

United States Senate

COMMITTEE ON VETERANS' AFFAIRS
WASHINGTON, DC 20510

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November 23, 2020

The Honorable Robert Wilkie
Secretary of Veterans Affairs
810 Vermont Ave, NW
Washington, DC 20420

Dear Secretary Wilkie,

As the COVID-19 pandemic rages on and with one pharmaceutical company reporting positive preliminary data, and another already submitting an application for Emergency Use Authorization (EUA), the Department of Veterans Affairs (VA) must be ready to act to protect the health of veterans, VA staff, and their families. VA must have a comprehensive plan in place to ensure the safe, equitable, and smooth distribution of a forthcoming COVID-19 vaccine. Currently, more than 1,000 Americans are dying each day of COVID-19 and any delay in deploying a vaccine once authorized will cost lives.

Safety and Efficacy:

First and foremost, safety must lead the way. We must listen to scientists and only push forward with distributing and administering a vaccine once our top public health and scientific officials have independently deemed it safe. A tweet from the outgoing President or political pressures should not force a vaccine into distribution before it is ready. As of now, Pfizer and Moderna have announced promising results from clinical trials of their COVID-19 vaccines, but these results have yet to be reviewed by the Food and Drug Administration (FDA). The American public, veterans, and health care workers need to be able to trust leaders at the top to review the safety and efficacy data and only move forward with a COVID-19 vaccine once it is proven safe.

Approval and Allocation:

Typically, vaccines are reviewed and approved through the FDA's Biologic License Application (BLA) process. However, during a public health emergency like the COVID-19 pandemic, the FDA can grant an EUA for the use of a vaccine before full BLA approval. On November 20, Pfizer applied for EUA status for its COVID-19 vaccine candidate, and Moderna is expected to follow suit in the coming weeks. Initial doses of any COVID-19 vaccine are expected to be limited and public health experts agree high-risk health care workers and vulnerable populations should be first in line.

VA runs the largest, integrated health care system in the country, with more than 357,000 employees serving more than 6 million veteran patients annually. VA health care workers are facing unprecedented risks day-in and day-out as they care for veterans amid this pandemic. Given the size and scope of VA's health workforce, has the Trump Administration, specifically the Department of Health and Human Services, indicated how many initial vaccine doses or what proportion of initial doses it will be allocating for VA? How will VA allocate its initial doses among staff and vulnerable veterans to ensure those at highest risk receive the vaccine first?

In the “Framework for Equitable Allocation of a COVID-19 Vaccine” developed by the National Academies of Sciences, Engineering, and Medicine (National Academies), frontline health care workers are the top priority, and would be vaccinated under “Phase 1a.” Has VA identified how many of its employees would be considered “frontline” to be vaccinated under Phase 1a under the National Academies’ framework? Overall, who will make vaccine allocation decisions within VA? Will decisions be made at the national level, at the VISN level, or at the medical center level? When and how will VA communicate the allocation and prioritization plans to its staff, veterans, Congress, and the public?

Vulnerable Veterans:

Under the National Academies’ vaccine allocation framework, Phase 1b of vaccine distribution would include older adults living in congregate settings (e.g. nursing homes, long-term care facilities, homeless shelters) and people of all ages with pre-existing health conditions that put them at significantly higher risk of severe COVID-19 disease or death. The population VA serves is much older and has more comorbid conditions than the general population. More than 105,000 veterans receive institutional, long-term care directly from, or paid by, the Department annually. How will VA ensure all veterans receiving VA-funded long-term care – in VA-run Community Living Centers, state-run State Veterans Homes, or privately-run Community Nursing Homes – receive the COVID-19 vaccine in a timely manner? Will veterans living in State Veterans Homes and Community Nursing Homes receive their COVID-19 vaccine through their state’s COVID-19 vaccination program, or through VA?

VA must also ensure adequate outreach to veterans experiencing homelessness and provide them with necessary vaccination services. In addition, almost half of veterans using VA health care services – about 4.2 million – are aged 65 and over, and many have pre-existing conditions putting them at higher risk for contracting the coronavirus or needing hospitalization. Due to these factors, VA may need more doses of a COVID-19 vaccine earlier than other providers due to the many vulnerable veterans that the Department serves and the risk COVID-19 poses to them. Is the higher number of vulnerable veterans – as compared to the non-veteran population – being taken into account as the Trump Administration determines how many doses to allocate to VA?

Equitable Distribution:

The current COVID-19 surge is hitting rural areas of the U.S. particularly hard. While urban cores have more cases overall, rural communities are experiencing higher cases and deaths per capita, and local hospitals are being overwhelmed. To what extent will VA prioritize current “hot spot” areas when determining allocation of COVID-19 vaccine doses? This could include daily new cases, cases per capita, hospital capacity levels, and more. Further, how will VA ensure veterans living in rural areas receive equitable access to a vaccine? In particular, there are concerns about transporting and storing the leading vaccine candidates from Pfizer and Moderna, which need to be stored at -94 °F and -4 °F, respectively. How will VA secure the refrigeration and transport equipment needed to safely ship and stock potential COVID-19 vaccine doses at rural locations? This is especially paramount as the COVID-19 pandemic takes hold in rural America.

In addition, a September 2020 study by VA researchers (CT Rentsch et al) found that Black and Hispanic veterans were twice as likely to test positive for COVID-19 as white veterans. This mirrors trends from the rest of the country, where Black, Hispanic, and Native American communities have experienced higher COVID-19 transmission and mortality rates than their white counterparts. Given the striking disparities in how the pandemic has affected people of color and minority veterans, how will VA ensure that veterans from minority racial/ethnic groups receive timely, equitable access to a COVID-19 vaccine?

Trust and Misinformation:

Developing a safe, effective COVID-19 vaccine is no easy task. However, making sure all Americans feel comfortable being vaccinated in order to provide population-level protection from the virus is the next big hurdle. There is growing fear about the potential effectiveness of a COVID-19 vaccine if people have concerns about the safety of the immunization and avoid being vaccinated. Public health campaigns combatting misinformation and building trust in a potential vaccine to reassure veterans, VA staff, and their families would go a long way to meeting the goal of a widely vaccinated population. How is VA soliciting feedback from veterans and conducting outreach with Veterans Service Organizations, local communities, and other stakeholders to communicate effectively the benefits and potential side effects or risks of a COVID-19 vaccine?

Federal, State, and Tribal Partners:

At a recent briefing for Committee staff, Department leadership mentioned VA plans to provide COVID-19 vaccinations for mission-critical Department of Homeland Security employees. Given VA's Fourth Mission role in times of national emergency, does the Department anticipate providing COVID-19 vaccination services for any other Federal agencies, states/localities, or tribes? For example, VA has provided Fourth Mission assistance to the Indian Health Service, State Veterans Homes, and others throughout the COVID-19 crisis. How does VA see its role in the overall national COVID-19 vaccine distribution effort?

Planning:

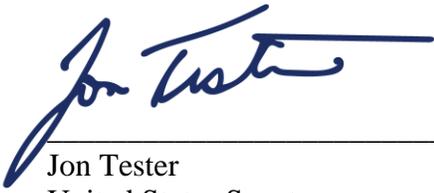
For COVID-19 vaccine distribution to succeed there must be a well-organized plan to meet the needs of all veterans and their providers. I understand VA is developing a draft plan on COVID-19 vaccine allocation and distribution, but that it is not ready for release to Congress or the public yet. Given all 50 states already had to submit their COVID-19 vaccine plans to the Centers for Disease Control and Prevention (CDC) in mid-October and the CDC already released their COVID-19 Vaccine Program Interim Playbook on October 29, I am concerned VA is behind the curve. If the states and other Federal agencies have already publicly released their plans, why is VA lagging behind? When will VA's COVID-19 vaccine plan be available and released to Congress and the public?

In conclusion, the progress made in developing a COVID-19 vaccine is a testament to the hard work of dedicated scientists and a significant investment of taxpayer dollars. VA needs to take steps to swiftly develop and release its own COVID-19 vaccine strategy, ensure equitable allocation and meet the needs of staff and veterans, combat vaccine misinformation, and strengthen cross-government and community partnerships. Veterans and staff need to feel safe

receiving any future COVID-19 vaccine, and this vaccine should be administered at no-cost to them.

While the incoming Biden-Harris Administration is just a few months from taking office, the COVID-19 pandemic is still causing unprecedented sickness and death in our communities. Veterans and VA staff can't afford to wait until January 20 for a COVID-19 vaccine plan. The Department needs to take action now to ensure the health and safety of veterans, staff, and their families during this pandemic. Thank you for your attention to this important issue.

Sincerely,



Jon Tester
United States Senator



Richard Blumenthal
United States Senator



Mazie K. Hirono
United States Senator



Sherrod Brown
United States Senator

cc: The Honorable Alex M. Azar