Pfizer/BioNTech COVID-19 vaccine, bivalent – Additional dose(s) in 6 months – 4 years with immunocompromise

- On April 28, 2023, the FDA authorized the following uses of the Pfizer/BioNTech COVID-19 vaccine, bivalent for individuals 6 months through 4 years of age with certain types of immunocompromise who have previously received three 0.2 mL doses (Pfizer/BioNTech COVID-19 vaccine or Pfizer/BioNTech COVID-19 vaccine, bivalent):
    - A fourth dose administered at least 1 month following the most recent dose;
    - Additional doses that may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

- Per the FDA, based on available safety and immunogenicity data from post-authorization experience with additional doses of mRNA vaccines in immunocompromised adults, it is reasonable to conclude a favorable benefit-risk balance in these individuals.

- The FDA stated in its updated emergency use authorization (EUA) letter that a fourth bivalent dose in this patient population, as well as additional doses, may be effective in preventing serious or life-threatening disease or conditions that can be caused by SARS-CoV-2, including Omicron variant sublineages BA.4/BA.5 and other Omicron subvariants such as XBB.1.5.

What's Next:

- Once the Centers for Disease Control and Prevention's (CDC) Director accepts and recommends the new dosing information, updated guidance will be posted on the CDC website located here. There are no plans at the moment for the CDC's Advisory Committee on Immunization Practices (ACIP) to discuss the updated indication.