

**The Food and Drug Administration's Emergency Use Authorization:
Lessons Learned from the Past to Guide the Future
A Workshop
October 5-6, 2021**

Tuesday, October 5, 2021 (All times U.S. Eastern)

9:00 AM Welcome and Opening Remarks

Speaker: William B. Schultz, Zuckerman Spaeder LLP *

9:10 AM An Overview of Emergency Use Authorizations (EUAs) and Similar Authorities

Speakers: Margaret A. Hamburg, Nuclear Threat Initiative**
Emer Cooke, European Medicines Agency

10:00 AM Break

10:15 AM Panel 1: Use of the Emergency Use Authorization During the COVID Pandemic

Moderator: Joshua M. Sharfstein, Johns Hopkins Bloomberg School of Public Health**

Speakers: Patrizia Cavazzoni, U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research
Peter Marks, FDA Center for Biologics Evaluation and Research
Jeffrey Shuren, FDA Center for Devices and Radiological Health

11:15 AM Break

11:45 AM Panel 2: Communication and Transparency for EUAs Used During the COVID Pandemic

Moderator: Nirav Shah, Maine Center for Disease Control**

Speakers: Scott Becker, American Public Health Laboratory Association
Mike Fraser, Association of State Health Officials
Mariângela Simão, World Health Organization (WHO)
Anne Zink, Alaska Department of Health and Social Services

1:00 PM Panel 3: An Evaluation of the Process for Authorizing EUAs and Transitioning to Full Approval

Moderator: William B. Schultz, Zuckerman Spaeder LLP *

Speakers: Luciana Borio, ARCH Venture Partners and Johns Hopkins University
Ruth Faden, Berman Institute of Bioethics, Johns Hopkins
Monica Gandhi, University of California, San Francisco
Aaron Kesselheim, Harvard Medical School and Brigham and Women's Hospital

2:00 PM Additional Perspectives on EUAs from FDA Center Directors

Moderator: Joshua M. Sharfstein, Johns Hopkins Bloomberg School of Public Health**

Speakers: Patrizia Cavazzoni, U.S. Food and Drug Administration (FDA) Center for Drug
Evaluation and Research
Peter Marks, FDA Center for Biologics Evaluation and Research
Jeffrey Shuren, FDA Center for Devices and Radiological Health

2:30 PM Adjourn

Wednesday, October 6, 2021

9:00 AM Welcome

Speaker: William B. Schultz, Zuckerman Spaeder LLP*

9:05 AM Panel 4: International Cooperation

Moderator: Agnès Saint-Raymond, Former European Medicines Agency**

Speakers: Soumya Swaminathan, WHO
Nicole Lurie, Coalition for Epidemic Preparedness Innovations (CEPI)
Murray Lumpkin, Gates Foundation
Analia Porras, Pan American Health Organization (PAHO)/WHO
Jörg Schläpfer, Swiss Agency for Therapeutic Products (Swissmedic)

10:45 AM Panel 5: How Should EUA Authority be Used for Future Pandemics?

Moderator: David Vladeck, Georgetown University Law Center**

Speakers: Peter Lurie, Center for Science in the Public Interest
Dave A. Chokshi, New York City Department of Health and Mental Hygiene
Patricia Zettler, Ohio State University School of Law
Robert M. Califf, Verily and Google Health

Break 11:45 AM

12:00 PM Panel 6: The Path Forward: Equities and Enhanced Preparation for the Future

Moderator: Rogério Gaspar, Regulation and Prequalification Department, World Health Organization**

Speakers: Richard Hatchett, Coalition for Epidemic Preparedness Innovations (CEPI)
Helen Rees, University of Witwatersrand and South African Health Products Regulatory Authority
June Raine, Medicines and Healthcare Products Regulatory Agency (MRHA), United Kingdom
Seth Berkley, Gavi, The Vaccine Alliance

1:00 Concluding Roundtable with All Panel Moderators

Moderator: William B. Schultz, Zuckerman Spaeder LLP*

Speakers: Margaret A. Hamburg, Nuclear Threat Initiative**
Joshua M. Sharfstein, Johns Hopkins Bloomberg School of Public Health **
Nirav Shah, Maine Center for Disease Control**
Julie L. Gerberding, Merck & Co, Inc.**
Agnès Saint-Raymond, Former European Medicines Agency**
David Vladeck, Georgetown University Law Center**
Rogério Gaspar, World Health Organization**

2:00 – Adjourn

Support for this workshop has been provided by the Rockefeller Foundation and the Gates Foundation

*Chair of the Planning Committee

**Member of the Planning Committee