COVID-19 Vaccines – HHS Statement on Booster Doses

- On August 18, 2021, multiple health care leaders from the U.S. Department of Health and Human Services (HHS) issued a joint statement about upcoming plans for COVID-19 vaccine booster doses. Key elements of the announcement include the following:

  — The COVID-19 vaccines have been effective in reducing the risk of severe disease, hospitalization, and death due to COVID-19.
  — Protection is expected to wane over time and a booster shot will be needed to maximize vaccine-induced protection and prolong its durability.
  — HHS has developed a plan to begin offering booster doses in fall 2021.
  — The HHS plan is subject to FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer-BioNTech and Moderna mRNA vaccines and CDC's Advisory Committee on Immunization Practices (ACIP) issuing booster dose recommendations based on a thorough review of the evidence.

- On August 12, 2021 the FDA expanded the Emergency Use Authorization (EUA) to provide for a third dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccines for certain immunocompromised individuals, notably solid organ transplant recipients or individuals with conditions that are considered to have an equivalent level of immunocompromise. The FDA has not yet authorized booster does of COVID-19 vaccines for the general population.

- Before booster doses of the COVID-19 vaccines can be implemented for the general population, the FDA must authorize the expanded use and the CDC's ACIP panel will review the evidence and issue recommendations as they have done throughout the COVID-19 pandemic. The FDA is still reviewing data on boosters and has not yet revised the EUA. However, ACIP has a meeting scheduled for August 24, 2021 and more details may come forward after that meeting.

- It is important to recognize that the pandemic response related to booster doses includes logistical planning to ensure rapid rollout if booster doses are warranted. Today's announcement signals that HHS is gearing up for such a response. However, the FDA and ACIP must still evaluate the evidence and determine if boosters are safe and effective before they will be widely available for the general population