### CDC Announcement August 18, 2021

(This announcement was made previous to the FDA approval announced August 23)

## Media Statement from:

CDC Director (Dr. Rochelle P. Walensky, MD, MPH)
FDA Acting Commissioner (Dr. Janet Woodcock)
US Surgeon General (Dr. Vivek Murphy)
Director NIH (Dr. Francis Collins)
Director NIAID (Dr. Anthony Fauci)
Asst. Secretary for Health (Dr. Rachel Levine)
Chief Science Officer (Dr. David Kessler)
Chair of COVID-19 Health Equity Task Force (Dr. Marcella Nunez-Smith)

# Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots

https://www.cdc.gov/media/releases/2021/s0818-covid-19-booster-shots.html

## Article highlights:

- The available data make very clear that protection against SARS-CoV-2 infection begins to decrease over time following the initial doses of vaccination
- The current protection against severe disease, hospitalization and death could diminish in months ahead, **esp. among those who are at higher risk** or **were vaccinated during the earlier phases of the vaccination rollout** (i.e. many health care providers, nursing home residents, and other seniors, will likely be eligible for the booster).
- We are prepared to offer booster shots for all Americans beginning the week of September 20 and starting 8 months after an individual's second dose. (For many SHSST community members, this would be November 2021 as our second dose clinic was Mar 22, 2021)
- We have developed a plan to begin offering these booster shots this fall **subject to FDA** conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer and Moderna mRNA vaccines.

#### Takeaways:

- The media announcement is not definitive . The article is saying that 'it is preparing to issue guidance on giving booster doses to fully vaccinated people'
- Read '<u>What about people with adequate immunity that is waning</u>?' (in the article 'US CDC recommends third dose of Pfizer and Moderna COVID-19 vaccines for immunocompromised people' Aug 23, 2021)
  - US CDC distinguishes between a third dose for people who may not have developed adequate protection and a booster dose for fully vaccinated people with waning antibody responses.

In a <u>separate announcement last, week, US CDC and other US health authorities</u> said **that it was preparing to issue guidance** on giving booster doses to fully vaccinated people who received the Pfizer or Moderna vaccines, subject to review of the scientific evidence. US CDC says the number of breakthrough infections with the delta SARS-CoV-2 variant, together with evidence of

waning antibody levels in people vaccinated more than eight months ago, may justify offering a third dose more widely.

However, <u>some experts disagree</u>, saying that the decision is premature and arguing that increasing vaccine coverage in the United States will do more to reduce overall spread of the delta variant.

- With the recent FDA approval of the Pfizer vaccine on 8/23/2021, it does seem more likely than not that the White House will make a definitive statement soon at least for the Pfizer vaccine.
- At the time of this email, neither Moderna or J&J have submitted their FDA authorization requests yet.
- The email below speaks to the modification of the mRNA vaccine Emergency Authorization Use (EUA) for a third dose, and only for very specific populations.