

# ACIP COVID-19 IMMUNIZATION WG: INTRODUCTION

Professor Retsef Levi, PhD, MIT

# Immediate Goals

- 1) Formulate possible recommendations regarding the recent FDA authorized products with respect to sub-populations for discussion and vote during the ACIP meeting on Sep 18-19 (with supporting data/analyses):
  - What are the appropriate subgroups (age, risk factors, prior infection, others)?
  - Options: Recommend, not recommend, Individual-based decision
- 2) Formulate a list of risks and uncertainties the WG suggests should be communicated to patients and medical providers as part of informed consent (changes to the Vaccine Information Statement)

# Medium-Term Goals

- 1) Expansive Terms of Reference
- 2) Three focus clusters assigned to WG members based on expertise
- 3) The goal for each cluster is to summarize ALL available knowledge for discussion in the WG and highlight important issues and knowledge gaps
- 4) Formulate policy options on broad vaccination-related issues for consideration by ACIP

# Values & Conduct

- 1) Leverage all relevant published and unpublished scientific, clinical and public health data, information and knowledge, including experiences from the field
- 2) Personalized risk-benefit analyses vs. 'safe & effective' (broad set of questions)
- 3) Debate with respect
- 4) Communicate the WG members' diverse positions and opinions with maximum transparency

# Today's WG Member Presentations

- 1) Professors Wafik El-Deiry (Brown University) and Charlotte Kuperwasser (Tufts University):

## **Safety Uncertainties of COVID-19 Vaccines**

- 2) Professor Bruce Carleton (University of British Columbia):

## **Genomics of Vaccine-Induced Myocarditis**

- 3) Professors Hennerly Bernstein (Hofstra/Northwell in New York), Mitchell Miglis (Stanford) and Stanely Perlman (University of Iowa)

## **WG Minority Opinion**

# Other ACIP Members on WG

1. James Pagano, MD, FACEP, Emergency Medicine Physician with More than 40 Years Clinical Experience, ACIP Committee Member
2. Robert Malone, MD, MS, Vaccinologist, Scientist, Biochemist, Contributor to mRNA Vaccine Technology, ACIP Committee Member

# WG External Subject Matter Experts

1. Henry H. Bernstein, DO, MHCM, FAAP, Professor of Pediatrics, Zucker School of Medicine at Hofstra/Northwell
2. Christine Stabell Benn, PhD, DMSc, Bandim Health Project, OPEN, Department of Clinical Research, University of Southern Denmark
3. Bruce Carleton, Pharm.D, Professor, University of British Columbia
4. Wafik El-Deiry, MD, PhD, FACP, Director, Legorreta Cancer Center at Brown University
5. Joseph Fraiman, MD, Emergency Medicine Physician, Baton Rouge, LA
6. Suzanne Gazda, MD, Medical Director, Neurology institute of San Antonia (NISA)
7. Douglas H. Jones, MD, FAAAAI, FACAAI, Board certified American Board of Allergy and Immunology; CEO Global Allergy Immune Network
7. Charlotte Kuperwasser, PhD, Professor, Developmental, Molecular & Chemical Biology, Director, Tufts Convergence Laboratory of Biomedical, Physical, and Engineering Sciences, Tufts University
8. Mitchell Miglis, MD, Clinical Associate Professor, Department of Neurology and Neurological Sciences, Secondary in Department of Psychiatry and Behavioral Sciences, Stanford University
9. Stanley Perlman, MD, PhD, Professor, Department of Microbiology and Immunology, University of Iowa
10. Erle Robertson, PhD., Harry P. Schenk Endowed Chair Professor, Vice-Chair, Department of Otorhinolaryngology, Head and Neck Surgery
11. Jordan Vaughn, MD, CEO of MedHelp Clinics

# ACIP Ex Officio

1. Tracy Beth Hoeg, MD, PHD, Senior Advisor for Clinical Sciences, Food and Drug Administration Ex Officio
2. Andrew Johnson, Centers for Medicare & Medicaid Services Ex Officio