Advisory Commission on Childhood Vaccines (ACCV) update

(March 2023 – August 2023)

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Workshop

27 April: In collaboration with BARDA, FDA conducted a workshop on Recombinant Protein-Based COVID-19 Vaccines. The goals of the workshop were to provide: 1) a forum for product sponsors to discuss progress and technical challenges in the manufacturing when changing strain composition to currently circulating variants of SARS-CoV-2; and 2) an open forum for collaborative discussions to facilitate advancement of recombinant protein-based COVID-19 vaccines.

Moderna and Pfizer-BioNTech COVID-19 Vaccines

14 March: emergency use authorization of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to provide for a single booster dose of the vaccine in children 6 months through 4 years of age at least 2 months after completion of primary vaccination with three doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine.

18 April: emergency use authorization of the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for all doses for individuals 6 months of age and older. This action simplifies the vaccination schedule for most individuals.

28 April: 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.

Janssen Biotech COVID-19 vaccine

22 May: Janssen Biotech, Inc. requested the voluntary withdrawal of the emergency use authorization (EUA) of the Janssen COVID-19 Vaccine. Janssen Biotech, Inc. informed the FDA that the last lots of the vaccine purchased by the U.S. Government have expired, there is no demand for new lots of the vaccine in the U.S., and they do not intend to update the strain composition of this vaccine to address emerging variants. On June 1, 2023, FDA revoked the EUA for this vaccine.

Prevnar 20

27 April: approved Prevnar 20, for the following indications and use:

for the prevention of invasive disease caused by the 20 different serotypes of *Streptococcus pneumoniae* contained in the vaccine for individuals 6 weeks through 17 years of age; and for the prevention of otitis media (ear infection) caused by 7 of the serotypes of *Streptococcus pneumoniae* contained in the vaccine for children 6 weeks through 5 years of age.

Prevnar 20 was initially approved by FDA in 2021 for the prevention of pneumonia and invasive disease caused by the 20 different Streptococcus pneumoniae serotypes contained in the vaccine for individuals 18 years of age and older.

Cyfendus

20 July: approved Cyfendus, a vaccine for post-exposure prophylaxis of disease following suspected or confirmed exposure to Bacillus anthracis (anthrax) in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs.

Ervebo

27 July: approved Ervebo, a vaccine for the prevention of Ebola virus disease caused by Zaire ebolavirus in individuals 12 months through 17 years of age. Ervebo has been approved for use in individuals 18 years of age and older since December 2019. Cases of Ebola are very rare in the U.S., and those that have occurred have been the result of infections acquired by individuals in other countries who then traveled to the U.S., or health care workers who became ill after treating patients with Ebola.

Respiratory syncytial virus (RSV) vaccines

3 May: approved Arexvy, the first RSV vaccine approved for use in the United States. Arexvy is approved for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older.

31 May: approved Abrysvo, the second RSV vaccine approved for use in the United States. Abrysvo is approved for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older.

21 August: approved Abrysvo, the first vaccine approved for use in pregnant individuals to prevent lower respiratory tract disease and severe lower respiratory tract disease caused by RSV in infants from birth through 6 months of age. Abrysvo is approved for use at 32 through 36 weeks gestational age of pregnancy.

VRBPAC meetings

15 June: meeting of the Vaccines and Related Biological Products Advisory Committee to discuss and make recommendations on the selection of strain(s) to be included in the 2023-2024 COVID-19 vaccines for use in the United States.

FDA COVID-19 Website

- FDA has a website dedicated to its COVID-19 activities, including FDA's pandemic response activities pertaining to vaccines, testing, therapeutics, and devices. The website is frequently updated and is a resource for the public, including healthcare providers and industry. https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

Questions?

The opinions expressed herein – *especially in response to questions* – are an informal communication and represent my best judgment. These comments/responses do not bind or obligate FDA.