MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Centers for Disease Control and Prevention (CDC)
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Tom Harkin Global Communications Center, Kent "Oz" Nelson Auditorium
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Excerpt: Public Comments

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Mr. Del Bigtree
Founder, Informed Consent Action Network (ICAN)

My name is Del Bigtree. I speak for the Informed Consent Action Network (ICAN), which is my nonprofit. I would like to address our concerns about the safety trials that are taking place on all of the vaccines for COVID-19. Specifically, I want to point out that I think the ACIP committee—that you sit in an unprecedented moment of the potential of having one of the greatest accidents in science that has ever taken place, and that would be rushing this vaccine given what we know about the science. Of course, I'm talking about the possibility for antibody-dependent enhancement (ADE), complement-mediated antibody-dependent enhancement, cellular-mediated enhancement, Th2. All of these problems which have appeared in Dengue vaccine, which killed over a hundred people in the Dengue vaccine campaign in the Philippines; the RSV (Respiratory Syncytial Virus) vaccine program, which was discontinued because of the death of children; and this occurring in virtually every animal trial over the last 20 years. This is not any other vaccine. This is one of the most dangerous vaccines ever attempted, To know that we are using warp speed and that we have Governors around this country and leaders around the world say they will immediately mandate this product upon all of their population means that we could have a vaccine that could potentially kill unknown, untold amounts of people because their bodies don't protect them after this vaccine but, in fact, enhance the problem. When I look at the trials that are taking place—when we look at the Moderna trials, we are not doing challenge studies on human beings. The challenge studies are being done on macaque monkeys, which are known to have a very mild reaction, which is not the way to, you know, to weed out a problem. We're using the young monkeys and even then, we did not test them. We did not challenge them after the first vaccine, which only created binding antibodies, which is one of the theories that creates the immune enhancement. We only tested after they knew they had neutralizing antibodies, which only took place two weeks after the booster shot, which means we are allowing the pharmaceutical industry to cherry-pick their moments of research to make their vaccine look good. Of course, they're going to try and make it look good. They stand to make potentially hundreds of billions of dollars. If not trillions of dollars, off of the vaccines should they be selected. Under these circumstances, I would like to see more rigor from the CDC and demanding more constant testing. The United States of America is putting billions of dollars into these vaccine trials. We should be having all sorts of animal trials on a constant basis, truly challenging to make sure that we have overcome immune enhancement. If we have not, we could seriously put our species at risk. And the only conversations I hear going on is, "How quickly can we get it to everybody?" And the risk of the disease—what about the risk of this vaccine? That is in your hands and you will be remembered in history should you make a diabolical, catastrophic mistake. Thank you very much.

Andre Montoya-Barthelemy, MD, MPH
HealthPartners Occupational and Environmental Medicine (OEM)

My name is Andre Montoya-Barthelemy. First of all, all of those held in jails, prisons, and detention centers really must be included in Tier 1 of the ACIP recommendations for COVID vaccination. As I said, I'm Andre Montoya-Barthelemy, physician with specific training in public health and epidemiology and I lead a task force investigating the hazards of the correctional environment. Today, I represent leaders of the American College of Correctional Physicians (ACCP) and the American Association of Public Health Physicians (AAPHP). Together, we've reviewed the ACIP's current plan for COVID vaccination. We have to recommend modification of your criteria based on a fundamental public health principle that individuals are at high risk for COVID based on structural and environmental forces which promote transmission of the virus, as well as their individual high-risk health conditions. Increased risk is increased risk and it leads

to disease regardless. Let me be more specific, though. Individuals who live in congregate settings including group homes, shelters, long-term care facilities (LTCF), prisons, jails, and detention centers must be provided the protection against the very environment in which they live. In these settings, vaccinations can do more. Today, our group advocates specifically for prisoners. We look at their environment, possibly overcrowded facilities where social distancing is extremely challenging. Where masks, hand sanitizer, cleaning supplies, and even soap are rationed and restricted. Where a visit to a clinic can cost a full week of your prison wages. Recent research demonstrates death rates up to 3 times higher and case rates more than 5 times higher than the general population. Vaccination here will go farther. It will save lives. And as we look at our windows, many of the COVID hotspots in our country are in prisons. Although often considered isolated, inmates are regularly released from prisons and jails and correctional staff daily travel home to their families. Without a damper on the transmission inside the facility, they'll act as incubators storing and releasing financial, legal, and public health burden back into the general population. The solution is what in medicine we call "source control." Without it, transmission will continue as long as the hotspots remain uncontrolled. As a physician, I care for the individuals who live and work under the constant and invisible threat of this pandemic. As a public health professional, I'm obligated to apply the fundamental principles to arrest spread in the community. As our government-appointed advisors, you have a very difficult position—a responsibility to balance both of those imperatives. It is terribly difficult, but vaccination of inmates accomplishes all three: good medicine, good public health, and good governance. So, I'm imploring you to protect those individuals living in congregate settings, especially those in jails, prisons, and detention centers. Include them in Tier 1 of your COVID vaccination schedule. Thank you.

Santa Ric Erwin
Chairman, Board of Directors
Fraternal Order of Real Bearded Santas (FORBS)

Thank you. Not since the depths of the Great Depression or the Darkest Hour of World War II have so many sane and sober adults wondered aloud whether America may be facing a year without Christmas. Every professional Santa has a story or 20 about the kid who asks nothing for himself, but wants daddy to get a job, or an abuela to get better, or a sibling to be safe overseas, or insert personal favorite here. This is because to the young at heart, Santa is the very image of faith, hope, and charity and that's during the good times. For most, times they ain't good. I'm Santa Ric Erwin, Chairman of the Board of Directors for the Fraternal Order of Real Bearded Santas (FORBS), the nation's original Santa fraternity. We're a 501(c)7 dedicated to the professional cause and we've successfully lobbied on behalf of the Christmas community to various state and federal agencies whenever significant issues have called for it. Today, I'd like to call your attention to one of our more successful efforts. The 2009 Christmas season was under serious threat by the H1N1 epidemic and with the vaccine approved but not yet publicly available, FORBS led the industry in petitioning for early access to the vaccine on behalf of America's front-line seasonal workers. Our efforts were admittedly reliant on media support and public pressure. But you know what? It worked. Armed only with our letter to CDC, Food and Drug Administration (FDA), Department of Health and Human Services (HHS), and National Foundation for Infectious Diseases (NFID), I went to Kaiser on November 18th and received my H1N1 vaccination during or shortly after Tier 1 release and nearly a full month before Tier 3. Following my example, members in other parts of the country where able to do the same. Cumulatively, we were able to provide vaccinated Santas to nearly all major events and locations that year, not to mention the countless private parties that were saved. This year, Christmas will be more important to the American psyche than ever before. Our country is enduring an historic disaster trifecta and nearly all Americans endure unparalleled suffering, but

we are still America and if past is prologue, families will do everything possible to end a bad year on a good note. Promising vaccines are in Phase 3 testing already and remaining social restrictions may be easing by Christmas. We're asking that professional Santas and other frontline seasonal workers be granted early access to the COVID-19 vaccine as soon as practicable after Tier 1 release for the following reasons: 1) Traditionally, professional Santas place themselves in close personal contact with anywhere between 5 and 15,000 family members each holiday season; 2) Our target demographic, our clients if you will, are young children, notorious distribution vectors for all things infectious; 3) Most professional Santas are in the most at-risk category due to advanced age or underlying medical issues; and 4) Despite all of this, Americans are going to want Santa to be at Christmas 2020. I await your questions or comments. Thank you.

Dr. Romero: On behalf of the voting members of the ACIP, Santas in America, we want to thank you for your comments and really enjoyed hearing from you. Thank you, and I really did believe in you all my life.

Ms. Dorit Reiss
Professor of Law
Hastings College of the Law
University of California

Well, even as a Jew, I realize that Santa is a hard act to follow, but I'll try. I appreciate the committee's careful work in overseeing and discussing COVID-19 vaccines. The presentations showed how much attention you put into safety and how many mechanisms are already in place, and more to be added. We really need this oversight. I also appreciate the transparency with which you present this to the public. We also need the transparency of seeing the oversight—of seeing what's going on. It is critical that any decision about COVID-19 vaccines are made in the public eye just as you provide through this publicly available webcast today. This is just as important for the Emergency Use Authorization (EUA) and for licensing or recommending a vaccine, which is why I sincerely hope that the Vaccines and Related Biological Products Advisory Committee (VRBPAC) and FDA will review the data for the vaccine candidates and welcome public input before approving an EUA, and ACIP will have a strong role in the process as well. I also want to remind everyone that it is not only important to exercise oversight over the vaccine-making process, but it is important that the oversight be known. I think speaking to the public is intuitive to many of the scientists that do the heavy lifting in ACIP in the WG and committee, but the work to oversee that vaccine needs to be visible in order to create trust. This public meeting is great, but it is not enough. I hope that ACIP will make visible to the public their role in overseeing vaccines and the extensive work. For example, it would be useful to have fact sheets explaining your role in oversight generally—a fact sheet about the wonderful and many systems of monitoring that were presented here, and maybe a fact sheet highlighting the COVID-19 Work Group. We have a group of tons of independent experts, many with established careers, extensive experience, and no direct stake looking closely at the data, discussing it openly, and making sure it meets high standards. The public should know this. I hope you make an effort to bring this information to the pubic in multiple forms. Finally, as I said in my previous comment, I really hope ACIP considers adding a legal expert that has experience with equal protection to the Work Group. I am not an expert in equal protection, but I know enough to know that when you start considering race for allocation, you're touching on issues that can have real legal pitfalls and a legal expert can help you avoid them? Thank you.

C. Grace Whiting, JD
President and Chief Executive Officer
National Alliance for Caregiving (NAC)

Hi. Good afternoon. I'm Grace Whiting. I'm the President and CEO at the National Alliance for Caregiving (NAC). I just want to thank all of you for the great work you're doing and for giving us a chance just to speak, and say hello, and weigh-in. So the National Alliance for Caregiving is a 501(c)3 nonprofit organization. We're based in the Washington, DC area and our mission is to build partnerships and research advocacy and innovation that can make life better for family caregivers. We just have two brief comments today to share. First is that family caregivers can be valuable partners in improving adult vaccination rates, and second that preventive care models should incentivize providers to include caregivers in shared decision-making. We know that there are roughly 53 million people in the United States, which is about 1 in 5 Americans who care for a friend or family member because of a healthcare need or functional disability. While we think about caring for another person as an intimate activity, in the aggregate it's foundational to our health and social care systems. In fact, AARP estimates that the economic value of unpaid caregiving is roughly $470 billion dollars each year. That's how much it would cost if we wanted to replace each caregiver with a paid worker as someone to help with activities of daily living such as grocery shopping, managing finances, high-touch activities like bathing and toileting, and medical nursing tasks such as wound care or colostomy care. Despite broad support from this committee and from other leaders in this space, adult vaccination remains low. We know from pediatrics that caregivers, when included in shared decision-making by formal care providers, can be critical partners and the same is true of adult partners in care. In the national research that we do with AARP, most caregivers who seek outside information prefer to talk to a doctor or healthcare professional. The next most trusted source is friends and family. Here, the Medicare program can provide some insight into how to incentivize shared decision-making between providers, patients, and family caregivers. Currently, the Medicare program can reimburse providers for family support related to transitional care, evaluation and management, chronic care management, education to a family member, patient monitoring, comprehensive clinical visits, a written care plan, the annual wellness visit, and advanced care planning. We would encourage this committee to consider models of care delivery that could likewise incentivize providers to have early, often, and open conversations with families about preventing infectious disease. Finally, as we heard this morning on COVID-19, the needs of older adults are front and center There's an opportunity to meet the moment and recruit additional experts with expertise in adult and geriatric care. Thank you.

Maria Gahry, DNP
Nurse Practitioner
Private Practice

My name is Maria Gahry and I am a Doctor of Nursing Practice, Board Certified as a Family Nurse Practitioner. I speak on behalf of the patients I provide care for. We have a crisis of vaccine confidence and I fully understand why. I have personally cared for patients who have suffered a vaccine injury and have seen an increase in vaccine hesitancy and distrust over the last 6 months. My patients are questioning the safety of the new coronavirus vaccines. They know it's being rushed to market with a lack of long-term safety studies. They are concerned there will be no liability or recourse for injuries they may sustain. They are concerned about the risk of autoimmunity, impairment, infertility, and the possibility of this causing cancer because of the nature of an mRNA (messenger ribonucleic acid) vaccine. In some studies, safety will only be monitored for 1 month. It is unethical to monitor efficacy for 2 years, but not safety. All studies should be similar for safety monitoring. Inclusion criteria for the mRNA-1273 vaccine

shows evidence that their concerns about these risks are completely rational. Female participants must have non-childbearing potential, not be pregnant at the start of the trial, and must abstain from all activities in which they could become pregnant for 28 days prior to the first dose and 3 months following the second dose at Day 29. Male participants engaging in activity that could result in pregnancy of sexual partners must agree to practice adequate contraception and refrain from sperm donation from the time of the first dose and through 3 months after the second dose. Given the specific inclusion criteria, what is the specific mechanism of this vaccine and are you concerned about it getting into the germline cells? After its approval, will this specific recommendation regarding fertility continue to apply to those receiving the vaccine? Clearly, those conducting the studies are fully aware of the risk it poses to fertility and the potential to affect DNA (deoxyribonucleic acid). How can I instill confidence in my patients when we will have zero data about the impact of this vaccine on fertility and the long-term consequences the vaccine may have? Real-time monitoring will not pick up fertility or autoimmune conditions in VAERS (Vaccine Adverse Event Reporting System). Mortality for COVID-19 is 0.26% for those infected and a small fraction of that for children. The human papillomavirus (HPV) vaccine had an autoimmunity rate of 2.3% in the pre-license trials. If we translate that number to the US population and assume this new vaccine has a similar rate, that would equal 9 million new cases of autoimmunity. Can our healthcare system withstand this? Can you justify recommending a vaccine with a potential serious adverse event (SAE) rate that is significantly higher than the disease's morbidity or mortality rate? And how can we, as medical providers, possibly instill confidence in our patients with these numbers? Patients are paying attention. My hope is you are too, as your recommendations will become mandates forced on all of us to participate in society. Thank you.

Lindsay Clarke, JD
Vice President, Health Education and Advocacy
Alliance for Aging Research

Good afternoon. I'm Lindsay Clarke, Vice President of Health Education and Advocacy at the Alliance for Aging Research. For the past 4 years, the Alliance has led the "Our Best Shot" Campaign, which encourages older adults to play an influential role in their families and communities to debunk myths and make sure their own vaccinations are up-to-date. The CDC includes the campaign's educational film on its website and we thank you for featuring this resource. We appreciate the important work that ACIP is doing; however, we urge you to make some changes to better respond to the needs of the older adult population, especially in the face of the double threat of COVID-19 and influenza outbreaks this fall. First, while the 2020-2021 influenza season recommendations go into more detail on the evidence for enhanced influenza products, they continue to avoid recommending them over standard dose flu shots for people ages 65 and older. This is a clear missed opportunity to encourage older adults to seek out enhanced vaccines to protect themselves during one of the worst pandemics the US has ever experienced. Yes, any flu shot is better than no flu shot. But older adults are going to need all the protection they can get this year. Please take a stand on this. Second, we urge you to immediately add more experts in geriatrics and older adult vaccination research. Building better expertise on the ACIP and its working groups on how to care for older adults, including those with additional risk factors and those living in congregate settings, will be critical to assessing potential CPVOD-19 vaccines in the near-term and other promising adult vaccines in the future. Third, we believe that the committee's current interpretation of conflict of interest (COI) for ACIP nominees is more restrictive than intended by the Federal Advisory Committee Act (FACA) and that this overly-strict interpretation may have dissuaded or even prevented experts in older adult vaccination from ACIP participation. We recommend that CDC develop clear and publicly available guidance on COI like the FDA has done. Please see our written comments for more

on this. Lastly, we strongly urge ACIP to immediately eliminate economic considerations from its charter. We remind the committee that US federal civil rights laws including the Americans with Disabilities Act (ADA), the Rehabilitation Act, and the Affordable Care Act (ACA) prohibit the use of quality adjusted life years (QALY) and similar cost-effectiveness assessments in coverage and reimbursement decision-making in both the Medicare and Medicaid programs. The reason for this is that QALY assessments assign a discriminatory financial value to the patients for whom a given treatment is intended under QALYs, if a group is sicker, older, and/or disabled, their value is less. When applied to healthcare decision-making, the results can mean that some patients (people with disabilities, veterans, older adults) are deemed too expensive to receive care. Effectiveness should be measured by improvements to a patient's condition and quality of life rather than personal characteristics or health status. Thank you for the opportunity.

Shoshona Fishbei
Communications & Marketing
Families Fighting Flu, Inc.

My name is Shoshona Fishbei and I represent Families Fighting Flu. Many people use personal stories to convey that vaccines are harmful or dangerous, but it's also important to use personal stories to demonstrate why vaccines are crucial to preventing and potentially eradicating deadly and debilitating diseases. I use anecdotes to explain why vaccines are necessary both in my personal and professional lives. Personally, my sister had a febrile seizure after receiving a Tdap vaccine at age 13. It's impossible to know if the vaccine was truly responsible for her seizure. But thankfully, this is an isolated event. We rely on science that shows that the benefits of vaccinating outweigh the risks, and this event has not stopped my family or myself from getting vaccinated. I know that sharing a story like this one allows people to begin to see the other side of the vaccine argument. That's why I started working for Families Fighting Flu, a patient advocacy organization that highlights the stories of people who have died or suffered from influenza. These stories show that not vaccinating is not a risk-free choice. Foregoing an annual flu vaccine comes with the risk of some being hospitalized, having lasting complications, or even dying from influenza. Our stories include people like Allison Miller, a 33-year-old woman who survived a flu illness but was hospitalized for 3 months and suffered an amputation above the knee as a result of flu. We also share the story of Anakin Das who was a 10-week-old premature baby as a result of his mother contracting influenza while pregnant. He now suffers from chronic lung disease. We use these stories to encourage evidence-based practices like annual flu vaccination for everyone 6 months and older. Storytelling is not just a method to be used by opponents of vaccines. Sharing stories of the benefits of vaccination allows us to help individuals understand the seriousness of influenza and the importance of annual flu vaccination. I implore you to share stories about the benefits of all vaccines to both individuals and communities and emphasize the risks of not getting vaccinated. We know that anecdotes are emotional, and emotions can motivate people to protect themselves and their loved ones against vaccine-preventable diseases. Thank you for your time.

Wexler Deborah, MD
Founder and Executive Director
Immunization Action Coalition (IAC)

Hi. My name is Dr. Deborah Wexler. I'm the Founder and Executive Director of the Immunization Action Coalition (IAC), a 30-year-old national nonprofit organization. Thank you for this opportunity to speak today. All of us are seriously concerned about the upcoming flu season and how we will be able to take care of our nation's people with two different contagious diseases, influenza and COVID-19 circulating concurrently across our country. Your

deliberations on COVID-19 vaccines will help lead the way to our ultimate control of that disease. But in the meantime, we must remember that we currently have the ability to provide and promote a critical public health intervention with readily available influenza vaccines. This fall, we must expand our influenza vaccination coverage to as many people as possible, reducing the likelihood of hospitalizations due to flu or, of even greater concern, hospitalizations resulting from dual infections with both influenza and COVID-19. Recently, IAC has learned of several colleges and universities that are putting influenza prevention into practice by making the policy decision to require flu vaccination for their students, faculty, and staff. On a larger scale, two university-wide systems, the University of Tennessee (UT) at its 4 campuses and the University of California and its 10 campuses, have implemented flu vaccination requirements. All of this is quite impressive, but the flu vaccination policy decision that took center stage just last week was from Massachusetts. For the upcoming season, the State of Massachusetts will require influenza vaccination not only at all the state's colleges and universities, but also for all children and students who attended day care, childcare, and kindergarten through 12th grade. These types of decisions are the direct result of ACIP leadership. Ten years ago, you made your age-based influenza vaccination recommendations to vaccinate everyone 6 months of age and older, which was an easy-to-understand guidance for providers to carry out. Thank you ACIP for making these straightforward recommendations. And thank you to the colleges, universities, and the State of Massachusetts that are leading the way by thoroughly following ACIP's guidance. I hope many more will follow in their footsteps. Thank you.

Nissa Shaffi, BS, MS
Associate Director of Health Policy
National Consumers League

Good afternoon. My name is Nissa Shaffi. I am here today on behalf of the National Consumers League (NCL). Since The League was founded in 1899, we have educated consumers about the vital role of vaccines in society and continue to dispel myths about vaccine safety. Today, we extend our gratitude to the Advisory Committee on Immunization Practices for all that you do to protect public health and for the opportunity to speak here today. NCL strongly urges ACIP to increase and enhance infrastructure regarding vaccine confidence as the nation navigates the COVID-19 pandemic. COVID-19 has spread at an alarming velocity, and we need to ensure that we are utilizing our full reservoir of preventive services like vaccines. A small but vocal minority have politicized preventative health measures as perceived destructions and personal liberties. We need to ensure that vaccine hesitancy does not foil critical public health interventions, especially within the context of the pandemic. The American public should feel safe, informed, and empowered in their decisions to vaccinate once a vaccine for COVID-19 becomes available. Due to COVID-19-imposed lockdowns, routine vaccinations across all age groups have declined by over 30% since 2019, with the largest decline observed among ages 19 to 49 at over 60%. Medically under-served communities and people with underlying health conditions are more vulnerable to adverse outcomes should they develop COVID-19. A decline in vaccination rates will further compromise herd immunity and endanger public health. Minority communities are among the hardest hit during this pandemic. Additionally, we request that clinical trials for the potential COVID-19 vaccines are inclusive and consist of diverse subjects to curb vaccine hesitancy regarding efficacy. The vaccine must be safe and effective and ample outreach must be conducted to ensure optimal herd immunity and vaccine confidence across all demographics. In closing, to stem the tide of deaths from these vaccine-preventable diseases, NCL urges the committee to maintain and encourage strong vaccine recommendations and infrastructure. This recommendation serves to ensure that we fortify health providers, public health leaders, and advocates with evidence-based medical options to help protect and

advance the health of our nation during this pandemic and beyond. Thank you for your consideration of our views on this important public health issue.

Chari Cohen, DrPH, MPH
Senior Vice President
Hepatitis B Foundation

Yes, thank you very much for this opportunity to speak today. My name is Dr. Chari Cohen. I am the Senior Vice President for the Hepatitis B Foundation, a national nonprofit organization dedicated to finding a cure and improving the quality of life for those with Hepatitis B. Today, we urge ACIP to consider a recommendation for universal adult Hepatitis B vaccination. Despite being one of the world's leading causes of primary liver cancer, only 25% of adults in the country are fully protected against Hepatitis B. Most of the virus burden falls upon Asian American/Pacific Islander and African immigrant communities. When you add up the 17 separate groups recommended for either Hepatitis B testing or screening due to risk, including those who have diabetes and fatty liver disease, up to 84% of adults in the US are at risk and should be vaccinated. Recent projections show that several high-risk categories, including people living with diabetes and those with diagnosed sexually transmitted infections (STIs), are expected to continue rising over the next 20 years. With such a large proportion of adults meeting or expected to develop at least one risk factor, a universal HepB vaccine recommendation would improve the number of adults who are vaccinated and protected, preventing new infections in thousands of people. A universal adult Hepatitis B recommendation simplifies the vaccine process for providers, makes it easier for everyone to understand who needs to be vaccinated, and can eliminate a major barrier to vaccine uptake. Additionally, current guidelines are primarily focused on occupational exposures in healthcare settings. But increases in self-administered treatments and the opioid crisis have expanded occupational groups who may be at risk. Sanitation workers, cleaning service workers, and food service workers have all reported being accidentally stuck by a needle on the job. The CDC estimates that the average risk for contracting Hepatitis B from a needle stick is between 6% and 30% percent. While there are national and state protocols for safe needle disposal, an estimated 95% of needles are still discarded in municipal waste. Implementation of the Hepatitis B vaccine is currently limited by many logistical barriers. A universal adult vaccine recommendation is one large hurdle that we can jump to improve vaccine rates. We cannot eliminate HepB if we ignore key opportunities to protect our vulnerable populations. History shows that universal vaccine recommendations help increase vaccine rates and can open the doors for states to provide more aid. With increased awareness and support, we can reduce health disparities related to Hepatitis B and protect our communities. Thank you very much for your time.

Mrs. Pam Raitt
Concerned Individual

Thank you very much. I appreciate the opportunity. I will focus on the dangers of the coming fast track COVID-19 vaccines, pointing out the following facts. A healthy American has less than a 0.03% chance of dying from COVID-19. That is not a pandemic and is actually less than annual influenza season deaths. I recall Dr. Peter Hotez testifying in front of the Health Science Committee this March, "One of the things we're not hearing a lot about is the unique potential safety problems of coronavirus vaccine. It was first found in the early 1960s with the RSV vaccines that some of these kids that got that vaccine actually did worse, and I believe there were two deaths as a consequence of that study." This was actually a human trial cohort of 20 children performed in Washington, DC. Can we trust Moderna or Pfizer to develop a vaccine in only a short period of time that is safe and effective on SARS-CoV-2 when it hasn't been done

in the 18 years since the first outbreak of SARS? On March 15, 2020, HHS Secretary Alex Azar invoked the Public Readiness and Emergency Preparedness Act (PREP Act). This gave complete immunity to vaccine developers. Fast tracking has allowed vaccine development such as Moderna to bypass typical animal trials and go directly to Phase 1 human trials, bypassing a critical safety step. Despite hospitalizations in Phase 1 due to SAEs up to 20% in the high-dose group, they are moving ahead to Phase 2 and 3 trials and making 2 billion doses. In human trials, the vaccine is being giving to perfectly healthy individuals with exclusionary criteria like "could not be pregnant, overweight, never smoked, no family history of respiratory event problems, seizures, or any autoimmune diseases." What is going to happen when we give this vaccine to the average American? We're not only going to see 20% incidence of SAEs but likely much, much higher. And yet, with inadequate testing, we're going to mandate the vaccine to be administered to the 18 million Americans with chronic diseases, including HIV/AIDS, autism, autoimmune diseases, cancer, neuroimmune diseases associated with animal viruses acquired from vaccines contaminated with animal viruses from birds, dogs, cows, pigs, monkeys, and aborted fetal tissue. When recipients of the flu vaccine and coronavirus vaccine are subsequently exposed to the wild coronavirus, this is when we will see the spike in SAEs. The flu vaccine has been around for 90 years and is ineffective. Each year, it causes far more injury than benefit as evidenced by Vaccine Injury Compensation Program (VICP) payouts, which are almost exclusively from flu vaccines in the past several years, including deaths in the elderly. Why would the coronavirus vaccine be different? Cochran has performed three huge systematic reviews on the flu vaccine in 2010, 14, and 17 and concluded that there is little evidence that flu vaccine prevents hospitalization or death. Given the above, moving forward and administering the coronavirus vaccines to the general population would constitute human experimentation and thus informed consent must be given by all Americans. In conclusion, these COVID-19 vaccines cannot be made mandatory to the general public, health care workers, military, or first responders. We the people will not consent. We have Constitutional and basic God-given rights to decide what's injected into our bodies and those of our children. Thank you.

LeeAnn Ducat
CT Family Advocates

Thank you so much for having me. I'll get right to it. Recent lawsuits have uncovered proof that the CDC, specifically this panel, recommended mandated vaccines to children that were never placebo safety tested. Without inert placebo testing, no one can point to any vaccine, even a COVID one, and say that it is more or less dangerous than the infection itself. My point is that we're already at warp speed with these children's vaccines and now we're going even faster to approve a COVID one when we should be pumping the breaks. Rushing products to market in the name of greater good and using active placebos instead of inert ones is playing God. Dr. Fauci even told us that hydroxychloroquine couldn't be given to dying COVID patients because of no placebo-controlled studies. By that logic why on earth would anyone recommend that healthy people receive a product that has not been held to the same standard? Is this really about public health or profitability? Because if you really cared about public health, why is this panel not recommending sunshine, exercise, organic food, vitamins, and adequate sleep? Because your current recommendations have created the sickest generation of kids ever. Ever. You have shut down the entire country and caused massive spikes in suicides, addiction, abuse, and hardship. Well, the day of reckoning is coming. The truth cannot be suppressed forever, even with censorship, no matter how much Ms. Dorit Reiss calls for it. Government health authorities are rapidly losing credibility due to blatant inconsistencies, half-truths, and lies. The false narrative about vaccine safety is crumbling. Even the CrossFit® guys sued you and won. They said, and I agree, "The CDC prioritizes industry partnerships over its charter to protect and inform the American public." They also said that, "The CDC and HHS have

simultaneously failed to address the chronic disease epidemic." And they're not alone. These complaints span from every racial and socioeconomic demographic. We want answers, we want accountability, and we want immediate change. The blunders made by the CDC surrounding vaccines in general and COVID-19 have recruited more activists at warp speed faster than I could have ever imagined. So, really, I'm here to thank you. You're doing my job for me just by being yourselves—warp speeding the American public to justice for the lives we lost to Big Pharma. Your charade is almost over. There is honor in admitting when you're wrong. It's time to stand up for truth and it's time to pick people over profits. Thank you for your time and thank you for having me.

Acronyms

AAPHP	American Association of Public Health Physicians
ACA	Affordable Care Act
ACCP	American College of Correctional Physicians
ACIP	Advisory Committee on Immunization Practices
ADA	Americans with Disabilities Act
ADE	Antibody-Dependent Enhancement
CDC	Centers for Disease Control and Prevention
COI	Conflict of Interest
DNA	Deoxyribonucleic Acid
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
FORBS	Fraternal Order of Real Bearded Santas
HHS	(Department of) Health and Human Services
HPV	Human Papillomavirus
IAC	Immunization Action Coalition
ICAN	Informed Consent Action Network
LTCF	Long-Term Care Facilities
mRNA	Messenger Ribonucleic Acid
NAC	National Alliance for Caregiving
NCL	National Consumers League
NFID	National Foundation for Infectious Diseases
PREP Act	Public Readiness and Emergency Preparedness Act
QALY	Quality Adjusted Life Years
RSV	Respiratory Syncytial Virus
SAE	Serious Adverse Event
STI	sexually transmitted infection
UT	University of Tennessee
VAERS	Vaccine Adverse Event Reporting System
VICP	Vaccine Injury Compensation Program
VRBPAC	Vaccines and Related Biological Products Advisory Committee