



**Senate Committee on Health, Education, Labor & Pensions (HELP)**

**Wednesday, September 9, 2020**

**Vaccines: Saving Lives, Ensuring Confidence, and Protecting Public Health**

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**Members of the Committee**

***Republicans***

Lamar Alexander (TN) Chairman\*  
Michael Enzi (WY)\*  
Richard Burr (NC)\*  
Rand Paul (KY)\*  
Susan Collins (ME)\*  
Bill Cassidy (LA)\*  
Pat Roberts (KS)  
Lisa Murkowski (AK)\*  
Tim Scott (SC)  
Mitt Romney (UT)\*  
Mike Braun (IN)  
Kelly Loeffler (R-GA)

***Democrats***

Patty Murray (WA) Ranking Member\*  
Bernie Sanders (VT)\*  
Robert Casey (PA)\*  
Tammy Baldwin (WI)\*  
Christopher Murphy (CT)  
Elizabeth Warren (MA)  
Tim Kaine (VA)\*  
Maggie Hassan (NH)\*  
Tina Smith (MN)\*  
Doug Jones (AL)\*  
Jacky Rosen (NV)\*

*\*Indicates Member was in attendance*

**Witnesses**

**Francis Collins, MD, PhD**  
Director  
National Institutes of Health  
Bethesda, MD

**VADM Jerome M. Adams, MD, MPH**  
Surgeon General of the United States  
U.S. Department of Health and Human Services  
Washington, DC

**Opening Statements**

**Chairman Alexander:** I have been reading *Guns, Germs, and Steel*, the book Jared Diamond wrote in 1997 that won the Pulitzer Prize. He wrote that there is nothing new about epidemics that cause mass deaths and social upheaval. And that there is nothing new about where most of the infectious diseases that cause those death come from—for the last 10,000 years humans have acquired most of our infectious diseases from animals. During most of history there were three ways to deal with these epidemics. One was to isolate the infected, as in leper colonies. Two was that, according to Jared Diamond, over thousands of years there have been genetic changes in human populations in response to infectious diseases that cause major outbreaks, like smallpox. But that did not help Native Americans who had no resistance when European settlers arrived sometimes wiping out 90 percent of a native tribe by handing them a blanket with smallpox on it, because the tribe had not previously been exposed to the virus. Throughout most of

history the most common way to deal with epidemics was to let them run their course through populations until everyone had either been killed or recovered and therefore developed resistance against the disease. Diamond says that the Black Death killed about one third of Europe's population between 1347 and 1351 and recurred with lower death tolls for many decades thereafter. What is new about dealing with epidemics is modern medicine, including the ability to diagnose the disease and then to 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 schoolchildren are required to take vaccinations for diphtheria, tetanus, pertussis, polio, measles, rubella, and chicken pox 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 1940s and into the 1950s. Many saw their children die or be left dependent on an iron lung to breathe for the rest of their lives. Of those who contracted polio, the lucky children were like Majority Leader McConnell, who was only left with a limp. The disease terrified Americans until Dr. Jonas Salk developed the polio vaccine in the 1950s. After the vaccine was developed, the United States undertook a large-scale vaccination campaign, and polio was declared eradicated from the United States in 1979. Dr. Francis Collins, the Director of the National Institutes of Health, is with us today to talk about vaccine research and development, including Operation Warp Speed, which is working around the clock to develop, manufacture, and distribute safe and effective COVID-19 vaccines as rapidly as possible. Some people incorrectly believe “warp speed” means cutting corners, but it refers to the extraordinary investment in research, development, and manufacturing scale-up for a COVID-19 vaccine. Perhaps most significantly, the Biomedical Advanced Research and Development Authority (BARDA) has taken the unprecedented step to help speed up manufacturing for hundreds of millions of doses of vaccines early in the process by buying these doses in advance so they can be ready to distribute as soon as the new vaccines are approved by the Food and Drug Administration (FDA). Despite the speed with which scientists are developing a COVID-19 vaccine, Dr. Stephen Hahn, the Commissioner of the FDA, said the 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,” he has 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 vaccines as soon as they are authorized or approved, prioritizing vaccines for health care workers and vulnerable populations. CDC's plan will be a fair system informed by nonpartisan health experts from the National Academies of Sciences, Engineering, and Medicine and the Advisory Committee on Immunization Practices (ACIP). Why are some Americans saying they won't take the vaccine? Let's address three questions: Are they safe? Vaccines are reviewed and approved by the FDA. FDA can either license a vaccine or authorize a vaccine for use during a public health emergency (PHE) —and the FDA's stringent approval process is the gold standard for the rest of the world. The vaccines that are routinely given to children are specifically recommended by ACIP, an outside group of health experts that looks at all available scientific information about each vaccine. Medical associations like the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians work with ACIP to develop these recommendations. In a 2015 article for Scientific American, Dina Fine Maron writes: “By age two, most children will receive almost 30 shots designed to boost a child's natural defenses against disease. Yet at the same time, parents who take their children for those recommended vaccinations might be inundated with web site and celebrity-espoused rumors making false claims that shots are not necessary or cause autism. At best, navigating this landscape can be confusing. But when weighing the risks of encountering life-threatening disease against the benefits of receiving a vaccine there's no contest. The vast majority of children do not experience anything worse than short-lived redness or itching at the spot of the injection.” Are they effective? According to the CDC, there is evidence that smallpox was ravaging humans as early as the 3rd century BCE. The disease

killed 3 out of 10 people who were infected. Then in 1796, an English doctor named Edward Jenner saw that milkmaids who had gotten cowpox seemed to be immune to smallpox, so he scratched some pus from a cowpox blister on an 8 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 is officially eradicated. Polio was one of the most dreaded childhood diseases of the 20th century. "Following introduction of vaccines—specifically, trivalent inactivated poliovirus vaccine in 1955 and trivalent oral poliovirus vaccine in 1963—the number of polio cases fell rapidly to less than 100 in the 1960s and fewer than 10 in the 1970s," according to the CDC. "Thanks to a successful vaccination program, the United States has been polio-free since 1979." Diphtheria terrified parents in the 1920s but today there are only a few cases a year, according to AAP, which attributes the change to vaccinations. Is the doctor's office safe? The pandemic has made some parents leery of the doctors' office. In an analysis of patient records from 1,000 pediatricians in 40 states, the immunization rate for recommended, routine childhood vaccines declined about 40 percent from late February through mid-April, according to the Wall Street Journal. For parents who are worried about taking their children to the doctor during the pandemic, AAP says pediatricians are working to ensure their offices are as safe as possible for children to visit. AAP published guidance in May on how pediatricians can safely conduct well-child visits during the COVID-19 pandemic. According to AAP's Dr. Sean O'Leary, "Medical offices are among the safest places you can be right now given the really extensive measures they've taken to prevent spread of COVID-19 both to themselves and their patients. Parents shouldn't be afraid to go to their doctor." I started my statement with comments from Jared Diamond and I will end with a warning he wrote recently in the Wall Street Journal. On June 23, 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 yet conquered this one? In a Wall Street Journal weekend essay on May 23, Jared Diamond provides an answer to this question: 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, and Ebola. But the good intentions evaporated as each epidemic ended. As one example, in 2012 the Department of Health and Human Services, with the support of Congress, created three manufacturing plants so that when the next epidemic arrived, we could produce vaccines rapidly. Fortunately, two of those plants are playing a role in manufacturing hundreds of millions of doses of vaccines for COVID-19. However there is still a need to improve and sustain these types of facilities so they are able to pivot even more quickly to the next threat when it emerges. In a similar way, stockpiles were created, but then depleted. Former HHS Secretary and Governor Mike Leavitt told this committee that public health programs, according to testimony before this committee, have been underfunded for the last 30-40 years. The nation goes from panic to neglect to Panic. Fortunately, thanks to an unprecedented effort by private sector and 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 early in 2021. Some of the challenges apart from finding a vaccine are: how to distribute it, to whom it should 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 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 because the next pandemic could be next year.

**Ranking Member Murray:** Thank you, Mr. Chairman. While you still have a few months left—as well as a few more hearings—I want to start off by saluting you for your many years of service to this country, including as a 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, emptied schools, and 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, nursing homes, and other congregate care facilities. It has strained our economy, our mental health, and so much more. It has claimed around 190,000 lives so far, and claims 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's 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 repeatedly insisted that this will all just go away. The list of inaccuracies and outright lies—at a time when truth is a matter of 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 and inaction, 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 instead, Republicans sit down with Democrats to work on a package that helps our economy and keeps American families safe. A package that actually increases testing, and access to health care, actually supports schools and addresses the child care crisis, actually protects workers, and—most relevant to our hearing today—that helps ensure 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 we encourage uptake of flu vaccines each year to keep people safe, ensure vaccines are available and administered to kids across the nation, including through efforts like the Vaccines For Children program, and build vaccine confidence while combatting misinformation. But this pandemic has made these challenges more urgent than ever. So I'm glad we have Surgeon General Dr. Adams, and NIH Director Dr. Collins here to share their expertise. But I'm also frustrated that despite my request to the Chairman, FDA Commissioner Dr. Hahn, and CDC Director Dr. Redfield were not invited to testify today. These agencies play critical roles in developing and distributing vaccines and should absolutely 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've not only watched President Trump directly promote conspiracies about FDA and CDC, we've 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 guidance for community reopening. Recently, FDA Commissioner Hahn announced he was prepared to authorize a COVID-19 vaccine before Phase III trials were complete—but without providing any guidance about when that would be appropriate. When it comes to a COVID-19 vaccine, we can't 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, campaign strategists, or corporate lobbyists. And 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 its 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 for 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 an emergency use authorization, including standards for the independent review of phase III data; by waiting for the completion of phase III 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 DoD, rather than CDC, lead much of this effort, and who will get priority when the first doses are available. We also need transparency on Operation Warp Speed's contracts and how it is addressing any potential conflicts of interests. In short, we need transparency from top to bottom. And of course, in addition to transparency, we still need a comprehensive national vaccines plan—one of several steps I called for in the vaccines white paper I put out on vaccines months ago. We have seen with testing how many problems the Trump Administration caused by throwing up its hands, refusing to develop a plan, and leaving states to fend for themselves. Testing is an ongoing catastrophe and we can't risk a repeat performance when it comes to vaccines. The Administration must develop an end-to-end national vaccines 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 health disparities; 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 strong, science-driven leadership from the federal government. So I'm glad we have this opportunity to discuss the important challenges that lie ahead—but there are so many more questions we need to answer, and so many more witnesses we need to hear from. And I'm absolutely going to keep pushing to make sure that happens. Thank you.

## **Witness Testimony**

**Dr. Collins** discussed Operation Warp Speed and the importance of developing safe and effective vaccines. We are working to prevent, diagnose, and treat the novel coronavirus. He provided an illustration of how vaccines work. The goal of a vaccine is to present a harmless part of the virus to your body allowing your body to create a blueprint for an antibody. There are six vaccine candidates engaged in largescale U.S. trials. Three of the six are already in phase three of testing. The goal is to inject 30,000 volunteers with a vaccine or placebo in areas where the virus is actively spreading. We will follow all of them for up to two years to assess safety. These six vaccines represent three different scientific approaches. We hope and expect that more than one vaccine will succeed. We know that people who have survived COVID-19 make neutralizing antibodies to SARS-CoV-2. He reviewed the three platforms under vaccine development. Safety will not be compromised. It is foremost in all our minds, and we cannot compromise here. A single case of an unexpected illness is sufficient to require a clinical hold – as is happening with AstraZeneca. We have carried out steps in parallel that are traditionally done in sequences. We have started to manufacture doses before we know if the vaccine works. We may have to throw them away. But the rigor of scientific evaluation of safety and efficacy will not be compromised.

**Dr. Adams:** My central message is this: equitable vaccination against preventable diseases is safe, smart, good for the economy, and critical in our fight against COVID-19. Vaccines save lives, and our vaccine supply is the safest in the world. Vaccines prevent disease – keeping people out of the hospital and keeping people in the workplace. Vaccination amongst ethnic and minority adults falls behind already poor health averages. It's important to note that childhood vaccination rates remain high nationally, but many do refuse a single vaccine or delay vaccines. The fear and access issues induced by COVID-19 have put many at risk of vaccine-preventable diseases. Obstacles, which are also opportunities, include public education and combating misleading information. With both COVID-19 and the flu circulating this fall, this will be the most important flu season of our lifetimes. The best way to prevent the flu will be to get the flu vaccine. We must all practice the three Ws – wash your hands, wear your mask, and watch your



distance. And we must ensure that everyone receives the recommended vaccinations. CDC provides over 80 million doses of vaccines annually. HHS recently launched the Catch Up to Get Ahead toolkit. HHS has authorized licensed pharmacists to administer routine vaccines to children as well as an eventual COVID-19 vaccine. The Public Health Commissioned Corps. is leading efforts to increase the acceptance and uptake of the flu vaccine. Get your flu shot, ideally before the end of October. Catch up on childhood and adult immunizations right now. Practice the three Ws. Use your bully pulpits to shout that vaccines are safe, effective, and more important now than ever. Go to [vaccines.gov](https://www.vaccines.gov) for more information. We are in the middle of social justice movement the likes of which we have not seen in my lifetime. Vaccines are the quickest and easiest way for minorities to protect their health. They are safe, effective, and how we achieve health equity.

## Questions and Answers

**Chairman Alexander** asked about Astra Zeneca slowing its trials. What does that do to our goal of producing hundreds of millions of doses before the end of the year? **Dr. Collins:** We are investing in six different vaccines because of the expectation that they won't all work. To have a clinical hold because of a single adverse event is not at all unprecedented. It was done out of an abundance of caution, and a careful investigation will follow – this ought to be reassuring. We will make no compromises on safety. All doses will be thrown away if the spinal cord issue turns out to be caused by the vaccine. **Sen. Alexander:** When you take a vaccine for COVID, you are not giving me COVID – correct? **Dr. Collins:** Correct. These vaccines take a small bit of the virus and put it into a fashion that the body can raise an antibody against. **Sen. Alexander:** Last year's flu vaccine was 39 percent effective. The polio vaccine seems to be 100 percent effective. What will the COVID vaccine be like? **Dr. Collins:** I wish I had a crisp answer. We are doing large scale trials to see what the protection will be and how long it will last. If I had to guess, it will be better than the flu vaccine. **Sen. Alexander:** Is it possible that hand washing, masking, and distancing practices will mean that we will have fewer deaths from flu this year? **Dr. Collins:** It may be possible, and that could be a silver lining of what we are going through. That has been seen in the southern hemisphere. But that's no reason to avoid a flu shot.

**Ranking Member Murray:** What steps do you think federal agencies should be taking to build trust with Americans and to make sure science and not politics dictates decision making for vaccines? **Dr. Collins:** We need to be as transparent as possible. People need to see the facts. Our best antidote is to say exactly what we are doing. None of these trials will even go to an FDA review until the Data and Safety Monitoring Boards (DSMB) looks at the data – these are experienced, qualified scientists. Nine CEOs all signed a statement that they won't put forward something to FDA until they are convinced that it meets the baseline for safety and quality. You can be confident in the FDA as well. **Sen. Murray:** If confidence in a vaccine is eroded by political interference, what impact would that have on a successful COVID-19 vaccination campaign? **Dr. Adams:** We have unprecedented levels of vaccine hesitancy in our country and globally. We have a once in a century global pandemic superimposed over a presidential election. As a member of the White House task force, there has been no politicization of the vaccine process whatsoever. **Sen. Murray:** Are you making sure the President understands this risk? **Dr. Adams:** I am telling Americans to focus on the process, and not the politics. **Sen. Murray:** I'm concerned about the lack of transparency around the DSMBs. Who sets their standards? **Dr. Collins:** When a trial is first proposed, the FDA stated that the vaccine is at least 50 percent effective. The DSMB has those parameters in front of them.

**Sen. Enzi:** Will you be involved in communication efforts when the vaccine is available to help people understand how it works and why it works? **Dr. Collins:** Yes, NIH has a role to play in communication and

education with HHS and CDC. This is along with professional societies who will be important in educating their members on the pros and cons of a particular approach. **Sen. Enzi:** What do we know about the natural immune response that kids have to COVID-19? **Dr. Adams:** The initial vaccine trials will be on people age 18 and up. We will make sure it is safe and effective in adults, and then we will slowly start to move down in age. That's the way we've done it for every vaccine. Here's the important point – that's why we must ensure vaccine confidence in adults. It will be even more important to have a higher level of adults being vaccinated to reach herd immunity. **Dr. Collins:** There is an effort in one of the trials to enroll children in the next month or so, but as Dr. Adams said, you generally want to wait a little bit. With a clear sense of wanting safety and efficacy reviews – we don't want to take any risks here with children.

**Sen. Sanders:** The taxpayers have already spent billions on R&D for this new vaccine. We must make this vaccine free of charge to all people if we want to maximize the number of people who will get it. Will you join us in this effort? **Dr. Adams:** Yes. As surgeon general, we will use every federal tool to make sure that cost is not an obstacle. **Dr. Collins** agreed. **Sen. Sanders:** Is that the posture of the administration right now? **Dr. Adams:** The most honest answer I can give you – to the extent that we can ensure this from a federal perspective, yes. **Sen. Sanders:** Will you join me and others in telling the President to get out of science, and let the scientists do their job in moving as rapidly as possible? **Dr. Collins:** I'm a scientist. I can't say strongly enough that the decisions about how to evaluate this vaccine will be based on science. That can be the only basis on which these decisions will be made. To try and predict whether this will happen before or after a date in November is well beyond what any scientist could tell you. **Dr. Adams:** I want the American people to hear me say that there will be no shortcuts – this vaccine will be safe and effective, or it won't get moved along.

**Sen. Burr:** Are we doing something novel here? Or are we doing this the way we've always done? **Dr. Collins:** We're doing something very novel. You have been instrumental through your work with BARDA. He discussed the ACTIV partnership, which designed master protocols to launch clinical trials without the long process that it usually takes. Out of that has come trials on anticoagulants, monoclonal antibodies, and more. **Sen. Burr:** And you had the latitude in statute to do that? **Dr. Collins:** We did. **Sen. Burr:** So we're seeing the U.S. government actually functioning, in coordination with the private sector. We've exercised the latitude in statute for this pandemic instance. With the quarantine of our younger population – a lot of infants have not been exposed to the things that they usually would have been. What concerns do you have about this? **Dr. Adams:** I'm incredibly concerned that almost five million children are behind on their childhood vaccinations, and about the herd immunity of the populace. It is critically important to protect our youngest and most vulnerable – everyone who can catch up on their vaccinations should catch up on their vaccinations.

**Sen. Casey:** Will you commit to receiving the COVID vaccine in public view? **Dr. Adams:** Yes. **Dr. Collins:** I'm ready to roll up my sleeve as soon as it's determined safe and effective. **Sen. Casey:** Given that most of the vaccine candidates will require two doses, it's essential to track which vaccines people are getting. Has HHS provided any support to the state immunization information systems? **Dr. Adams:** We are working with states and advisory committees to figure out distribution. We will lean on existing infrastructure.

**Sen. Paul:** Not every disease is the same, and that's what annoys me about this discussion. There is a difference between small pox and everything else. I think each individual needs to make their own decision, and assess the risks of the disease versus the risk of the vaccine. Let's try this through persuasion, and not requirements. We need to rethink our fervor here. Considering the death rate for COVID among children is 0.68 per million, are you in favor of a school mandate? **Dr. Collins:** I think it would be premature

for me to answer this. I would have to understand the consequences. I do think there is an issue of children getting infected and then infecting those around them. And 0.68 is not zero.

**Sen. Baldwin** asked about the importance of having diversity in the clinical trials that are taking place for a vaccine. What should you and others be saying about the Astra Zeneca announcement to those who are already participating in stage three trials? **Dr. Collins:** This is very fresh information. This was a single adverse event that may or may not have anything to do with the vaccine. I assume that not much time will go by until everyone involved will receive a communication. **Sen. Baldwin:** How does a lack of confidence in the health care system undermine our efforts to reach a safe, effective, and accessible vaccine? What should clinical trial sites take into consideration as they work to recruit participants? **Dr. Collins:** We need to work especially hard to achieve diversity in clinical trials, because particular groups have been hit hard by COVID-19. There are concerns though in those communities about whether this is something they can trust. Recruiting efforts have to be done with particular intention to do community outreach. You might see PSAs in areas where trials are happening. This is a steep hill to climb. This has to be one of those things that we do all together.

**Sen. Collins:** Who is going to make the decision on the allocation of the vaccine once it becomes available? **Dr. Adams:** Health care workers, nursing home workers, and people of color have been disproportionately impacted. We are working with the National Academy of Medicine to come up with an answer to this incredibly difficult question. We agree on the principles that health care workers should be at the front of the line, followed by others who are most vulnerable and where the vaccine will have the biggest impact. This needs to make sense and be ethically appropriate. **Sen. Collins:** How can we ensure that we don't create inequities and uneven access unless we help with the purchase of expensive refrigeration units required to store the vaccines? **Dr. Collins:** There are intense discussions around this. This is a challenge. I think Warp Speed is totally in this space to make sure that this is not a deterrent to distribution.

**Sen. Warren** asked about estimates for what percentage vaccine uptake could achieve herd immunity. **Dr. Adams:** Estimates I've seen range from 60 percent to 90 percent. But we certainly need to get over half of the population. **Sen. Warren:** So the question is, can we do that? Less than half of adults got the flu vaccine last year. Do the President's actions encourage public trust in vaccines? Or do they discourage Americans from getting vaccinated? **Dr. Collins:** I'm not sure, I am more focused on working to explain how these vaccines get made to the American people. We will have to work really hard to get the facts out there about how decisions are being made, and what the evidence is to support a vaccine. **Sen. Warren:** I appreciate that, but I asked about whether what the President is doing is helpful or not. **Dr. Collins:** I just hope that Americans will take the information they need from scientists and not politicians.

**Sen. Cassidy:** Has there been any thought as to how to figure out who has already been exposed, thereby protected naturally, who don't need the vaccine or are of lower priority? **Dr. Adams:** We have antigen testing and antibody testing – to figure out who has been exposed to the virus. If you have had the coronavirus in the past, then that is someone who would not go to the front of the line. But the virus has fooled us many times, and we don't know what we don't know. **Sen. Cassidy** asked about vaccine surveillance. Has any effort been made to adapt existing immunization registries for COVID vaccines? Have any contracts been awarded? **Dr. Adams:** We're working with ASTHO and NACCHO which already have systems in place in anticipation of a vaccine. We will have CDC follow up with you – these conversations are happening right now. **Sen. Cassidy:** Has any thought been given to giving monoclonal antibodies to an obese diabetic, for example? **Dr. Collins:** Yes, this is like a passive vaccine. We have trials underway for people in nursing homes and for others who are at risk. **Sen. Cassidy:** Did AstraZeneca see Guillain-Barre in their trial? **Dr. Collins:** What we've seen reported is transverse myelitis.



**Sen. Kaine:** Is there any benefit to not participating in the WHO COVAX project? **Dr. Collins:** We are engaged on the global stage regarding COVID-19, and we would want to make sure that if we have a tangible vaccine in six to nine months that those around the world who need it also have access. **Sen. Kaine** asked about vaccines that require two doses. For other similar vaccines, a significant percentage of people who get the first dose don't get the second, or don't get it on time. **Dr. Collins:** You can look at the production of antibodies after the first dose – it looks like there is some response, but not at the level you would like to see. If you want to be as effective as possible, get the second dose. It's not ideal – ideally, we would have a single-dose vaccine that doesn't require the refrigeration, etc.

**Sen. Murkowski** spoke about S. 4427, the *Safe Authorization for Vaccines during Emergencies (SAVE) Act*, which would make sure that we have a level of public, independent, expert review of vaccine candidates. Help me encourage Alaskans on how we build trust for a vaccine. Do we need more than the SAVE Act to build credibility and trust? **Dr. Collins:** There is a need for all hands on deck – leaders in Congress, local communities – need to get together to convey this message. **Dr. Adams:** People trust their local provider more than anyone else out there. So we are trying to arm local providers with the facts, with FAQs. We need to engage. We need to encourage people to stop attacking the process. The process is strong. There are protections built in, and people should have confidence.

**Sen. Hassan:** What protocols are in place to ensure that boards do not stop clinical trials until they collect safety data for high risk populations? **Dr. Adams:** These trials have 30,000 patients in them. This isn't about time so much as events. We have the potential to recognize a safety and efficacy signal much sooner than under the typical 3,000 participant trial. **Sen. Hassan:** Do you believe CDC's Advisory Committee on Immunization Practices (ACIP) should hold public meetings and release information to the public before a vaccine is approved, as it normally would? **Dr. Adams:** I believe we need to follow the process because the process works. We need to be careful about inserting new barriers to the process. **Sen. Hassan:** This is the existing process. She discussed the introduced SAVE Act to help ensure that independent FDA and CDC reviews take place in a transparent way.

**Sen. Romney:** Wouldn't it make sense for our government to put a comprehensive effort toward our government dispelling this idea that vaccines are bad? **Dr. Collins:** This has been an issue for our country since before COVID-19, and we have seen the consequences of this with measles. People have forgotten that kids die, and continue to die, from that disease. A generation has lost track of the fact that vaccines save lives. This kind of misinformation is so readily spread. **Dr. Adams:** HHS is using a three-tiered approach to improve vaccine confidence. We're working with Twitter and Facebook to make sure appropriate and accurate information is displayed prominently. We have a strategic framework, and are working with minority medical schools. More than 90 percent of parents are doing the right thing. And most of the people who aren't are in the vaccine hesitancy – not vaccine resistance – category. We must be compassionate and patient with them.

**Sen. Smith:** How can we make sure that folks aren't stuck with out-of-pocket costs for a vaccine? The federal government will buy this vaccine and the supplies necessary to administer it, and provide it to providers at no cost? **Dr. Collins:** Yes, this is a part of Operation Warp Speed. The only thing that needs to be dealt with is the charge for the provider to administer the dose. No one should be denied this vaccine. It needs to be completely free. **Sen. Smith:** If a booster is needed, would or should that cost be covered by the federal government? **Dr. Collins:** I'm not sure if this conversation has happened yet. We are hopeful that this vaccine will produce long-lasting immunity, but that's not always the case. **Dr. Adams:** All vaccines should be provided at minimal costs to people – because they save lives and are cost saving. **Sen.**

**Smith:** What would be the endpoint for knowing that vaccine trials should be concluded? **Dr. Collins:** Those who got the vaccine should have significantly fewer COVID cases than those that got the placebo. If your vaccine is at least 50 percent effective, you will see a skewing of who got the disease and who did not.

**Sen. Jones:** I'm not seeing efforts by the federal government to debunk anti-vaccination theories. **Dr. Adams:** Vaccines do not cause autism. We've looked at this. **Dr. Collins:** The craziest one I've heard is that a vaccine will have a chip in it to watch everything you do. **Sen. Jones:** So it's not designed to be big brother? **Dr. Collins:** Correct. **Sen. Jones:** I encourage you to do more in terms of debunking theories, and not just getting the accurate information out there. He asked about encouraging minority participation in trials. **Dr. Adams:** Support the University of Alabama in Birmingham. They are engaging the local community in research. We need to acknowledge past wrongs. We need to acknowledge Tuskegee, we need to acknowledge Henrietta Lacks. We need to acknowledge, address, and engage.

**Sen. Rosen:** What recommendations do you have for making sure that rural areas are not left out of vaccine distribution and delivery? I know of communities with no hospitals and pharmacies. **Dr. Collins:** The distribution issues are critically important and under intense planning processes right now. We need to think about rural communities and work with states. CDC is already deeply engaged on this. **Dr. Adams:** I grew up in a rural community – the nearest hospital was quite far away. We've utilized the vaccines for children program, we have infrastructure in place to get vaccines out to these areas. I stand ready to work with you to make sure that the practical issues are addressed. **Sen. Rosen:** Should we pair up giving existing vaccinations along with the COVID vaccination? **Dr. Collins:** The general vaccination rate should be attended to right now. If you fell behind on childhood immunizations – it's time to catch up.

**Chairman Alexander** reiterated his strong feeling that the time to sustain our preparedness is now – when our eye is on the ball. While dealing with this pandemic we should make sure we are prepared for the next. **Dr. Adams:** We need to fund public health. We need to fund vaccinations. Thank you for your strong advocacy to make sure we have the resources we need to protect the American people. **Sen. Alexander:** Developing herd immunity is a good thing, correct? **Dr. Collins:** Correct. It's the way you get there. **Sen. Alexander:** How many fast tests has the shark tank produced? Do you have the funding you need? **Dr. Collins:** We are now up to 16 of these technologies that have made it through the process – those add up to roughly two million tests a day.

## **Closing Statements**

**Chairman Alexander** thanked the witnesses and adjourned the hearing.