Final - October 27, 2020

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Centers for Disease Control and Prevention Atlanta, Georgia 30329 October 28-30, 2020

AGENDA ITEM PRESIDER/PRESENTER(s) Wednesday, October 28, 2020 10:00 **Welcome & Introductions** Dr. José Romero (ACIP Chair) Dr. Amanda Cohn (ACIP Executive Secretary, CDC) 10:30 **Immunization Schedules** Introduction to combined immunization schedule work group? Dr. Hank Bernstein (ACIP, WG Co-Chair) Dr. Kevin Ault (ACIP, WG Co-Chair) Dr. Patricia Wodi (CDC/NCIRD) Proposed changes to 2021 child/adolescent immunization schedule2 Proposed changes to 2021 adult immunization schedule Dr. Mark Freedman (CDC/NCIRD) 11:30 Break 11:45 **Seasonal Influenza Vaccines** Introduction Dr. Keipp Talbot (ACIP, WG Chair) Efficacy of cell-derived quadrivalent influenza vaccine (Flucelvax Dr. Gregg Sylvester (Seqirus) Quadrivalent) in children & adolescents ≥2 years to <18 years old Influenza Disease Burden and Vaccine Impact Estimates, 2019-20 Dr. Carrie Reed (CDC/NCIRD) Season End-of-Season Estimates of 2019–20 Seasonal Influenza Vaccine Dr. Lisa Grohskopf (CDC/NCIRD) Effectiveness against Medically Attended Influenza from three U.S. Networks **Updates and WG Considerations** Dr. Lisa Grohskopf (CDC/NCIRD) Lunch 12:30 1:15 **Orthopoxvirus Vaccine** Introduction Dr. Beth Bell (ACIP, WG Chair) Orthopoxvirus work group background Dr. Brett Petersen (CDC/NCEZID) JYNNEOS® (MVA-BN®) Smallpox and Monkeypox Vaccine Dr. Heinz Weidenthaler (Bavarian Nordic) Variola virus plaque reduction neutralization assay for the Dr. Christina Hutson (CDC/NCEZID) Vaccinating against monkeypox in the Democratic Republic of the Dr. Brett Petersen (CDC/NCEZID) Congo with JYNNEOS® **Next Steps** Dr. Agam Rao (CDC/NCEZID) 2:45 Break 2:55 **Dengue Vaccines** Introduction Dr. Robert Atmar (ACIP, WG Chair) 3:05 **Pneumococcal Vaccines** Work group introduction Dr. Katherine Poehling (ACIP, WG Chair) Dr. Miwako Kobayashi (CDC/NCIRD) 3:15 **Cholera Vaccines** Work group introduction Dr. Pablo Sanchez (ACIP, WG Chair) 3:25 Break **Public Comment** 3:30 Break 4:15 **Vote - Immunization Schedules** Dr. Mark Freedman (CDC/NCIRD) 4:20

4:30

Adjourn

Final - October 27, 2020

Thursday, October 29, 2020 10:00 **Unfinished Business and Agency Updates** CDC, CMS, FDA, HRSA, IHS, NIH, OIDP 10:15 **Zoster Vaccine** Introduction Dr. Grace Lee (ACIP, WG Chair) Update on post-licensure safety monitoring of recombinant Dr. John Su (CDC/NCEZID) zoster vaccine (RZV, Shingrix) in the Vaccine Adverse Event Reporting System (VAERS) Vaccine Safety Datalink (VSD) update on post-licensure safety Dr. Jennifer Nelson (Kaiser Permanente) monitoring of RZV Risk of Guillain-Barré syndrome following herpes zoster Dr. Tara Anderson (CDC/NCIRD) Dr. Tara Anderson (CDC/NCIRD) Summary and planned risk-benefit analysis regarding use of RZV in immunocompetent adults Planned risk-benefit analysis regarding use of RZV in Dr. Tara Anderson (CDC/NCIRD) immunocompetent adults 11:45 Lunch 12:20 **Tick-borne Encephalitis Vaccine** Introduction Dr. Katherine Poehling (ACIP, WG Chair) Overview of tick-borne encephalitis (TBE) and TBE vaccine Dr. Susan Hills (CDC/NCEZID) Immunogenicity and safety of Pfizer's TBE vaccine Dr. Dr Heinz-Joseph Schmitt (Pfizer) Next steps for TBE vaccine work group Dr. Susan Hills (CDC/NCEZID) 2:00 Break **Rabies Vaccine** 2:15 Dr. Sharon Frey (ACIP, WG Chair) Introduction Dr. Susan Moore (Kansas State University) Minimum acceptable rabies antibody titer and implications on **ACIP** recommendations Pertinent fundamentals of rabies immunology Dr. Deborah Briggs (Kansas State University) 3:30 Pre-exposure prophylaxis schedule: Grading of recommendations Dr. Agam Rao (CDC/NCEZID)

Dr. Agam Rao (CDC/NCEZID)

Dr. Agam Rao (CDC/NCEZID)

assessment, development, and evaluation (GRADE)

Evidence to recommendation framework (EtR)

Summary and next steps

Adjourn

4:50

Final - October 27, 2020

Friday, October 30, 2020

10:00 Coronavirus Disease 2019 (COVID-19) Vaccines

Introduction Dr. Beth Bell (ACIP, WG Chair)

Update from Vaccines and Related Biological Products Advisory Dr. Doran Fink (FDA)

Committee (VRBPAC) meeting

NVX-CoV2373 Vaccine Candidate Dr. Filip Dubovsky (Novavax)
Janssen's SARS-CoV-2 Vaccine Program Dr. Jerry Sadoff (Janssen)

11:45 Break

12:00 Update on vaccine implementation planning Dr. Janell Routh (CDC/NCIRD)

Vaccinate with Confidence Dr. Amanda Cohn (CDC/NCIRD)

12:30 Lunch

1:15 FDA safety surveillance systems Dr. Steven Anderson (FDA)

Post-authorization safety monitoring plans Dr. Tom Shimabukuro (CDC/NCEZID)

Modeling strategies for the initial allocation of COVID-19 vaccines Dr. Matthew Biggerstaff (CDC/NCIRD)

Discussion

2:30 Break

2:45 Updates to immunity and epidemiology to inform COVID-19 Dr. Megan Wallace (CDC/NCIRD)

Ethical principles for early vaccine allocation Dr. Mary Chamberland (CDC/NCIRD)

Work Group interpretation of data Dr. Sara Oliver (CDC/NCIRD)

Policy questions, Evidence to Recommendation Framework, and Dr. Kathleen Dooling (CDC/NCIRD)

Discussion

4:45 Adjourn

Acronyms

CDC Centers for Disease Control and Prevention
CMS Centers for Medicare and Medicaid Services

COVID-19 Coronavirus Disease 2019

EtR Evidence to Recommendations Framework

FDA Food and Drug Administration

GRADE Grading of Recommendations Assessment, Development and Evaluation

HRSA Health Resources and Services Administration

IHS Indian Health Service

NCHHSTP National Center for HIV, Hepatitis, STD and TB Prevention [of CDC/OID]

NCIRD National Center for Immunization & Respiratory Diseases [of CDC/OID]

NCEZID National Center for Emerging and Zoonotic Diseases [of CDC/OID]

NIAID National Institute of Allergy and Infectious Diseases
OIDP Office of Infectious Disease and HIV/AIDS Policy

RZV Recombinant Zoster Vaccine

SAGE Strategic Advisory Group of Experts

SARS-CoV-2 Severe Acute Respiratory Syndrome coronavirus 2

WG Work Group

WHO World Health Organization

VAERS Vaccine Adverse Event Reporting System

VE Vaccine Effectiveness