COVID-19 Vaccines – FDA Advisors Discuss Vaccine Boosters

- On September 17, 2021, the Food and Drug Administration convened a Vaccine and Biologic Products Advisory Committee (VRBPAC) to discuss expanding the indication for Pfizer's COVID-19 vaccine Comirnaty®. Pfizer is seeking FDA approval of a 3rd dose of Comirnaty administered 6 months after the initial 2-dose series, in individuals ages 16 years and above. The OptumRx Pipeline team attended the virtual VRBPAC meeting and below are some key take-aways from the event.

- To support the expanded indication, Pfizer presented results of a sub-study from their pivotal trial for Comirnaty, in which 306 individuals received a booster dose of 6 months after completing their initial vaccination series.

    - The sub-study met the pre-specified endpoint of boosting immunity to levels similar to the original series.
    - The safety profile following the booster dose, was similar to the safety profile observed following the initial series.
    - The study was conducted in individuals 18 to 55 years old, and the FDA and Pfizer believe the results could be extrapolated to younger individuals (16-17 years) and older (older than 55 years).

- The 18 VRBPAC members discussed the study findings and the current state of vaccination against COVID-19; when asked to vote on approving a 3rd Comirnaty booster dose for the general population, 16 members voted against approval vs 2 in favor of approval. Among the major concerns leading to the negative vote were:

    - Small sample size: The data base of safety/efficacy (306 individuals) is on the smaller side of data typically used to approve booster doses.
    - Extrapolation to younger and older groups: Many were not comfortable with extrapolating the findings to other groups, especially to the younger population (16 – 17 years old).
    - Myocarditis: Little is known about the risk of myocarditis with the 3rd dose. The risk of myocarditis is higher in young males, and more data is needed to better understand the risk vs benefit before the Committee could endorse widespread use of a 3rd dose in this group.
    - Even though immunity to COVID-19 illness appears to wane with time, vaccine effectiveness against hospitalization and death due to COVID-19 remain very high.
    - Booster does not address the unvaccinated issue: Some committee members expressed concern that the primary factor driving the pandemic is the unvaccinated and that a booster for those already vaccinated will not meaningfully improve the overall public health picture.

- After the negative Committee vote, the FDA posed a second question asking if the VRBPAC would support expanding the emergency use authorization (EUA) for Comirnaty to include administration of a 3rd dose (booster) at least 6 months after completion of the primary series for use in individuals 65 years of age and older and individuals at high risk of severe COVID-19, including healthcare workers and others at high risk for occupational exposure. The committee voted unanimously in favor of this revision to the EUA, instead of full FDA approval of expanding the indication.

    - Emergency Use Authorization can be modified or rescinded at any point by the FDA and provides more regulatory flexibility while the data evolves. Expanding the EUA opens up access for boosters for those at highest risk while preserving the ability to make other changes rapidly based on new data.
    - FDA has not yet officially updated the EUA to include the booster dose but is expected to do so sometime this week.

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- Previously, on August 12, 2021 the FDA expanded the Emergency Use Authorization to provide for third dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccines for certain individuals immunocompromised individuals, notably solid organ transplant recipients or individuals with conditions that are considered to have an equivalent level of immunocompromise.

- 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 has not yet revised the EUA. However, ACIP has announced two COVID-19 meetings for September 22, and 23rd. The OptumRx Pipeline Team plans to attend these meetings and will provide an update after that meeting.

- COVID-19 vaccine information is changing rapidly. Pfizer today released data on a COVID-19 vaccine for children ages 5 – 11 years old, using a lower dose but achieving immunity similar to Comirnaty in individuals 16 to 25 years old. Moderna is in the process of submitting data to the FDA to support booster doses of their COVID-19 vaccine mRNA-1273.