Johnson & Johnson Single-Dose COVID-19 Vaccine

There are currently two approved vaccines being used in the United States, Pfizer/BioNTech and Moderna, both of which require two doses. A third one-dose vaccine from Johnson & Johnson (J&J) is expected to be approved in the coming days.

At this time, the Delaware Division of Public Health (DPH) recommends that the decision to get vaccinated should be based on availability of vaccine, regardless of type. DPH will not target specific populations for specific vaccine type. DPH's goal is to provide vaccines to the greatest number of people in the shortest timeframe. DPH supports that the choice of a vaccine will be determined at the discretion of the individual or designee (e.g., employer, enrolled provider). DPH will continue to collaborate with enrolled providers and the public on the allocation and administration of all available COVID-19 vaccines in the state and will review further recommendations from the CDC Advisory Committee on Immunization Practices regarding the single-dose vaccine.

This position statement is based on the following:

1. J&J has submitted its COVID-19 vaccine to the Food and Drug Administration (FDA) for Emergency Use Authorization (EUA).

2. J&J's EUA submission is based on topline efficacy and safety data from the Phase 3 ENSEMBLE clinical trial, demonstrating that the investigational single-dose vaccine—a weakened and modified adenovirus vector containing the gene to the SARS-CoV-2 spike protein—met all primary and key secondary endpoints.

3. The ENSEMBLE trial has suggested that the vaccine candidate is 72% effective in the US and 66% effective overall at preventing moderate-to-severe COVID-19, 28 days after vaccination. ENSEMBLE also demonstrated the vaccine candidate to be 85% effective overall in preventing severe disease and 100% effective against COVID-19 related hospitalization and death as of day 28 following immunization.

4. While overall efficacy data appears to be lower, the J&J vaccine is 100% protective against hospitalization and death and is consistent with public health goals of protecting and promoting the general welfare while mitigating the effects of the COVID-19 pandemic on hospital and health care infrastructure.

5. No significant differences in adverse events and/or safety data have been reported between the J&J vaccine and the two currently available vaccines.

6. Although the approval of the J&J vaccine candidate is expected to increase the number of vaccine doses delivered to states for allocation and administration, vaccine availability remains extremely constrained with allocation and distribution controlled through the federal government.

7. The J&J vaccine candidate offers logistical and operational benefits over the two currently available vaccines, including single-dose administration and transport and storage simplicity. Such benefits may make the J&J vaccine ideal for certain settings where cold storage is not available and/or where second dose administration is less likely to occur.

8. At this time, DPH has determined that all vaccines will continue to be offered equally to all eligible populations, however operational considerations or logistical requirements may prompt distribution of one vaccine over another.