COVID-19 Vaccines – FDA Advisors Discuss Vaccine Boosters and Future COVID-19 Vaccine Strain Selection

- On April 6, 2022, the Food and Drug Administration (FDA) convened a Vaccine and Biologic Products Advisory Committee (VRBPAC) to discuss considerations for use of COVID-19 vaccine booster doses and the process for COVID-19 vaccine strain selection to address current and emerging variants. The OptumRx Pipeline team attended the virtual VRBPAC meeting. VRBPAC was asked to discuss key principles of vaccine development without any specific voting or determinations.

- The current vaccines are based upon the original strain of the COVID-19 virus and the virus has demonstrated an ability to rapidly change (approximately 5 times faster than influenza) such that the existing vaccines does not match up well against the current BA.1 and BA.2 subvarianst of Omicron and may be even less well matched for future variants expected in the fall.

    - Current vaccines and boosters are still effective in preventing severe disease.
    - Immunity wanes with the existing vaccines and boosters and every four-month boosting is not a sustainable strategy for the long term.

- There was recognition that a new process is needed to coordinate development of the next generation of vaccines to prepare for the next phase of the pandemic.

- Considerable discussion involved leveraging the approach for seasonal influenza vaccines, but influenza is well understood and has a defined seasonality whereas SARS-CoV-2 is less defined and has not yet demonstrated a specific seasonal pattern.

- Today's meeting was the first step toward developing a process and more developments will come in the next few months. However, there are a few key elements that had broad VRBPAC support:

    - A unified approach to vaccine production should be implemented where all vaccines should contain the same viral strains.
    - Next generation vaccines should provide the broadest coverage possible to address a wide variety of potential variants. A new vaccine may involve a multi-valent approach, rather than the current single-valent approach.
    - FDA will coordinate the variant strain selection with the VRBPAC as it is does with influenza vaccines but with additional dialog with other federal agencies (eg, CDC, BARDA) and the World Health Organization, as well as with pharmaceutical companies.
    - The focus of vaccine development should be the prevention of hospitalization and death.

- More information and dialog are expected in the future.