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U.S. FOOD & DRUG ADMINISTRATION

Introduction

187th Vaccines and Related Biological Products Advisory Committee Meeting

David C. Kaslow, M.D.
Director, Office of Vaccines Research and Review/CBER/FDA
10 October 2024

187th VRBPAC Meeting Topics

Topic I: Discuss the Strain Selection for the Influenza Virus Vaccines for the 2025 Southern Hemisphere Influenza Season.

Topic II: Discuss Pandemic Preparedness for Highly Pathogenic Avian Influenza Virus Including Considerations for Vaccine Composition for (H5) Vaccines.

Topic III: Overview of research programs in the Laboratory of Pediatric & Respiratory Viral Diseases (LPRVD) and the Laboratory of DNA Viruses (LDNAV) in the Division of Viral Products (DVP | OVRR | CBER).

Topic I: Discuss the Strain Selection for the Influenza Virus Vaccines for the 2025 Southern Hemisphere Influenza Season.

- Introduction to Seasonal Influenza Vaccine Strain Selection Southern Hemisphere 2025
  - Dr. Jerry Weir, FDA
- CDC: Global Seasonal Influenza Virus Surveillance and Characterization
  - Dr. Rebecca Kondor, CDC
- Open Public Hearing
- Committee Discussion, Recommendations, and Voting

Topic I: Discuss the Strain Selection for the Influenza Virus Vaccines for the 2025 Southern Hemisphere Influenza Season.

Voting Questions

1. For the composition of egg-based trivalent 2025 SH formulations of influenza vaccines, does the committee recommend:
   - Inclusion of an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
   - Inclusion of an A/Croatia/10136RV/2023 (H3N2)-like virus; and
   - Inclusion of a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

2. For quadrivalent 2025 SH formulations of influenza vaccines, does the committee recommend:
   - Inclusion of a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus as the 2nd influenza B strain in the vaccine.

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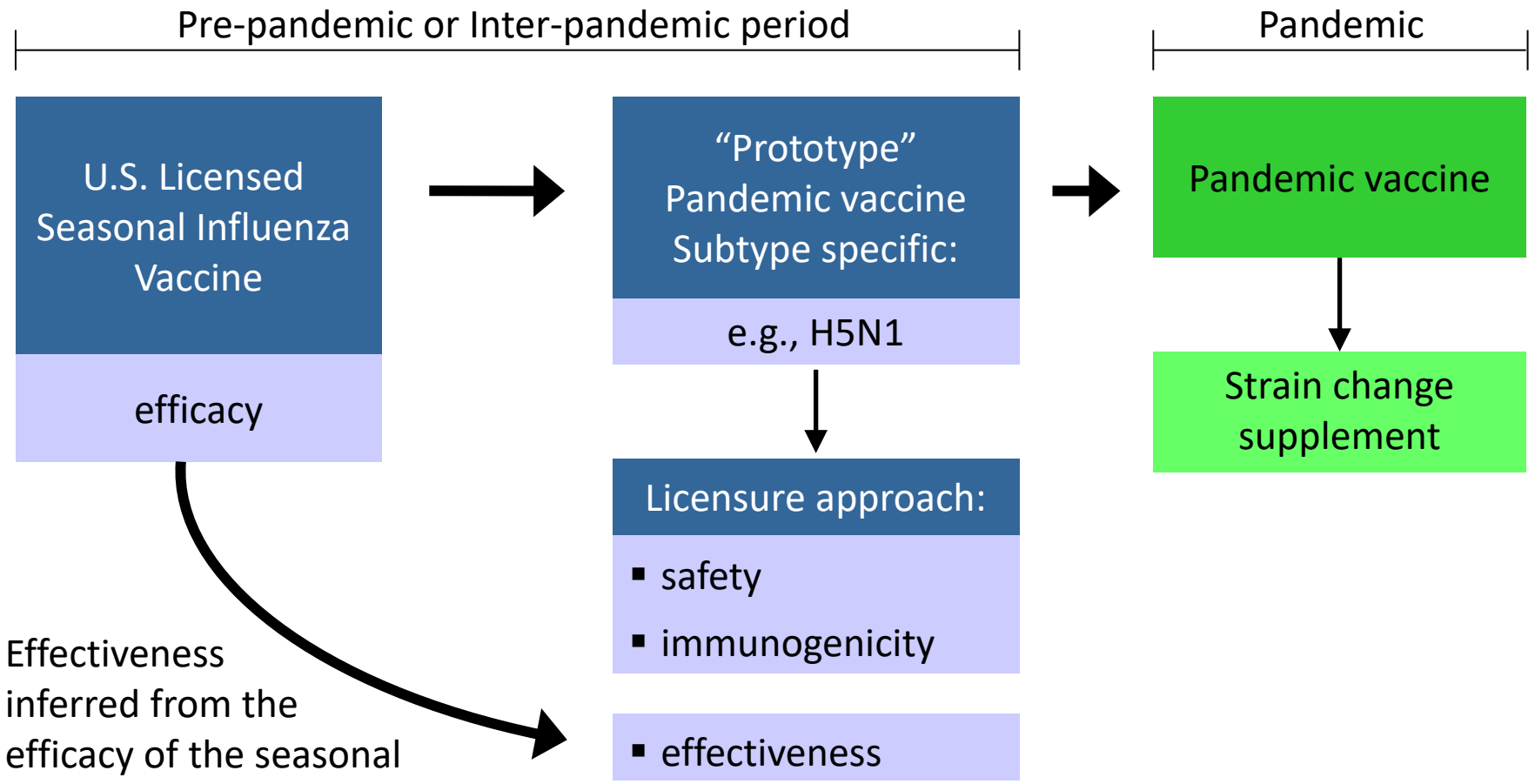
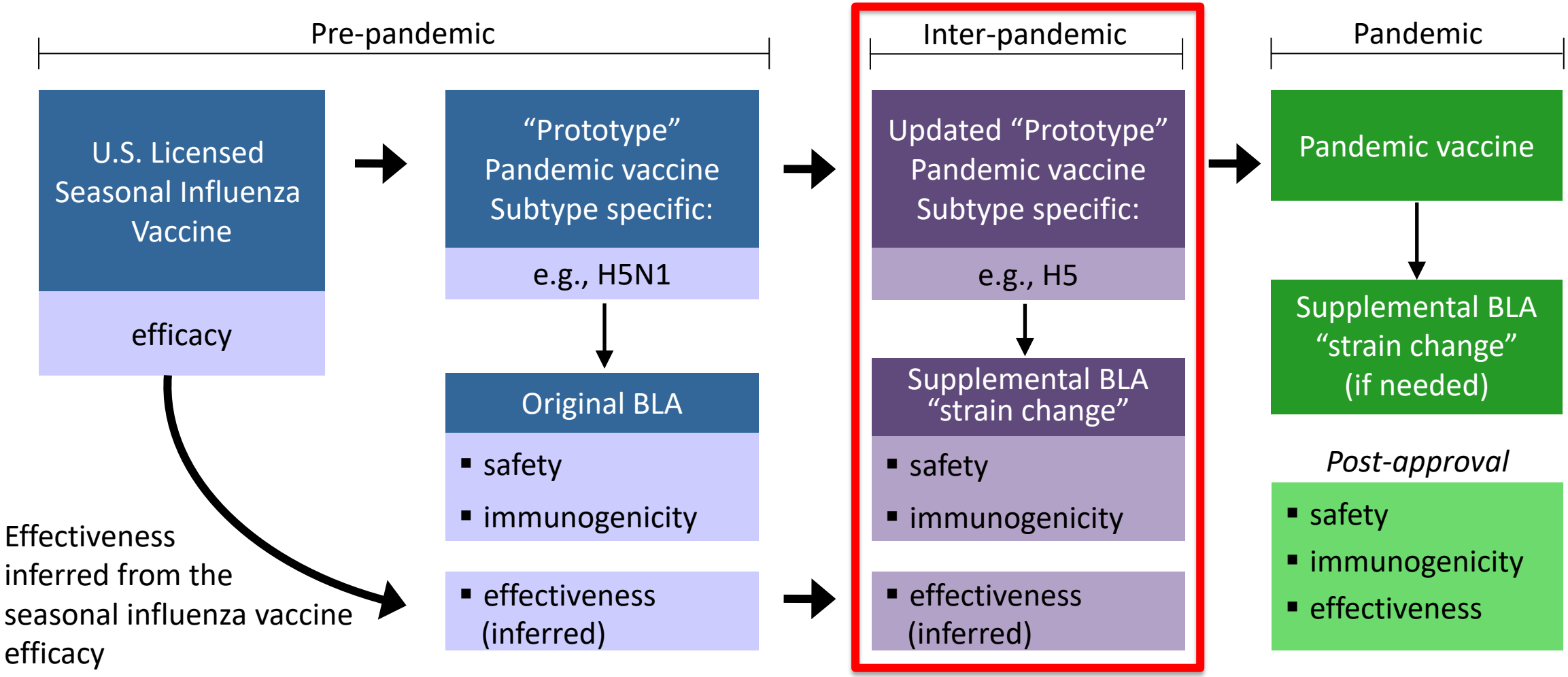
Strain Change Process (circa 2016)



Topic II: Discuss Pandemic Preparedness for Highly Pathogenic Avian Influenza Virus Including Considerations for Vaccine Composition for (H5) Vaccines.

Proposed Inter-Pandemic Period Strain Change Process



Topic II: Discuss Pandemic Preparedness for Highly Pathogenic Avian Influenza Virus Including Considerations for Vaccine Composition for (H5) Vaccines.

- Call to Order
  - Dr. Hana El Sahly
- Introduction to Highly Pathogenic Avian Influenza (H5) Virus Vaccines
  - Dr. Jerry Weir
- CDC: Highly Pathogenic Avian Influenza A(H5Nx) Virus Surveillance and Characterization in the United States and Globally and Recommendations for Candidate Vaccine Virus Development
  - Dr. Todd Davis
- BARDA's Pandemic Influenza Preparedness and Response Program
  - Dr. Christine Oshansky
- Open Public Hearing
- Committee Discussion

Topic II: Discuss Pandemic Preparedness for Highly Pathogenic Avian Influenza Virus Including Considerations for Vaccine Composition for (H5) Vaccines.

Discussion Topics

- Please discuss and provide input on the proposed strain change process during the inter-pandemic period.
- Please discuss whether a change to the current composition of licensed prototype vaccines using the proposed process is needed for preparedness purposes and whether candidate vaccine viruses are available that are appropriate to update currently licensed prototype vaccines.

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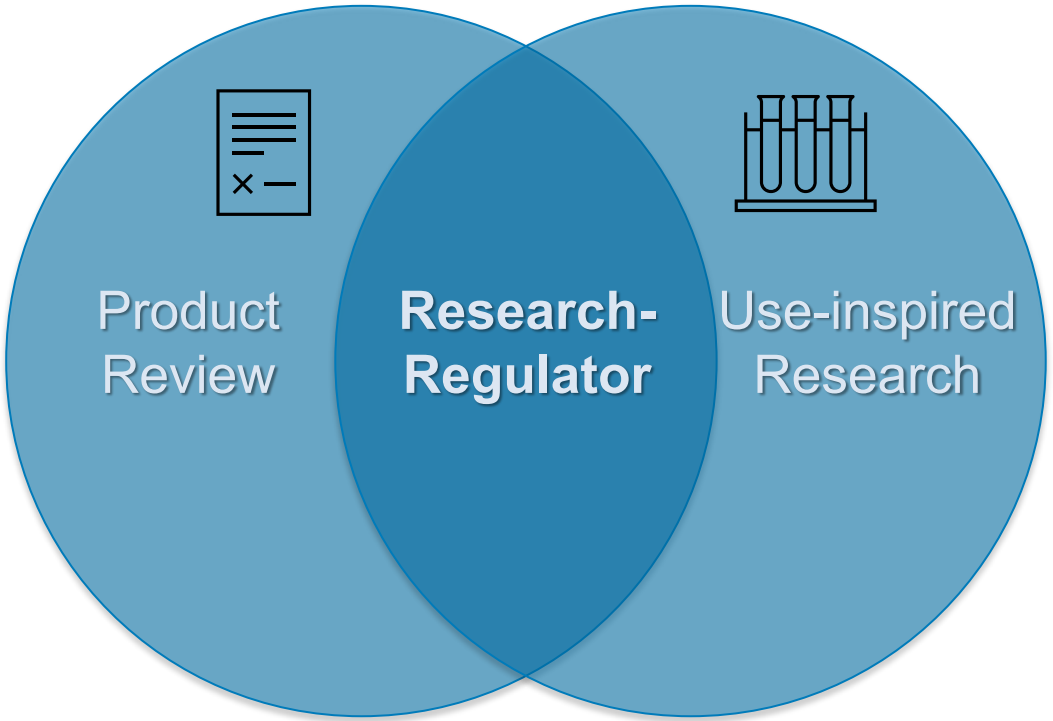
- Roll Call, Conflict of Interest Statement
  - Kathleen Hayes
- Overview of CBER Research Programs
  - Dr. Karen Elkins
- Overview of OVRR & DVP Research
  - Dr. Tod Merkel
- Overview of Laboratory of Pediatric & Respiratory Viral Diseases (LPRVD)
  - Dr. Zhiping Ye
- Overview of Laboratory of DNA Viruses (LDNAV)
  - Dr. Keith Peden
- Open Public Hearing
- Closed Session for Committee Discussion, Recommendation, and Voting

OVRR Regulatory Use-Inspired Research

- Product review and 11 regulatory use-inspired research laboratories focused in two divisions:
  - **Division of Bacterial, Parasitic and Allergenic Products** (DBPAP)
    - Laboratory of Bacterial Polysaccharides
    - Laboratory of Immuno Biochemistry
    - Laboratory of Respiratory and Special Pathogens
    - Laboratory of Mucosal Pathogens and Cellular Immunology
  - **Division of Viral Products** (DVP)
    - Laboratory of DNA Viruses
    - Laboratory of Hepatitis Viruses
    - Laboratory of Immunoregulation
    - Laboratory of Method Development
    - Laboratory of Pediatric and Respiratory Viral Diseases
    - Laboratory of Retroviruses
    - Laboratory of Vector Borne Diseases
- Current FTEs: 166

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