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COVID-19 vaccines – FDA advisors discuss composition of vaccines for booster doses in the Fall 2022

- Experts are increasingly recognizing the rapid evolution of the SARS-CoV-2 virus with recent wave caused by variants that are related to but distinctly different from the original strain of the virus. This shift is prompting consideration of revising the existing vaccines to retain immune protection if the pandemic continues to persist as expected.

- On June 28, 2022, the Food and Drug Administration (FDA) convened a Vaccine and Biologic Products Advisory Committee (VRBPAC) to discuss and make recommendations for the inclusion of a SARS-CoV-2 Omicron component for COVID-19 booster vaccines in the U.S. The FDA will have to approve emergency use authorizations (EUA) for updated vaccines containing Omicron component prior to manufacturers rolling out the updated vaccines.

    - The SARS-CoV-2 Omicron variant has become dominant in the U.S., poses a higher risk of re-infection than previous virus strains, and continues to evolve into new sub-lineages (eg, BA.4, BA.5).
    - Moderna stated they could have Omicron variant booster vaccines available in August/September (bivalent vaccine with prototype + BA.1) and late October/early November (BA.4/BA.5).
    - Pfizer stated they could have Omicron variant booster vaccines available in the first week of October (both BA.1 and BA.4/BA.5).
    - If EUA is granted, Novavax stated they could have prototype primary vaccines available in July 2022 and Omicron variant booster vaccines (both BA.1 and BA.4/BA.5) by the 4Q2022.

- There is limited data available from Moderna and Pfizer about using bivalent (prototype + Omicron) booster vaccines and monovalent (Omicron only) booster vaccines with activity against the Omicron variant. Preliminary data has been released by both manufacturers showing superior neutralizing titers and non-inferiority for seroresponse rates with the Omicron containing vaccines vs. the prototype (original formulation) vaccines.

- Novavax has a pending EUA request for their prototype vaccine and is currently conducting a clinical study using an Omicron booster vaccine.

- There was discussion about the lack of data regarding safety (eg, myocarditis risks), additional cellular protection (eg, T-cell immunity), and children for the Omicron containing vaccines.

- The Committee felt the bivalent vaccine rather than a monovalent vaccine should be utilized as a booster after a primary series because it is likely to provide the broadest coverage and immunity against future variants. They also felt the strain change should include the BA.4/BA.5 variant rather than the BA.1 variant.

- The Committee voted 19 to 2 to recommend inclusion of a SARS-CoV-2 Omicron component for COVID-19 booster vaccines in the U.S.

What's Next?

- The FDA will review the recommendations of the VRBPAC and make recommendations for vaccine composition.

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- Manufacturers of COVID-19 vaccines will submit their data for booster dose vaccines with the recommended composition to the FDA. FDA will review the submissions and issue an EUA if appropriate.
- If the FDA approves EUAs for new booster dose vaccine composition, then the CDC will convene its Advisory Committee for Immunization Practices (ACIP) to review and make recommendations for who should receive this vaccine.