Bivalent mRNA COVID-19 vaccines – ACIP discusses transitioning to bivalent primary series

- On February 24, 2023, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) supported (they did not vote) harmonizing the vaccine strain composition for mRNA COVID-19 vaccines across both the primary series and booster doses.
    - The current recommendation for people ages 6 months and older is a primary series of two monovalent vaccines followed by a bivalent booster dose (in most ages). For children 6 months to 4 years of age who start a Pfizer/BioNTech primary series, the third dose in a 3-dose primary series is a bivalent dose.
    - The future proposed recommendation for people ages 6 months and older is a primary series of two bivalent vaccines followed by a bivalent booster dose (in most ages).

- The ACIP's discussion follows the recommendation of the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) on January 26, 2023. VRBPAC voted unanimously in favor of harmonizing the vaccine strain composition of primary series and booster doses used in the U.S. to a single composition, meaning that the composition for all vaccines would be a bivalent vaccine (ie, Original strain plus Omicron BA.4/BA.5 strain).

- The FDA still needs to authorize the change either by changing the current emergency use authorizations (EUAs) or by approving new biologic license applications (BLAs) for the vaccines.
    - Pfizer/BioNTech has already submitted for approval of their Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine as a primary series and booster dose(s) for individuals 12 years of age and older. The expected FDA approval date is still to be determined.

- ACIP also discussed the number of vaccines needed by different groups on a yearly basis. ACIP felt that one vaccine per year is still appropriate for all age groups and for immunocompromised individuals.