S. HRG. 116–527

VACCINES: SAVING LIVES, ENSURING CONFIDENCE, AND PROTECTING PUBLIC HEALTH

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING VACCINES, FOCUSING ON SAVING LIVES, ENSURING CONFIDENCE, AND PROTECTING PUBLIC HEALTH

SEPTEMBER 9, 2020

Printed for the use of the Committee on Health, Education, Labor, and Pensions

Available via the World Wide Web: *http://www.govinfo.gov*

U.S. GOVERNMENT PUBLISHING OFFICE

45–225 PDF WASHINGTON : 2022

For sale by the Superintendent of Documents, U.S. Government Publishing Office
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C O N T E N T S

STATEMENTS

WEDNESDAY, SEPTEMBER 9, 2020

VACCINES: SAVING LIVES, ENSURING CONFIDENCE, AND PROTECTING PUBLIC HEALTH

Wednesday, September 9, 2020

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–430, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

Present: Senators Alexander [presiding], Murray, Enzi, Sanders, Burr, Casey, Paul, Baldwin, Collins, Warren, Cassidy, Kaine, Murkowski, Hassan, Romney, Smith, Jones, Rosen, Scott, Braun, and Loeffler.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Committee on Health, Education, Labor, and Pensions will please come to order. First, I would like to welcome everyone and go through some administrative matters that we do at the beginning of the hearing. We have done this after consulting with the attending physicians, Sergeant-at-Arms, CDC, Health and Human Services. Individuals in the room are seated six feet apart so there is no room for the public to attend and the press is working as a pool. The hearing maybe watched gavel-to-gavel online.

Both of our witnesses today, Dr. Collins and Surgeon General Adams are participating in person. Some Senators are in person, some are participating by video conference. The Office of Attending Physician has advised that Senators and witnesses may remove their masks to talk in the microphone since our chairs are six feet apart or more. So that is why my mask is off. I am more than six feet apart. When I am in the hall or when I am walking on the Senate floor, I wear my mask. So we are grateful to the Rules Committee, the Sergeant-at-Arms, the Press Gallery, the Architect of the Capitol, Chung Shek and Evan Griffis, all who have helped us maintain a safe environment for this hearing. I would like to say to that their votes have begun at 11:15 a.m., but we will continue the hearing so that all Senators will have a chance to participate. And if necessary, I will leave and I will ask someone else to preside during the time that I am voting and then I will come back.

Senator Murray, and I will each have an opening statement. We will then turn to our witnesses who we thank for being with us. We would like to ask the witnesses to summarize their remarks in 5 minutes to leave more time for back and forth questions. I will

ask each Senator, questions of 5 minutes or of up to 5 minutes. I have been reading, I was saying to Senator Tim Kaine and Maggie Hassan that I have been reading Guns, Germs, and Steel the book that Jared Diamond wrote that won a Pulitzer Prize in 1977. He wrote that there is nothing new about epidemics that cause mass deaths and social upheaval, and there is nothing new about where most of the infectious disease come from.

Over the last 10,000 years, he says, humans have acquired most of our infectious diseases from animals. During most of history there were basically three ways to deal with these epidemics, one was to isolate the infected. Leper colonies, for example. Two, according to Jared Diamond, was that over thousands of years there have been genetic changes in human populations in response to infectious diseases that cause major outbreaks like small pox, but that didn't help the Native Americans who had no resistance when European settlers arrived here, wiping out 90 percent for example of a native tribes by handing them blankets with smallpox on it because the tribe had not previously been exposed to the virus. And then there is a third way that was most common throughout most of history and that was really to let it rip, let the virus run its course through the population until everyone had either been killed or recovered and develop some immunity. Diamond says that the Black Death killed about one third of Europe's population between 1347 and 1351.

What is new about epidemics is modern medicine, including the ability to diagnose the disease and create treatments to make it easier to recover. But the true miracle of modern medicine is vaccines which can prevent humans from acquiring the disease at all. That is why today in all 50 states and the District of Columbia school children are required to take vaccinations for the following diseases, diphtheria, tetanus, the whooping cough, polio, measles, rubella and chickenpox before entering school. The vaccination will protect the child from getting the disease which in turn prevents the child from infecting someone else, a pattern that has caused these diseases eventually to disappear.

Americans of my generation remember how polio terrified our parents in the early 1940's and 50's. Many saw their children die or be left depended on an iron lung to breathe for the rest of their lives. Of those who contracted polio, the lucky children were like Senator Mitch McConnell, the majority leader, who was left only with a limp. The disease terrified Americans until Dr. Jonas Salk developed the polio vaccine in the 1950's. After the vaccine was developed, the United States undertook a large-scale vaccination program and polio was declared eradicated from the United States in 1979. So the purpose of this hearing is to explore the remarkable progress that science is making toward a COVID–19 vaccine to remind parents to get their child vaccines and to encourage as many Americans as possible to get the flu vaccine this fall.

First the progress toward a COVID vaccine. Dr. Collins, the Director of the National Institutes of Health, is here today to talk about that, research and development, Operation Warp-Speed which is working around the clock to develop manufacture and distribute a safe and effective vaccine to hundreds of millions of Americans. Some people incorrectly believe that warp speed means cut-

ting corners, but it refers to the extraordinary investment in research, development, and manufacturing scale up for the COVID–19 vaccine. Perhaps most significantly the Biomedical Advanced Research and Development Authority, we call it BARDA, has taken up the unprecedented step to help speed up manufacturing for hundreds of millions of doses of the vaccine early in the process so they can be ready as soon as the new vaccines are approved by the Food and Drug Administration.

In other words, they will be manufactured before they are approved, and if they are approved, they will be ready to distribute and if they are not approved, they will be thrown in the dumpster. Despite the speed with which scientists are developing this COVID–19 vaccine, Dr. Hahn, the Commissioner of FDA, said the Administration is not or his agency, "is not skimping on its review of safety and efficacy. This is going to be a science, medicine data decision. This is not going to be a political decision," Dr. Hahn said. That means that if the FDA determines that a vaccine is not safe or effective after reviewing the science and clinical trial results, the vaccine will not be distributed.

At the same time, CDC is working on a plan to distribute the vaccine as soon as they are authorized or approved, prioritizing vaccines for healthcare workers and vulnerable populations. CDC's plan will be a fair system informed by nonpartisan health experts from the National Academies of Science, Engineering and Medicine and the Advisory Commission on Immunization Practice. As inevitably happens, some have suggested, well, you are speeding up the vaccine because an election is coming and you have asked states to distribute it because an election is coming. Well, I was thinking this morning, what if Dr. Collins showed up and Dr. Adams saying well, it will be 5 years before we are going to get a vaccine. I think we probably throw them out of the room and ask the President to try to find some more effective people. Or what if we didn't ask states to get ready to distribute the vaccine and show that we hadn't learned our lesson from what happened with the H1N1 virus when the vaccine was ready, but the states weren't ready to distribute it. So we should move as rapidly as we can, both to develop the vaccine and to be prepared to distribute it.

Why are some Americans saying they are not persuaded to take the vaccine? Well, there are three reasons. One is are they safe? Vaccines are approved and reviewed by the Food and Drug Administration. FDA can either license a vaccine or authorize it for use during a public health emergency and the FDA stringent approval process is the world's gold standard. The vaccines are routinely—that are given to children are specifically recommended by the advisory committee on immunization practices and outside group of health experts that look at all available scientific information about each vaccine. And the medical associations like the American Academy of Pediatrics ,the American Academy of Family Physicians work with that agency to develop these recommendations.

In a 2015 article in Scientific American, Nina Fimeran writes, "by age two, most children will receive almost 30 shots designed to boost a child's natural defenses against disease yet the same time parents who take their children for those recommended vaccinations might be inundated with website and celebrity espoused ru-

mors making false claims that shots are not necessary or cause autism." She continues, "at best navigating this landscape can be confusing but when weighing the risk of encountering life-threatening disease against the benefits of receiving a vaccine, there is no contest. The vast majority of children do not experience anything worse than short-lived redness or itching at the spot of the injection." And then are they effective? According to CDC there is evidence that smallpox was ravaging humans as early as the 3rd century B.C.E.

The disease killed three out of 10 people who were affected. Then in 1796 an English doctor named Edward Jenner saw that milkmaids who had gotten cowpox seemed to be immune from smallpox. So he scratched some pus from a cowpox blister on an eight-year-old boy and the boy became immune to smallpox. Jenner published his results in 1801 leading to the development of mankind's first ever vaccine and no one on earth has naturally acquired smallpox since 1977. It has been officially eradicated. Polio was one of the most dreaded childhood diseases. Following the introduction of vaccines, specifically the vaccine in 1955 and then another in 1963, the number of polio cases fell rapidly to less than 100 in the 1960's to fewer than 10 in the 1970's according to CDC.

Thanks to a successful vaccination program, the United States has been polio-free since 1979. Diphtheria terrified patients in the 1920's but today there are only a few cases a year according to the AAP which attributes the change to vaccinations. And then there is, is the doctor's office safe? The panic has made some parents leery of the doctor's office, but analysis of patient records according to the Wall Street Journal, shows that the immunization rate for recommended routine childhood vaccines has declined about 40 percent from late February through mid-April. So for parents who are worried about taking the children to the doctor, the American Academy of Pediatrics says pediatricians are working to make their offices as safe as possible. They say they are among the safest places you can be. Don't be afraid to take your child to see your doctor.

I started my statement with comments from Jared Diamond. I will end with a warning he wrote recently, on June 23rd this Committee held a hearing on preparing for the next pandemic. One member of the Committee asked, why would we worry about the next pandemic when we haven't even conquered this one yet? Well in a Wall Street Journal essay on May 23rd Jared Diamond provides an answer to that comment. He says that in this age of jet planes with millions of people carrying infections from one place to another overnight, the next pandemic could be next year and we would be wise to prepare for it. Congress tried to do that in response to the other new diseases that have emerged over the last 40 years. HIV/AIDS, SARS, MERS, Ebola, but good intentions often evaporated as the epidemics ended. As one example, in 2012 Congress created three manufacturing plants, so that when the next epidemic arrived we could introduce vaccines rapidly.

Fortunately two of those plants are playing a role in manufacturing hundreds of millions of doses of vaccine for COVID–19. Senator Burr, and I took a virtual tour of one of them not long ago. However, there is still a need to improve and sustain these types

of facilities so they are able to pivot more quickly to the next threat when it emerges. In a similar way, stockpiles were created and then stockpiles were depleted. Former HHS Secretary and Governor Mike Leavitt told this Committee that public health programs have been underfunded for the last 30 to 40 years. The Nation goes, he said, from panic to neglect to panic. Fortunately, thanks to an unprecedented effort by the private sector in our Government as well as scientists around the world, there is likely to be a COVID–19 vaccine ready for the most vulnerable citizens by the end of the year and hundreds of millions of doses available in 2021. Some of the challenges apart from finding a vaccine are how to distribute it, whom should it go first, and how to persuade Americans that it is safe to take.

But while we are in the midst of dealing with this pandemic, it would be wise to remember in any legislation that Congress passes this year to make sure that onshore manufacturing plants are functioning, stockpiles are full, public health is properly funded, and states have the right tools and resources. The reason to do that now while our eye is on the ball is at the next pandemic, as Jared Diamond wrote, could be next year.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you very much, Mr. Chairman. And while you still have a few months left, well and a few more hearings, I do want to start off by saluting you for your many years of service to this country, including as Senator and Chairman of this Committee. I know my Democratic colleagues and I will miss you next year. On the topic of today's hearing. Mr. Chairman, our country is in the middle of a painful crisis.

The COVID–19 pandemic has crowded hospital intensive care units. It has emptied schools. It has shuttered businesses. It has deepened damaging health disparities among Black, Latino, and tribal communities, people with low incomes and people with disabilities. It has ravaged prisons and nursing homes and other congregate care facilities. It has strained our economy, our mental health, and a lot more. It has claimed around 190,000 lives so far and more each day. Unfortunately, instead of leading us in the war against this virus and fighting the pandemic, President Trump is fighting public health experts.

Instead of supporting facts and science, he is supporting conspiracies. He has spread absurd false theories about FDA officials being deep state agents and CDC overstating the death toll. He has promoted unproven treatments and junk science. He has called for less testing, which he blamed for the rising number of COVID–19 cases, wrongly claimed kids aren't likely to get or transmit the virus, and has repeatedly insisted this will just all go away. The list of inaccuracies and outright lies at a time when truth is a matter and life and death goes on and on. And unfortunately, President Trump is not alone in his deeply flawed response.

In July, after months of delay in an action, Republicans put forward a proposal that didn't even come close to addressing the harsh realities of this pandemic. Now, we are hearing their new plan is to force a vote on a proposal that does even less. I hope in-

stead that Republicans will sit down with Democrats to work on a package that helps our economy and keeps our American families safe. A package that actually increases testing and access to healthcare, that actually supports our schools and addresses the child care crisis and actually protects workers, and most relevant to this hearing today helps make sure we get safe, effective, trusted vaccines that are widely and equitably distributed and administered.

Vaccines have long been a critical public health tool, and even before this crisis, it was important that we encourage uptake of flu vaccines each year to keep people safe, to make sure vaccines are available and administered to kids across the Nation including through efforts like the Vaccines for Children program, and to build vaccine confidence while combating misinformation. But this pandemic has made these challenges more urgent than ever. So I am glad we do have Surgeon General Dr. Adams and NIH Director Dr. Collins here today to share their expertise, but I am also frustrated that despite my request to the Chairman, FDA Commissioner Dr. Hahn and CDC Director Dr. Redfield were not invited to testify today. Those agencies play a very critical role in developing and distributing vaccines and should be here today. Hearing from them is even more urgent in light of recent political interference. By waiting to bring them before the Committee, we are losing valuable time to avoid costly mistakes.

In the past few weeks, we have not only watched President Trump directly promote conspiracies about FDA and CDC, we have also seen reports that he exerted political pressure on FDA to issue an emergency use authorization for convalescent plasma, and on CDC, which changed testing guidelines to be more restrictive with no justification and running counter to the consensus of public health experts from across the country. And these aren't the first reports of political interference. The Trump administration has previously promoted unproven treatments like hydroxychloroquine and blocked CDC guidelines for community reopening.

Recently FDA Commissioner Hahn announced he was prepared to authorize a COVID–19 vaccine before Phase 3 trials were complete but without providing any guidance about when that would be appropriate. When it comes to a COVID–19 vaccine, we cannot allow President Trump to repeat his alarming pattern of putting politics ahead of science and public health. FDA scientists' efforts to ensure the safety and efficacy of vaccines must not be undermined by political meddling. CDC's role in distributing a vaccine and prioritizing who receives the first doses must not be supplanted by politicians or campaign strategists or corporate lobbyists.

If we are going to begin to turn the page on this pandemic, people across the country must not have any doubt in this process or in the final product, which is why we need to hear directly and immediately from our public health agencies about how they will prevent political interference and why we need to push to the transparency required to hold this Administration accountable. We need the FDA to be transparent by issuing an official guidance with standards for granting any vaccine and emergency use authorization, including standards for the independent review of Phase 3

data by waiting for the completion of Phase 3 clinical trials before moving on any candidates and by committing to make public any data used to green-light a vaccine.

We need transparency from CDC about how it plans to handle distribution, how its experts will drive the process despite the ill-advised decision to have the Department of Defense rather than CDC lead a lot of this effort and who will get priority when the first doses are available. We also need transparency on Operation Warp-Speeds contracts and how it is addressing any potential conflict of interest. In short, we need transparency from top to bottom. And of course in addition to transparency, we still need a comprehensive national vaccine plan, one of several steps I have called for in the vaccine white paper I put out on vaccine months ago. We have seen with testing how many problems the Trump administration caused by throwing up its hands and refusing to develop a plan and leaving our states to fend for themselves. Testing is an ongoing catastrophe and we cannot risk a repeat performance when it comes to vaccines.

The Administration must develop an end-to-end national vaccine plan that addresses how we make sure vaccines are safe and effective, how we produce, distribute, and administer hundreds of millions of doses, how we alleviate rather than deepen the health disparities we know exist, and how we overcome barriers to access like cost and proximity to providers, and how we promote vaccine confidence and fight misinformation, especially when there is so much misinformation coming from the President of the United States. Developing and distributing safe, effective vaccines is a huge undertaking and one that cannot be accomplished without a strong science driven leadership from the Federal Government.

I really am glad we have this opportunity to talk about the important challenges that lie ahead but there are many more questions we need to answer and so many more witnesses that we need to hear from. And I will absolutely keep pushing to make that happen. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray, and as usual, you are having some considerable effect. We have announced our next health hearing which will be in two weeks. Dr. Redfield from CDC will be a witness. Admiral Giroir will be here. Dr. Hahn, head of FDA will be here. And Dr. Anthony Fauci will be a witness. Today, we have two witnesses. We welcome them.

Dr. Francis Collins is Director of the National Institutes of Health. He oversees the largest public funding of biomedical research in the world. He is a physician geneticist. Prior to becoming the NIH Director in 2009, he served as Director of the agency's National Human Genome Research Institute from 1993 to 2008, and he led the International Human Genome Project. He is a member of the National Academy of Medicine, National Academy of Science and was awarded the Presidential medal of freedom and received the national medal of sciences. He is a graduate of Virginia and Yale, University of North Carolina School of Medicine, and he is the only National Institutes of Health Director I know who has ever played the guitar at the Bluebird Cafe in Nashville and played it pretty well I might say.

Next, we hear from Vice Admiral Jerome Adams, Surgeon General of the United States. He oversees Public Health Service Commission Corps, a group of over 6,000 public health professionals working throughout the Federal Government for the advancement of public health. He previously served as the Indiana State Health Commissioner. He led that state's response to Ebola, HIV, and Zika.

He was staffed anesthesiologist and assistant professor at the Indiana University School of Medicine. He has been at the University of Maryland Baltimore County where he obtained a degree, Masters from the University of California at Berkeley and MD from Indiana University where he completed his residency. Welcome to both witnesses. Dr. Collins, let's begin with you.

STATEMENT OF FRANCIS COLLINS, M.D., PH.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD

Dr. COLLINS. Well, thank you very much and perhaps we could get the visuals up on the screen if that is possible. Chairman Alexander, Ranking Member Murray and distinguished Members of this Committee, thank you for inviting me to discuss Operation Warp-Speed and the importance of developing safe and effective vaccines. I am grateful for your long-standing support of NIH and for this opportunity to address how we are working tirelessly with other parts of the Government and with industry partners to prevent, diagnose, and treat the novel coronavirus, SARS COVID 2. Let me provide a metaphorical illustration of how vaccines work.

Your immune system is like an antibody factory. Yes, you have a very sophisticated biotech company inside your body. When your body sees an invader like these three viruses, it designs an antibody, a y-shaped protein that can counter that specific threat. It may take a week or two for the factory to make that new product but then it keeps the blueprints on file for every antibody it has ever made. The goal of a vaccine therefore is to present a completely harmless part of the virus to your body, allowing your factory to work out an effective production strategy. Now, if at some time in the future the actual virus enters your body, your factory can quickly pull out the blueprints and ramp up production wiping out that virus before it has a chance to multiply and make you sick. For COVID–19, there are six vaccine candidates engaged in large-scale U.S. trials.

Each vaccine has already undergone rigorous testing in animals followed by Phase 1 safety testing and a small group of humans. For three of the six vaccines, we are already in Phase 3 of testing, where the goal is to inject 30,000 volunteers located in areas where the virus is actively spreading. Half of the volunteers are injected with the vaccine and half placebo and nobody knows which is which. Over the next weeks, they are followed closely to see if infections occur. A successful vaccine should have many fewer cases of COVID–19 in those who got the actual vaccine versus those who got the placebo. We will also follow all of them for as long as two years to assess safety. We expect the other three candidates to enter Phase 3 in the coming weeks and months. Now these six vaccines represent three different scientific approaches.

Having this mix of strategies is the best insurance against some unexpected problem with safety or efficacy. We hope and expect that more than one of these will succeed. They all have one thing in common, the initiation of immune responses against the spike protein of the SARS COVID 2 virus and you have seen this picture so many times but that is the protein you want to raise that antibody against. We know that people who have survived COVID–19 make neutralizing antibodies to this spike. So we want the vaccine to do the same. Now, the first scientific approach is a very traditional method, recombinant protein technology. Basically, you purify the spike protein in the laboratory and you inject that purified protein and the antibody factory goes to work. The laboratory process to produce and purify the protein means that this approach, although tried and true, is on a bit lower trajectory than some of the other candidates but not much.

Novavax plans to initiate their Phase 3 trial in mid-October. Santa Fe and GSK announced their Phase 1 clinical trial last week. If results are positive, Phase 3 would start for them by the end of the year. The second scientific approach also uses a well-known vaccine technology, harnessing a harmless viral vector called an adenovirus and using it basically as a delivery truck. The adenovirus is modified by inserting a gene for the spike protein. Once the virus enters the individual cells, the spike protein is produced triggering an immune response. Phase 3 clinical trial of this approach was launched by AstraZeneca on August 31st, though it is now as of yesterday on clinical halt ,and a similar Phase 3 trial will be launched by Jansen later this month.

Finally the newest platform technology is one that was developed at NIH using supplemental funds from the Ebola epidemic a few years ago. In this approach, which is now being pursued separately by Pfizer and by Moderna, a small, non-infectious snippet of messenger RNA or mRNA from the genome of SARS COVID 2 is prepared. Injecting this mRNA, which codes for this spike protein, into muscle will spur a person's own cells to make that protein and then encourage the production of those protective antibodies against SARS COVID 2. Before I conclude, I want to address concerns about safety. This is foremost in all our minds. We cannot compromise here. The announcement yesterday about the AstraZeneca vaccine is a concrete example of how even a single case of an unexpected illness is sufficient to require a clinical halt for the trial in multiple countries. And that is what is happening. There are ways however that we have adopted in warp speed to move quickly while retaining those most rigorous scientific standards.

I think you would want us to do that. People are dying. Delays that traditionally require many years for a vaccine to be developed had to be addressed. In some instances we have done that by carrying out steps in parallel that are traditionally done in sequence. We have eliminated downtime by moving into new phases before data from the previous phase is completely analyzed. We have, as the Chairman said, started to manufacture doses of all these vaccines before we know if they work, understanding that we are spending hundreds of millions of dollars for a vaccine doses that we may have to throw away if they don't work. But please hear me

out, the rigor of the scientific evaluation on safety and efficacy will not be compromised.

As a scientist, I am excited that the pace of discovery is allowing us to respond to this crisis in record time. As a physician, I am hopeful when I think of the millions of lives that have been saved from other diseases through vaccination and the millions more that we can save by developing a safe and effective vaccine for COVID–19. Thank you again for your support. I look forward to your questions.

[The prepared statement of Dr. Collins follows:]

PREPARED STATEMENT OF FRANCIS S. COLLINS

Chairman Alexander, Ranking Member Murray and distinguished Members of this Committee thank you for inviting me to discuss the Department of Health and Human Services' (HHS) Operation Warp Speed (OWS) efforts and the importance of vaccination. I am grateful for this opportunity to address how the National Institutes of Health (NIH) is working tirelessly with other parts of the government, and with industry partners, to prevent, diagnose, and treat the novel coronavirus SARS-CoV–2. We thank Congress for your continual partnership in response to COVID–19.

I am also pleased to be here today to reinforce the importance vaccines play in protecting public health from childhood immunizations to the annual flu and pneumonia vaccines in keeping Americans safe and healthy. While our immediate focus has been on the development of a COVID–19 vaccine, we can't lose sight of the need to encourage the continued uptake of all vaccines by the American people.

To accelerate the development and subsequent production of a vaccine for COVID–19, in mid-May, President Trump announced Operation Warp Speed (OWS). OWS aims to deliver up to 300 million doses of a safe and effective vaccine for COVID–19 in early 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID–19 vaccines, therapeutics, and diagnostics (collectively known as medical countermeasures). OWS is a partnership among components of HHS, including NIH, Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), and Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD), with the aim of a unified government approach to respond to the pandemic. OWS engages with private firms and other Federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. OWS coordinates with existing HHS-wide efforts, including the NIH's Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV) partnership, NIH's Rapid Acceleration of Diagnostics (RADx) initiative, and research activities by the National Institute of Allergy and Infectious Diseases (NIAID).

NIH is the HHS agency leading the biomedical research response to COVID–19 and the novel coronavirus that causes the disease, SARS-CoV–2. We have done everything possible to unleash the most rapid and innovative approaches to address this global pandemic. The importance of studying the safety and efficacy of vaccine and therapeutic candidates during the critical clinical trial phases is now NIH's top priority. OWS has been selecting the most promising countermeasure candidates and providing coordinated government support. Protocols for the demonstration of safety and efficacy are being aligned, which allows the trials to proceed more quickly. The protocols for the trials are being overseen by the Federal Government, in contrast to traditional public-private partnerships, in which pharmaceutical companies are solely responsible for design and implementation of their own protocols. Rather than eliminating steps from traditional development timelines, steps are proceeding simultaneously. That includes starting manufacturing of a vaccine candidate at industrial scale well before the demonstration of vaccine efficacy and safety, as happens normally. This increases the financial risk in the event of non-optimal product performance, but not the product risk.

It is important to highlight that none of the safety and efficacy assessments will be skipped or abbreviated. Efforts to shorten the timeline from bench to bedside, but still achieve a safe and effective vaccine, have been accomplished by eliminating down times and assuming the costs of at-risk manufacturing. Throughout the clinical trials, an independent data and safety monitoring board (DSMB) continues to monitor ongoing results to ensure study participant well-being and safety as well as study integrity. The critical final steps in clinical trials will be well-coordinated

and done in parallel with manufacturing, but with NIH and industry providing the FDA with all of the critical safety and efficacy data necessary for sound scientific decisionmaking.

NIH is deeply engaged in the vaccine trial program. NIAID recently established the COVID–19 Prevention Network (CoVPN) by leveraging four existing NIAID-funded clinical trials networks: the HIV Vaccine Trials Network (HVTN), the HIV Prevention Trials Network (HPTN), the Infectious Diseases Clinical Research Consortium (IDCRC), and the AIDS Clinical Trials Group (ACTG), in partnership with the DoD. The CoVPN is engaged in assisting enrollment of tens of thousands of volunteers in large-scale clinical trials testing a variety of investigational vaccines, monoclonal antibodies (mAb), and drugs intended to treat and protect people from COVID–19. The CoVPN is a functional unit of the OWS partnership led by HHS to invest in and coordinate the development, manufacture, and distribution of COVID–19 vaccines, therapeutics, and diagnostics. The CoVPN is participating in harmonized protocols, developed in collaboration with the ACTIV public-private partnership, vaccine manufacturers, and BARDA. The network will participate in numerous trials at more than 100 clinical trial sites across the United States and internationally. The CoVPN has developed an extensive community engagement framework to reach out to the diverse communities most affected by COVID–19; understand interest in, and concerns about, research participation; and partner with them to ensure their input is reflected in study implementation. The CoVPN plans to evaluate both therapeutic and vaccine candidates. While the long-term goal is to have a safe and effective vaccine, NIH is continuing its vital work on researching and evaluating all potential therapeutic approached against SARS-CoV–2.

Identifying Therapeutics to Treat COVID–19

NIH, in collaboration with the Foundation for the NIH, launched an innovative public-private partnership to speed up the development of COVID–19 therapeutics and vaccines. The ACTIV public-private partnership brings together stakeholders from across the U.S. Government, industry, and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID–19 pandemic. The ACTIV public-private partnership is led by an Executive Committee co-chaired by me and Dr. Paul Stoffels of Johnson & Johnson, and has engaged more than 100 experts from both sectors in a 24/7 effort to prioritize therapeutic options. ACTIV has designed five adaptive master protocols for ACTIV clinical trials. These master protocols provide an efficient and coordinated evaluation of multiple investigational agents as they become available within the same clinical trial structure and across multiple study sites. Adaptive master protocols reduce administrative burden and cost, provide a flexible framework to identify rapidly drug candidates that work, and quickly move additional experimental agents into the trial.

Effective therapeutics for COVID–19 are critically needed to treat patients who have been infected with SARS-CoV–2. NIH was engaged in this effort from the very beginning of the pandemic. On February 21, 2020, NIAID launched a multicenter, randomized placebo-controlled clinical trial, the Adaptive COVID–19 Treatment Trial (ACTT), to evaluate the safety and efficacy of therapeutics for COVID–19, initially examining the antiviral drug remdesivir for treatment of severe COVID–19 in hospitalized adults (ACTT–1). An analysis of preliminary data from ACTT–1 indicated that those who received remdesivir had a 32 percent faster time to recovery, a median of 11 days compared with 15 days for those who received placebo. These initial findings were published on May 22, 2020, in the *New England Journal of Medicine*. The adaptive design of this trial will enable the evaluation over time of additional promising therapies, such as the anti-inflammatory drug baricitinib. This drug was added to the second iteration of the study (ACTT–2); enrollment for ACTT–2 is now complete. The third iteration of the study (ACTT–3), announced by NIH on August 6, 2020, is a randomized, controlled clinical trial to study the use of interferon beta–1a, which is typically used to treat individuals with multiple sclerosis.

Monoclonal antibodies (mAbs) are another promising approach for the treatment of COVID–19. At least 21 companies are developing mAbs that target SARS-CoV–2 and several of them are already being studied in clinical trials. On August 4, 2020, NIH launched two clinical trials under the ACTIV–2 and ACTIV–3 master protocols. ACTIV–2, a Phase 2/3 clinical trial, will evaluate potential therapeutics in study participants with mild to moderate COVID–19 who do not require hospitalization. The first stage of ACTIV–2 is looking at the potential of synthetic mAbs to treat the disease. The trial may also investigate other experimental therapeutics

later under the same trial protocol. Another Phase 2/3 randomized, controlled trial known as ACTIV–3 will test mAb treatments in *hospitalized* patients. The initial stage of the ACTIV–3 clinical trial plans to enroll approximately 300 volunteers who have been hospitalized with mild to moderate COVID–19. ACTIV–3 will initially study the investigational mAb from Lilly, LY-CoV555, discovered by Abcellera Biologics in collaboration with NIAID's Vaccine Research Center (VRC).

Developing Vaccines to Prevent SARS-CoV–2 Infection and/or COVID–19 Disease

A safe and effective vaccine for SARS-CoV–2 will be essential to stopping the spread of infection, reducing rates of morbidity and mortality, and preventing future outbreaks. It is among our best hopes for getting our country back to normal.

NIAID has been supporting development of several SARS-CoV–2 vaccine candidates, including vaccines based on platform technologies that have shown promise against coronaviruses that cause SARS and MERS. As part of a longstanding collaboration, the NIAID VRC worked with biotechnology company Moderna, Inc., to develop a vaccine candidate using a messenger RNA (mRNA) vaccine platform expressing the SARS-CoV–2 spike protein. On July 14, 2020, encouraging interim findings from the Phase 1 clinical trial were published in the *New England Journal of Medicine*. The investigational mRNA–1273 vaccine was generally well tolerated and induced robust neutralizing antibody responses in healthy adults in this interim analysis of data from the ongoing trial. On May 29, 2020, a Phase 2 clinical trial, sponsored by Moderna, was initiated to further study the safety and immune response to the experimental mRNA vaccine. The Phase 2 study closed to enrollment on July 30, 2020, and is now in follow-up—no safety concerns have been identified. The Coalition for Epidemic Preparedness Innovations (CEPI) funded the manufacture of the vaccine candidate for the Phase 1 trial, and BARDA is supporting advanced development of the candidate.

Scientists at NIAID's Rocky Mountain Laboratories (RML) in Hamilton, Montana, are collaborating with University of Oxford researchers to develop the SARS-CoV–2 chimpanzee adenovirus-vectored vaccine candidate AZD1222, formerly known as ChAdOx1. The University of Oxford has partnered with the pharmaceutical company AstraZeneca on this vaccine candidate, now in a Phase 3 clinical trial in the U.S. supported by NIAID and BARDA. BARDA has announced plans to support advanced development and production of AZD1222.

In July, OWS committed to working with Novavax on their new COVID–19 vaccine candidate after Phase 1 trials of this vaccine were done in Australia with promising results. A Phase 3 trial is expected to begin in the U.S. by the end of September. Janssen Pharmaceutical Companies of Johnson & Johnson have a viral vector COVID–19 vaccine candidate that has demonstrated protection in nonhuman primate models. OWS is working with this company and Phase 1 trials began on July 27, 2020, in the U.S. Depending on results from the early trials, a Phase 3 clinical trial is expected to begin this month. Additionally, Sanofi working with GSK developed a protein-based vaccine candidate that is currently in preclinical development. A Phase 1 trial is expected to begin this month with a goal of entering Phase 3 by the end of 2020.

Lastly, Pfizer working with BioNTech developed an RNA vaccine candidate for COVID–19. Phase 3 trials for this vaccine began on July 27, 2020. The RNA vaccines, developed by Pfizer in partnership with BioNTech, and by Moderna in partnership with NIAID, have already begun large scale manufacturing in order to be ready to distribute if the Phase 3 trials show promising results on the safety and efficacy of the vaccine candidates. OWS is working to refurbish manufacturing sites to scale up manufacturing for the other COVID–19 vaccine candidates in testing. The CoVPN at NIH is currently working to enroll thousands of volunteers in the clinical trials for vaccine candidates and preventive interventions. We continue to prioritize enrollment of racial and ethnic populations impacted disproportionately by this disease. It is critical that we continue to engage all communities in this effort with transparency and the highest standards of safety and ethics.

The CoVPN developed a community engagement framework to assist researchers in reaching out to communities, and potential research volunteers. In order to have the trust of the community, NIH has prioritized open and transparent communication with participants, sharing the specific details involved in participating in the clinical trials for COVID–19 vaccine candidates or therapeutics and using their feedback to improve the trial designs. To facilitate outreach to key communities, the CoVPN established expert panels of 10–15 scientific experts from within those respective communities. NIH believes that by engaging communities early we can ad-

dress any concerns about the treatments and vaccines in advance of potential distribution of FDA-approved/licensed vaccines.

COVID–19 and Seasonal Influenza

The fight against the COVID–19 pandemic may become more difficult as we enter the fall and winter "flu season". Each year influenza causes a surge in hospitalizations. This expected surge, in combination with COVID–19, is a serious concern for healthcare systems across the U.S. In addition to the expected surge in patient numbers, the clinical symptoms for influenza and SARS-CoV–2 can overlap, and an increase in influenza infections will require testing for SARS-CoV–2 in order to determine if the patient has COVID–19 or influenza. NIAID is currently supporting studies investigating the impact of seasonal influenza co-circulation with SARS-CoV–2, and coinfections have already been observed in the Southern hemisphere. An increase in the vaccination rate for influenza will help to safeguard our healthcare systems against this surge, by reducing flu morbidity, to allow for COVID–19 surge capacity in hospitals and reducing the number of sick individuals presenting to outpatient clinics. During the 2018–2019 fall and winter, the influenza vaccination rate for adults was 45.3 percent. It is imperative that we increase this vaccination rate to protect our healthcare systems. Last, it is important to remind the public that childhood vaccinations are another way we can protect our communities and healthcare systems from avoidable illnesses and deaths.

Conclusion

The rigorous clinical testing required to establish vaccine safety and efficacy means that it may take some time for a licensed SARS-CoV–2 vaccine to be available to the general public, but there is growing optimism that one or more of these vaccine candidates will prove safe and effective by late 2020 or early 2021.

The NIH is the world's largest biomedical research funder, but we are also America's research engine. Right now, our funded scientists are working around the clock to find the best ways to diagnose, prevent, and treat COVID–19. We won't rest until this job is done.

The CHAIRMAN. Thank you, Dr. Collins.

Dr. Adams, welcome.

STATEMENT OF JEROME M. ADAMS, VADM, M.D., MPH, SURGEON GENERAL OF THE UNITED STATES, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. ADAMS. Well, good morning. And thank you Chairman Alexander, Ranking Member Murray and Committee Members for allowing me to address the importance of childhood and adult immunizations particularly in the context of COVID–19. My central message today is this, equitable vaccination of America's children and adults against preventable diseases is safe, smart good for the economy and critical in our fight against COVID–19.

The science here is clear. Vaccines save lives and the U.S. vaccine supply is the safest in history and the safest in the world and they are at great value as every dollar invested in the measles vaccine, for instance, saved society up to twenty. This is because the vaccines actually prevent disease keeping people out of the hospital and clinic and keeping employees and parents in the workplace. Yet despite these benefits, less than half of adults get a yearly flu vaccine. Flu vaccines reduce a pregnant woman's risk of hospitalization by 40 percent and a newborn baby's risk by 72 percent. However, only half of all pregnant women get recommended flu and whooping cough vaccinations. And pregnant African Americans have even lower vaccination rates, a fact which may contribute to higher infant and maternal mortality. In fact, vaccination among

ethnic and minority adults lags far behind already poor national averages.

37 percent of Hispanics, Native Americans, and African Americans get their flu shots versus 48 percent of whites. Among adults, rates of pneumococcal vaccination exceed 70 percent in whites but are just over 50 percent in Blacks and Hispanics, and these disparities persist for tetanus, zoster and Tdap as well. I want to move to childhood vaccinations and it is important to note that childhood vaccination rates remain high nationally, but one in ten parents refuse at least one childhood vaccine and almost a third delay a vaccine.

We know that unvaccinated children are more likely to be uninsured to live below the poverty level and to live in rural areas. Unfortunately, the fear and access issues induced by COVID–19 has put millions of additional children and adults at risk for vaccine preventable diseases. So to ensure the benefits of vaccines for all Americans, we must acknowledge and address obstacles to vaccination and in particular those encountered by racial and ethnic minority communities. These obstacles, which I think are also opportunities, include public education and rebuttal of misinformation, addressing practical issues related to access, and increasing provider engagement and trust that the final decision point. Realizing the opportunities will not only save lives, prevent suffering and make wise use of resources now, but will further serve millions of Americans when we get a safe and effective COVID–19 vaccine. And with both COVID–19 and the flu circulating the fall, this will be in my opinion the most important flu season of our lifetimes.

Less flu and fewer hospitalizations will help conserve precious healthcare resources. So let me be clear, the best way to prevent the flu is to get the flu vaccine and I hope all of you, all of you here today will get your flu vaccine early and publicly. That is why my COVID–19 prescription is twofold. First, we must all practice the three Ws, wash your hands, ware your mask, and watch your distance. And second, we must use every lever to ensure all ages, races, and ethnicities receive recommended vaccinations. In my written testimony, I outlined efforts underway across HHS to boost vaccination rates and I will finish by highlighting just a few. CDC works with providers through the Vaccines for Children or VFC and the section 317 immunization programs to provide over 80 million doses of vaccines annually, and they have increased their flu vaccine purchase 20 fold this year. You can find out where to get vaccinated using CDC's *vaccinefinder.org*.

HHS recently launched Catch Up to Get Ahead, informing parents that it is important to and safe for their children to get vaccinated during COVID–19. The Catch Up to Get Ahead toolkit is available on *vaccines.gov*, and again, to Senators out there, I would encourage you to send your staff there because there are great printable documents and digital documents to help people understand that vaccines are safe and effective. Through a recent amendment to the Prep Act, HHS authorized licensed pharmacist to administer routine vaccines for children ages 3 through 18 during the COVID–19 pandemic, and breaking news that I just got the okay to tell you all about right before I came in, today HHS will be issuing guidance to expand access to safe and effective COVID–

19 vaccines when they are made available. State licensed pharmacists will now be able to administer COVID–19 vaccinations to persons aged 3 and older.

Office of Minority Health is working with Morehouse School of Medicine on a $40 million plan to help engage and inform racial and ethnic minority communities about COVID–19 on vaccinations. And then finally the Public Health Service Commissioned Corps, which I helped lead along with Admiral Giroir, works with underserved populations, including Indian Health Services and Bureau of Prisons, leading efforts to increase acceptance of and uptake of the flu vaccine. PHS officers are also working with racial and ethnic communities to engage them in culturally competent ways in to increase access through partnerships with states and federally qualified health centers. So I want to close with calls to action to again U.S. Senators, to your family, to your staff and to your constituents.

No. 1, get your flu shot. Ideally before the end of October. We want everyone to get their flu shots by Halloween. Second, catch up on childhood and adult immunizations right now. Clinics and pharmacies around the country are safe, open, and ready to vaccinate. No. 3, stop COVID–19 in its tracks by practicing my three Ws, washing your hands, wearing your mask, and watching your distance. Fourth, use your bully pulpits to tweet, text, blog, and shout that vaccines are safe, effective, and more important now than ever. And then finally go to *vaccines.gov* for more information. And I just want to throw in a quick personal note.

We are in the midst of a social justice movement the likes of which we haven't seen since the 60's in my lifetime. As Surgeon General of the United States, I want you to hear me say that achieving health equity is necessary to achieving social justice and vaccines are the quickest and the easiest way for minority and at-risk populations to protect their health. So now more than ever we need to help people understand vaccines are safe, vaccines are effective, vaccines are how we achieve health equity and social justice. Thank you and I look forward to your questions.

[The prepared statement of Dr. Adams follows:]

PREPARED STATEMENT OF JEROME M. ADAMS

INTRODUCTION

Chairman Alexander, Ranking Member Murray and distinguished Members of the Committee, thank you for the opportunity to address the importance of immunizations in children and adults, particularly in the context of the COVID–19 pandemic, and the actions we are taking to ensure the health and safety of all Americans.

I am grateful to you for focusing attention and action on this critical health issue. Getting children and adults immunized, protecting millions from preventable infections, is a battle we can win—and win now.

I would like to start by clarifying terms often used in discussions on this topic. **Vaccination** refers to the act of introducing a vaccine into the body to produce immunity to a specific disease. **Immunization** is the process by which a person develops immunity through the act of vaccination. Though their meanings are different, they are often used interchangeably.

I should also define a couple of other terms. **Vaccine confidence** is the trust that parents, patients, or healthcare professionals have in the safety and effectiveness of vaccines, and the processes and policies involved in vaccine development, licensure, manufacturing, and recommendations for use. Secretary Azar has declared that "one of the most pressing public health challenges our country faces is vaccine hesitancy, driven in part by misinformation. **Vaccine hesitancy** refers to delay in

acceptance or refusal of vaccines despite their availability and is different from the anti-vaccine movement according to researchers.[1, 2, 3] Vaccine hesitancy, named one of the top 10 global health threats in 2019 by the World Health Organization, is a product of complacency, inconvenience, and lack of confidence.[4]

While I will describe the current status, benefits, challenges, and actions related to childhood and adult vaccinations, including that for seasonal influenza, I want to ground this discussion in the reality of COVID–19. The pandemic has affected every household and almost every facet of our lives and livelihoods. We are deep in the fight against the virus that causes COVID–19, and that fight may become more complex in the weeks and months ahead when it and the flu virus will most likely circulate together.

We are confident that safe and effective vaccines will be developed for COVID–19. But they are not yet available. In the meantime, we rely on the heroic efforts of the frontline healthcare workers to treat those who become ill and dedicated public health workers to test the people who need to be tested and implement control and prevention practices that prevent further spread of the disease. In addition, I want to highlight the three things we can all do right now to protect ourselves and each other—washing our hands, wearing a mask, and watching our distance by maintaining at least 6 feet between others and avoiding large gatherings.

One more action is critical. One of the most powerful acts that Americans of every age can take is to be up-to-date on their immunizations. Keeping up with recommended vaccinations is important for all age groups. Teens should be protected against meningitis and preventable cancers with recommended vaccinations. Adults need vaccines too to help them stay healthy and avoid diseases such as shingles, influenza, whooping cough, tetanus, and pneumococcal pneumonia. Children and adults with health conditions are particularly susceptible to diseases and there are vaccines specifically recommended for them. Missing or delaying vaccines puts our country at risk of having to fight outbreaks of preventable disease and could take precious resources away from the COVID–19 response in communities across America.

As a physician, public health expert, parent, and the Nation's Doctor, I can confidently and unequivocally state that **vaccines are safe, effective, and life-saving**. The science is indisputable and the benefits are real. To help all Americans reap these benefits, we must ensure that they have the facts on vaccines, communicate vaccine confidence and overcome vaccine hesitancy, and make the case that, this year, **more than ever**, being current on recommended vaccinations is essential to preserve health, prevent disease, reduce the burden on the healthcare system, and restore our economy.

CHILDHOOD IMMUNIZATIONS

Vaccinating babies according to the recommended immunization schedule ensures that they are protected against 14 serious childhood illnesses such as measles, meningitis, and whooping cough.[5] The good news is that over 90 percent of parents choose to protect their children through vaccinations.[6, 7]

However, in some communities in the United States, misinformation has contributed to parents choosing to delay or refuse vaccinations for their children. While overall vaccination rates remain high, nearly 12 percent of parents refuse at least one recommended childhood vaccine,[8] over 30 percent of parents delay one or more

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recommended childhood vaccines,[9] and many parents are getting school immunization exemptions for personal, rather than health reasons.

These trends tend to be concentrated in geographic pockets and in certain communities. For example, the large outbreaks of measles in and around New York City in 2018 and 2019 were concentrated among unvaccinated children. They began when a returning traveler who was infected with measles abroad exposed a community that did not have a communitywide or "herd" immunity. New York accounted for nearly 75 percent of the 1,270 reported measles cases across 31 states in the United States in 2019, the most in a single year since 1992.[10] As a result, our country nearly lost its status as a measles-eliminated country, an important public health milestone that was achieved in 2000.[11] More importantly, people, primarily children, suffered needlessly from a preventable disease.

What stopped the measles outbreak in New York was the community coming together with elected, religious, and other leaders speaking as one voice to connect public health messages and vaccination efforts with community members, including parents who had not vaccinated their children. This coalition spoke on how safe vaccines are and how they protect people, listened to concerns expressed by the parents of children and the community and dispelled myths and misinformation on vaccines, and made it possible for the children and the community to get vaccinated conveniently.

In my role as Surgeon General, I was deployed to see some of these cases first hand and observed the vast disruption an outbreak can cause in a community. One example is the outbreaks in Washington State last year. I met with parents, clinicians, and public health experts to chart a path forward to tackle myths and misinformation surrounding vaccines and make informed decisions based on scientific evidence.

First, parents must have time with trusted, well-informed, and caring providers who listen to their concerns and address their questions. Some providers I spoke with went beyond their clinic walls to share their advice, hosting "ask the doctor" sessions, often after normal business hours, that enabled non-judgmental conversations with parents. Some parents visited their healthcare professionals two or even three times before ultimately deciding to get their children vaccinated. With time, support, and compassion from their clinicians, these parents made the choice to protect their children with vaccines. There's an old saying—"people don't care how much you know until they know how much you care." This adage comes true when healthcare teams talk with parents about giving vaccines to their children.

Second, start conversations on vaccines between parents and providers early. We need to talk to parents of infants and young children and with pregnant women, answer questions, and reduce vaccine hesitancy. We need to leverage available data and seek additional data on how to best communicate with African American, Latino/Latina, Asian American, Native American, and other racial and ethnic communities, cultures, socially or economically disenfranchised communities, and other close-knit communities subject to large outbreaks of measles in 2019.

Third, we have to further develop partnerships and work with trusted messengers to stop myths and contain the spread of misinformation on vaccines. We can do that by promoting trustworthy vaccine information to be disseminated by trusted voices through outlets to which people go to get information. We need to build and normalize a culture of immunization in healthcare practices, our schools, our workplaces, and our communities. To do that, we also need help from state and local policymakers who set the tone and advance policy decisions, and enable best public health practices such as immunization programs to protect us and our communities. Finally, we recognize the power of a communications campaign to reinforce social norms about vaccination, combat myths, and utilize tested and tailored messaging to respond to common questions and sharpen focus on personal and community benefits of vaccination.

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IMMUNIZATIONS DURING PREGNANCY

I mentioned earlier that we need to start the conversation on vaccines with parents early. It starts with expectant mothers and women who may become pregnant. They need to know the facts about vaccines and how vaccines protect them and their babies. However, only about half of pregnant women get the recommended flu and whooping cough vaccinations during pregnancy. African American and Latina women who are pregnant have even lower rates of these vaccinations. Those who do not get these vaccines are at risk for potentially serious complications during pregnancy.

When pregnant women are immunized against flu and whooping cough vaccines, they pass on antibodies to the unborn baby, providing protection for several months after birth, until babies can safely be vaccinated. Newborns whose mothers did not receive flu or whooping cough vaccines are at risk for the diseases and complications including hospitalization and death.

Pregnancy results in changes to women's respiratory and immune systems and doubles their risk for serious complications that require hospitalization if they get the flu. Pregnant women age 15 to 44 years account for 24 to 34 percent of hospitalizations due to flu each year in the United States. That disproportionate rate of hospitalizations for pregnant women with the flu is even more striking if we take into account that only 9 percent of women in this age group are pregnant.

How effective are the flu and whooping cough vaccines for pregnant women? Research has shown that getting a flu vaccine reduces a pregnant woman's risk of hospitalization due to the flu by 40 percent, and their newborn babies' risk of hospitalization by 72 percent. The case for flu vaccination for pregnant women cannot be much stronger than this. Pregnant women should get the flu vaccine at any time during her pregnancy to protect her and her baby against serious complications from the flu.

Whooping cough is a serious disease in babies, but they cannot get the vaccine until they're at least 2 months of age. Babies younger than 2 months of age who get whooping cough require hospitalization 67 percent of the time. Babies in this age group also make up 69 percent of deaths all caused by whooping cough. This is why the vaccine against whooping cough is recommended for pregnant women during her third trimester. The whooping cough vaccine prevents 78 percent of whooping cough in babies younger than 2 months of age.

ADULT IMMUNIZATIONS

Vaccines are recommended not only for children and pregnant women, but for adults throughout their lifespan. Adults need to keep up-to-date on their vaccines because immunity from childhood vaccines can wear off over time. Additionally, adults are at risk for different diseases because of their age, health conditions (like heart disease and diabetes), occupation, and other reasons. As it is for children, vaccination is one of the most effective, convenient and safest ways to prevent disease and stay healthy.

In the United States, 140,000 to 710,000 flu-related hospitalizations and 12,000 to 56,000 deaths occur from flu-related illnesses each year—mostly among the elderly. Additionally, about 320,000 people get pneumococcal pneumonia each year, resulting in 150,000 hospitalizations and 5,000 deaths—again mostly among the elderly. Most of us know at least of someone who has had to endure the severe, unrelenting pain that accompanies shingles, long after the disease itself has cleared. Each year, 1 million people get shingles in the United States.

There are vaccines for adults that can prevent these and other diseases that can cause serious illnesses, hospitalizations, and even death. Young adults should get the flu vaccine; the tetanus, diphtheria, and pertussis vaccine (Tdap); and, if they did not receive it before, the human papillomavirus (HPV) vaccine. Older adults should get the flu, Tdap, shingles, and pneumococcal vaccines. Other vaccines are indicated for adults with health conditions.

Despite the benefits of these routine vaccinations, the vaccination coverage rates for adults are low. Only about 45 percent of adults age 19 years or older receive the flu vaccine each year, with racial and ethnic minorities and younger adults having lower coverage rates. Pneumococcal vaccination coverage among adults age 19–64 years at increased risk for pneumococcal disease is about 25 percent and for those age 65 years or older is about 69 percent. Shingles vaccination rate is about 35 percent for adults age 60 years or older. The shingles vaccine is now recommended for adults age 50 years or older, so going forward, data on the shingles vaccination rate will change.

Given these low vaccination coverage rates for adults, additional efforts to promote vaccines for adults are needed. Similar to efforts for children, trusted, well-informed, and caring providers need to listen to the concerns expressed by their adult patients, answer questions, and strongly recommend vaccines; have conversations on vaccines early and frequently; and actively work to stop myths and contain the spread of misinformation on vaccines. These efforts require time, energy, and resources. We need to better equip and enable our healthcare providers to do this critical preventive health work.

IMMUNIZATION DURING THE EARLY COVID–19 PANDEMIC

Unfortunately, but not surprisingly, the COVID–19 pandemic disrupted life-saving vaccinations at all levels, putting millions of children and adults at risk for vaccine-preventable diseases. Efforts to control the spread of COVID–19 during the early months of the pandemic resulted in providers closing their practices and patients canceling their appointments as communities were subject to social distancing, stay-at-home and other public health response measures.

Early pandemic data on the Vaccines for Children (VFC) program—CDC's over $4 billion program that supports a network of public and private health care providers to administer free vaccines to about half the children in the United States—painted an alarming picture. VFC providers across the country ordered 3 million **fewer** doses of vaccines compared to the same period in 2019[12]. At the same time, there was a substantial decrease in childhood vaccine administration rates in eight large healthcare systems in the United States. When the vaccination status at milestone ages of children in Michigan was evaluated in the aftermath of the national public health emergency declaration in March 2020, coverage rates for essentially all childhood vaccinations declined substantially compared to the same time period in previous years. Data indicate that vaccination coverage rates for adults were similarly adversely impacted.

Subsequent data suggest that vaccine ordering through the VFC program and vaccine administration rates have largely recovered from the declines in the early months of the pandemic but the backlog of vaccinations that have been delayed, particularly for adults, have not yet been resolved.

IMMUNIZATION DURING THE UPCOMING INFLUENZA SEASON

For the upcoming flu season, the viruses that cause COVID–19 and influenza will be inextricably linked. The question is how we can best prepare Americans to stay healthy from both threats. Although the world has changed over the last nine months due to COVID–19, one thing has not: **getting the flu vaccine is the best way to prevent the flu**.

Everyone six months of age or older should receive a flu vaccine every year. We should do better to reach people with high risk for serious complications from the flu, such as older adults and those with health conditions, African American and Latino/Latina communities, and younger adults who have the lowest flu vaccination rates among adults.

At least part of this lower participation is due to a reluctance and mistrust of vaccines and health systems. We need to do a better job of conveying the right message the right way. We need to be sensitive to the cultural norms of the diverse communities that comprise America and work with the trusted leaders and service providers in those communities to communicate that vaccines are safe and effective and that vaccines save lives. Again, we need to work with our communities to establish an expectation that children and adults are current in their vaccinations and that being up-to-date is the norm.

The disparities in low uptake of flu and other vaccinations echo those we have observed with how COVID–19 has disproportionately impacted racial and ethnic minority communities. In recent data (August 22), African Americans and Native Americans are hospitalized due to COVID–19 at four to five times the rate of whites. Hispanic Americans are hospitalized at three times the rate of whites. The reasons are many and are rooted in long-standing socioeconomic conditions that reduce resilience, opportunity, and health. These conditions make it harder for people of color to get and stay healthy.

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[12] Santoli, J. M. (2020). Effects of the COVID–19 pandemic on routine pediatric vaccine ordering and administration—United States, 2020. MMWR. Morbidity and Mortality Weekly Report, 69.

That is why it is imperative public health leaders, Members of Congress, Federal and state agencies, and communities all across the country, concentrate our efforts to ensure that the most vulnerable populations are protected from both the flu and other vaccine-preventable diseases, in addition to COVID–19.

While widespread vaccination for the flu each year is **always** important, we must aim for record-breaking vaccination rate for **this** upcoming season. Of course the flu vaccine does not protect against COVID–19, but the possibility of coming down with the flu amidst the COVID–19 pandemic is concerning. We should take advantage of all the tools available to protect ourselves, our families, and our communities. And getting the flu vaccine gives each of us one big tool to do that. As I described earlier, the flu vaccine can help us stay out of hospitals and reduce possible exposure to COVID–19, and help conserve healthcare resources that our healthcare professionals and healthcare systems desperately need.

PATH FORWARD

This moment in our national and global lives is one of unprecedented challenge. It is also one of unparalleled opportunity. With will, intention, collaboration, and intelligent (data-informed) resourcing, we can close past gaps and break past records to vaccinate millions of Americans, across all age groups, genders, races, ethnicities, and geographies. We can protect and preserve health—and healthcare resources—if we work together now.

Secretary Azar has declared that "one of the most pressing public health challenges our country faces is vaccine hesitancy, driven in part by misinformation." [13] Vaccination saves lives, but only if people trust that they are safe and effective, and agree to receive the vaccine. We must take responsibility to counter misinformation and ensure that every American understands the importance of vaccines throughout their lives.

The U.S. Department of Health and Human Services (HHS) is using a three-tiered approach to improve vaccine confidence through: (1) research and evaluation, (2) collaboration and partnerships, and (3) communication strategies and knowledge dissemination. We continue to look for opportunities to advance and promote vaccinations for all Americans and have championed vaccinations in a variety of ways. From the more traditional avenues like an *op-ed in the New York Times* and events in town halls, hospitals, and community centers across the Nation, to connecting with individuals on digital platforms and social media by hosting things like the #HHSVaxChat, we have strived to reach people directly.

Our efforts also include advancing research to better understand vaccine confidence as well as partnerships to help counter misinformation. The Department has a long history of working with external and trusted partners to counter misinformation online. Last year, in partnership with Twitter, the platform provided a resource box *Vaccines.gov* when a Twitter user searched for vaccines or immunization. This collaboration gave Twitter users direct access to accurate, science-based information on *Vaccines.gov*.

On top of that, HHS has also made improvements to *Vaccines.gov* to make it mobile-friendly and increase both the ease of and access to information about vaccines, making it a go-to resource for common questions and a resource hub for others to communicate about the life-saving value of vaccines.

In addition, CDC developed *Vaccinate with Confidence*, a strategic framework to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the United States. *Vaccinate with Confidence* will strengthen public trust in vaccines by advancing three key priorities: protect communities, empower families, and stop myths.

The HHS Office of Minority Health (OMH) recently announced funding of the National Infrastructure for Mitigating the Impact of COVID–19 (NIMIC) Initiative. NIMIC seeks to develop and coordinate a strategic and structured national network of national, state/territorial/tribal and local public and community-based organizations that will mitigate the impact of COVID–19 on racial and ethnic minority, rural and socially vulnerable populations.

The NIMIC initiative is a three-year cooperative agreement between OMH and the Morehouse School of Medicine to fight COVID–19 in racial and ethnic minority, rural and socially vulnerable communities. The Morehouse School of Medicine and

[13] Youtube. Highlights of HHS Secretary Alex Azar's remarks to NVAC & commitment to vaccination. June 7, 2019. *https://www.youtube.com/watch?v=SpJHDl09SQs*. Accessed September 10, 2019.

OMH will lead the initiative to coordinate a strategic network to deliver COVID–19-related information to communities hardest hit by the pandemic. Though focused on COVID–19, this network will nurture community level connections, build trust, and enhance local capacity and infrastructure, generating benefits well beyond those related to the pandemic.

The Office on Women's Health serves as a trusted resource for women and families, including recommendations for vaccinations during pregnancy and the most current updates about the health impacts of COVID–19.

U.S Public Health Service Commissioned Corps officers are leading efforts to increase acceptance of and access to influenza vaccine, particularly in underserved and racial and ethnic minority communities. Officers are implementing innovative strategies to ensure that culturally competent messages on the importance of influenza vaccination reach these communities, while also increasing access through partnerships with states, federally qualified health centers, and Federal entities such as the Bureau of Prisons and the Indian Health Service.

The Health Resources and Services Administration (HRSA) launched a social media campaign with the hashtag #WellChildWednesdays to encourage parents and stakeholders to maintain a regular schedule of well-child visits and immunizations. Every Wednesday for ten weeks, social media messages promoted the importance of immunizations and well child visits with pediatric providers. The Office of the Surgeon General, along with numerous HHS operating divisions and other national, state and local public health partners amplified the 10 HRSA posts, which reached more than 330,000 people and generated at least 500 additional posts using the #WellChildWednesdays hashtag.

The Administration on Children and Families supported distribution of HRSA's eNews messages (sent via tweet #WellChildWednesdays), including their message encouraging parents to bring their children to the doctor for vaccinations and extending their reach in the following ways:

- The Office of Child Care posted the message on its website, and sent it to 4,450 stakeholders through the OCC Announcements email blast.
- The Early Childhood Development Office sent the message to its Federal partners' list serve of over 73 Federal staff across multiple agencies.
- The Office of Head Start sent the message to over 1600 Head Start Grantees and conducted a webinar: *Keeping Our Children Well During COVID–19*, which included information on the early childhood vaccination schedule.
- Head Start can send messaging about vaccinations for children and flu shots for parents/staff to 1,600 grantees, 250,000 staff and 1,000,000 children.
- The Children's Bureau will send communication to all child welfare offices including foster parents and courts regarding the importance of vaccination schedules including the flu vaccine.

Last month marked "National Immunization Awareness Month," a time when our messaging is usually ramped up on the importance of vaccinations. This year, we launched **Catch Up to Get Ahead**, an effort to increase childhood immunization rates that fell so dramatically during the early months of the pandemic. The Catch Up to Get Ahead toolkit is available on *vaccines.gov* and includes talking points, safety protocols, payment information, and other helpful materials to help get children catchup on the vaccines that have been delayed by the COVID–19 pandemic.

The effort focused on increasing vaccination opportunities, informing parents that it is important and safe for their children to get vaccinated during COVID–19. Its goals were to: (1) increase access to childhood vaccines by encouraging vaccination service providers to expand their service hours, (2) redouble communication efforts about vaccine safety and the importance of staying up-to-date on vaccinations, and (3) promote policies that reduce barriers to vaccinations. This was a coordinated HHS effort through my office, the Office of the Assistant Secretary for Health (including the Office of Infectious Disease and HIV/AIDS Policy, the Office on Women's Health, and the Regional Health Offices), the Office of Minority Health, CDC, the Health Resources and Services Administration, and the Indian Health Service.

Lastly, on August 19, HHS issued a third amendment to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to increase access to childhood vaccines by authorizing state-licensed pharmacists to administer all routinely recommended vaccines for children age 3 through 18 years during the COVID–19 pandemic. The goal was to decrease the risk of vaccine-preventable dis-

ease outbreaks as children begin to return to daycare, preschool, and primary and secondary school across the United States. Looking ahead, when COVID–19 vaccines are licensed and recommended for use, the PREP Act will greatly increase the vaccines' access to children and adults in the United States.

CLOSING

Our goal is to communicate the best available evidence to the public to help them stay safe and healthy. To protect children, adults, and pregnant women through vaccinations in the time of COVID–19, we offer the following recommendations, gleaned from experts across the Federal Government and healthcare systems.

First, everyone should know that all vaccines including the flu vaccine can be delivered safely during the COVID–19 pandemic. Healthcare providers for children and adults should:

- Communicate with patients about how they can be safely vaccinated during the pandemic;
- Follow infection control guidance to prevent the spread of COVID–19;
- Assess the vaccination status of all patients at every visit;
- Strongly recommend the vaccines they need;
- Administer recommended vaccines or refer patients to a vaccination service provider such as a pharmacy or health department (delay vaccination for people with suspected or confirmed COVID–19);
- Ensure that vaccination records are maintained at the patient's usual medical home;
- Implement effective strategies for catch-up vaccinations such as patient reminder-recall; and
- Submit records of vaccines administered in the state or local immunization information system.

We're frequently asked when the best time to get the flu vaccine is. The timing of onset of the influenza season is unpredictable, and there are concerns that vaccine-induced immunity might wane over the course of a flu season if given too early in the season. To address this concern, Americans 6 months and older should get vaccinated for the flu during October or as soon as possible after October, as additional flu vaccine becomes available.

We have all been deeply affected by the pandemic and there is much work to be done to mitigate the challenges we face as a result of COVID–19. Despite the challenges, I remain steadfast in my resolve to use our scars, losses, and lessons learned during COVID–19 as an opportunity to make our communities healthier, more resilient and more just. And increasing vaccination rates for children and adults is a key part of that opportunity.

The CHAIRMAN. Thank you, Dr. Adams. We will now begin a round of 5 minute questions. I am going to ask Senators to try—and the witnesses to try to keep the questions and the answers within 5 minutes so all the Senators have a chance to participate with the votes coming up. Dr. Collins, let's take the announcement to which you referred about AstraZeneca slowing it's trials this morning or stopping it.

What does that do to the effort, to the goal of producing hundreds of millions of vaccines by the end of the year? We have always said that if vaccine is not safe and does it work, we will throw away the vaccines that are manufactured. But let's say AstraZeneca or one of the others doesn't work or isn't safe, will we still have enough vaccines?

Dr. COLLINS. Thank you, Senator. The reason that we are investing not in one but six different vaccines is because of the expectation that they won't all work. Although it would be lovely if they did. To have a clinical hold as has been placed on AstraZeneca as of yesterday because of a single serious adverse event is not at all

unprecedented. This certainly happens in any large scale trial where you have tens of thousands of people invested in taking part and some of them may get ill and you have to try to figure out, is that because of the vaccine or were they going to get that illness anyway.

With an abundance of caution at a time like this, you put a clinical hold, you invest to gate carefully to see if anybody else who received that vaccine or any other vaccines might have had a similar finding of a spinal cord problem. So this ought to be reassuring to everybody listening when we say we are going to focus first on safety and make no compromises, here is Exhibit A about how that is happening in practice. If it turns out that is a real consequence of this vaccine and can be shown to be cause and effect then all the doses that are currently being manufactured for that will be thrown away because we do not want to issue something that is not safe.

The CHAIRMAN. As I understand your description, when I take a COVID–19 vaccine shot, it doesn't give me COVID. It sits—at one time in the history, I guess that was the way with smallpox. For example, you gave somebody a mild case of smallpox and hope they recovered and were inoculated. But when you take a vaccine shot for COVID-19, you are not giving me COVID, correct?

Dr. COLLINS. Absolutely. The old way of making vaccines, and it is still done in some instances, is to take the actual virus, inactivate it in a certain way or kill it, and then use that as the way of inducing an immune response. Hoping that you were completely successful in that inactivation. None of the vaccines I am talking about today are done that way. They are taking a small bit of the virus, namely that spike protein, and are putting it into a fashion that the body can raise an antibodies to it. But that is all you are getting is that part, that little bit of the virus. You are not going to get infected by COVID–19 by any of these, I promise you.

The CHAIRMAN. The Center for Disease Control said that last year the flu vaccine was 39 percent effective and that last year between 24,000 and 52,000 Americans—24,000 and 62,000 Americans died of the flu. On the other hand, the polio vaccine seems to be 100 percent effective. If you get the polio vaccine, you don't get polio. Same with some others. Will the COVID–19 vaccine be more like the flu vaccine or more like the polio vaccine in terms of effectiveness?

Dr. COLLINS. Senator, what a great question and I wish I knew a really crisp answer to that. That is why we are doing these large-scale trials to look at safety and efficacy to see how protective this will be and how long the protection lasts. If I had to guess I would say this is probably a better virus for a vaccine to really work well than the influenza virus which is a tough one because it is changing every year and that is why we have to be getting a new shot every year. It will be as good as polio or as good as measles, which is 95, 98 percent effective. I would love it if that turned out to be the case, but we will not know until we get through these trials and see what really happens.

Dr. ADAMS. Mr. Chairman, can I jump in really quickly? You mentioned——

The CHAIRMAN. Let me finish my question, if I may. Between 24,000 and 52,000 or 62,000 Americans died of flu last year. Is it possible that the hand-washing, masking and six feet staying apart practices will mean that we will have fewer deaths from flu this year?

Dr. COLLINS. It is entirely possible and that would be, I guess, a silver lining of this very difficult year we are all living through. It has already been observed in the southern hemisphere that is going through their flu season already that they had a lower number of cases of influenza by far than usual. And again, they have been practicing most of them the same kind of measures that we are talking about. So we might in fact benefit that way but that is no reason for anybody to say, oh, we will be fine. Get your flu shot everybody. This is a really important year to do that as the Surgeon General has already emphasized. Thank you very much.

Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman. And Dr. Collins as I said, I have been very concerned about political interference in decisionmaking we have seen in this Administration's response and the impact it might have on the acceptance of a vaccine. I wanted to ask you, what steps you think Federal agencies should be taking right now to build trust with the American people and develop our type processes to make sure science and public health, not political interest, dictate decisionmaking for COVID–19 vaccines?

Dr. COLLINS. Well, thank you, Senator. I am a scientist and I believe that the best way we can engender that kind of trust is by being as transparent as possible, and you use the same word in your opening statement, so that people can see the facts. There is so many conspiracy theories out there right now, even before we have a vaccine that has come anywhere near to being judged safe and effective. About what is going on here, some of those are breath taking in terms of their stretch of the imagination and yet sometimes some people seem to attach themselves to those. So our best antidote is to say exactly what we are doing. I am reassured and I hope it will be reassuring to you that there are a number of steps in terms of how vaccines are going to be evaluated that are going to give that kind of sense of scientific objectivity.

First of all, none of these trials will go even to an FDA review until the DSMB, the Data and Safety Monitoring Board, which is the only group that gets to see what happens as protection as far as safety events looks at the data. And these are not Federal employees. These are very experienced, qualified scientists. Only when they say something is happening here, that looks like it might be actually worth reviewing, does this get brought forward. I hope you also saw the nine CEOs of the companies involved in vaccine development all signed a statement that they won't put forward something to FDA until they are convinced that it meets the highest standards of safety and efficacy.

Then FDA has its own advisory process and Commissioner Hahn who will speak to you all in 2 weeks has already said that he will use this Vaccine and Related Biological Products Advisory Committee, the VRBPAC, to advise about any idea of using an emergency use authorization for this purpose.

You can be confident in that as well. If we can put all that information forward in a way that is digestible, I am hoping it will help turn the tide in what is right now a troubling situation where a lot of people are quite skeptical about this vaccine. And what a heartbreak that would be if we go through all of this, we come up with a vaccine that is safe and effective, we have already lost 190,000 people, we could prevent many more deaths, and yet people are afraid to use it. We can't let that happen.

Senator MURRAY. Yes. Well, Dr. Adams, let me ask you because polls show that about 35 percent of Americans wouldn't get a COVID vaccine even if it were FDA approved and available to them at no cost. If confidence in COVID–19 vaccines is eroded by political interference or misinformation, what impact would that have on a successful COVID–19 vaccination campaign as well as vaccine confidence for years to come?

Dr. ADAMS. Well, thank you so much for that question. And I think it is important that we start understanding that we have unprecedented level of vaccine hesitancy in our country. And globally the World Health Organization has called this one of their top 10 public health threats. I think it is also important to understand that we have a once in a century global pandemic superimposed on top of a Presidential election and that has made messaging even more difficult and concerning. Here is what I can tell you. As a member of the coronavirus task force, there have been no politicization of the vaccine process whatsoever. We have a process in place that I trust as a doctor, as a dad. I get vaccinated every year. I get my family vaccinated every year and we will be——

Senator MURRAY. Okay. I appreciate that and I am running out of time so I just wanted to say, we need vaccine confidence and that is really important and political interference can be a huge detriment to that, so can misinformation. Are you making sure the President understands that risk?

Dr. ADAMS. I am using my bully pulpit as Surgeon General to make sure the entire country understands that vaccines are safe and effective. In this COVID vaccine, I am telling people to focus on the process over the politics and the process is what will assure us that these are safe.

Senator MURRAY. Okay. Dr. Collins, you mentioned in your answer to me the data safety monitoring board. I am concerned about the lack of transparency around the role of these boards in evaluating the safety and efficacy of COVID–19. Who sets the standards for the DSMBs to determine the data and whether the data from a Phase 3 trial showed a vaccine is safe and effective enough to end that trial early, as some have said?

Dr. COLLINS. When the trial is first proposed, the FDA has to review whether in fact the demonstration of safety and efficacy is going to meet a certain standard, and that means you have to prove, and FDA has already said this, that the vaccine is at least 50 percent effective. If it is less than that, it doesn't meet that standard. The DSMB has those particular parameters in front of them and they are very careful statistical expertise——

Senator MURRAY. Okay, who sets the standards?

Dr. COLLINS. Sorry?

Senator MURRAY. Who sets the standards DSMB uses?

Dr. COLLINS. The FDA.

Senator MURRAY. Does NIH have access to those?

Dr. COLLINS. We are certainly consulted but it is FDA's authority and responsibility to set those standards.

Senator MURRAY. Okay. I hope that NIH has that critical information. It is alarming if they don't.

Dr. COLLINS. I would say yes, we do. I do want to make it clear though that we are not the deciders when it comes to exactly what is going to be considered acceptable. That is FDA's Congressional authority.

Senator MURRAY. Okay.

The CHAIRMAN. Thank you, Senator Murray.

Senator Enzi.

Senator ENZI. Thank you, Mr. Chairman and Ranking Member. Thanks to the two who testified. Some great information. I really enjoyed watching Dr. Collins and Rene Fleming last night use all of their talents in a marvelous performance at the Whitehead Awards. It is good to see you this morning in your normal role. I appreciate the questions that Senator Murray asked about the people worrying about a fast track and accelerated approval and the FDA perhaps short changing the safety.

One of the things that worries me is what we can do to make sure that the health professionals that may be helping patients to make their decisions about a COVID-19 vaccine understand the regulatory terminology and then feel comfortable communicating that the patients about what it means. Dr. Collins, I am very appreciative of your explanation of how vaccines work in the charts that you had. That was very helpful. I hope that—will you be involved in some of these communication things for when the vaccine is available to help people understand how it works and why it works?

Dr. COLLINS. Thank you, Senator. And yes, NIH has a role there in terms of communication and education about the science behind all of this, working closely with our colleagues in the Department of Health and Human Services and especially with CDC. Just in terms of clinical guidelines, we do have a role there that has already been helpful, I think, in providing physicians with information about how best to treat patients who have fallen ill with COVID-19.

When it comes to the vaccines, in terms of information for physicians, we will try to help in that space as well, along with their professional societies, who will also be very important in terms of educating their own members about what are the pros and cons of a particular approach. So, yes, we will be right in the middle of that.

Senator ENZI. I am appreciative of that and have more confidence in it because of that. Vice Admiral Dr. Adams, you mentioned childhood vaccination. I know that plays an important role in predicting other age groups and limiting the spread of the disease, and helps kids get back to school, which is back to normal, which helps to reassure adults and also allows adults to go back to work. There are unique challenges in that pediatric vaccine research because of the safety and ethics concern about enrolling kids in trials. There can be differences in how their manufacturing im-

mune systems work compared to adults. What do we know about a natural immune response that kids have with COVID-19? And when should the company start the process of developing these pediatric products?

Dr. ADAMS. Great question. Thank you for that, Senator. Important to understand that the initial vaccine trials will be on people aged 18 and up. And we will make sure—and this is the way we have done it for other vaccines that have been developed in the past. We will make sure it is safe and effective in adults and then we will slowly start to move down in age.

The next round, I anticipate, will be aged 12 to 18. And then after that, if it continues to be safe and effective, we will test in people younger than that. And that is the way we have done it for every vaccine because we can't just assume that something is safe and effective in an adult will be safe and effective in a child. But here is the important point. That is why it is even more critical that we work to ensure vaccine confidence and that all adults who can't get a vaccine do get a vaccine because it will be even more important that we have a higher percentage of adults getting vaccinated to get closer to that level of herd immunity that we need to break transmission of disease, knowing that the initial round of vaccinations won't be available for children. And Dr. Collins, anything that you want to add about testing in kids?

Dr. COLLINS. I think there is maybe an effort in one of the trials to begin to enroll children in the next month or so. But again, as the Surgeon General very accurately said, we generally want to wait until you are sure that it looks safe and effective in adults before you take that next step. But it shouldn't be a whole lot longer.

Senator ENZI. You are actually working on—working with the process for getting that envelopment started as soon as possible too Dr. Collins?

Dr. COLLINS. Yes, again, with a clear sense of wanting to have the safety and efficacy reviews through the DSMBs and through the FDA before deciding it is time to move downward in age. We don't want to make any risks here happen to children in particular that we could avoid. So first, we want the data from the adults.

Dr. ADAMS. You mentioned the COVID vaccine. It is important, again, that folks go to *vaccine.org*. We have a catch up to get a head campaign. Over four million children are behind on childhood vaccinations. So we want to prevent the disease that we can prevent right now and every child should get their flu vaccine this year.

Senator ENZI. Thank you both.

The CHAIRMAN. Thank you, Senator Enzi.

Senator Sanders.

Senator SANDERS. Let me thank Dr. Collins and Dr. Adams not only for being here today, but for the years of public service. Gentlemen, thank you very much. Senator Murray covered a lot of the territory that I was interested in. But I want to ask two questions. No. 1, the taxpayers of our country have already spent billions of dollars, many billions of dollars on research and development for this new vaccine.

It seems to me with that type of development and with the fact that we have some 90 million Americans today who are uninsured

or underinsured, it seems clear to me and I think a number of other Senators that we must make that vaccine free of charge to all people if we want to maximize the number of people who will, in fact, get it and given the fact that we have already paid for it. This is something I am going to be working very hard on. Other Senators will as well. Will you join us in the effort to make sure that this vaccine will be distributed free of charge to all Americans?

Dr. ADAMS. Senator Sanders, this is the Surgeon General, Vice Admiral Adams here. Thank you for bringing that up and I will give you a very direct answer. Yes, as surgeon general of the United States, I promise you we will use every Federal tool that we have to make sure that cost is not an obstacle for people receiving what will perhaps be the most important and highly anticipated vaccine of our lives.

Dr. COLLINS. I share that 100 percent.

Senator SANDERS. Okay. Thank you both for that very definitive statement. Is that the posture of the Administration right now? Is the Administration saying that vaccine will be distributed free of charge to all Americans?

Dr. ADAMS. I asked that question right before I came in to make sure because I feel strongly about this, the most honest answer I can give you is to the extent that we can ensure that from a Federal perspective, yes. As you know, there are things we can do in the executive branch. There are things that you all can do through the legislative branch. But every tool that we have, we will bring to bear to make sure that cost is not an obstacle.

Senator SANDERS. Well, thank you very much for that answer. Gentlemen, let me just raise another issue, and it is an issue that Senator Murray touched on. You know recently we had a President, the President of the United States, telling us that this vaccine will be ready to go or develop before Election Day, not a week after the Election Day, not 2 weeks after not a month, but before Election Day because of his great leadership and that it would have taken President Obama years more to develop that process. What we need is assurance from scientists and doctors like yourself and from others in the Administration to make it clear that this President is not speaking for the scientists of this country. That you believe, as I believe and I think every Member of Congress believes, we need to get that vaccine out to the American people as quickly as possible, whether it is a week after Election Day or 6 months after the election or before Election Day.

But what is most important is that vaccine is safe, is safe and ready to go. Will you join me? I know this is difficult given the political moment and the nature of that Administration, but will you join me and many others in telling the President of the United States to get out of science and let the scientists do their job in moving as rapidly as possible, in getting a safe vaccine out to the American people?

Dr. COLLINS. Senator, I am a scientist. I have had the privilege of serving as the NIH director for 11 years. I can't say strongly enough that the decisions about how this vaccine is going to be evaluated and assessed is going to be based on science. And I know I speak for my colleagues in the Government and certainly for the

scientific community broadly, that can be the only basis upon which this decision is made, otherwise the public would not be expected to trust us. So that will be the only measure. Will it be done by a certain date? I could not possibly tell you right now because I don't know what is going to happen in the coming months.

I do have cautious optimism that by the end of 2020 at least one of these vaccines will have emerged and turned out to be safe and effective. But even that is a guess and certainly to try to predict whether it happens on a particular week before or after a particular date in early November is well beyond anything that any scientist right now could tell you and be confident that they know what they are saying. So, yes, science and science alone will be the way in which this decision is made. Otherwise, I will have no part of it.

Dr. ADAMS. Senator, I know that some people still do care about what the Surgeon General has to say so I think it is important that I weigh in on this—.

[Laughter.].

Dr. COLLINS. Jerome, I care what you have to say. Please go.

Dr. ADAMS. I want the American people to hear me say this. There will be no shortcuts. This vaccine will be safe. It will be effective or it won't get moved along. And when a vaccine is either approved or authorized by the FDA, I and my family will be in line to get it.

Senator SANDERS. Well, thank you, gentlemen. I think that is the kind of answer that the American people are looking to hearing. Thank you very much.

The CHAIRMAN. Thank you, Senator Sanders.

Senator Burr.

Senator BURR. Thank you, Mr. Chairman. To both our witnesses today, thank you for the long hours that you have devoted in this infection to try to come up with solutions for the American people and for the health care of the world really. Admiral, I may have a question for you if I have got time, but I think this is a good inflection point to talk about how we got to where we are.

I think Dr. Collins, you know really well that we have spent two decades changing statute to allow some of the processes that we have seen enacted for COVID that aren't the first time. We created BARDA so that we had an agency that looked at novel threats. They were the first ones to look at how we stack some of the processes, the trowels, how we process the data. That we don't wait until the end of the session dump. That we process it in real time. And what we have seen is we have seen Congress, this legislative body, every so many years change that legislative statute to allow emergency youth authorizations, not just from a President, from a secretary of HHS down to the FDA itself.

Dr. Hahn has been unbelievable at how you use the emergency use authorizations in consultation with NIH, HHS, CDC to provide new testing out there in real time, which is what the American people wanted and needed. We haven't harmed anybody. In some cases, we found that the data didn't support the tests that was out there and they have been yanked from the marketplace. Vaccine production historically has taken, as you said, tens of years to actually happen, and now we are trying to do it in one. And what is

important for the American people to understand is we haven't rewritten the protocols.

We haven't said the FDA operate outside of the powers that we have given in statute, nor NIH nor HHS or CDC. But we have said we are giving you these new authorities, use them. And for the first time, I think in development of drugs, vaccines, biologics, we have actually seen clinical trials that are stacked. If at any point the data doesn't support, at the end of the day, they are stopped as we saw with the AstraZeneca, Oxford trial.

Now, in your testimony, Dr. Collins, you talked about NIH's efforts to partner with private sector to develop so-called adaptive master protocols for clinical trials. Are we doing something novel here or are we doing it exactly the same way we have always done it?

Dr. COLLINS. We are doing something very novel, and I appreciate your raising all of the background here about how we got here. And Senator, your role in getting BARDA to where it is right now has just been critical for where we are with Operation Warp-Speed and having that capability of moving quickly and doing things in a very business friendly way to try to get the tools that we need in place.

But another thing that I had the privilege of helping make happen back in late March and April was to go to all the pharmaceutical companies that we knew had things they could offer here, both in therapeutics and in vaccines, and saying instead of all going off in our own directions, let's see if we could do something together. And out of that came this partnership called ACTIV, which stands for Accelerating COVID-19 Therapeutic Interventions and Vaccines. That group rolled up their sleeves 24/7.

100 people, mostly high ranking scientists in both public and private sector, designed these master protocols to be able to launch clinical trials without the long process that it often takes to decide about the nitty gritty of protocol details and out of that have come a whole series of trials on monoclonal antibodies, on anticoagulants, on immunomodulators. And all of that, I think has gotten us much further than we would have been if we hadn't decided, let's do it differently this time. Let's really get everybody around the same table—.

Senator BURR. All driven by the scientific community?

Dr. COLLINS. Absolutely. From both sectors——

Senator BURR. Because you had the latitude in the statute to do that?

Dr. COLLINS. We did. And it helped a lot that nobody was feeling like, oh, my gosh, we have got to do 6 months of legal consultation because we already had the framework to see how we could do it.

Senator BURR. I think the takeaway for today is we actually see the U.S. Government functioning. We see the process of development, partnership with the private sector in coordination with the Government actually working. We haven't changed the rules. We haven't changed the protocols. We have exercised the latitude that was there in statute for an instance just like this. Admiral, I will ask you one question as we end.

As I end, with the quarantine of especially our younger population over the past 7 months, we have got a lot of infants to 1 year

old that have not been exposed to the normal things that they will be exposed to had they not been quarantined. As our public health entity, doctor, what concerns do you have about the normal exposure that they haven't had and how that is going to affect us, especially as we determine, do they need to go to get a COVID test or is this a normal thing that they are just running into?

Dr. ADAMS. Well, I am incredibly concerned about, again, the fact that over 4 million, almost 5 million children are behind on their vaccinations because of the COVID-19 pandemic. Their regular childhood vaccinations. I am concerned about the levels of herd immunity among the populace because adults and children now haven't gotten their vaccinations that they normally would have and that lowers the levels of herd immunity.

For measles, for instance, we know you need 90 to 93 percent of people in a community to be vaccinated in order to have herd immunity and prevent an outbreak like we saw in New York. And so it is critically important to protect our youngest and our most vulnerable that everyone who can catch up on their vaccinations gets caught up on their vaccinations—.

The CHAIRMAN. Admiral, we need to move on to the next—.

Dr. ADAMS. Yes.

Senator BURR. Thank you.

Dr. ADAMS. Thank you.

The CHAIRMAN. Thank you, Senator Burr.

Senator Casey.

Senator CASEY. Mr. Chairman, thank you very much for the hearing. I want to thank you and Senator Murray for having this hearing as we start this new work period. And I want to thank Dr. Collins and Dr. Adams for their appearance as well as their testimony and their public service. While it is encouraging, as I think all Americans are encouraged by the pace of the work that is being done to develop vaccine candidates, we still have a lot of questions. So many Americans have questions about how the vaccine will be both manufactured and distributed.

Many Americans also have real concerns, grave concerns, about how the Trump administration appears to be interfering with the FDA's review process for political gain. And some see it. Also, Americans trust in public health and in public health that expertise has been undermined by a history of institutional racism and injustice in our health care system, as well as by misinformed anti-vaccination campaigns. It is imperative, and I think this bears repeating, imperative that any COVID-19 vaccine authorized or approved by the FDA and recommended for widespread dissemination be both safe and effective, of course, as evidenced by reliable data from randomized control clinical trials.

It is also imperative the President, the Vice President, the White House COVID-19 Task Force must A, tell the truth all the time, not play political games, and lead by example. And though I understand, as many of us do, that there will be recommendations from public health experts on who should receive the vaccine first and what we should do, and all of us should follow those recommendations, I also believe that the American people should see that any COVID-19 vaccine is safe and effective and essential for ending the pandemic.

Americans have to see it. They have to see others taking the vaccine. So I ask both of you, starting with Dr. Adams, will you commit to receiving the COVID-19 vaccine in public view once a vaccine becomes available and as authorized or approved by the FDA? Yes or no?

Dr. ADAMS. Absolutely.

Senator CASEY. Thank you, and Dr. Collins?

Dr. COLLINS. I am ready to roll up my sleeve as soon as they say it is safe and effective.

Senator CASEY. Thank you. I think it is important we practice what we preach. That means all of us in public office and in appointed office as well, because it is important for the American people to see this. I wanted to move to a question, a more focused question on immunization information systems for Dr. Adams. And this is a question I hope to ask Dr. Redfield. And I know, and as Senator Alexander mentioned, Chairman Alexander, that he is going to be testifying in 2 weeks but I had hoped he would be here today.

But given that most of the vaccine candidates being tested will require not just one but two doses, it is absolutely essential to track which vaccines people are getting. We have to understand who received the dose and ensure that each person receives the correct number of doses, especially initially where over vaccination or cross vaccination of different vaccine types could further stress the already short supply. We know that the immunization information systems already exist at the state level and they do exactly this type of tracking.

I am concerned the Administration may be planning to use—maybe plan to not use these existing systems. An article in USA Today on September the 6th cited the CDC documents saying, "people getting vaccinated will get a COVID-19 vaccination record card that will tell them which vaccine they got, when they got it, and when they should get their next shot."

My first question for you, Dr. Adams is has HHS, Health and Human Services, provided any support to these state immunization information systems, and how are you integrating their capabilities into your planning or vaccine distribution?

Dr. ADAMS. Well, very quickly, we are working with states, with advisory committees and with professional organizations to figure out the distribution of what will likely be the most logistically difficult vaccine that we have ever deployed. We recognize that there are infrastructures in place at the state level through the Vaccines for Children's Program, and we are going to lean on that existing infrastructure. And so what I can promise you is we are going to work with all the appropriate partners and we are not going to try to reinvent the wheel when we don't have to.

Senator CASEY. I will have some follow-up questions, but I am out of time. Thank you very much.

The CHAIRMAN. Thank you very much, Senator Casey, for sticking to the time. I appreciate that and so do your colleagues.

Senator Paul.

Senator PAUL. No one disputes the medical miracle of vaccines. In fact, we have discussed some of Edward Jenners contributions, but even 70 years prior to that, we were doing inoculation and

maybe even a couple hundred years prior to that in the Middle East. There were inoculating with live, from live pustules, basically live virus with maybe some antibodies in the mix. They did this, though, because the disease was incredibly deadly. You know, 10 percent, maybe 20 percent of the public, 30 percent of those who got it.

But not every disease is the same. And I think that's what annoys me some about the discussion is that we think everything is smallpox and we say submit or else and you can't go to school unless you get this. And this is the debate we are going to have is how mandatory and what we are going to do to people. But there is a difference between smallpox. So you had 10 to 20 percent, maybe even 30 percent mortality. For children with COVID from the CDC website, it is 0.68 per million. So we are talking about a different disease here. And while the recommendation on vaccines may be appropriate, I think each individual needs to make their decision. If we are prioritizing it, the death rate for those in their 80's are those in nursing home is incredibly high, 10 fold, 20 fold, maybe a 100 fold higher. It is significantly higher.

That is where the priority should go. But really, I think in each individual in a free society should assess the risks of the disease versus the risks of the vaccine. But it is important that we not get so carried away with, oh, we have a vaccine. Everybody has got to have it and you can't go to school and we are going to ostracize you if you don't take it.

Now, why don't we try to through persuasion? I mean, this worked for the most part for most of our history. Let's try to persuade people about it. Look, we have vaccines that we have recommended for a certain age groups, pneumavax is mostly recommended for those over 65 or those who have a significant comorbidity. I have had it. I am 57. I have had all my vaccines. I have been to Central America—I have had all my vaccines. But I am still for choice. Doesn't mean we just turn our brains off and say blindly, everyone must submit or else. I had pneumavax, had part of my lung removed and I thought, well, maybe I am at some risk for it so I took the pneumavax. But even that, it wasn't absolutely recommended. Flu vaccines used to be more recommended for those who were in risk categories and those who were older.

I think a one-time flu vaccine was recommended over 50. Now it sounds like it is more extensive and that is fine. You know, the vaccines are incredibly safe, but at the same time, I think we really, really, really need to think through sort of our fervor here before we start mandating and making people take these tests. And so my question to Dr. Collins is, considering that the death rate for COVID among children is 0.68 per million, are you in favor of adding a school mandate that you can't go to school unless you get a COVID vaccine?

Dr. COLLINS. Well, I think it would be premature for me to make a statement about what would be appropriate or not, since we don't even know to what extent the vaccines that are currently being studied are going to be safe and effective in adults. And as we have talked about, we won't know until later how they work for children.

Senator PAUL. Let's say they are safe and effective for children. Would you—are you in favor of mandating that you can't go to school unless you take one?

Dr. COLLINS. I would have to really understand what the consequences would be. I am not ready to give an answer to that right now. I do think there is this issue about children getting infected and then infecting others around them that may have an immune system that can't handle it. And that is one of the reasons I think we are so concerned about having children vaccinated to avoid the kind of terrible circumstance where a child who is getting chemotherapy for cancer and ends up getting sick and gets much more sick. The 0.68 is not zero.

Senator PAUL. But that was never—that was always true. We have hundreds of thousands of people every year on chemotherapy and yet we have never sort of decide to mandate to everyone that they get vaccinated to protect us on chemotherapy. What we did traditionally is those on chemotherapy try to protect themselves from others, acknowledging that the common cold was—can be devastating to someone who is on chemotherapy and with very low immune response. So it is important that we think about that and we not say that we are going to mandate everyone because of a certain population. We have a vaccine that works, by all means let's try to vaccinate everybody that is willing to, voluntarily take it, particularly the nursing homes. Those and the elderly. And we should prioritize that. But we should acknowledge that there is an extraordinary difference in mortality. From the CDC website, less than one per million children die from this.

That has to be weighed into the fact of whether or not you are going to mandate. If you are going to tell every kid in America they can't go to school, you are not willing to tell me you are not, that is a big deal. The death rate is less than one per million, and if we are going to mandate you can't go to school without that, when you look at contact tracing studies in China, the Netherlands, Bermuda and England we find very little transmission.

I just talked to a gentleman who runs a school called—can't remember the name of the school in North Carolina, they have 6,000 students and teachers and have been open for 8 weeks, they have zero cases. You know, lots of schools have been open. And it is a question we need to answer and we need to discuss and not have it all be about fear, fear, fear. The truth of the matter is, kids don't get it as often, don't transmit and rarely die from it.

We need to tell the truth about the statistics and not overblow the statistics into telling people something is not true. But that is also why the decisionmaking ought to be decentralized, where people in Washington don't get to tell everybody what to do. Every individual, every thinking individual in a free society gets to make those choices. Thank you.

The CHAIRMAN. Thank you, Senator Paul.

Senator Baldwin.

Senator BALDWIN. Alright. Thank you, Mr. Chairman. This is for—this first question is for Dr. Collins, and I am going to ask a bit about the importance of having diversity in the clinical trials that are taking place for a vaccine. And I am going to note this context. Last month, the University of Wisconsin announced that it

had been selected as one of the first sites in the country to participate in Phase 3 clinical trials for AstraZeneca's COVID-19 vaccine candidate.

Before I get into the importance of recruiting a diverse population, I want to just note the news that you have commented on already that AstraZeneca is pausing their Phase 3 because, to investigate whether an unexpected medical event in one of their eligible candidates was related to the vaccine. So before I ask you about the importance of diversity, I just want to note that we have already enrolled in Wisconsin many participants in this Phase 3 trial. What should you and others in, look at overlooking project warp speed, be telling these folks who are already about to or already participating in this Phase 3 trial? I imagine some of them are very concerned.

Dr. COLLINS. Yes, I agree, they probably are, and again, this is very fresh information. But again, the company who has connections now and knows exactly who the individuals are who have already been enrolled are in the best position to basically let them know why there is currently a clinical hold.

Again, this is based upon a single severe adverse event which may or may not have anything to do with the vaccine, but it is the best sort of cautious approach to quickly stop and look and see if there is any other evidence to be concerned about. I assume and I can certainly check and see if this is the case. Not much time should go by until all the people involved in the trial get a direct communication from the company and the sites where they were enrolled about the fact that it is on hold and this is why and that more information will be forthcoming.

Senator BALDWIN. Great. I appreciate that and I am sure I will get some constituent feedback on that very issue. The University of Wisconsin has announced that it will focus on ensuring that a diverse population takes part in the trial and they have developed resources in both Spanish and Mang to help address language barriers. And they are going to have qualified medical interpreters available to speak with potential participants in 240 different languages.

Researchers are also working to enroll a diverse patient population across gender, age, race and ethnicity. I would like for you, Dr. Collins, to describe how a lack of diversity in clinical trials undermines our efforts to develop safe, effective and accessible vaccines. And given the disproportionate impact that COVID–19 has had on communities of color, what should clinical trial sites take into consideration as they work to recruit participants?

Dr. COLLINS. Well, thanks for the question, because this is something that I am passionate about and where I think we have to work especially hard to try to achieve that kind of diversity in the participants in these trials. As you said, particular groups have been hit hard by COVID–19, African-Americans, Latinos, Native Americans. And we particularly therefore want to know, does the vaccine provide benefits to those groups because they may be the ones who will benefit the most if we can develop one that is safe and effective.

But it is without a doubt that there is also concerns in many of those communities about whether this is something they should

trust to be in their best interest. There is skepticism. There is distrust. We are at a time of considerable social upheaval, which means that the recruiting efforts have to be done with particular intention to try to do the community outreach and engagement that might just not happen. And I appreciate what you have said is going on in Wisconsin. And my hat is off the way in which you describe the kinds of outreach you are doing in the communities, including those who speak other languages. We are trying to do that same sort of thing across other vaccine trials.

The NIH has a long history in doing this kind of community engagement for other things like HIV, for instance. We are tapping into that. Just a couple of days ago, you might now see public service announcements in the areas where vaccine trials are happening that are particularly reaching out to African-Americans to explain why this might be something to look at and think about seriously getting engaged in. And we know that is a steep hill to climb, but we are trying to climb it. If we don't succeed in having diversity in the participants in these trials, I think that takes scientifically away from the value of what we are trying to learn and it certainly makes people wonder, was this really something that I could say is about me and my community if we weren't involved in the trial? Why should we then think about getting engaged when you say you have succeeded? This has to be one of those things that we do all together.

Senator BALDWIN. Thank you.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman. Dr. Adams in my state the three groups of people who have been disproportionately affected by COVID-19 have been frontline healthcare workers, Black residents of my state and nursing home residents. Who is going to make the decision on the allocation of the vaccine once it becomes available? Who will decide who gets the vaccine first?

Dr. ADAMS. Thank you for that question, Senator. And you hit on some of the key points, healthcare workers and nursing home workers and people of color are disproportionately hit by this virus. It is important for people to know that we aren't just making this decision in a room. We are working with the National Academies of Science Engineering and Medicine, with again, professional organizations and other advisory groups to come up with an answer to this incredibly difficult question about who gets the vaccine first. I can tell you some principles that we agree on. There are no final recommendations yet, but principles are that healthcare workers and front line workers should be first in line because we know they are most likely to be exposed and most likely to spread.

Behind them, it is looking at who is most vulnerable and using a scientifically driven and data-driven process to determine who is most vulnerable and where that vaccine will have the biggest impact. So what the American people need to know is we are thinking about this now, we are working with an array of partners to make sure it makes sense and it is ethically appropriate to distribute vaccines in a way that we ultimately will have the largest impact.

Senator COLLINS. Thank you. Dr. Collins, a major healthcare system in the State of Maine has contacted me to express concern

about the equipment that they may need to store the vaccine safely. They have already bought additional refrigeration units in order to store the flu vaccine and they are stocking up on that. But at least some of the vaccine presentations that are under study would require a subzero refrigeration. That is expensive, particularly for rural hospitals in a State like Maine that are already struggling financially.

If we are going to ensure that there is access to the groups that I mentioned with Dr. Adams, how can we do so—how can we ensure that we are not creating inequities and uneven access unless were helping with the purchase of those very expensive refrigeration units?

Dr. COLLINS. That is a great question, Senator. And I think there is an intense effort underway right now to figure out how best to address this and certainly the Surgeon General and I have been engaged in some of those discussions. This is an Operation Warp-Speed component that is being done in a way that has never really been done before. To try to imagine how to do the distribution when we aren't even quite sure yet which vaccines are going to end up being the ones to distribute.

You are right that one of the vaccines, the one that is being produced by Pfizer, requires storage at –70 degrees Celsius, which is I think—94 Fahrenheit or some really low number and that is a challenge for a lot of refrigeration situations. But I think warp speed is totally in the space here trying to figure out with CDC how to make sure that doesn't become a deterrent to distribution. If that turns out to be the vaccine that they need, then we want to be sure that is the vaccine that they can get, and that includes in rural areas not just in the big cities. So intense attention.

I have to say I have been very impressed General Perna who is leading this part of the effort for Operation Warp-Speed. He is a guy who knows how to do supply chain and that is what we are going to be all about here and that is being intensively pursued.

Senator COLLINS. Thank you both.

The CHAIRMAN. Thank you, Senator Collins. The voting has begun. And I will go vote in a few minutes. Senator Burr will preside while I am gone.

Senator Warren. Senator Warren.

Senator WARREN. Thank you. Can you hear me, Mr. Chairman?

The CHAIRMAN. I can now. Welcome.

Senator WARREN. Okay. I was—I couldn't hear you either. Thanks very much. So the coronavirus pandemic has claimed the lives of roughly 190,000 people. Our best hope to stop these deaths is a safe, effective COVID-19 vaccine. So, Dr. Adams, let me start with you. Estimates vary, but some epidemiologists believe that at least 70 percent of the population will need to be immune to COVID-19 ideally through taking the vaccine in order to provide herd immunity necessary to end this pandemic. Is that correct?

Dr. ADAMS. Yes, ma'am. The estimates that I have seen from experts range from 60 percent to 90 percent. But we certainly need to get over half of the population vaccinated so that we can achieve herd immunity and stop the transmission of this virus.

Senator WARREN. Okay. So as I hear it, kind of our minimum target would be about 70 percent, give or take. So the question is,

can we do that? Now, the last flu season for which we have complete data, less than half of U.S. adults, only about 45 percent, got the flu vaccine. Currently, a CBS News poll shows that only 21 percent of people surveyed would take a coronavirus vaccine as soon as it became available.

Convincing enough Americans to take a COVID-19 vaccine is a big job. So let's talk about what makes it harder and what makes it easier. People are more likely to be vaccinated if they trust that Federal officials are basing a vaccine decision on science and on data and not on politics or self-interest or conspiracy theories. Unfortunately, President Trump has undermined this trust. He has overruled scientists and pressured the FDA into approving products based on weak evidence.

He has spread dangerous misinformation about COVID-19, a practice that other Republicans have parroted. And he has appointed a former drug industry executive with financial ties to vaccine makers to run the Government's vaccine efforts. And now in recent days, he has hinted that he will deliver a vaccine, "before the end of October," a claim that public health experts fear is driven not by scientific evidence, but to boost his chances of winning the election in November. It has gotten so out of hand that companies making COVID-19 vaccines put out a public statement promising to adhere to, "high ethical standards and sound scientific principles when seeking vaccine approval." So, Dr. Collins, I know that you and the scientists at NIH and the researchers across the Federal Government are working night and day to produce a safe, effective vaccine for the American people and we are deeply grateful for that.

But, Dr. Collins, let me ask, do the President's actions encourage public trust in vaccines and increase the number of people likely to get the vaccine? Or do they discourage Americans from getting vaccinated for COVID-19?

Dr. COLLINS. I am not sure I know the answer to that question. I am more focused on what we can do in the scientific community to try to explain how it is that these decisions get made and certainly working with the Surgeon General, trying to be sure that message is out there.

You know, Senator, I am hopeful that those scary numbers and you just quoted one 21 percent people now saying they would accept this vaccine, that is based upon not really knowing what the facts are going to be. We are going to have to work really hard, though, in the coming weeks and months to get the facts out there about how the decisions are going to get made and how once we have, and I hope we will by the end of 2020, at least one safe and effective vaccine, what is the evidence that anybody would want to look at in making their own decision, discounting whatever political words they heard, whatever conspiracy theories popped up in their Facebook feed and actually saying, okay, let's see what the doctors say.

I hope if we can enlist trusted voices out there in the community, not just people in the Government like me, but people who are out there, the physicians in the community, other community leaders who also get informed about this and share that information, that America, which always after a while figures out how to do the right

thing, will do it again. And we will take advantage of something to save lives.

Senator WARREN. Dr. Collins, with all due respect, I really appreciate that you are doing everything you can and the scientists will continue to do that. And lots of people will. But the question I asked you is about what the President is doing here and whether what he is doing is helpful or not. You know, just in the past few weeks alone, the President has accused FDA officials of being deep state operatives.

He has tweeted conspiracy theories about COVID-19 deaths. And he has implicitly tied vaccine development to his reelection campaign. If Americans who are watching all of this hesitate to take the vaccine because of what he has done, does that help us get to the levels we need to be able to create herd immunity?

Dr. COLLINS. I just hope Americans will take choose to take the information they need from scientists and physicians and not from politicians.

Senator WARREN. Well, I hope you are right. You know, the American people deserve a safe, effective coronavirus vaccine. But Congress is lying to itself and to the public if it pretends that the President cares about anything other than his own political survival when it comes to vaccine development. It is time to kick profits and politics out of the vaccine effort and let the scientists do their work. Thank you, Mr. Chairman.

The CHAIRMAN. Senator, we are out of time. Your time has expired.

Is Senator Cassidy on? I believe he is.

Senator CASSIDY. Yes, Senator Cassidy is on. Can you hear me?

The CHAIRMAN. I can. Proceed.

Senator CASSIDY. Thank you, gentlemen. And if I occasionally ask you to make your answer shorter, it is not about the rudeness, it is just I have so much to ask. To Dr. Adams. Dr. Adams, there is at least one survey granted a little bit selected out of New York City suggesting that 20 percent of Americans have already, at least New Yorkers, had already been exposed. Now we can argue whether or not they have antibodies that are protective. But since the whole point of immunization is to mimic natural infection, I think it is best to assume that the most likely are, and in the case of people being reinfected after initial infection occur, but they occur about as rare as hen's teeth. So it does seem as if we are going to presume vaccines works, we presume the natural infection works.

Has there been any thoughts as to how to figure out who has already been exposed thereby protected naturally and don't need the vaccine or at least lower priority as opposed to, let's just vaccinate everybody? I say this because as a high ranking official, one of the companies producing a vaccine called to say that would be very helpful.

You know, he knew I was concerned about that and he said we do have a shortage of vaccine and problems in delivering, knowing that 10, 20 to 30 percent have already been exposed in certain areas would winnow down those who need to be vaccinated. What is your reply to all that?

Dr. ADAMS. Well, that is a great question. And I will be brief. We have antigen testing. We have PCR testing. And then we have

antibody testing. An antibody testing is how we figure out who has been exposed to the virus. And that is one of the questions that has come up in conversations about who gets vaccinated first. If you are someone who have been proven to have had the coronavirus in the past by antibody testing or by a diagnosis, then that is someone who we would not put necessarily at the front of the line to get vaccinated until we get to the point where we have enough vaccines for everyone. But also important to remember, this virus have fooled us many times and we still don't know what we don't know in terms of how long immunity will last for someone——

Senator CASSIDY. I get that but if I may. But of course, it is rare that a vaccine is more effective than actual infection in terms of inducing long-term immunity. And so even if it is for the next three to four months, that will relieve the pressure. Let me return to what Senator Casey asked because it is related.

Senator Casey asked regarding are we going to continue to use our immunization registries to document who has been vaccinated? The reply was not to reinvent the wheel, but on the other hand, if you are going to know whether this person has been previously diagnosed, previously infected and or has been documented to have antibodies, how are we going to store that information and integrate it with the delivery of immunization to those who are frontline?

Dr. ADAMS. Very quickly, we work with ASTHO, the Association of State and Territory Health Officers, and NACCHO, the National Association of City and County Health Officers, these institutions that already have the systems in place. And these discussions are occurring right now in anticipation of the vaccine——

Senator CASSIDY. Let me ask you this because I spoke to—yes, I'm sorry, had some indirect conversations with CDC. It is my understanding that for state immunization registries to be able to address this, they would have to get an appropriation from the Federal Government. They would have to get the vendor who does their software to fix it for them. And that vendor, there is only four of them and there is obviously 60 something states and territories. And so therefore, there would be a backlog. Has any effort been made already to adapt these registries to take the information as regards to the COVID vaccination and or preexisting COVID immunity?

Dr. ADAMS. To be brief, I will say that we will have CDC follow-up with you, but the answer is, yes, these conversations that are occurring right now and the other answer that I have to say as Surgeon General is that public health has been long underfunded, including surveillance and registries and so we would be happy to work with you to figure out how to make——

Senator CASSIDY. To move beyond that, as you move beyond the conversations to the actual implementation. For example, have RFPs been let in order for these immunization registries to be upgraded or is it still on the conversation stage?

Dr. ADAMS. I am sorry, I didn't hear the question. Can you repeat that?

Senator CASSIDY. Is still on the conversation stage or have contracts actually been let to upgrade the immunization registries or whatever system we use to document who is immune?

Dr. ADAMS. Dr. Redfield will be here in 2 weeks, but I will make sure we follow-up with you and get you an answer to that question, sir.

Senator CASSIDY. Sounds great. Dr. Collins. One use—there has been some question as to whether or not monoclonal antibodies will work to prevent infection. Obviously, there are several ways that you could get a monoclonal antibody, but one would be to give it to those who are vulnerable. Now, a monoclonal antibody is merely, again, a mimicry of a vaccine. Has any thought been there to give monoclonal antibody to, say, an obese diabetic in order to prevent her from being infected initially?

Dr. COLLINS. Yes, there has. Monoclonals might be useful therapeutically for people already sick, but they might also be useful as prevention. And you say, yes, this is like a passive vaccine. And we do have trials already ongoing for monoclonal antibodies for people in nursing homes and also for people in families where there have been lots of other infections to try to prevent them from getting sick. We don't know yet exactly how that is going to work in a preventative mode but that is something we really want to know. It is great questions.

The CHAIRMAN. Senator Cassidy, your time has expired.

Senator CASSIDY. Last question to ask, does AstraZeneca have Guillain Barre? Because you suggest in your testimony that it may have had Guillain Barre.

Dr. COLLINS. I am sorry, I didn't hear your question again.

Senator CASSIDY. You suggested that the fellow who had an adverse event in the AstraZeneca may have had Guillain Barre. Is that the case?

Dr. COLLINS. The word that we have had and this is—put in The New York Times is it is transverse myelitis, which is different. Guillain Barre, although sometimes confused for that first presentation, I don't have any other details than that.

Senator Burr.[presiding]. Senator Cassidy, your time has expired.

Senator CASSIDY. Thank you, Mr. Chairman. I yield back.

Senator BURR. I am going to recognize Senator Kaine first but just for the purposes, since there is a vote going on, on the majority side, it will be Senator Murkowski, Scott, Romney in that order. Senator Kaine, Senator Hassan on the other side of people that I know that are here.

Senator Kaine, you are recognized.

Senator KAINE. Thank you. Thank you to the witnesses. This is a great hearing and observation in three topics for questions. Just an observation. We had a hearing in this Committee on May 12th. The title was safely getting back to work and back to school. I have been critical of the Administration for not setting a national testing goal, a numerical goal that we should be achieving as tests.

I was asking questions during the hearing to Admiral Giroir. And what he said in the hearing was this, by September, taking every aspect of development, authorization, manufacturing and supply chain into consideration, we project that our Nation will be capable of performing at least 40 to 50 million tests per month if needed at that time and if new technologies are authorized by whole genome sequencing approaches or any novel solutions uncov-

ered by NIH's new diagnostics initiative, that number will be much higher.

40 to 50 million tests a month is 1.3 to 1.7 Million tests a day. That number is not accepted by all at Harvard. They indicate that they think we need 1.2 million tests today to mitigate to kind of bump along or 4.3 million tests a day to suppress coronavirus. On September 4, we did 900,000—902,000 tests. That is about 52 percent of the high range of what Giroir said we should do by September or 69 percent of the low range. So we are still dramatically behind what the Administration suggested we should be doing in terms of testing to safely open for schools and our workplace.

I will have a chance to talk to him about that at the next hearing. Here is what I want to ask about first. Is there any benefit to the United States for not participating in the KOVACK Project of the World Health Organization, GAVI and SEPI?

Dr. COLLINS. I will say that the United States is engaged on the global stage in trying to see what can be done about COVID-19, and that is for me personally, a very important priority. We have invested and continue to in GAVI, which is a critical part of how vaccines can get manufactured and distributed. All of our global health experts are deeply engaged in communicating and working with their colleagues in other countries.

I do think you have heard from the Administration a clear sense that if we are able by the end of the next 6 or 9 months to have hundreds of millions of doses of vaccine, we would want to be sure that those become available to those countries that need the most and may not have their own resources.

Senator KAINE. Dr. Collins, I recognize that we are engaged at the international level, and there is good reasons for it, as you state. I understand that you appreciate it. I can see no tangible benefit to the United States not participating in KOVACK, just as we are looking at multiple vaccines and the theory that competition is good. And then there may emerge the contenders that we want to. It seems like the diversification of portfolio would suggest we have nothing to gain from withdrawing from KOVACK. That is my own opinion. I want to ask about a particular element of the leading contenders in the vaccine which required two doses. I think there is at least one candidate that has a one dose vaccine.

Building upon this and maybe get your guys advice on this one. We know that a significant percentage of people have said they will not get a vaccine and that is for any vaccine but in particular in this and so we have to educate people about it. We also know that in other vaccines that require two doses and in this case, the leading contenders would require at least 21 or 28 days between the doses, is my understanding.

In other vaccines that require two doses, a significant percentage of people, somewhere between 40 and 65 percent in some studies who get the first dose will not get the second dose. And then a significant percentage of the people who get the second dose don't get it in time. They will get it months or many months later after they are able to get it. What is the effect on a two dose vaccine if you just get the first dose and don't get the second dose?

Dr. COLLINS. We know a little bit about that, Senator, from the fact that we have run these Phase 1 trials. And again, you can look

and see what happens after the first dose as far as the production of antibodies, which is our best way of assessing whether it worked. I think with all of the two dose trials, it looks as if the first dose does give some response, but if not at the level that you would really like to see, and then you give that second dose and you are up in the range of antibodies that people have developed who got actually natural infection from COVID-19.

Hence, if you want to be as effective as possible, you go to that second dose. It is not the ideal. I think ideally we would love to have a single dose that didn't require refrigeration and was easily transported and was totally safe and effective. We may not be lucky enough in this very big push to get something quickly, to have something with the perfect parameters. But it is most important, I think, we get something that works and saves lives.

Senator KAINE. For the record and to our next panel, I will ask questions about what we will do to try to educate people on the need to get that second dose and get it in a timely fashion. I also have a question about vaccine testing on pregnant women that I will save for a question for the record. I appreciate your testimony today.

Thanks, Mr. Chairman.

Senator BURR. Thank you, Senator Kaine.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman. And thank you, gentlemen, not only for your comments this morning, but just your leadership in this. I take particular interest in this discussion about vaccines because Alaska has lagged historically in terms of our vaccination rate. We have chronically been last, last among the 50 states. It is my understanding that we are in there at about 74.2 percent compared to all the other 50 states.

Other states, you get some—Massachusetts is the highest at 92. So Alaska has a long way to go. And unfortunately, we have been this way for a while. So when we talk about vaccine hesitancy in Alaska, we know we get it. And so I am very concerned about where we are moving forward with this vaccine. I also recognize that we have some of the most vulnerable populations in Alaska with our Alaska native people. We have limited health care facilities. You have had opportunity in this hearing date to hear all about it. So we are exactly the type of state that needs to have that assurance that, yes, this vaccine is going to be safe, that this vaccine has not been subject to political initiatives that would speed it up in any such way that would cause it to be less effective.

We have every interest to make sure that there is an education campaign that people can believe in. I have been working with several of my colleagues on this Committee, Senator Braun, Senator Hassan here on the SAVE Act. This is the Safe Authorizations for Vaccines during emergencies, basically making sure that we are ensuring a level of public independent expert review of the vaccine candidates. I know you may not wish to comment on specific legislation. Dr. Collins, you have already spoken in your initial remarks to the Chairman, into the Ranking Member about the assurance that we must, in fact, make sure that this process that we have is true, is honest, and is going to result in a level of trust and credibility.

I would just ask you to help me in encouraging Alaskans on and other Americans on how we build this trust for a vaccine. What can you give me? Do we need more than just the SAVE Act here to build that credibility and trust? Because otherwise I am fearful that the rates that we have seen with our vaccinations, generally what we have seen just this year compared to April of last year, we saw a 48 percent decrease in total vaccines administered in this state. This past May and June we have seen a slight improvement, but we are in a tough spot right now. Give me some level of assurance, please.

Dr. Collins.

Dr. COLLINS. I think we have a tough situation for the whole nation. But I am sympathetic with your particular circumstances, with the history in Alaska of hesitancy being even greater. This is going to be a need for all hands on deck. Leaders in the Congress, people in the local communities have to get all together to figure out how to convey this message. The Surgeon General is right in the middle of trying to organize a lot of this effort so maybe I should ask him to speak as well.

Senator MURKOWSKI. I mean, do we need a public relations campaign that is really amped up? Messengers are important. Who is the right messenger? Is that the Surgeon General? Is it the—who is it? Because right now it is not working.

Dr. ADAMS. Well, we know that when it comes to vaccines and most health advice, that people will trust their local provider more than they will trust anyone else out there. So what we are trying to do with arm local providers, with the facts. CDC's campaign really has scripts and sheets to help people talk about some of the frequently asked questions. We are engaging with social media influencers. So I was in Kotzebue and they knew about rappers.

In the San Francisco 49ers, I remember there was a guy wearing a San Francisco 49ers hat. We need to get Lady Gaga, for instance, is someone who I never thought I would invoke in Congressional testimony. But I gave her a shout out because she had mask that she worked the Video Music Awards last week and people will listen to Lady Gaga before they listen to the Surgeon General. So we need to very much engage. The other thing that I would implore you to think about is we need to encourage people to stop attacking the process. And there is a lot of politics going on here.

People don't like one party or the other, one person or the other. The process is strong. And Dr. Collins and I have been adamant that we want people to understand there are protections built in. The process is strong. If we follow the process and people understand the process, they will have confidence. But everyone out there who says, I won't take this vaccine if I don't trust this vaccine unless is instilling further hesitancy and hurting us.

Senator MURKOWSKI. I think that is important. And that is exactly why the SAVE Act is there to focus on the integrity of that process. Thank you, Mr. Chairman.

The Chairman [presiding]. Thank you, Senator Murkowski.

Senator Hassan.

Senator HASSAN. Well, thank you, Mr. Chairman and thanks to the Ranking Member as well and to both of our witnesses today, thank you for your service. And I will echo what other people have

said. We know everybody in your shops are working round the clock here, and we are very, very grateful to you and all of them. We have been talking a lot today about public trust in the vaccine approval process, which we all agree is critical to achieving the widespread use of a vaccine. But right now, people are concerned, as you have heard Senator Murkowski say, as you heard Senator Warren reference, a CBS poll released this past weekend found that two thirds of Americans would think the process had been rushed if we got a vaccine this year and only one in five plan to get vaccinated as soon as possible.

Let's drill down a little bit on what the process is so we can provide some of this confidence to the American people. Dr. Adams, last week you told ABC News that you have confidence in the COVID-19 vaccine review process because data safety monitoring boards would not allow a product to move forward unless there is, "good evidence that these vaccines are efficacious." But in addition to ensuring that a vaccine is effective, we also have to ensure that it is safe. So could you please tell us, Dr. Adams, what protocols are in place to ensure that these boards do not stop clinical trials until they also collect sufficient safety data, including for high risk populations? And what specific steps have been taken to ensure that these decisions will not be subject to political influence from the White House?

Dr. ADAMS. I will be very quick in my answer, because this is more on Dr. Collins' lane. But as an example, the FDA generally advises a minimum population size for pre licensure safety data base for preventive vaccines to exceed 3,000 patients. These trials have 30,000 patients in them. This isn't so much about time as it is about events. And we have so many more people, tenfold involved in these trials that we have the potential to be able to recognize a safety and efficacy signal a lot sooner. We also have a higher incidence of background disease prevalence, and that is a bad thing, but it means that in terms of getting a signal, there are valid scientific reasons to expect that we will both get a safety and an efficacy signal in a very short order.

Senator HASSAN. Hold on, just a second please, Dr. Collins. Look, I appreciate that. But what people are looking for is administratively what are we doing? What systems do we have? Because, look, if this Administration's vaccine review process is as evidence based and free from political influence, as you both are suggesting, why do you believe the leading COVID-19 vaccine manufacturers took the unprecedented step of jointly releasing a public pledge yesterday, committing to an evidence based vaccine review process focused solely on safety and efficacy?

Dr. ADAMS. I can give you at least part of that answer, and that is because Dr. Collins and I have been on the phone with them and really putting forward a full court press to help instill confidence in the vaccine process that we know is, as Senator Murkowski just mentioned, has been wavering long before COVID.

Senator HASSAN. Okay. And because my time is short, I am going to move on to another topic. I understand you have something to say too Dr. Collins, but I want to touch again on the SAVE Act that Senator Murkowski was talking about. If we expect the American public, Dr. Adams, to have confidence in these products, we need

to ensure that they have full confidence in the review process. In addition to the general meeting they are holding in October, do you believe FDA's vaccines and related biological products advisory committee should hold public meetings, review clinical trial data and release their findings to the public before FDA approves or authorizes any vaccine product as they normally would?

Dr. ADAMS. I think we need to follow the process because the process works. I think we need to be careful about inserting new barriers in the process because it is just as unethical to prolong——

Senator HASSAN. But excuse me, just because the time is limited, this isn't a new barrier or a new process. This is the existing process, right?

Dr. ADAMS. I believe we need to follow the existing process.

Senator HASSAN. You support that. Do you believe that the CDC's Advisory Committee on Immunization Practices should meet publicly, review data and issue public recommendations for each COVID-19 vaccine that enters the market so health care providers across the country are confident giving these vaccines to their patients?

Dr. ADAMS. Again, I believe we need to follow the process and engage health care providers so that everyone has confidence.

Senator HASSAN. Okay, because a vaccine is really only effective if people are willing to use it. So I just want to touch on what the SAVE Act does a little bit. Working with Senator Murkowski and Senator Braun, for instance, we have introduced, this is bipartisan legislation, that would improve public confidence in the vaccine review process by helping to ensure that these independent FDA and CDC reviews take place in a transparent way, free from political influence without slowing down the development of safe and effective vaccines. So I just want you both to know that is what the SAVE Act is about. We believe these processes are in place.

These experts are used to doing this work. They are independent. I am going to continue to push for this legislation to be included in the next COVID relief package. And I look forward to working with you with ideas about other ways we can strengthen the transparency of this process and really, again, help the American people understand what the processes are and why you both are so confident that the scientists will be able to do their work.

The CHAIRMAN. Thank you, Senator Hassan. Your time has expired. I am going to let Dr. Collins, if you had something to add, I will give you the time to do it.

Senator HASSAN. Thank you.

Dr. COLLINS. Well, just very quickly, you asked about the statement by the nine CEOs and I think they were responding out of their concern, which we keep very much share, Surgeon General, and I think all of you do that there is this strong public distrust and skepticism and they wanted to come out and say very clearly, hey, we are not trying to pull something here. We don't believe in putting forward anything that is not absolutely safe and effective. We are pledging this in writing. I hope that added a little bit more confidence to the people who are still looking at this and wondering. I was glad to see it——

The CHAIRMAN. Thank you, Dr. Collins.

Senator Romney.

Senator ROMNEY. Thank you, Mr. Chairman. And I want to thank members of the panel for your testimony today. I have to thank in particular Dr. Collins for the slide, said this description of the process that is leading toward a vaccine was most informative and colorful. I want to pick up on the line of questioning Senator Murkowski described, and that is with regards to the growing sentiment, I think, across our country of people who are, if you will, anti-vaxxers, people who are avoiding vaccines.

I have been approached during business to my state by people who have the whole books that are written describing why vaccines are bad and why they are made from adulterated sources. And I won't go into all the details, but it is not like just a social media phenomenon. It is literally there are literally books out there that are written to describe why vaccines are bad. And I wonder if it does not makes sense for our Government to put out a very comprehensive effort to dispel this growing sense of vaccines being bad.

I don't know how you do that, but it would kind of mind that you are doing that with regards to tobacco and massive advertising on TV. You can have debates. You could call in these people who write these books and have discussions with them, which are publicized. You could have a much more aggressive campaign on social media.

I guess the question I am asking is, should we be doing more than we are doing and what could we be doing to resolve the debate, the uncertainty that so many Americans have about the wisdom of receiving vaccine? Now, I will ask Dr. Collins and the Surgeon General, both of you respond to that.

Dr. COLLINS. Well, I will start. But the Surgeon General will have a lot to say about this. This has been, of course, an issue for our country, not just in this season of COVID-19, but before that. And particularly one has seen the consequences of that with measles, for instance, which in the year 2000, we declared that the U.S. had succeeded effectively in getting rid of measles. And now last year, we had more than a thousand cases. And people have forgotten that kids die of that disease and continue to die in other parts of the world.

I think we have benefited from the success of vaccines so that a generation has sort of lost track of the fact that these are preventing diseases that take lives. I just saw an estimate that if you looked at all the children born in 2009 and you ask what would have happened if none of these vaccines had been available? 42,000 of them would have died. Imagine that, 42,000 kids dying for preventable conditions because vaccines were not available.

Well, they are available now but if they are not getting used, we are facing that same kind of terrible consequence. And it is heartbreaking and I must say frustrating and sometimes even causes you a little bit of anger and frustration that this kind of misinformation is so readily spread by people who have another agenda. And we have a hard road to go to try to counter that when so many people don't see in their own experience the reason why this is such a lifesaving activity. But I am going on a bit. Surgeon General, please say what we should do about it.

Dr. ADAMS. No, thank you, Senator. And I will very quickly walk through the Department of Health and Human Services is using a three tiered approach to improve vaccine confidence through re-

search and evaluation, collaboration and partnership, communication strategy, the knowledge dissemination. I put out an Op-ed earlier this year with the secretary and with CDC Director Redfield. We are working with platforms like Twitter and Pinterest and Facebook to make sure appropriate and accurate information is displayed prominently when people do a search.

CDC developed vaccinate with confidence, the strategic framework to strengthen vaccine confidence. We are working with minority medical schools like Morehouse and beyond. But you mentioned vaccine, vaccine resistance and the anti-vaccine community. It is important to understand that 90 plus percent of parents out there are actually doing the right thing. And that when you look at the 10 percent who weren't, most of those 10 percent aren't in that anti vaxx or I say vaccine resistant category. They are in the vaccine hesitant category. And that is what we need to really work on.

We need to work on educating them and engaging them and being compassionate with them and patient with them to answer their questions. And I went out to Washington when they had the measles outbreak last year. And I found that when they had after hours of conversations with parents, they would come back to three, sometimes four times. But most of those parents, when they got their questions answered, actually got vaccinated.

Senator ROMNEY. Thank you, gentlemen. My time is virtually out. I will just make one more comment. And that is for Dr. Collins. And that is what it regards to the Russian announcement of a vaccine. Clearly, very little data. But are we evaluating the promise of vaccine efforts in other countries? And do they have much prospects for being of value to us?

Dr. COLLINS. We certainly are to the extent that the information is being made available and obviously what you would like to see is a publication that has been peer reviewed and some of that is starting to come now from the vaccines that are being developed in China and Russia. I must say, the way in which the Russians roll this out, declaring victory before they had gone much beyond a Phase 1 trial, did not win them a lot of confidence in the scientific community. And so we really have to be insistent that if somebody is going to say this vaccine is safe and effective, that they have lived up to that very high standard.

I think our country establishes those standards and others generally follow them as well. So, yes, we are watching but some might have said that the effort that Russia had put forward was putting a lot of people at risk, asking them to take a vaccine that hadn't gone through that. Some even called that Russian roulette.

The CHAIRMAN. Senator Romney, your time has expired. Thank you.

Senator ROMNEY. Thank you.

The CHAIRMAN. Senator Smith.

Senator SMITH. Great. Thank you so much, everyone. I want to first thank Dr. Collins and Dr. Adams for your service to our country and for everything that you were doing. I know that everybody on this Committee is dedicated and optimistic even about the goal of having a safe and effective vaccine that distributed at scale and also can be free for everyone. And so I want to just touch on that for a minute. You—last month I introduced my COVID-19 Treat-

ment Act, which would ensure that folks get their health insurance through Medicaid or CHIP or people who don't have health insurance at all would be able to get a free COVID-19 vaccine.

This builds on the actions that we have already taken in Congress to make sure that folks that have private insurance or receive their insurance through Medicare have a free vaccine. So, Dr. Collins, I want to drill in on this a little bit with you and just understand a little bit about how we can make sure that this happens and that folks aren't stuck with out-of-pocket costs that they are not expecting if they get their insurance through Medicaid or CHIP or if they are not insured at all. So first, can you just to confirm that the Federal Government will buy this vaccine and also will—and also the supplies that are needed to administer the vaccine and make that available to providers at no cost?

Dr. COLLINS. Yes, I can confirm that. It is part of Operation Warp-Speed. As these various vaccines are chosen to be put forward and new deals are negotiated, that allows the Government to buy and own tens or in some cases hundreds of millions of doses that then can be provided for free to providers. And along with that, of course, all of the other materials you need, like syringes and vials and PPE is part of the package. The only thing that then needs to be dealt with is any kind of charge that the provider might give for administering the dose. And I know the Administration is committed to making sure that does not become a barrier to anybody and you can get this completely for free if that is what you need to do.

Senator SMITH. Right. That was my—that is perfect. That was my second question, that there aren't hidden charges, administrative costs, but that would also be reimbursed by the Federal Government so that folks don't get stuck with something they are not anticipating, which is, of course, particularly a barrier if you don't have any insurance at all or if you have Medicaid.

Dr. COLLINS. I think the Administration has made it clear that no one should be denied this vaccine. It needs to be completely free.

Senator SMITH. If let's say that we found out that we needed a booster, some sort of a booster shot or shot like a two round vaccine that you need to get a booster like we do for other infectious diseases over time, would or should the Federal Government also cover the cost of those boosters at no cost to source?

Dr. COLLINS. I don't know that I have heard that conversation going on yet because we really don't have the data to know whether such boosters will be needed and if so, how frequently with the booster have to be provided. We are all hopeful, of course, that this vaccine will produce long lasting immunity, but that is not always going to be the case. I think that is a downstream discussion, at least it is for me.

Dr. ADAMS. We are talking about COVID but I think it is important that we just operate under the underlying belief that all vaccines should be provided at minimal cost to people because they save lives and they are cost effective——

Senator SMITH. Well, and Dr. Adams, I think the point here, of course, too, is that this is really a matter of public health but it is also a matter of equity because we know that black and brown and indigenous people, people of color, are more likely to be unin-

sured and more likely to be facing a struggle. So I think it is just extremely important. So I am going to ask all my colleagues on this Committee, I would be so grateful if you would join me on this bill. I think it makes a very important statement. It also makes a very important step toward ensuring that this vaccine, when it is available and we all are optimistic about that and eager to make sure that it is safe and effective, that vaccine is available to everyone, and not just free of charge. I think I just have a couple more questions.

Dr. Collins, I want to just ask you one question. I think people are so concerned about this, how does a process which we have to trust and can be trusted? So can you just explain to us a little bit about how an event they have—what would be the endpoint or when we know that this vaccine trials should be completed and be done? What is the end point?

Dr. COLLINS. Let me quickly explain how that works. Let's say we have 30,000 people involved in a trial, which is the number we are aiming for all of these trials. Half of them received the vaccine. Half of them received an injection of a placebo. Nobody knows whether they got the vaccine or the placebo. But then you track those individuals and you look to see who, in fact, gets infected with SARS COVID 2.

What you are looking for, of course, is a circumstance where those who got the vaccine have significantly fewer cases than the well-matched folks who got the placebo. That tells you the vaccine is working. As it turns out, by the time you have seen 150 cases of SARS COVID 2 in this group of 30,000 people, if your vaccine is at least 50 percent effective, you are going to know it because you are going to see a big skewing in terms of who got the disease and who did not. And that is basically why we say this is an event based decision process for deciding about efficacy. You count those events and whether it worked or not.

If the DSMB, which is the part of this enterprise that is looking at this, sees that, then they raise their hand, assuming they have also looked at safety and found it acceptable and said, Okay, FDA, it is time to have a look. That is how it works.

Senator SMITH. Thank you. I know I am out of time,

Mr. CHAIRMAN. Thank you very much.

The CHAIRMAN. Thank you, Senator Smith.

Senator Loeffler.

Senator Jones.

Senator JONES. Thank you, Mr. Chairman. And thank you, both to our witnesses today for your service and for being here. You know, I want to go at this a little bit—I want to get some specifics on some of these crazy theories out there, guys. We talk about them and we see this. And I appreciate Dr. Adams saying that 10 percent of parents out there are only 10 percent are not doing the right thing by getting vaccinations. But all of this, has been with small pox and measles and other things which we have grown up in a different era.

Now we are in an age of social media and we see Facebook, we see Twitter, we see the Internet full of all of these conspiracy theories. I would like to get both of you an opportunity right now, because one of the things I am not seeing from NIH or from the Fed-

eral Government is efforts to really debunk these theories as opposed to just getting positive information out there.

Dr. Collins, Dr. Adams, each take one or two of these theories. Tell us what you have heard. What is the most outrageous thing and debunk it for us as quickly as you can so that the American people right here on the record know that they should not follow these absolutely crazy theories that are out there about vaccines. Can I go for comment?

Dr. ADAMS. I will take the first one. Vaccines do not cause autism and people need to understand that. We have looked at the trials. We have looked at studies. Vaccines do not cause autism.

Dr. COLLINS. I am agreeing with that one. But I will tell you the craziest one I have heard, which is this is all designed by Bill Gates. And when you get the vaccine, it has a chip in it that is going to get stuck into your system and it is going to watch everything you are doing. And people believe that stuff.

Senator JONES. None of the vaccines are designed to kind of be Big Brother over people and to follow them. They are designed, I take it, to save lives. Correct?

Dr. COLLINS. That is exactly right.

Dr. ADAMS. Exactly. To save life and to save money, sir. Vaccinations are over $402 billion in direct cost and $1.5 trillion in societal cost. And that is just the flu vaccine every single year.

Dr. COLLINS. I have a T-shirt that I like to wear sometimes, although it isn't always well received. And it has three words on it. It says vaccines cause adults. Think about it.

Senator JONES. Very good. I would though encourage both of you with your respective positions to do a little more in terms of actually debunking theories. I appreciate all that you are doing to get accurate information out there. I have been doing a lot of Facebook live every week with a health care professional to try to get accurate information out there. But still debunking the theories is also important.

I would encourage you to kind of do that on your websites and do that in information, not just trying to get the accurate, but to debunk some of this garbage that we are hearing out there. So, Dr. Adams, I want to follow-up with you a moment, because I really do think you are in a unique position about encouraging minority participation in some of these clinical trials. We know that minority participation in these clinical trials is down. We know and on the flip side, that minority populations are being disproportionately affected by this, by COVID-19. And unfortunately, the United States has somewhat of a sordid history when it comes to minorities and clinical trials. So what would you can you do? What would be your voice to encourage more minority participation? And how can we in Congress help get that voice out there because I believe it is so important to get a saving a vaccine, effective vaccine for everyone.

Dr. ADAMS. Senator, one of the things you can do is to support an institution right in your own community, University of Alabama at Birmingham. I was there just two weeks ago and they have done a tremendous amount of work in terms of engaging the local African-American community in cardiovascular and hypertension re-

search. But I think, No. 1, we need to acknowledge past wrongs that have occurred.

You all might be surprised to hear me giving a shout out to Bill Clinton. But Bill Clinton apologized for the Tuskegee experiment several years ago. We need to acknowledge Tuskegee. We need to acknowledge Henrietta Lacks. We need to acknowledge the wrongs occurred. And then we need to address the situation that caused them to happen. And again, we talk about the process, Phase 1, Phase 2, Phase 3 trials, data safety monitoring boards, committees, and whole agencies, that HHS that have been stood up to make sure these types of things never, ever happen again.

Then we need to engage. And that is what you're talking about, sir. We need to get out there where the people are and use trusted advocates. I have been working with faith communities. I spoke to rabbis last week. I have spoken to a pastor of the largest megachurches in the country. We are talking to social media influencers like Kylie Jenner and T.I. and again, Lady Gaga, because my kids will do something because, I believe, because they say it before they believe it because Dr. Collins or I say it. But that is kind of our approach that we are taking to engage with people, address—acknowledge, address and engage.

Senator JONES. Well, thank you, Dr. Adams, and thank you for coming down to Birmingham for the opening of some of those free clinics. We very much appreciated your visit. And those are being very successful. Thank you. Thank you, Mr. Chairman, for this opportunity.

The CHAIRMAN. Thank you, Senator Jones.

Senator Rosen.

Senator ROSEN. Can you hear me?

The CHAIRMAN. I can. Welcome, Senator Rosen.

Senator ROSEN. Sorry, I had a little trouble unmuting. Thank you, Mr. Chairman. Thank you for holding this hearing. Thank you both doctors for being here today. I really appreciate your work and your testimony. But to begin with, I really want to raise again the importance of ensuring that we got a robust, longitudinal studies on how the virus impacts a wide range of patients in the short and the long term, including what treatments are most effective. So I have introduced a bipartisan Ensuring Understanding of COVID-19 to Protect the Public Health Act to make sure that this critical research happens. And this includes a very diverse set of patients.

This bill was included in the House's passed CARES Act and I ask support from my colleagues and especially on this Committee, to ensure it is included in the next COVID package passed by the Senate. That is going to help us determine future—But I would like to move on now to rural access to vaccines and information. And so the CDC has asked the states to draft and be ready to follow vaccine distribution plans in less than 2 months.

Our health departments are doing the work of the heroes but they are stretched thin and they still lack the robust Federal support they need. Last month I was on a statewide virtual tour. I heard how the need for basic health care services remains a huge issue, particularly in rural towns. In Beatty, Nevada, they still lack access to regular primary health care. Rural access—across the country, rural areas are continuing to struggle as the pandemic ex-

acerbates existing problems with access to adequate medical care. So with this in mind Dr. Collins, what recommendations do you have for making sure that rural areas are not left out of the critical vaccine distribution? Both the actual delivery of the vaccines, information about who should receive the vaccines.

I have communities that have no hospital, no physicians' offices and no pharmacies with the closest medical services potentially 100 miles away. So what is a national plan to deploy these vaccines across our states? Mobile clinics, perhaps? Can you tell us what is to happen or do will we have to figure it out on our own?

Dr. COLLINS. Well, I will start. But I am sure the Surgeon General might want to add something because even more in his domain. But certainly the distribution issues are critically important and are under intense planning processes right now, recognizing that warp speed has not just the role of trying to encourage their clinical trials, but also the manufacturing and then the distribution. Everything like the cold chain and how do you actually get these doses to the places where they need to be, recognizing that we are going to need to do this in a priority way so that the most vulnerable people get the doses first.

That means thinking about rural communities and all the ways that can happen, but it is going to be working with the states and CDC is already deeply engaged in that. I think they got a little misunderstood when they said to the states, we need to be ready by November 1st just in case. I think they were trying to say, let's be prepared here and not wait to the last minute. And that is very much the conversation that is going on. But the Surgeon General may want to say a little bit more about rural areas in particular.

Dr. ADAMS. Well, I will be very brief—.

Senator ROSEN. Yes. I want to make sure that Congress is your partner and being sure that we leave no rural communities behind.

Dr. ADAMS. I will be very brief. I grew up in a rural community in Southern Maryland where the nearest hospital was quite far away. And I ran the State Department of Health in Indiana, which is a mostly rural state for three years. We have utilized the Vaccines for Children's Program, VFP. We have utilized the Section 317 immunization program. We have infrastructure in place to get vaccines out to those territories. But you are right, we have to acknowledge that we still have done a poor job of making sure we have equitable distribution of vaccines before there is COVID vaccine in those communities and we need to double up on those efforts.

We are working with state and local health departments to make sure that occurs. And I stand ready to work with you to make sure people know vaccines are safe and effective and that we are addressing the practical issue with availability, convenience, cost, service, quality and satisfaction, making sure that not just there, but that people can get it easily and are happy with the way they received it. And either all issues that are on my radar and that we are working with local partners to try to figure out before we get a vaccine.

Senator ROSEN. Thank you and I only have a moment left but I am going to submit this for the record. But we have seen a troubling decline in vaccination rates overall during the pandemic. It

was reported in May this year, vaccinations generally were down by approximately 64 percent. This is extremely concerning not just to me, but to everyone across our state. And I am sure other states have similar statistics.

Dr. Collins, how do you think that current drop in vaccinations could impact getting a COVID-19 vaccination out? Should we pair up getting existing vaccinations to people along with the COVID-19 vaccination? Would you recommend that or how do you think that we can bring our general vaccination rates back to where they should be as well?

Dr. COLLINS. Well, the general vaccination rate is a crisis right now that ought to be attended to right now. There is no reason to have to wait until we see what happens with the current COVID-19 vaccines that are in clinical trials. So all of those folks who might be listening to this, who fell behind on childhood immunizations because of concerns about going to the doctor's office, those doctors' offices have figured out how to make themselves about the safest place you can be. It is time to catch up.

I know your physicians will be very willing and interested to help you do so. And then that ought to be happening this fall, as well as everybody getting their flu shot, which is another vaccine whose appropriateness and urgency is going to be even more the case than ever.

Senator ROSEN. Thank you. My time has expired and I really appreciate your service. Thank you, Mr. Chairman.

The CHAIRMAN. A couple—thank you, Senator Rosen. We will wrap the hearing up now. We have votes going on the Senate floor. I have got a couple of questions in conclusion. Dr. Collins, there was some talk earlier during the hearing about multiple shots for a vaccine. If I remember right we already do that, don't we? I mean, some vaccines require more than one shot.

Dr. COLLINS. For instance, the HPV vaccine, which is saving lives from cervical cancer in prodigious numbers, started out as a three dose. I think it is looking pretty good. That two will do. But we are not down to one yet. And yet that is clearly something that motivated parents very much want their children to have, as I think they should. So, yes, this is not the first time.

The CHAIRMAN. I believe I have taken tetanus booster shots.

Dr. COLLINS. Yes. Every 10 years. That is right.

The CHAIRMAN. That shouldn't be—second, Senator Burr made an interesting point, which was that a lot of the statutory authority to do all the extraordinary things that the Administration is doing right now is already on the books. In other words, Congress, after the last several pandemics, took a number of steps giving the Food and Drug Administration more authority, giving the National Institutes of Health additional funding and some more flexibility, creating—moving the stockpile management, creating manufacturing plants that would be ready in case we needed them.

How valid is that point that in fact, as we think about preparing for the next pandemic, which Jared Diamond reminds us could be next year in this age of jet planes, that a lot of good work has already been done by the last three or four Presidential Administrations of both parties and Members of Congress, of both parties, and

that this Administration is simply using to a full extent the authority Congress has given you.

Dr. COLLINS. I think that is very true. I think it is traditional right now to bemoan that we weren't ready for COVID-19, that we somehow let things lapse. We weren't perfectly ready, that is for sure. And there were some things that probably could have been in better position to be ready for this. But there were things that Congress had done over the past couple of decades, the creation of BARDA, other things that you have mentioned that made it possible to move more swiftly now. Now we need to learn from this one.

Of course, this is the worst pandemic we have had in more than a century so maybe we will learn even better this time to be prepared so that as we get through this and we are going to get through this COVID-19 will slip into the rearview mirror, that we don't imagine that we are done with pandemics because COVID 23 or whatever the next thing might be is out there lurking. And we should learn from these lessons and not do anything other than prepare.

The CHAIRMAN. Well, one of the lessons, and Senator Frist, Governor Leavitt, a number of others who preceded both of you in your positions have said we go from panic to neglect, to panic. And even though we have taken some significant steps to be better prepared and you are taking advantage of those, I mean, there is no way you could have had—you could be developing a vaccine this rapidly, this safely, this effectively without these steps. Still, we are not as prepared as we should be because in between epidemics, we lose our focus, which is why I am urging that on onshore manufacturing that we make sure we keep those plants warm, as Governor Leavitt said.

On stockpiles, that we make sure the stockpiles stay full and aren't depleted because of budget problems at the state or in the hospitals or in the Federal Government. And Governor Leavitt said we had underfunded public health in this country for the last 30 or 40 years. So we need to—and the time to be prepared for that is now.

I have reiterated my strong feeling, and I hope you agree with it, that the time to sustain our preparedness is now while our ire is on the ball and that while we are dealing with this pandemic, we should make sure we are prepared for the next one. Dr. Adams, you agree with that?

Dr. ADAMS. I have been in public health my entire life. And as you mentioned, and we have chronically underfunded public health. I have been coming to DC every year for the last 20 years asking for funding for basic public health. The problem with public health is that it is like the oil change in your car. You wait until the engine blows up before you decide you need to check the oil. We need to fund public health.

We need to fund vaccination. And I want to thank you for being a strong advocate, knowing that this may be the last time I testify before you, for your strong advocacy, not just for the State of Tennessee, but for the United States in terms of making sure we have the resources we need at the Federal level and are using our tools to protect the American people.

The CHAIRMAN. Well, thank you, Dr. Adams. One other thing. The phrase herd immunity has come up. There is another phrase that has been thrown around let's just say inelegantly in the news media, and I think it is misunderstood by a lot of people. The way I am hearing you talk is that developing herd immunity is a good thing, right? I mean, you want to get to a point where a large number and I believe you used the numbers, 60 to 90 percent of the population has some form of immunity from a disease. So herd immunity by itself. Nothing wrong with herd immunity, right?

Dr. COLLINS. No. It is how you get there.

The CHAIRMAN. It is how you get there that is the question. And there is the old way to get there, which is just later, as Dr. Collins once said, let her rip this, let it roar through the whole population, killing people until everybody's either killed or recovered with some form of immunity or we have vaccines, which is the way we get there. And that is—I think it is very important that the American people understand we want herd immunity, but we don't want to do it, we can't do it by locking everybody in their room the way they used to do with leprosy and put everybody with leprosy in a leper colony. Well, that is a form of quarantine. But they didn't get rid of the disease necessarily.

What we can do today, we believe and the testimony has been consistently, that every one of the public health experts in this Administration and most outside are cautiously optimistic that we can have a safe vaccine that is also effective by the end of the year, cautiously, at least for the most vulnerable. And that during 2021 there should be hundreds of millions of doses of this. Now, there is no guarantee of that.

You have told us we have six tracks of vaccines already moving, that we don't necessarily expect everyone to work. That if they don't work, even though we are manufacturing them ahead of time, even while we are testing them, we'll throw them away and they will not never be distributed. You have said you will be the first of the line to take a safe and effective vaccine as Senator Casey, I believe, asked. So to me, it seems important to say to the American people that their herd immunity is what we want. We want most Americans to be immune to COVID-19. And if that happens, then the infection rate will go down. Disease will gradually become a minor event in American society. But there are only two ways to get there.

One is just to let it roar through the population killing people until we have killed enough and infected or enough of recovered to have herd immunity or the much preferable way is the vaccine that has a good prospect of being available by the end of the year. So I thank you and your colleagues for what you have and are doing. I know how hard you are working, Dr. Collins, I can't let you get away without asking you one last question. You have headed up the so-called Shark Tank, the RADx operation, which we funded.

I want to make sure that I know one. What is the output right now? How many how many fast tests have the shark tank produced that people can take to determine whether they have COVID-19? And do you have the funding you need to get done what we ask you to do?

Dr. COLLINS. Well, Senator, I really appreciate your leadership in making it possible just beginning on April 25th for us to ramp up something that has never been done before and invite a lot of small businesses and academics who had really creative ideas about how to do testing for SARS COVID 2 to come forward and jump into the shark tank and show what they could do and get a lot of advice and sometimes some difficult criticism and see whether they were ready for the big time. Could they actually expand their capacity, develop a sufficient validation and get exported and deployed?

Just as of last week, we are now up to 16 of these technologies that have made it through this process. Very interesting technologies too. 16 different ones. And collectively now those add up to roughly 2 million tests a day that would not have been there before all of this came along. Some of them are lab based tests. Some of them are based on genome sequencing. Some of them are point of care. But collectively, they are moving along. And together with what Admiral Giroir has been doing, which is also dramatic in terms of its expansion with things like the Abbott test, I think we are on that pathway toward getting to enough tests that almost anybody would say.

Fortunately, I think now increasingly many of them are point of care tests. I am also glad to say the lab based tests, which were afflicted by slow turnaround time, have now gotten down to the point where 97 percent of all the tests are returning a result in 3 days or less, which is where we needed to be and weren't, frankly, a few months ago. So we are in a much better place and we have——

The CHAIRMAN. You are saying 2 million a day simply from those that have come out of the shark tank?

Dr. COLLINS. That is right.

The CHAIRMAN. That is 2 million times 30. That is 60 million.

Dr. COLLINS. That is a lot.

The CHAIRMAN. A month. And then you add to that what was already happening.

Dr. COLLINS. What was already—.

The CHAIRMAN. Then you add to that the Abbott test, which Abbott says will produce 40 million tests a month in October. So I think, Dr. Adams, you said that Admiral Giroir gave a number for September and October that was in the neighborhood of 100 million tests a month, which is twice as many as he testified here a few weeks ago when he estimated that we would have 40 to 50 million tests in September, October.

My own view is when we have an oversupply of fast tests, they will cease, testing will cease to be an issue. That as soon as everybody knows they can get it fast, test quickly if they want one, they will probably not want as many. But scarcity causes people to want more. And then on the other hand, as you were talking about the University of Illinois testing students twice a week. They are able to do that.

Dr. COLLINS. Yes, and faculty too.

The CHAIRMAN. Students—and that is a great big—how many students and faculty in that universe?

Dr. COLLINS. Tens of thousands. It is a lot.

The CHAIRMAN. Yes. So we are moving to the point where there are many different strategies and no one is saying you have to test everybody every day or twice a week or whatever, but different colleges, different schools, different workplaces will develop different strategies and if they know that if an employee comes up and says, I feel worried working here, I am afraid I might have COVID, you could say, come right in here in 50 minutes we will tell you whether you do or not.

I think that will help give people the confidence to go back to work, back to school, back to child care, out to eat. And until we have vaccines broadly available, distributed and administered, which surely will be sometime next year, if we are successful, then that will—between now and then, that sort of testing, plus the treatments that we could discuss at our next hearing are a very impressive story.

Dr. COLLINS. Senator, just what are you close down, I want to add my voice to the Surgeon General to thank you for your leadership. And you have just been pointing out a dramatic example, which is this area of testing, but you have been a clear, compelling, authoritative, evidence based source of information for all of us and remarkable voice of leadership in the Congress. It has been a great pleasure and a privilege to have the chance to work with you in settings like this, but in other settings as well, even including the Bluebird Cafe. And I just want to say, you are going be sorely missed by all of us who have had the chance to work with you.

The CHAIRMAN. That is very generous. And it is a privilege to work with both of you. And I am not gone yet. So on that note, the hearing record will remain open for 10 days. Members may submit additional information for the record within that time if they wish.

The CHAIRMAN. I want to thank Senator Murray and her staff for working with us on this hearing. One of the Senators said to me on the floor, this is the most civil hearing that he had attended in the Senate in several weeks and most of our hearings are pretty civil. We each get our points in, including our political points, but we do that with respect for those of you work for the American people like Dr. Adams and Dr. Collins do.

I thank Senator Murray and my Democratic colleagues for allowing us to conduct hearings in that way. Our Committee will meet twice next week. We will meet again at 10 a.m. on Tuesday for a hearing entitled Compensating College Athletes Examining the Potential Impact of Athletes and Institutions. So, the Commerce Committee is the lead committee in the Senate on that.

But we are we are looking into that in cooperation with them because this makes a difference to students, to student athletes and to the American people who like to watch sports. And then on Thursday, we will have a hearing on something that this Committee has been working on in a bipartisan way for six years, which is simplifying the FAFSA, the Federal aid application form that 20 million families fill out every year. We have made progress on that in the Obama administration, we made progress in the Trump administration.

Senator Murray and I introduced and Congress passed a bill making important steps earlier, I guess, earlier this year when we fully or recently when we permanently funded historically black

colleges. But we would like to finish the job and we will have a hearing on that next Thursday with the same four witnesses, plus one who got us involved in it in the first place six years ago. Thank you for being here today. The Committee will stand adjourned.

[Whereupon, at 12:40 p.m., the hearing was adjourned.]

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