Senate Armed Services Committee
Advance Policy Questions for General Gustave F. Perna
Nominee for Appointment to be Chief Operating Officer, Operation Warp Speed

Duties

1) What is your understanding of the duties and responsibilities of the Chief Operating Officer, Operation Warp Speed (OWS)?

Answer: Synchronize and integrate the capabilities of HHS, DOD, other supporting Government agencies, Non-governmental agencies and Industry to deliver safe and effective Countermeasures; including Vaccines, Therapeutics and Diagnostics; to protect US citizens from COVID-19 by January 2021.

2) What background and experience do you possess that you believe qualify you to perform these duties?

Answer: I have had the honor to serve our Nation in the U.S. Army as a logistician. Extensively working logistics efforts with all services of the Department of Defense, partnering with Whole of Government and leveraging Industry to deliver required effects to meet our Nation's most pressing National Defense Logistics requirements.

I have served in numerous command assignments overseeing our Army's Organic Industrial Base, Worldwide Contracting and Procurement, Global Distribution, Life Cycle Management, Technical Services and the associated Physical and Network Security.

In addition, I have served in numerous staff positions; responsible for developing and implementing the U.S. Army's sustainment policy and procedures. Finally, I have served in positions focused on the complexity of driving sustainment plans and policies for strategic and operational logistics to sustain U.S., coalition and joint forces.

3) Do you believe that there are any steps that you need to take to enhance your ability to perform these duties and responsibilities?

Answer: Both Hon Azar and Hon Esper have set conditions for success; more important, the collective talent and experience within both the Departments of Health and Human Services and Defense, industry and academia must be enabled. Both industry and our government's supporting agencies, resourcing and execution processes must also move at Warp Speed for success; I will have to ensure that our collective bureaucracies do not distract us from Winning!

4) What specific tasks would you expect the President to assign to you, if confirmed?

Answer: If confirmed, I expect to be asked to provide leadership and oversight of the operational planning and execution of Operation Warp Speed, ensuring a feasible distribution and administration strategy is ready for implementation when safe and effective vaccines are approved by the FDA for the American people.

Major Challenges and Priorities

5) What do you consider to be the most significant challenges you will face, if confirmed?

Answer: Based on the advice of the great professionals at HHS and the insights of Dr. Slaoui, I understand that the most significant challenges will be to rapidly develop safe and effective vaccine(s), and therapeutics. The pace of development proven through clinical trials, and validated by the Food and Drug Administration (FDA), and then build trust and confidence in the American people of these results will be a Herculean task for all involved.

It is my understanding that challenges exist in assuring adequate security and safeguarding clinical trials and other data when transitioning from an open, collaborative medical / PHARMA environment into government agencies, protecting that data from theft or corruption, and thus preventing disruption of production and distribution of a safe and effective vaccine(s) by January 2021.

6) What plans do you have for addressing each of these challenges?

Answer: If confirmed, I will collaborate with the Chief Advisor, Dr. Slaoui and the Operation Warp Speed team to develop a robust Clinical Trials strategy for candidate vaccine and therapeutic products, which I understand must be in conjunction with the candidate vaccine company, the Food and Drug Administration and the National Institute of Health. This strategy must align with the approved guidelines from the Food and Drug Administration and be properly planned and resourced. In parallel Operation Warp Speed will support the Centers for Disease Control in developing a comprehensive distribution, administration and strategic communications strategy to inform the American population about the safety of these products and how each will become available.

Regarding Security Assurance, OWS will leverage a whole of government approach utilizing a combination of interagency legal authorities, agreement, and contract language to assist industry partners and government agencies in securing data and protecting production and distribution systems. We will harden networks in the government agencies that are recipients of data, and will leverage HHS and DoJ interagency partners to benefit from with their established relationships and authorities, where necessary.

Operation Warp Speed (OWS) Initiatives

As we understand it, Operation Warp Speed (OWS) will focus on initiatives in five major areas:

1. **Development and testing of vaccines;**
2. **Development and testing of therapeutics;**
3. **Development and testing of diagnostics;**
4. **Supply, production, and distribution of diagnostics, therapeutics, and vaccines; and**
5. **Security and assurance of diagnostic, therapeutic, and vaccine development, testing, supply, production, and distribution.**

7) What is your understanding of each of these initiatives, as well as others on which OWS will focus?

Answer: If confirmed, I view the first three of these areas as our priority of initiatives. I see the 4th and 5th areas as imperatives to ensuring success.

I understand, with respect to vaccines, that the Department of Health and Human Services already has candidate vaccine development efforts underway with industry partners and is looking to enter additional agreements. The testing of these candidate vaccines is a part of the clinical trials program and must be a major focus of the Operation Warp Speed leadership. Similarly, development and evaluation projects on potential Therapeutic and Diagnostics products are also underway.

The supply, production, and distribution initiative is synergistic with simultaneous development initiatives for vaccines, therapeutics and diagnostics. OSD in support of HHS and industry, will provide logistics subject matter experts (SMEs) to augment these initiatives. Together, we will ensure the right materials are available to support production and distribution. The delivery and administration of safe and effective finished products to support diagnosing, treating and preventing COVID-19 across the nation is our clear end state. .

In the Security Assurance realm, if confirmed, I will ensure that not only will OWS use a whole of government and industry approach to development for vaccines, but will apply equally inclusive approach to protect this critical work and enterprise required to deliver a vaccine to our nation, allies and partners. It is my understanding that we will offer information, guidance, and assistance to industry partners and reinforce government agencies, within applicable authorities.

8) If confirmed to be the Chief Operating Officer of OWS, what goals and objectives would you establish for each of these OWS initiatives?

Answer: If confirmed, the goals and objectives for Vaccine development will be to develop, produce, and distribute one or more safe and effective vaccines in sufficient quantity to support the population of the United States... The Therapeutic and Diagnostic initiatives' goals will be to validate or develop multiple safe and effective tests and patient treatment with COVID-19, in order to identify and reduce fatalities from this disease.

Regarding Security and Assurance, if confirmed I will increase protection of our critical work and safeguard the enterprise required to deliver a vaccine to our nation. We will strengthen our ability to protect the manufacturing and distribution processes, including the integrity, availability, authenticity, non-repudiation and confidentiality of data and materials. These are crucial steps to enable decision makers and ensure the American people have confidence in the data, the process, and the products.

9) How will your background and experience contribute to each of these initiatives?

Answer: My nearly 37 years on active duty and 2 years in the National Guard, culminating as the Army's senior logistician and commander of Army Materiel Command, has built my strategic, operational and tactical foundation to prepare me for this opportunity. Leading AMC's highly skilled, talented and global workforce of over 190,000 Soldiers, Civilians and Contractors, across 11 major subordinate commands, was challenging and incredibly rewarding. I consider one of my greatest accomplishments was synchronizing and integrating capabilities and efforts of the collective enterprise to accomplish our mission of delivering logistics, sustainment and materiel readiness from the installation to the battlefield. I am incredibly proud of the progress made to structure and position Army Materiel Command as the organization responsible for ensuring readiness of the Strategic Support Area in Multi-Domain Operations. I believe that lessons learned from these experiences, both set-backs and

accomplishments will enable me in my role as the Chief Operating Officer for the Operation Warp Speed Task Force.

10) In what stages or phases would you envision OWS proceeding with regard to each of these initiatives?

Answer: If confirmed, Operation Warp Speed will organize multiple, parallel lines of effort to manage the initiatives. Vaccine, Therapeutics, and Diagnostic developments or evaluations are taking place concurrently. HHS and DOD have already started to increase manufacturing and distribution capacity and capability. Upon approval from FDA, OWS will immediately energize manufacturing and distribution networks, in conjunction with industry partners, to speed delivery of those new products to the Nation. This is the considered risk we must evaluate and be prepared to take, expanding manufacturing prior to FDA approval.

Further, if I am confirmed, I will ensure OWS Director of Security and Assurance leverages a number of government and industry standard measures of effectiveness. As our team will include DOD, DoJ, HHS, and Pharmaceutical Industry partners, our measures of effectiveness will vary but are likely to include CARVER methodology (Criticality, Accessibility, Recuperability, Vulnerability, Effect and Recognizability), Incident Response Volume, and Security Audits.

11) If confirmed, how would you measure OWS progress toward each of these goals and objectives? What metrics would you apply to each and what criteria would you apply to ascertain whether or not a goal or objective has been met or achieved?
Answer: If confirmed, OWS will establish an Integrated Master Schedule to track and provide decision support on the development of candidate vaccines and therapeutics, through their respective clinical trial testing, and production, to distribution and eventual administration. Identifying key objectives over time will be monitored by the OWS/HHS Team and reported weekly through a standard schedule of daily and weekly meetings, updates, and synchronization sessions with key stakeholders working specific initiatives. I will, in all things, scientific rely heavily on the judgment and insights of the Chief Advisor, Dr. Moncef Slaoui to achieve our end state.

I understand that metrics such as production capacity per company, clinical trial site selection and preparation, manufacturing yield rates, distribution and storage capacity/utilization, along with administration ancillary equipment on-hand levels are but a few of the metrics the OWS Team must track to monitor progress, make timely decisions, and inform leaders. The OWS team continues to assess additional metrics and criteria and collaborate with government and industry experts to employ best practices

12) If confirmed, what steps would you take to ensure that each of these initiatives proceeds concurrently, rather than sequentially?

Answer: If confirmed, I will rely on the established Project Coordination Teams (PCT) of experts from across the HHS, DOD and USG's agencies and industry partners involved in vaccine, therapeutic and diagnostics development to synchronize concurrent efforts. OWS will apply resources toward every opportunity to safely streamline development, testing, and manufacturing against clearly established goals. Our Team will use an Integrated Master Schedule to track and make timely decisions on the development of candidate vaccines and therapeutics, clinical trial testing, and the production, distribution and eventual administration of safe and effective products.

13) If confirmed, how would you expect to accomplish OWS goals and objectives when a significant portion of the work in developing and testing vaccines, diagnostic testing, and therapeutics is being conducted in countries other than the United States?

Answer: There is substantial capability and capacity that can be provided inside the USA and by our established Allies throughout the world. If confirmed, I will work closely with both interagency partners and industry experts to accomplish the goals and objectives of OWS. I will rely extensively on their experience working with the international network who develop vaccines, therapeutics and diagnostics capabilities to ensure our Nation benefits from reliable support of trustworthy partners.

14) How will OWS work collaboratively with other countries to advance common global goals and objectives to defeat COVID-19?

Answer: It is my understanding that our industry and NIH partners have extensive trial networks throughout the globe. They have experience working with foreign governments to implement ethical trials which are mutually beneficial to all involved. We will continue to work with our partners to implement FDA and NIH approved trials and products. OWS, with our counterparts at Department of State, may assist their efforts to develop those relationships, and support those foreign sites logistically.

(Alternative comments)
If we experience a shortfall of COVID-19 hot spots within the US, we are prepared to work with other nations who are experiencing high infection rates to establish clinical trials within their borders to establish the efficacy and safety of potential countermeasures.

15) In your view, how will the Department of Defense (DOD) work with other federal and private-sector partners to deliver on the goals and objectives of OWS?

Answer: Collaboration with other federal and private-sector partners is critical to OWS' success. American innovation and intellect spans all sectors of our economy, and is it imperative OWS leverage the collective power of biopharmaceutical companies, manufacturing enterprises, academic institutions, and the federal government. We plan to leverage existing contractual and other relationships between DOD and the federal government and the private sector, which have been fostered through efforts like the FEMA Supply Chain Task Force and DOD's Joint Acquisition Task Force. Both have forged relationship across Federal agencies and with industry since the COVID-19 pandemic started, that will be invaluable to our success.

16) If confirmed, how do you plan to leverage DOD's expertise in vaccine and therapeutics development to achieve OWS goals and objectives?

Answer: If confirmed I will work closely with Dr. Slaoui to ensure we maximize teaming with DOD medical and biological research experts across all lines of effort. I understand that some of this collaboration is already underway with our biomedical research organizations and I would look to expand these integrations where beneficial.

OWS plans the most rapid development of a vaccine ever accomplished. Many experts have expressed doubt that a COVID-19 vaccine can be developed, tested for safety and effectiveness, produced, and administered in the large quantities required so quickly.

17) In your view, what are the risks to the American public in rushing to produce a vaccine for any communicable disease?

Answer: First and foremost we must deliver a vaccine that is safe and effective. Achieving this significantly reduces the risk to the public. All medical protocols are being fully executed to that intent.

18) How would you mitigate those risks for a COVID-19 vaccine, if confirmed?

Answer: It is my understanding that the clinical trials being planned will include significantly larger numbers of participants than normal to more rapidly identify efficacy and safety of the treatment under consideration. Make no mistake, OWS will rely heavily on the FDA to ensure safe and effective thresholds are met without any shortcuts or workarounds that could compromise the safety of the American public. Established safeguards and larger trials, combined with data gathered by continuous tracking of early phase trial participants are expected to mitigate risk.

There has been much discussion in the media regarding human challenge trials.

19) What is your view of the feasibility, advisability, and suitability of human challenge trials?

Answer: It is my understanding that current plans do not involve human challenge trials.

20) Would you be comfortable engaging in human trials under the auspices or sponsorship of OWS, if confirmed? Please explain your answer.

Answer: Based on my limited experience in human challenge trials, I defer to the FDA and other qualified regulatory authorities to accurately address this question.

<u>Organization and Staffing</u>

21. If confirmed, how would you organize and staff OWS? Please provide an organizational chart and explain the organizational structure and staffing of OWS, including leader and staff titles, position descriptions, and lines of authority and responsibility.

Answer: If confirmed, the OWS staff structure will be organized in accordance with the inter-departmental MOU (hereinafter referred to as the OWS MOU) that took effect 05 June 2020. OWS is a joint effort of HHS and DOD, co-chaired by the Secretaries of HHS and Defense. In order to support OWS project goals, the Secretaries of HHS and Defense have designated qualified personnel to assume key positions.

HHS has designated Dr. Moncef Slaoui as the Chief Advisor overseeing the science efforts on the countermeasures (Vaccines, Therapeutics and Diagnostics). If confirmed as the COO, OWS operating directorates will be the 1) Supply, Production and Distribution (SPD) and 2) Security Assurance (SA) directorates. Both of which will be direct reports to me.

22) Will your staff include military personnel? If so, how many and what grades will be included? What functions will these military personnel perform?

Answer: If confirmed, the OWS staff will include military personnel. Currently, we have initial

requirements for 31 detailed personnel, 27 of which have been identified with 4 more pending Joint sourcing. Other than myself and the General Officer leading the Security Assurance directorate, all of these personnel are Field Grade Officers primarily O-6 (23 of 31), with a few (6 of 31) O-5 and O-4 officers.

These military personnel will serve as staff subject matter experts in support of the Supply, Production and Distribution directorate (plans, operations and analytics officers), Security Assurance directorates and as our legislative affairs and support staff (Secretary of the General Staff, Executive Officers to the Chief Advisor, COO, SPD and SA directorates). They will also provide critical Program Management expertise to assist the Vaccine and Therapeutic lines of effort.

Relationships

If confirmed to be the Chief Operating Officer of OWS, what would your relationship be with each of the following officials?

23) OWS Chief Advisor, Dr. Moncef Slaoui

Answer: Dr. Slaoui serves as an HHS contractor. If confirmed, I will work with the OWS Chief Advisor, Dr. Moncef Slaoui, to ensure he understands of all DOD capabilities available to support this effort, so that that he is best positioned to provide scientific recommendations on the Nation's response to COVID-19.

DOD Officials
24) Secretary of Defense

If confirmed, I will serve as a direct report to Secretary Esper. We will provide weekly in person updates and written updates to Secretary Esper and provide special topic briefings as directed by the Secretary.

25) Assistant Secretary of Defense for Health Affairs Brig Gen Friedrichs

Answer: The ASD- Health Affairs (ASD (HA)) is the principle advisor to the Secretary of Defense for all DOD health and force health protection programs, policies and activities. When the OWS COO requires DOD medical support for OWS programs, he and his staff will coordinate with the ASD (HA), through the DoD COVID Task Force. In addition, OWS COO will synchronize with ASD (HA) to ensure whole of government efforts to provide safe, efficient and effective vaccines, therapeutics and diagnostic capabilities.

26) Assistant Director for Combat Support, Defense Health Agency (DHA)
Answer:

- Maj Gen Payne has been assigned as the DoD COVID-19 Task Force Lead for Diagnostic Testing and serves as the DoD representative to OWS in support of the HHS lead Dr. Bruce Tromberg
- Since OWS was announced, Maj Gen Payne has been engaged with Dr. Tromberg to assist the OWS Diagnostics effort and has worked to align the DoD stakeholders to support that effort
- Maj Gen Payne attends the weekly Diagnostics updates to me by the HHS Lead, Dr. Tromberg, and provides any DoD-specific input

- Maj Gen Payne also attends the COVID-19 Task Force Meetings where OWS updates are provided to the Deputy Secretary of Defense and Vice Chairman of the Joint Chiefs as the COVID-19 Task Force Leads

27) Director, Research and Development at DHA.

Answer: It is my understanding, that OWS is already leveraging the vast experience and knowledge base of Joint Program Executive Office to enable the successful development and distribution of countermeasures to the threat. I would fully support continuing this partnering. Additionally:

- Dr. Sean Biggerstaff, Director for Research and Development, has been assigned as the DoD COVID-19 Medical Research and Development Task Force Lead and serves as the DOD representative to OWS in support of the HHS lead for Therapeutics, Dr. Janet Woodcock.
- Dr. Biggerstaff regularly briefs the Secretary of Defense and Deputy Secretary of Defense on the status of the COVID-19 research investments portfolio and submits weekly activity reports.
- Dr. Biggerstaff ensures leaders within the DHA, OASD (HA), and OUSD (P&R) are apprised of key milestones and decision points related to the DoD COVID-19 research portfolio and strategy. Monthly in-progress reviews are organized for DOD components receiving funding for COVID-19 research to present their accomplishments and timelines.

29) Director, COVID-19 Joint Acquisition Task Force/Principal Deputy Assistant Secretary of Defense for Acquisition Enablers

Answer: If confirmed, I intend to work with the Principal Deputy Assistant of Defense for Acquisition Enablers to use all available acquisition tools to expedite delivery of a safe, effective vaccine to the American people.

As soon as I was nominated to serve as the COO of OWS, the Undersecretary of Defense for Acquisition & Sustainment (USD (A&S)) reached out to offer lessons learned and support from her team to include the COVID-19 Joint Acquisition Task Force (JATF). The JATF director shared lessons learned with me and my lead for Supply, Production & Distribution from her experience in supporting acquisition activities across the interagency. The JATF, was organized across seven medical product lines – one of which is vaccine delivery. The JATF's work in that area has transitioned to OWS and allowed us to build upon those efforts. In addition, USD (A&S) has streamlined processes between HHS and DOD to support timely and efficient execution of contracts, enabling the OWS team to adopt the same practices and quickly scale this interagency effort.

30) Director, Defense Logistics Agency

Answer: It is vital to maintain a coordinating relationship with the Director, DLA as the agency retains capabilities in acquisition, supply, distribution, and other logistics that could become key to bridging any gaps identified while planning to meet OWS objectives.

Throughout the response to COVID-19, the Defense Logistics Agency (DLA) has provided outstanding support to our Federal Agency partners while meeting internal DOD demand for both COVID-19 requirements and normal logistics support. Moving forward, I will leverage DLA's deep market

knowledge to help shape acquisition strategies that will meet not only customer needs but also achieve policy goals with regards to strengthening the domestic industrial base.

31) Director, Defense Contract Management Agency

Answer: If confirmed, I will maintain a coordinating relationship with the Director, DCMA. DCMA may provide additional contracting planning and execution capability necessary to maintain the appropriate contract oversight necessary in support of overall efforts.

32) Deputy Assistant Secretary of Defense, Industrial Policy

Answer: If confirmed, I intend to leverage Industrial Policy's vast resources in supply chain analysis to better understand shortcomings in our manufacturing and distribution plans. Identifying and addressing those challenges early, and implementing mitigating strategies, will be critical to successful deployment of countermeasures against the threat.

33) Service Acquisition Executives for the Army, Navy, and Air Force

Answer: It is my understanding that OWS has already initiated contact with Service Acquisition Executives in an effort to gather a team of acquisition experts to support the OWS mission. If confirmed, I will continue to work with the Service Acquisition Executives to provide support in executing this critical mission.

34) Chief Intelligence Officer for CBRN Defense

Answer: If confirmed, The JPEO-CBRND Chief Intelligence Officer ("Chief Intelligence Officer for CBRN Defense") will continue directly supporting Operation Warp Speed through my Deputy for Security & Assurance BG McCurry. Dr. Andy Kilianski is an integral member of the SA team and brings his expertise on securing the defense medical industrial base to help deliver an uncompromised COVID-19 response capability for the United States.

35) Director, Defense Advanced Research Projects Agency

Answer: If confirmed I intend to leverage DARPA's vast knowledge in science and technology and earlier research investments in COVID-19 and other pandemics as they apply to OWS efforts. Understanding how DARPA addressed challenges in the past will be critical to successful deployment of countermeasures against the current threat.

36) Director, Defense Research and Engineering for Modernization

Answer: If confirmed I intend to leverage the Director for Defense Research and Engineering for Modernization vast knowledge in science, technology, and engineering to apply to OWS efforts. Through this office, we can leverage efforts by the Defense Advanced Research Projects Agency, the Defense Innovation Unit, and the DOD Laboratory enterprise.

Leaders of the Department of Health and Human Services

37) Assistant Secretary for Preparedness and Response ASPR, Dr. Kadlec

Answer: If confirmed, I intend to leverage the Assistant Secretary for Preparedness and Response's existing expertise, efforts and expenditures by its Biomedical Advanced Research and Development Authority (BARDA) in the development of COVID -19 medical countermeasures. ASPR and BARDA began its development of vaccines, therapeutics and diagnostics against COVID-19 with DOD in late January. Collectively, they have laid a very solid foundation that OWS can advance and accelerate.

38) Acting Director, Biomedical Advanced Medical Research Authority

Answer: If confirmed, I will work to establish and maintain a collaborative relationship with the Acting Director, for Biomedical Advanced Medical Research Authority (BARDA) and his team to align work streams between DoD, BARDA, National Institute for Health (NIH), Food and Drug Administration (FDA), Center for Disease Control and Prevention (CDC), Strategic National Stockpile (SNS) and all line of efforts for vaccines, therapeutics and diagnostics. Continue collaboration between agencies will ensure issues identified by Project Coordination Teams (PCTs) are resolved quickly.

39) Director, Centers for Disease Control

Answer: If confirmed, I will work closely with Dr. Redfield and CDC to build off existing national and state infrastructure for immunization to ensure vaccine distribution and administration is adequately supported to ensure priority populations have access to the vaccine, uptake of the vaccine in the population is high, and safety and vaccine effectiveness continues to be monitored.

40) Commissioner, Food and Drug Administration FDA, Director

Answer: Answer: If confirmed, I would work with the FDA on a broad spectrum of issues. Congress has given FDA a critical statutory role in protecting our Public Health through helping to ensure products are safe and effective for their intended use. I would leverage their expertise on a wide ranging topics, to include: the acceleration of development for treatments, maintaining and securing drug supply chains, providing guidance to manufacturers, advising developers on how to handle clinical trial issues, and keeping the public informed.

41) Leaders of other Federal Departments and Agencies

Answer: If Confirmed, OWS Security and Assurance will leverage a number of government and industry partners. Our Security and Assurance team will likely include Department of Defense, Department of Health and Human Services, Department of Homeland Security, Department of Justice (FBI), and members of the intelligence community to ensure we leverage all existing authorities, responsibilities, and relationships, resulting in a shared understanding of potential threats to our operations and potential application of appropriate security countermeasures.

42) Private Sector Partners and Stakeholders

Answer: If confirmed, I will collaborate with Private Sector Partners and Stakeholders to ensure we ultimately achieve the OWS goals and objectives. DOD considers the U.S. industrial base a strategic enabler and partner in this effort.

OWS Security and Assurance will integrate and leverage the best practices for the protection of the OWS enterprise to include our manufacturing and production industry leaders.

Research

43) If confirmed, how would you plan to identify and leverage existing research projects in furtherance of the goals and objectives of OWS?

Answer: If confirmed, I intend first to understand what work is already being leveraged between Health and Human Services, DOD, other government agencies and universities. For projects that show promise in any area, I intend to have the OWS team evaluate each and, if appropriate, incorporate them into the effort to provide safe and effective vaccines and therapeutics to the Nation.

44) How would you plan, if confirmed, to leverage the significant technical talent and capabilities across the DOD science and technology research enterprise to support OWS?

Answer: It is my understanding that the OWS team has already begun to collaborate with experienced DOD scientists, program managers, and DOD Science and Technology Research laboratories. These individuals and organizations have significant experience across the research and development spectrum, to include biomedical experience. If confirmed, I intend to continue this effort to ensure existing government teams are properly resourced and involved to ensure OWS success.

45) What is your understanding of the current coronavirus research underway at the U.S. Walter Reed Army Institute of Research (USWRAIR) and how will OWS utilize the expertise and resources of USWRAIR?

Answer: The overall goal and scope of USWAIR research effort is to develop faster, more sensitive and deployable diagnostic tests that enable clinicians to more easily diagnose COVID-19 among US military and civilian populations, to guide clinical decision making. Translational research and development efforts will focus on improving molecular assays to diagnose acute infection as well as serologic assays for acute, sub-acute and past infection.

WRAIR seeks to identify, characterize, and develop monoclonal antibodies for use in diagnostic tests, for scientific understanding of the virus, and as a product to prevent and treat infection in patients. Furthermore, WRAIR seeks to discover and develop novel and/or repurposed molecules for use as drugs that can treat or prevent infection. OWS will utilize WRAIR efforts to identify patient populations and establish clinical trial sites, develop advanced immunology, conduct full-scale manufacturing, conduct phase II clinical trial, and analyze data to advance novel vaccine candidates.

46) What is your understanding of the current coronavirus research underway at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and how will OWS utilize the expertise and resources of USAMRIID?

Answer: Propagation and characterization of the USAMRIID viral stock of SARS-CoV-2 is required for the development of assays and animal models. The viral stock is being used to assess the efficacy of therapeutics in high throughput screening. The stock is also being used to challenge various species to identify the most relevant animal model(s).

Small animal models enable the rapid down-selection of therapeutics and/or vaccines prior to utilization in the more accurate, but less efficient non-human primate model. The development of a small animal

model will speed the testing of medical countermeasures to COVID-19. Furthermore, studies will aim to evaluate immunosuppressed and immunocompetent hamsters as small animal disease models for COVID-19. While high-throughput screening of small molecules enables the rapid identification of new therapeutic options. Experiments will need to be conducted to directly assess if a vaccine or therapeutic has the ability to prevent or treat COVID-19 disease in the NHP model. Finally, a transmissibility study will evaluate animal models for their utility as models of transmission. Models of transmission are important to determine whether countermeasures are impacting the infectiousness of the exposed individual.

47) What is your understanding of the current coronavirus research underway at the U.S. Navy Medical Research Center (NMRC) and how will OWS utilize the expertise and resources of NMRC?

Answer: NMRC has two vaccine candidates in development (psoralen-inactivated and phage-based) and a polyclonal antibody candidate that may be used as a therapeutic or a pre- or post-exposure prophylactic.

NMRC is also conducting an epidemiological study in Marines at the recruit depot in Parris Island to bolster Force Health Protection. This effort seeks to enroll volunteers at the beginning of their 14-day quarantine prior to beginning training to assess SARS-CoV-2 in individuals over 8 weeks of observation through nasal swabs (PCR test) and/or blood test (serology).

This study will assess the number of individuals positive for SARS-CoV-2 (PCR and/or serology) with mild or no symptoms. Researchers will seek to correlate antibody response (type and magnitude) to symptoms based on questionnaire and medical records. Finally, an assessment of the ability of serum to neutralize virus in laboratory models, biomarker levels in blood, and T and B cell response will be conducted.

Much of the research and development of vaccines and therapeutic trials will be in collaboration with industry, involving intellectual property developed between the U.S. government and industry.

48) What actions will you take to avoid any conflict of interest between OWS and industry?

Answer: Pursuant to the OWS MOU, the Secretary of Defense designated a DOD civilian attorney to serve as the Senior Counsel. The Senior Counsel will serve as designated ethics counsel for DOD personnel participating in OWS. HHS ethics counsel will continue to provide ethics advice to all HHS personnel participating in OWS. These designated ethics officials will be routinely involved in OWS matters and decisions to help proactively identify and mitigate any actual or perceived conflicts of interest from OWS staff.

If confirmed, I will personally lead, in tandem with the DOD and HHS designated ethics counsel, a discussion with all OWS personnel, on preserving the public trust, avoiding real or perceived conflicts of interests, protecting and conserving government resources, and obeying all ethical obligations. Our discussion will focus on avoiding conflicts of interest by complying with 18 U.S.C. Sections 201-209, 5 C.F.R. Parts 2635 and 2640, the Stop Trading on Congressional Knowledge (STOCK) Act, codified as Public Law 112-105, 41 U.S.C. §§ 2101-2107, formerly known as the Procurement Integrity Act, and applicable DoD regulations and policies. I will establish and communicate clear expectations concerning values based decision making and compliance with Federal ethics law and regulation.

If confirmed, I will work with the DOD and HHS designated ethics officials to identify personnel who are required to file public or confidential financial disclosure reports and will enforce strict compliance with filing requirements. I will work closely with OWS ethics counsel to promptly and effectively address any identified potential conflicts of interest.

DOD personnel assigned to OWS who transition from government service will receive guidance on relevant Federal and DoD Post-Government service restrictions as part of their out-processing in order to avoid conflicts of interest during their post-government employment.

Finally, if confirmed, I am committed to transparency in all OWS matters, to the maximum extent permitted by law.

49) How will you manage any reports of conflicts of interest or the perception of conflicts of interest from your staff?

Answer: If confirmed, I will establish and communicate clear expectations concerning values based decision making and compliance with Federal ethics laws and regulations in an effort to prevent reports of conflicts of interest or any appearances of impropriety. I will work with the DOD and HHS designated ethics officials to identify personnel who are required to file public or confidential financial disclosure and will enforce strict compliance with filing requirements. I will work closely with OWS ethics counsel to promptly and effectively address any identified actual or potential conflicts of interest.

If confirmed, one of my first priorities will be to ensure OWS's financial disclosure program is operating properly, to include annual internal and external inspections. This will ensure we proactively identify and alleviate any actual or apparent individual conflict of interests. I will take seriously any reports of conflicts of interest or the perception of conflicts of interest involving OWS staff. I will ensure any such reports are acted upon immediately, in coordination with the OWS Senior Counsel, and that appropriate remedial, administrative or investigative action is taken. I will coordinate closely with any investigating organization to ensure full and fair understanding of the facts. When warranted, allegations will be referred to the appropriate Department or Agency for adjudication. If confirmed, I will continually emphasize the importance of public trust and use ethics training to establish a culture of ethical compliance within OWS. I will publically encourage all personnel within OWS to proactively seek out, report, and address any potential violation of our ethical duty to preserve the public trust.

<u>Acquisition, Contracting, and Funding</u>

DOD has significant capabilities in the domains of industrial expansion, contract award and administration, large procurements, and supply chain management.

50) If confirmed, how would you utilize these DOD strengths in accomplishing OWS goals and objectives?

Answer: DOD excels at procuring, transporting, and delivering items – at scale and on time – whenever an urgent need arises. Our experience in providing material for our troops has been invaluable during the current pandemic, leveraging DOD's expertise in finding alternate sources or solutions, working with industry to leverage dormant capabilities.

As an example, DOD has executed a number of activities to support COVID-19 response since the start of

this pandemic. Since March, DLA has executed over 8,000 contract actions, obligating over $752 million through the end of May, to provide critical lifesaving medical supplies including test kits, ventilators, pharmaceutical drugs, and Personal Protective Equipment (PPE) such as masks, gloves, and gowns. Additionally, DLA has supplied food, clothing, fuel, construction materials, and repair parts to DOD and government partners.

The JATF has executed $284.1 million in industrial expansion efforts during the first two weeks of May 2020, including $138 million to increase capacity for injection technology, $146 million to increase N95 respirator masks. Additional industrial base expansion efforts are also in progress.

51) What is your understanding of the current industrial capacity to support manufacturing vaccines, therapeutics, and diagnostics?

Answer: OWS is working closely with industry to ensure the capacity exists to support the objectives of OWS. Efforts are underway to increase capacity through capital investments, long term contracts and regulatory support to speed the delivery of vaccines, therapeutics and diagnostics. In the past, the U.S. has sourced many critical medical resources overseas, but there are already efforts underway to reshore those capabilities. The DOD, working with HHS, has facilitated industrial base expansion in traditional performers while also incorporating novel technologies that will be transformative in addressing the U.S. response to the COVID-19 pandemic.

52) What is your understanding of DOD's Advanced Manufacturing Facility (ADM), including its current capacity and any efforts to further expand its footprint? How will OWS utilize the ADM?

Answer: I am aware DOD has provided funding to expand capacity to the ADM facility in order to allow for production of vaccines to meet the needs of the DOD. OWS will leverage any lessons learned from the DOD ADM facility expansion and apply then to any other similar efforts.

53) If confirmed, how would you lead OWS in leveraging existing strengths and mitigating weaknesses in the current industrial capacity?

Answer: I would leverage DOD's tools and expertise in illuminating the supply chain and understanding risks and key bottlenecks. Build on existing efforts for industrial base expansion (evaluation of activities and awards already made) to include broad national policy to ensure capacity brought back to the U.S. is sustainable. Continue to support efforts to onshore critical aspects of the supply chain for vaccine, therapeutic and diagnostics development and delivery.

54) If confirmed, how would you plan to leverage ongoing efforts by the Department of Health and Human Services and DOD to expand the industrial base for vaccines, therapeutics, and diagnostics?

Answer: The DOD has worked with HHS to seek out opportunities to expand the industrial base leveraging tools such as Defense Production Act Title III and CARES Act industrial expansion authorization and appropriations. These efforts provide a strong foundation upon which the OWS team can build. OWS will continue leverage all available tools to identify and execute additional industrial expansion efforts in vaccines, therapeutics, and diagnostics with OWS.

55) If confirmed, what acquisition approach would you apply to OWS initiatives, and how would

you ensure that OWS properly identifies and manages acquisition risks?

Answer: I would use any acquisition approach that is authorized by law to accomplish OWS initiatives. Most of the initiatives will be accomplished by established contracting procedures, including use of the Economy Act when appropriate, but I will consider the use of any statute or regulation that helps in accomplishing the mission.

56) If confirmed, how would you lead OWS in coordinating and deconflicting its acquisition and contracting activities with those of the COVID-19 Joint Acquisition Task Force?

Answer: Upon nomination to serve as OWS COO, I met with the Undersecretary of Defense for Acquisition & Sustainment and Director of the JATF to evaluate roles and responsibilities to ensure synchronization of efforts. JATF has provided me and my team a number of resources – both in terms of industry market research in vaccines, therapeutics, and diagnostics, as well as access to subject matter experts. The JATF will focus on its role in supporting HHS' the Strategic National Stockpile 2.0 and, as appropriate, we will coordinate on efforts that support both the Strategic National Stockpile and OWS.

57) Given OWS' commitment to speed, what mechanisms would you establish, if confirmed, to minimize the effects on OWS of the bureaucracy normally associated with complex interagency acquisition activities?

Answer: The current environment has provided the federal government a unique opportunity to work in new ways. My colleagues within DOD, particularly within the JATF, have led the way in streamlining processes and creating efficient mechanisms to enable the Services in DOD to support acquisition efforts on behalf of HHS. Many of the JATF's efforts were utilizing existing authorities, such as the Economy Act. I plan to leverage their lessons learned and transfer as much as that knowledge as applicable to the OWS effort.

58) If confirmed, how would you ensure that key government leaders have the data and information they need to make well-grounded acquisition and contracting decisions?

Answer: If confirmed, I intend to provide complete and timely acquisition and contracting updates or authorization documentation to key leadership in order to inform acquisition decisions. I will also build integrated, interagency teams, whose purpose is to support leaders with the appropriate data and analytics to support their timely decision making processes.

A May 15, 2020 press release about OWS on the Department of Health and Human Services public website states, "[m]anufacturing capacity for selected candidates, including the three to five selected vaccines, will be advanced while they are still in development, rather than scaled up after approval or authorization, as is the case with traditional development timelines."

59) If confirmed, how would you lead OWS in mitigating the cost and schedule risk associated with concurrent vaccine development and manufacturing?

Answer: If confirmed, I acknowledge that in order to provide safe and effective vaccines to the Nation as soon as possible that we, as a Nation, will be executing production of vaccines in parallel with clinical trials. This is an acknowledged risk that if confirmed, I absolutely support. That said, if confirmed, I intend to closely monitor the success of each company through clinical trials and demonstrated ability to scale up to meet manufacturing demands. Companies who fail to meet benchmarks in clinical trials or

manufacturing scale up will be subject to review for cancelation of existing and future contracts.

The same website press release goes on to say, "[t]he federal government is making investments in manufacturing and distribution at its own risk much earlier than usual, giving firms confidence that they can invest aggressively in development of countermeasures."

60) Please describe the specific investments that the federal government is making in this regard.

Answer: It is my understanding that the OWS team will award Advance Purchase Commitments with promising vaccine developers to initiate manufacturing prior to completion of Phase 3 clinical trials. These contracts will guarantee a certain quantity of vaccine is provided to the US Government in the event clinical trials are successful. This approach has the potential to speed up delivery to the American people by many months when compared to a more serial approach to development and manufacturing. This also requires the purchase of PPE and other secondary items.

61) In what way is DOD engaged in investing in the manufacturing and distribution of COVID-19 countermeasures?

Answer: It is my understanding that, to date, the vast majority of investment has come from funding provided to the Department of Health and Human Services. We will also invest in the PPE and other secondary items required.

62) If confirmed, what would be your role, and that of OWS, in coordinating and validating such investments across the interagency?

Answer: If confirmed, I intend to use my experience and contacts to leverage and synergize all investments across the US Government and Industry. In this way we can minimize waste and maximize forward progress to delivering safe and effective countermeasures to the COVID-19 threat.

63) What challenges do you envision that OWS might face in the distribution phase of its operations?

Answer: Vaccine distribution in a pandemic environment is unique. If confirmed, I intend to maximize all potential distribution methods that have significant historical success. These methods include both public and private distribution methods used successfully in yearly influenza vaccine distribution and administration. I understand additional capabilities might be required to address the uniqueness of a government-provided vice commercially-provided vaccine. The primary challenges we will face are most likely to occur in two areas: One, we may have challenges in the velocity of product distribution; and two, we may be challenged in tracking product distribution if we rely on collecting data across multiple vendor logistics tracking systems that do not currently communicate with the CDC's vaccine ordering and tracking system.

64) If confirmed, how would you propose to leverage the expertise of the Defense Logistics Agency and Army logistics in planning for the distribution of OWS products and services?

Answer: The Defense Logistics Agency (DLA) and the Army have decades of experiencing working with industry to procure, transport, and field items in time of need. We do this for a global network of Service members and have continued to do so during this pandemic, supporting both efforts within DOD

to ensure PPE is delivered to our troops overseas and domestically, as well as the on-going effort to support HHS.

65) What is your understanding of the source and amount of federal funding that will be made available to OWS to accomplish its mission?

Answer: The primary source of funding is the Emergency Appropriations for Coronavirus Health Response and Agency Operations of the CARES Act.

66) The Coronavirus Aid, Relief, and Economic Security (CARES) Act (Public Law 116-136) provided $10.7 billion to DOD. Do you believe that the portion of this funding for diagnostics and medical research is adequate to allow OWS to meet its goals and objectives?

Answer: It is my understanding the OWS team is still assessing the cost estimates of the vaccine, therapeutics, and diagnostic developments and associated distribution and administration impacts. If confirmed, I would assess the development of vaccines, therapeutics and diagnostics and identify any shortfalls for required funding.

The same Health and Human Services website press release commits to affordability, noting that, "[a]s a condition of receiving support from OWS, companies will provide a donated allocation of countermeasures developed, including an eventual vaccine."

67) If confirmed, how would you lead OWS in holding private sector companies accountable for their contributions in this regard? If you do not view this as an OWS responsibility, to which agency or activity should this responsibility be assigned, in your view?

Answer: First, I acknowledge the need to ensure strict accountability regarding industry in this monumental task. Experimental drug development is froth with risk. I am told that only 6% of experimental drugs make it to the market and it is my goal, if confirmed, to provide the requisite government oversight and checks and balances necessary to partner with numerous industry partners in a very high-risk, high-reward environment based on the urgency at hand. I intend to ensure that contractual agreements include an attempt to minimize government risk as much as possible acknowledging the fact that we must take extraordinary risk now in order to execute the mission given to OWS.

To this end, I would maintain direct and frequent communication with CEOs of each company supported by OWS to hold companies accountable for timelines and execution. If issues are identified by the Project Coordination Teams (PCT), I would be able to go directly to the company CEO and quickly resolve the issue.

<u>Congressional Oversight</u>

68) If confirmed, how would OWS report to Congress on its progress, and with what frequency would you make such reports?

Answer: Congress is a vital partner in the all of America's responses to the ongoing COVID-19 pandemic and the legislation Congress passed will have a direct impact on the success of OWS. In recognizing this important relationship, if confirmed, OWS will commit to be transparent with Members of Congress and their staff. In order to accomplish that transparency, OWS will provide regular, reoccurring briefings or provide written updates and announcements as OWS reaches new

milestones. The offices responsible for interacting with Congress at both HHS and DOD are in close coordination to ensure we keep Members of Congress and their staff frequently updated. In fact the first of many such briefings occurred on June 16th.

In order to exercise legislative and oversight responsibilities, it is important that this committee, its subcommittees, and other appropriate committees of Congress receive timely testimony, briefings, reports, records—including documents and electronic communications, and other information from the executive branch.

69) Do you agree, without qualification, and on request, to appear and testify before this committee, its subcommittees, and other appropriate committees of Congress? Please answer yes or no.

Answer: Yes, in accordance with applicable laws and long-standing Department and Executive Branch practice.

70) Do you agree, without qualification, and when asked before this committee, its subcommittees, or other appropriate committees of Congress to give your personal views, even if those views differ from the position of the Administration? Please answer yes or no.

Answer: Yes, I commit to giving my best military advice.

71) Do you agree, without qualification, to provide this committee, its subcommittees, other appropriate committees of Congress, and their respective staffs such witnesses and briefers, briefings, reports, records—including documents and electronic communications, and other information, as may be requested of you, and to do so in a timely manner? Please answer yes or no.

Answer: Yes, in accordance with applicable laws and long-standing Department and Executive Branch practice.

72) Do you agree, without qualification, to consult with this committee, its subcommittees, other appropriate committees of Congress, and their respective staffs, regarding your basis for any delay or denial in providing testimony, briefings, reports, records—including documents and electronic communications, and other information requested of you? Please answer yes or no.

Answer: Yes, in accordance with applicable laws and long-standing Department and Executive Branch practice.

73) Do you agree, without qualification, to keep this committee, its subcommittees, other appropriate committees of Congress, and their respective staffs apprised of new information that materially impacts the accuracy of testimony, briefings, reports, records—including documents and electronic communications, and other information you or your organization previously provided? Please answer yes or no.

Answer: Yes, in accordance with applicable laws and long-standing Department and Executive Branch practice.

74) Do you agree, without qualification, and on request, to provide this committee and its subcommittees with records and other information within their oversight jurisdiction, even absent a formal Committee request? Please answer yes or no.

Answer: Yes, in accordance with applicable laws and long-standing Department and Executive Branch practice.

75) Do you agree, without qualification, to respond timely to letters to, and/or inquiries and other requests of you or your organization from individual Senators who are members of this committee? Please answer yes or no.

Answer: Yes, in accordance with applicable laws and long-standing Department and Executive Branch practice.

76) Do you agree, without qualification, to ensure that you and other members of your organization protect from retaliation any military member, federal employee, or contractor employee who testifies before, or communicates with this committee, its subcommittees, and any other appropriate committee of Congress? Please answer yes or no.

Answer: Yes, I agree to protect DOD personnel from unlawful retaliation.