

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

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

Witness appearing before the
Senate Health, Education, Labor and Pensions Committee

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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

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.

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 approaches 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 SARSg0 G{mul)-3(ti)-3(ple stud)-10(y)30(sit)-4(e)4(s. Ada)-4(pti)-3(ve 108.0s Tf1 bit)-4(ed)0.89

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 pts pts pts pts pts pts pts pts pts pts pts pts pts pts pts ptsu2e

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

In July, OWS committed to working with Novavax on their new COVID-19 vaccine candidate

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 address 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. Lastly, 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