

# Consideration of Johnson & Johnson vaccine efficacy and safety

Western States Scientific Safety Review Work Group

Louis J. Picker, M.D.

Professor and Associate Director  
Vaccine and Gene Therapy Institute  
Oregon Health & Science University



# March 1 Evaluation of EUA Decision

## Conclusions/Recommendations:

1. J&J COVID-19 vaccine safe and effective; use in our states will lead to reduced severe/critical COVID-19 illness/hospitalizations/deaths
  - particularly noted demonstrated efficacy against “variants of concern”
2. The “single dose” nature of the vaccines and its stability at normal refrigerator temperatures offers significant advantages in providing COVID-19 vaccine immunity to rural and other limited resource communities.
3. Emphasized the need for continued close monitoring of vaccine safety.

# April 23 Safety Review

1. Thrombosis w/thrombocytopenia syndrome (TTS) with central venous sinus thrombosis (CVST)
  - 15 cases reported after 8 million doses (3 deaths; 7 hospitalized) – 1.9/million
  - Cases occurred in women (18-49 years old) = 7/million
  - Highest rate in 30-39 year olds = 11.8/million
2. Context – CVST background
  - CVST with thrombocytopenia ~1/million; CVST w/o thrombocytopenia ~20/million; CVST with hospitalized COVID-19 pts ~40/million
  - Motor vehicle deaths: ~47/million women; 90/million men
3. Modeling TTS risk vs. vaccine protection in “moderate” pandemic (per million vaccinations over 6 months period; direct and indirect benefits)
  - ~3-4 TTS
  - ~100 COVID-19 deaths; ~215 ICU admissions

# April 24 Western States Scientific Safety Review Work Group Review

## Conclusions/Recommendations:

1. J&J COVID-19 vaccine deemed to be generally safe and effective and that resumption of its use is warranted once appropriate patient and provider educational materials are available.
  - Noted that modeling indicates that resumption of J&J COVID-19 vaccine use would yield very large net public health benefit by preventing severe COVID-19 illness/deaths at the cost of a small number of serious adverse events
2. Work Group continued to emphasize importance of vaccine safety monitoring systems.