



Senate Committee on Health, Education, Labor and Pensions
Vaccines: Saving Lives, Ensuring Confidence, and Protecting Public Health
September 9, 2020
10:00 AM, 430 Dirksen Senate Office Building

Purpose

The purpose of this hearing was to provide an update on the nation's efforts to develop a COVID-19 vaccine and examine the state of vaccine hesitancy among the broader population.

Members Present

Chairman Alexander, Ranking Member Murray, Senators Enzi, Sanders, Burr, Casey, Paul, Baldwin, Collins, Warren, Cassidy, Kaine, Murphy, Murkowski, Hassan, Romney, Smith, Jones, and Rosen

Witnesses

Francis Collins, MD, PhD., Director, National Institutes of Health (NIH)

VADM Jerome M. Adams, MD, MPH., Surgeon General Of The United States, United States Department of Health and Human Services (HHS).

Opening Statements

(16:05) Chairman Alexander said that there is nothing new about epidemics that cause mass death and social upheaval. Furthermore, there is nothing new regarding where epidemics come from: animals. What is new about epidemics is modern medicine. The true miracle of modern medicine is vaccines. Vaccines can prevent the transmission of disease at the personal and population level. Not too long ago, polio terrified the nation. Now that disease is essentially eradicated. Thus, the purpose of this hearing is to examine the unprecedented progress made in developing a COVID-19 vaccine. Operation Warp Speed is working around the clock to deliver a safe and effective vaccine to the American public in record time. Some people falsely think that Operation Warp Speed is cutting corners on safety; however, that is simply not true. The Food and Drug Administration (FDA) has stated that they are not skimping on their regular safety and effectiveness reviews. In addition, the Centers for Disease Control and Prevention (CDC) is beginning to develop a plan to distribute a vaccine to vulnerable populations. The evidence has been clear for a long time now; vaccines are safe and prevent death. It is important for the American people to feel confident that any vaccine approved by the FDA will be safe for any individual to consume.

(30:45) Ranking Member Murray said that our country is in the middle of a painful crisis, and no community has been spared the burden. Unfortunately, instead of leading us in the war against COVID-19, President Trump is waging a war against public health experts. President Trump continues to repeat false claims to the American public, thus undermining public trust in our public institutions. Yesterday, Senate Republicans unveiled their latest COVID-19 relief package. It is clear that this package is woefully inadequate. This committee has a duty to improve public trust in the scientific process and any vaccine that is approved by the FDA. It is disappointing that Commissioner Hahn and Dr. Redfield were not invited to

testify in front of the committee today. It is crucial for the American public to hear from these public health experts on a regular basis. Americans are concerned that the Trump Administration is politically interfering in the scientific and public health process. The safety and efficacy of vaccines must not be undermined by political interference. The FDA must be transparent by publishing the standards used to approve any vaccine and by publishing all data from the clinical trials in review.

Testimony

(41:30) Dr. Collins said that the NIH is the agency leading the biomedical research response to COVID-19. 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. 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 decision-making. A safe and effective vaccine will be essential to stopping the spread of infection, reducing rates of morbidity and mortality, and preventing future outbreaks. 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 US.

(48:00) Dr. Adams said that he is 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, there are 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. In addition, 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. 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% of parents refuse at least one recommended childhood vaccine, over 30% of parents delay one or more recommended childhood vaccines, and many parents are getting school immunization exemptions for personal, rather than health reasons. 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. 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.

Questions and Answers

(55:00) Chairman Alexander asked if there will be enough vaccines for the American public in the event that one of the clinical trials does not result in success. **Dr. Collins** said yes. That is why there are

multiple trials occurring. **Chairman Collins** asked if it is true that the COVID-19 vaccine will not give the recipient COVID-19. **Dr. Collins** said the vaccine does not give the recipient COVID-19. **Chairman Alexander** asked if a potential vaccine is more like the flu vaccine or polio vaccine in terms of effectiveness. **Dr. Collins** said that is still unknown.

(1:00:00) Ranking Member Murray asked what the best strategy is to increase public confidence in vaccines. **Dr. Collins** said that full transparency is the best strategy. **Ranking Member Murray** asked what impact misinformation will have on vaccine confidence. **Dr. Adams** said that it is important to know that we are currently facing unprecedented levels of vaccine hesitancy. He trusts that there is no political interference that will undermine public trust. **Ranking Member Murray** asked who sets the standards for the Data and Safety Monitoring Board (DSMB). **Dr. Collins** said that the FDA sets these standards.

(1:06:30) Sen. Enzi asked if the NIH will be a part of the communication strategy once a vaccine is produced. **Dr. Collins** said yes. **Sen. Enzi** asked when manufacturers should begin developing a pediatric vaccine. **Dr. Adams** said that a vaccine needs to be proven safe in adult populations before the testing population can be broadened to include children. **Dr. Collins** said that there might be one trial that enrolls children within then next month.

(1:12:00) Sen. Sanders asked if the witnesses believe a vaccine should be free of charge. **Dr. Adams** said yes. **Dr. Collins** said yes. **Sen. Sanders** asked if this is the belief of the Administration. **Dr. Adams** said that to the extent that this can be assured from the executive branch, yes. **Sen. Sanders** asked if President Trump should not meddle in the vaccine development process. **Dr. Collins** said that he can assure Senator Sanders that any vaccine approved will be free from political interference. **Dr. Adams** said there will be no shortcuts in the development of a vaccine.

(1:18:30) Sen. Burr asked if the current vaccine development process is novel. **Dr. Collins** said yes. This is an unprecedented vaccine timeline.

(1:24:00) Sen. Casey asked if the witnesses will commit to receiving a COVID-19 vaccine in public view once approved by the FDA. **Dr. Adams** said yes. **Dr. Collins** said yes. **Sen. Casey** asked if HHS provided any support to state immunization systems. **Dr. Adams** said yes. The Administration is currently working with states to develop a distribution plan.

(1:29:30) Sen. Paul asked if there should be a mandate that children who go to public school must take the COVID-19 vaccine. **Dr. Collins** said that it is too early to answer that. It depends on what vaccine is developed.

(1:35:00) Sen. Baldwin asked what officials should be telling participants in the Astra Zeneca phase 3 clinical trial that was just put on clinical pause. **Dr. Collins** said that the company and the sites must be in direct communication with every participant that is involved. It is possible that the adverse reaction was not due to the vaccine, but it must be examined further. **Sen. Baldwin** asked what clinical trial sites should take into consideration as they try to recruit participants. **Dr. Collins** said that clinical trial sites need to work proactively to recruit diverse population sample.

(1:41:00) Sen. Collins asked who is going to make the decision on vaccine allocation. **Dr. Adams** said many stakeholders will be consulted on this matter. Most likely front line health workers will be among

the first groups to receive the vaccine. **Sen. Collins** asked how it is possible to ensure equitable access to vaccines if the federal government is not assisting in the purchasing of the materials needed to store vaccines. **Dr. Collins** said this is a very critical issue. Operation Warp Speed is working to ensure that there are no supply chain issues when distributing the vaccine.

(1:46:00) Sen. Warren asked if it is correct that at least 70% of the population will need to be immune to COVID-19 in order to defeat the pandemic. **Dr. Adams** said yes. **Sen. Warren** asked if the President's actions encourage public trust in vaccines, or do they discourage Americans from being vaccinated. **Dr. Collins** said that he is not in a position to answer this question.

(1:52:00) Sen. Cassidy asked if it is possible to identify individuals who may already have immunity to COVID-19. **Dr. Adams** said yes. Antibody testing can help provide this information. **Sen. Cassidy** asked how antibody information will be integrated to inform vaccination distribution. **Dr. Adams** said that the federal government is working with local and state leaders to make progress on this. **Sen. Cassidy** asked if there has been any consideration to deliver monoclonal antibodies to vulnerable populations. **Dr. Collins** said yes. There are several studies going on right now.

(1:59:00) Sen. Kaine asked if there is any benefit in the US not participating in the COVAX project at the World Health Organization. **Dr. Collins** said that the US is still participating in global vaccine development. **Sen. Kaine** asked what the effect is of only getting one dose of a two-dose vaccine. **Dr. Collins** said that data is still limited, however, it seems like it does still provide some immune response.

(2:04:30) Sen. Murkowski asked what can be done to build credibility and trust in vaccinations. **Dr. Collins** said there is a need for an all hands on deck approach. **Dr. Adams** said that research says that people trust their local provider the most. Thus, local providers should be leveraged in delivering the message that vaccines are safe and effective.

(2:10:00) Sen. Hassan asked what protocols are in place to ensure that sufficient safety data is collected before a vaccine is approved. **Dr. Adams** said that the FDA generally advises a minimum population in a vaccine trial of 3000 participants. The trials going on now have 30,000 participants. **Sen. Hassan** asked if the FDA vaccines advisory committee should hold public hearings and release their findings to the public. **Dr. Adams** said yes, it is important to trust the existing process.

(2:16:00) Sen. Romney asked what can be done to combat vaccine hesitancy. **Dr. Collins** said that this has been an issue for quite some time. **Dr. Adams** said that HHS is using a three tiered approach to improve vaccine confidence.

(2:22:00) Sen. Smith asked if the federal government will purchase a vaccine and make it available to providers at no cost. **Dr. Collins** said yes. **Sen. Smith** asked if the federal government will also cover the cost of a booster shot. **Dr. Collins** said that he has not been a part of any conversation on this specific topic. **Sen. Smith** asked how it is known when a vaccine trial is over. **Dr. Collins** said that over a period of time, researchers will observe a stark difference in positive COVID rates among participants. Once enough time has passed the researchers will deliver their data to the FDA to draw conclusions.

(2:28:30) Sen. Jones asked what vaccine theories can be debunked. **Dr. Adams** said that vaccines do not cause autism. **Dr. Collins** said that Bill Gates is not developing a vaccine to implant a microchip into people. **Sen. Jones** asked what can be done to encourage more minority participation in vaccine trials.

Dr. Adams said that local education institutes should be supported. They are often on the front lines of recruiting diverse participants. It is also important to publically acknowledge and apologize for events like the Tuskegee Experiment and Henrietta Lacks.

(2:33:35) **Sen. Rosen** asked what recommendations should be in place so rural communities are not left behind in vaccine distribution plans. **Dr. Collins** said that the federal government needs to work with each individual state to create a tailored distribution plan. **Dr. Adams** said that there are mechanisms in place to deliver vaccines to rural areas, but it is clear that more work needs to be done. The federal government is working with state and local health departments to make sure that this occurs.

(2:40:00) **Chairman Alexander** asked if some current vaccines require more than one shot. **Dr. Collins** said yes.
