College of the Law
University of California**

Thank you to the committee for the opportunity to speak. My name is Dorit Reiss. I'm a Professor of Law at the University of California, Hastings College of the Law. I want to make three points to the committee. First, I want to reinforce the point made by several other commenters and by Doctors Lee, Bell, and Romero in a recent *JAMA* piece, which reminds us of ACIP's long history of professional careful oversight of United States vaccines that some of the commentators already talked about, ACIP's procedural guarantees of transparency, and ACIP's broad membership in their workgroups makes its role in overseeing vaccine safety not only important generally, but crucial when we move forward with the COVID-19 vaccine process. I urge the committee, and I urge supporters of public health to support them in this, to do everything in their power to maintain full information and the ability to exercise the careful oversight that gives us such an incredible and safe vaccine supply. We need ACIP involved in COVID-19 vaccine. I know it is not completely in your power, but I want to reiterate that it is your duty and you're doing a public service when you do everything you can to maintain oversight. Second, I want to remind the COVID-19 Vaccine Workgroup that as you discuss vaccine priorities that you are working within a Constitutional framework and not just a scientific one. I haven't seen a legal person on your workgroup, and I think it's important to get a Constitutional expert, especially if you consider issues like race. Finally, I want to urge the committee when in the future days you can get back to having in-person meetings to consider limiting public comments to written comments only. I say that with regret because I would have hated to have missed some of the comments I have heard today. But as you know, in the past few years, anti-vaccine activists have used this platform of commenting before the committee to create videos of short speeches, basically using common themes to create theater and propaganda to promote anti-vaccine stance. The CDC background makes the comments look official. That is not the goal of public commenting. ACIP does not have to provide that opportunity. Legally, you can choose to allow public participation and commenting to be in writing only. I hope you seriously consider doing this at least for a while, even though I realize it will cause issues. Public participation is important, but providing an opportunity for theater isn't. Thank you again for all of your hard work in the public service and for keeping our children safe. Thank you.

In conclusion of the Public Comment Session, Dr. Cohn reported that over 10,000 comments have been submitted to the [regulations.gov](https://www.regulations.gov) docket. CDC has to review those comments before posting them, but all public comments will be posted over time as long as they do not contain any threatening language. She encouraged everyone to read those public comments as well and emphasized that CDC and ACIP look forward to hearing additional public comments during the next ACIP meeting in August 2020.

Acronyms

ACIP	Advisory Committee on Immunization Practices
AIC	Association of Immunization Managers
CDC	Centers for Disease Control and Prevention
<i>CID</i>	<i>Clinical Infectious Diseases</i>
CPR	Cardiopulmonary Resuscitation
DoD	Department of Defense
EMS	Emergency Medical Services
FDA	Food and Drug Administration
HCP	Health Care Practitioners
IAC	Immunization Action Coalition
IAFC	International Association of Fire Chiefs
ICU	Intensive Care Unit
JAMA	Journal of the American Medical Association
NAIIS	National Adult and Influenza Immunization Summit
NAM	National Academy of Medicine's
NWV	Nurses Who Vaccinate
NVAC	National Vaccine Advisory Committee
VICP	National Vaccine Injury Compensation Program
OWS	Operation Warp Speed
PPS	Post-Polio Syndrome
RN	Registered Nurse
SAE	Serious Adverse Event
STI	Sexually Transmitted Infection
SWIC	Southern Wisconsin Immunization Consortium
TDH	Tennessee Department of Health
US/USA	United States of America
VAERS	Vaccine Adverse Event Reporting System
VPDIP	Vaccine-Preventable Diseases and Immunization Program (TDH)
WIN	Wisconsin Immunization Network