RECORD VERSION

STATEMENT BY

GENERAL GUSTAVE F. PERNA
CHIEF OPERATING OFFICER, FEDERAL COVID-19 RESPONSE
FOR VACCINE AND THERAPEUTICS

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Introduction

Chairman Reed, Ranking Member Inhofe, distinguished Members of the Committee: Thank you for the opportunity to testify before you today on the Vaccines and Therapeutics Operation supporting the federal coronavirus (COVID-19) response. I am grateful and deeply humbled to be here with you and my fellow witnesses. Over the past nine months, I have had the privilege to co-lead the operation with Doctor David Kessler, and with Doctor Moncef Slaoui as chief adviser, to accelerate the development, manufacturing and delivery of vaccines and therapeutics for our Nation. Your Congressional support and advocacy has been pivotal to accomplishing each milestone that we have reached.

Our mission has been clear: save lives by distributing safe and effective countermeasures to the American public. Today, I am proud to say that vaccines and therapeutics developed through this effort are the direct result of the greatest public-private partnership in modern times. This has been a whole-of-America approach and a nonstop effort by the finest scientists, logisticians and medical professionals, in partnership with expert professionals from private industry, who all came together with a singular focus.

Federal Partnership

Operation Warp Speed was formalized on May 15, 2020, as a collaboration between the Department of Health and Human Services (HHS) and the Department of Defense (DOD) aimed at defeating the COVID-19 pandemic through accelerating the development, manufacturing, and delivery of vaccines and therapeutics. Our goal was to provide strategic leadership and guidance to identify the most promising vaccine and therapeutic candidates and enable expeditious, parallel execution of the necessary steps to manufacture doses at large scale and gain approval or authorization of safe products by the Food and Drug Administration (FDA).

The Operation was founded on the premise that fundamentally restructuring the way the federal government typically supports product development and vaccine

distribution would speed the delivery of lifesaving vaccines to the American people. With no blueprint, organizational chart or historical precedent in the context of a global pandemic, this partnership grew out of an acknowledged need to fundamentally restructure the way the U.S. Government typically supports product development and vaccine distribution. The initiative was premised on setting a “stretch goal” for vaccine development and availability for the American population — one that initially seemed impossible, but in the end was achieved in record time.

We drew upon the experience and expertise of the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Biomedical Advanced Research and Development Authority (BARDA), and Department of Defense (DoD), including the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense and the Defense Advanced Research Projects Agency. Our experts engaged with all critical aspects of medical countermeasure research, development, manufacturing and distribution.

The initiative set ambitious objectives: deliver tens of millions of doses of FDA approved or authorized, safe and effective COVID-19 vaccines for use by the end of 2020, with enough supply to vaccinate 300 million Americans across the U.S. by mid-2021. The pace and scope of such a vaccine effort were unprecedented. In comparison, the 2014 West African Ebola virus epidemic spurred rapid vaccine development. While preclinical data existed before the outbreak, the effort still took 12 months to progress from phase 1 first-in-human trials to phase 3 efficacy trials. Our goal focused on compressing this timeline even more. COVID-19 vaccine development began in 2020 with phase 1 clinical studies in March and the first phase 3 clinical trials in July. The objectives were based on advances in vaccine platform technology, improved understanding of safe and efficacious vaccine design, and similarities between the SARS-CoV-1 and SARS-CoV-2 disease mechanisms.

Vaccine Development

To date, our research and development efforts have already led to FDA's issuing Emergency Use Authorizations (EUAs) for two vaccines which both demonstrated nearly 95% efficacy, with additional vaccines likely to follow soon.

Vaccine candidates were selected based on four criteria. Candidates were required to have robust preclinical data or early-stage clinical trial data supporting their potential for safety and efficacy. Candidates had to have the potential, with acceleration support, to enter large phase 3 field efficacy trials as quickly as possible, amidst continued active transmission of the virus, to deliver efficacy outcomes in a matter of months. Candidates had to be based on vaccine-platform technologies permitting fast and effective manufacturing, and their developers had to demonstrate the industrial process scalability, yields, and consistency necessary to reliably produce more than 100 million doses by mid-2021. Finally, candidates had to use one of four vaccine-platform technologies that were deemed the most likely to yield a safe and effective vaccine against COVID-19: the mRNA platform; the replication-defective live-vector platform; the recombinant-subunit-adjuvant protein platform; or the attenuated replicating live-vector platform.[i]

The development strategy relied on a few key principles. First, the team sought to build a diverse project portfolio that included two vaccine candidates based on each of the four platform technologies. Such diversification mitigated the risk of failure due to safety, efficacy, industrial manufacturability, or scheduling factors. Furthermore, it permitted selection of the best vaccine platform for each subpopulation at risk for contracting or transmitting COVID-19, including older adults, frontline and essential workers, young adults, and pediatric populations. In addition, advancing six vaccines in parallel increased the chances of delivering 300 million doses in the first half of 2021.

Second, the team sought to accelerate vaccine program development without compromising safety, efficacy, or product quality. Clinical development, process development, and manufacturing scale-up was substantially accelerated by initiating all

efforts streams, fully resourced, in parallel. Doing so required the federal government taking on substantial financial risk, as compared with the conventional sequential development approach. Phase 3 trial sizes were maximized (30,000 to 50,000 participants each) and trial-site locations were optimized by consulting daily epidemiologic and disease-forecasting models to ensure the fastest path to efficacy. Such large trials also increased the safety data set for each candidate vaccine.

With heavy, up-front federal investment, companies were able to conduct clinical operations and site preparation for phase 3 efficacy trials even as they filed their Investigational New Drug application (IND) for their phase 1 studies, thereby ensuring immediate initiation of phase 3 when the FDA approved them to do so. To permit appropriate comparisons among the vaccine candidates and to optimize vaccine utilization after approval by the FDA, the phase 3 trial end points and assay readouts were harmonized for consistency through a collaborative effort involving the National Institute of Allergy and Infectious Diseases (NIAID), the Coronavirus Prevention Network, and the sponsor companies. An unprecedented effort, all candidates agreed to harmonized critical trials with common endpoints and data sharing.

Finally, the federal government funded private industry to enable their development and large-scale manufacturing while their vaccines were in preclinical or very early clinical stages, instead of the usual lengthy process where companies wait until FDA approval before beginning full scale manufacturing. We assessed the U.S. domestic manufacturing capacity, identified choke points, and invested throughout the supply chain to increase availability and output of key enablers such as supplies, raw materials, and equipment. To ensure that industrial processes were set, running, and validated for FDA inspection when phase 3 trials ended, the federal government funded construction or refurbishing of various manufacturing facilities, equipment fitting, staff hiring and training, raw-material sourcing, technology transfer and validation, bulk product processing into vials, and acquisition of ample vials, syringes, and needles for each vaccine candidate. These decisions to support manufacturing prior to FDA approval resulted in millions of vaccine doses available for distribution to the American

people within 24 hours of FDA Emergency Use Authorization (EUA). This strategy accelerated vaccine development without curtailing the critical steps required by sound science and regulatory standards.

Therapeutics

The operation simultaneously launched therapeutics efforts in May 2020. The intent was to accelerate the clinical development and manufacturing scale-up of the candidates that were most likely to have a broad public health impact to complement vaccines. This was accomplished through a two-pronged approach that built on existing agency efforts, focusing on treatment candidates to: 1) attack the virus; and 2) manage complications.[ii]

The therapeutics research team, in conjunction with multiple agencies and 12 therapeutics manufacturers, assessed more than 50 potential drug compounds to accelerate product development and manufacturing. To date, these public-private partnerships resulted in three EUAs for monoclonal antibody treatments from the FDA. The first two received their authorization before the end of 2020. These treatments were found to decrease mortality and the risk of hospitalization by 70% in high-risk patients. Currently, the FDA is considering a fourth application for use of an authorized monoclonal antibody treatment. This application would allow use for both preventing spread of COVID-19 and the treatment of hospitalized patients. There are ongoing clinical trials for five additional therapeutics candidates, which include small molecule antiviral, immune modulators, and additional monoclonal antibodies.

Our manufacturing at-risk strategy allowed us to allocate and distribute 80,000 doses of monoclonal antibodies within 48 hours of FDA authorization. The operation partnered with the HHS Assistant Secretary for Preparedness and Response (ASPR) for the successful allocation, distribution and administration of therapeutics. To date, 850,000 courses of therapeutics have shipped to over 5,000 locations across the country. The U.S. healthcare system has treated between 300,000 and 470,000 high-

risk COVID-19 patients with mild-to-moderate symptoms, potentially preventing up to 22,000 hospitalizations and potentially 9,000 deaths since November.

Between January 1 and November 21, 2020, the average Medicare fee-for-service payment for patients hospitalized with COVID-19 was $23,558 for claims received by December 18, 2020. Using this value, monoclonal antibody treatment has helped to avoid $518 million dollars in hospital costs. We have purchased an additional 2.35 million doses of monoclonal antibodies with options to purchase 2.85 million more doses, based on need. To ensure the widest, fair and equitable administration of monoclonal antibodies, the operation established seven pilot programs to expand distribution to Long-Term Care Facilities, home infusion programs, Federally Qualified Health Centers (FQHCs), and dialysis centers.

In addition to partnering with pharmaceutical manufacturers, the operation successfully accelerated COVID-19 Convalescent Plasma (CCP). This treatment received an FDA EUA for treatment of hospitalized patients with COVID-19 in August of 2020. (That EUA was subsequently limited to high-titer CCP (CCP with high levels of COVID-19 antibodies).) The previous May of that same year, the U.S. Government assigned a $460 million contract with America's Blood Center and the American Red Cross for the collection and storage of CCP. To date, the operation has collected more than 740,000 units of CCP and distributed more than 569,000 units for use in the direct transfusions to hospitalized patients. CCP with high titers has the potential to reduce the severity and shorten the length of the COVID-19 illness in hospitalized patients when administered early in the disease course.

The clinical strategy for therapeutics included the design and launch of U.S. Government-funded platform clinical trials in partnership with the NIH. The team supported NIH’s public-private partnership known as “Accelerating COVID-19 Therapeutic Interventions and Vaccines” (ACTIV). This initiative, coordinated by the Foundation for the National Institutes of Health, brought together the biomedical resources from 20 pharmaceutical companies, multiple government agencies, academic

institutions, and non-profit organizations. The ACTIV trials currently include seven rigorous master protocols that covered the full spectrum of COVID-19 positive patient populations requiring treatment: outpatient, inpatient, and convalescent.

Overall, therapeutics efforts include significant financial investment, trial oversight, and logistical support, such as contracting, site set-up, mobile infusion centers, and drug acquisitions.

From the Factory to the Frontlines

Early in the planning phase, the team developed a distribution strategy to achieve the principal purpose and objective to deliver safe and effective doses of vaccine to the American people. Successful implementation of the National COVID-19 vaccination program required precise coordination across federal, state, local, tribal, and territorial governments and among many public and private partners. The plan to deliver vaccines leveraged major distributors, distribution networks, customer bases, and infrastructure to distribute and administer COVID-19 vaccine in a three-phased structure.[iii]

Operation leadership provided unity of effort to a whole-of-America approach for vaccine manufacturing and distribution. Contracting, acquisition, legal and program management experts responsibly and conscientiously coordinated, executed and oversaw the award of more than $31 billion in contracts, along with the related Defense Production Act (DPA) authorities, assuring the best value for U.S. taxpayer dollars. Since May 2020, the U.S. Government has contracted for 1.2 billion doses of vaccine with options to secure more, and issued 18 DPA priority ratings for physical plant enhancements, raw materials, supplies and countermeasures.

Military logistics experts closely managed the supply chain and embedded in manufacturing plants to scale up manufacturing and maximize industrial best practices, resulting in more than 20 million doses delivered by the end of 2020, and hundreds of millions projected in 1st Quarter 2021.

Assuring a ready supply chain included securing more than 1 billion needles and syringes for America's vaccination efforts. The operation developed and contracted for ancillary kits, securing all necessary supplies to administer vaccines – including syringes, needles, alcohol prep pads, face masks, face shields, and diluent or adjuvant if required – and coordinated distribution concurrently with the vaccines to administration sites at no cost to providers.

Synchronizing and integrating data was a critical effort for the operation. No single federal system existed to provide visibility of vaccine distribution and administration across the entire operation. The Tiberius platform was conceived and developed as a decision support tool for federal and state leaders, allowing unprecedented oversight and planning capabilities. Protecting the personal identification information of patients, data from hundreds of separate systems now provide full visibility of the vaccine operation – from supply and allocations through delivery to administration. To ensure the federal government could accurately and appropriately track vaccine administration information, Data Use Agreements were developed and coordinated with all 64 jurisdictions and the five federal entities.

Operation leadership initiated a series of reviews and exercises with CDC and the states to rehearse distribution plans, setting a goal of commencing vaccine distribution within 24 hours of an FDA EUA. These weekly sessions allowed the various government and industry partners involved in the effort to define roles and responsibilities, synchronize movements, identify gaps, and plan for potential challenges at every stage of the distribution process. Beginning distribution of vaccines within 24 hours of authorization was not only an achievable metric, it reflected the responsible and appropriate urgency of delivering vaccines to the American people during a pandemic where thousands of lives were and are being lost every day. Notably, delivery of both Pfizer and Moderna vaccines began within 24 hours of authorization, and to date, more than 75 million vaccine doses and 850,000 courses of therapeutics have been delivered to the right locations at the right time and in the right quantities and conditions, through nine winter storms, with above a 99% success rate.

To oversee distribution, the operation organized, managed and staffed an inter- and intra-agency Vaccine Operations Center, with liaisons from multiple industry and government agencies, that coordinated and tracked the movement of the vaccines – facilitating all cold chain requirements including dry ice refills, supplemental handling kits and temperature monitoring capabilities, from the manufacturer to distribution centers and finally to more than 30,000 administration sites to date.

A robust Security and Assurance effort developed physical, information, cyber, and personnel security measures to protect the vaccines and therapeutics operation. The operation's Security and Assurance team developed a security plan to support the U.S. Government production and distribution of supplies, diagnostics, therapeutics and vaccines. The team worked closely with more than 30 partners, including the Department of Justice, FBI, Cybersecurity and Infrastructure Security Agency from the Department of Homeland Security, Defense Digital Services, U.S. Marshals Service, law enforcement and industry, nationwide as part of a robust physical and cybersecurity effort to safeguard vaccines.

While vaccine administration was outside the scope of the operation's mission, leadership worked closely with the CDC to enable the ultimate goal of shots in arms. Military officers embedded alongside CDC representatives in Atlanta to form regional teams in a Vaccine Coordination Center that continues to remain in daily contact with the 64 jurisdictions' state health officials. In September, the CDC published an interim playbook for jurisdictions that provided initial guidance for states to commence planning. In the months that followed, regional teams worked closely with each jurisdiction to refine their plans, at times deploying strike teams to provide on-site support and capability.

Together with the jurisdictions and the CDC, the operation enrolled more than 119,000 COVID-19 vaccination providers across the 50 states, eight territories and six metropolitan cities, and five federal entities. To care for one of the nation's most vulnerable populations in Long-Term Care Facilities (LTCF), the operation conceived,

developed and executed a federal partnership with CVS, Walgreens, and Manage Health Care Associates to administer vaccines at 70,000 sites across the nation. This federal LTCF partnership eased the burden on states to manage and coordinate vaccinating our most vulnerable population group. By mid-February, CVS and Walgreens had completed first-dose clinics in more than 60,000 facilities.

The operation also worked with the CDC to create a federal retail pharmacy partnership to capitalize on the 40,000 chain and independent brick-and-mortar pharmacy locations across the nation where Americans primarily receive their vaccines. Through the partnership, initiated in November, states were able to transfer allocations to retail sites to assist them with vaccination efforts as a bridging strategy to the full program launch which occurred this month.

Whether at a doctor's office, retail pharmacy, federally qualified health center or hospital, the operation continues to work to ensure hundreds of thousands of sites will be available as supply increases so that no American is forced to travel far for their vaccination.

Conclusion

In closing, the pandemic has led to unprecedented partnering across industry, academia, the DOD and other federal agencies to deliver lifesaving measures to the American people. As a career Soldier I swore an oath to defend our Constitution against all enemies. I am proud to state that the DoD stands ready to defend our Nation against all adversaries, including this virus which is impacting our way of life. For the past nine months, a team of 100 Service members and DoD Civilians have dedicated themselves to defeating the enemy. DoD's contribution to the federal COVID-19 response, while unprecedented, has been monumental to moving our nation past this pandemic.

I appreciate the support of Congress in our work to develop, manufacture, and deliver vaccines and therapeutics to our nation. We look forward to continuing to partner with Congress and working together as the country continues to open safely

again. Thank you for the opportunity to testify today and we look forward to your questions.

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[i] Slaoui M, Hepburn M. Developing Safe and Effective Covid Vaccines - Operation Warp Speed's Strategy and Approach. N Engl J Med. 2020 Oct 29;383(18):1701-1703. doi: 10.1056/NEJMp2027405. Epub 2020 Aug 26. PMID: 32846056.

[ii] Slaoui M, Greene SE, Woodcock J. Bridging the Gap at Warp Speed - Delivering Options for Preventing and Treating Covid-19. N Engl J Med. 2020 Nov 12;383(20):1899-1901. doi: 10.1056/NEJMp2028535. Epub 2020 Sep 15. PMID: 32931679.

[iii] HHS/DoD: From the Factory to the Frontlines, As of September 16, 2020: https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf