

# **Current State of Research, Development, and Stockpiling of Smallpox Medical Countermeasures**

## **Committee**

### **Lawrence O. Gostin**

#### **Chair**

Lawrence O. Gostin, J.D., LL.D., is Distinguished University Professor, Georgetown University's highest academic rank, where he directs the WHO Organization Collaborating Center on National and Global Health Law and directs the O'Neill Institute for National and Global Health Law. At WHO, he serves on the International Health Regulations Review Committee for amendments to the IHR. He has worked at the intersection of law, national and global health, and ethics, including deep engagement with major novel infectious disease outbreaks, including SARS, Ebola, Zika, Influenza H1N1, and COVID-19. In 2016, NASEM conferred on Gostin the Adam Yarmolinsky Medal for "distinguished service by a Member who, over a significant period of time, has contributed in multiple ways to the mission of the Institute of Medicine." In 2015, the APHA conferred a lifetime achievement award. Prof Gostin has chaired and served on multiple experts NASEM committees, as well as serving several boards including global health, population health, and health sciences policy.

### **Georges C. Benjamin**

#### **Member**

Georges C. Benjamin, M.D., is a well-known health policy leader, practitioner and administrator. He currently serves as the executive director of the American Public Health Association, the nation's oldest and largest organization of public health professionals. He is also a former secretary of Health for the state of Maryland. Dr. Benjamin is a graduate of the Illinois Institute of Technology and the University Of Illinois College Of Medicine. He is board-certified in internal medicine, a Master of the American College of Physicians, a fellow of the National Academy of Public Administration, a fellow emeritus of the American College of Emergency Physicians, and a member of the National Academy of Medicine. He serves on several nonprofit boards such as Research!America, the Truth Foundation, and the Reagan-Udall Foundation. He is a former member of the National Infrastructure Advisory Council, a council that advises the President on how best to assure the security of the nation's critical infrastructure.

# **Nahid Bhadelia**

## **Member**

Nahid Bhadelia, M.D., M.A.L.D., is the Founding Director of Boston University Center for Emerging Infectious Diseases Policy and Research. She is a board-certified infectious diseases physician and an Associate Professor at the BU School of Medicine. She served the Senior Policy Advisor for Global COVID-19 Response for the White House COVID-19 Response Team in 2022-2023 as well as the interim Testing Coordinator on the White House MPOX Response Team. Between 2011-2021, Dr. Bhadelia helped develop and then served as the medical director of the Special Pathogens Unit (SPU) at Boston Medical Center, a medical unit designed to care for patients with highly communicable diseases. She was also previously an associate director for BU's maximum containment research program, the National Emerging Infectious Diseases Laboratories. She has provided direct care and helped lead medical and research response to multiple viral hemorrhagic fever outbreaks in East and West Africa. Dr. Bhadelia's research focuses on global health security and pandemic preparedness, including medical countermeasure evaluation and clinical care for emerging infections, diagnostics evaluation and positioning, infection control policy development, and healthcare worker training. She is a member of the National Academies Forum on Microbial Threats.

# Inger Damon

## Member

Inger Damon, M.D., Ph.D., retired from the CDC in September 2022, where her career spanned 23 years of work on deadly diseases and associated preparedness and response efforts. Currently, she continues to hold an Adjunct Faculty position with Emory University School of Medicine. She is one of the world's experts on orthopoxviruses including smallpox, an infectious disease that killed millions before it was declared eradicated in 1980 by global surveillance and vaccination campaigns. For over fifteen years, Dr. Damon directed CDC's smallpox research program conducting research to help develop new smallpox diagnostic tests, assess the effectiveness of new vaccines, and create better drugs for treatment. Her expertise leading this global poxvirus activity included programs to look for sources of poxviruses in wildlife, leading CDC's 2003 response to an outbreak of monkeypox in the United States linked to imported exotic pets, and reestablishment of collaborative work on mpox in the Congo Basin. From 2014-2022, Dr. Damon served as the director for the Division of High Consequence Pathogens and Pathology, overseeing the agency's expertise on deadly pathogens such as Ebola, other viral hemorrhagic fever viruses, smallpox, rabies, and anthrax. The Division has responsibility for a broad range of bacterial and viral pathogens, ME/CFS, as well as prion diseases and cross-cutting pathology roles. She served as the Incident Manager for CDC's response to the Ebola epidemic in West Africa to help direct the agency's national and global fight against Ebola. Dr. Damon has worked with multiple international organizations. Most recently, she served as Rapporteur on the IHR Emergency Committee on the multi-country outbreak of mpox, and standing recommendations committee. She served as a member of the Scientific Advisory Board for Coalition for Epidemic Preparedness Innovations from 2017-2023, and has been a member of the WHO Advisory Committee on Variola Virus Research from 2018 to the present. Dr. Damon has participated as a work group member with the Advisory Committee on Immunization Practices (ACIP) to review information to contribute to ACIP decision making on orthopoxvirus and mpox vaccination recommendations in the U.S. Dr. Damon has participated as a member of U.S. interagency smallpox preparedness efforts in the Public Health Emergency Countermeasure Enterprise (PHEMCE). In October 2023, Dr. Damon joined the WHO R&D Pathogen Prioritization workgroup considering Poxvirus family pathogens. Dr. Damon has been a member of the WHO Scientific Advisory Group on the Origins of novel Pathogens (SAGO) since its inception. Dr. Damon is a co-inventor on a patent for a poxvirus diagnostic assay. Dr. Damon has published, with multiple co-authors and collaborators, over 200 peer reviewed manuscripts, agency documents, or textbook chapters related to research to understand responding to orthopoxviruses and emerging pathogens. Her efforts and work have been recognized both within U.S. government and externally through multiple awards. Recent recognitions include the CDC's Lifetime Scientific Achievement Award in 2022, an Honorary Doctorate of Science from Amherst College in 2016, and the United States Public Health Service Distinguished Service Medal in 2017. Dr. Damon completed a combined M.D. Ph.D. program at the University of Connecticut Health Center in 1992, and a B.A., magna cum laude in Chemistry, from Amherst College in 1984. She trained in Internal Medicine at the Hospital of the University of Pennsylvania (1992-1995) and completed a fellowship in Infectious Diseases at NIAID in 1999 where she worked in the laboratory of Dr. Bernard Moss.

## Andrew Endy

### Member

Drew Endy, Ph.D., M.S., is a bioengineer at Stanford University who studies and teaches synthetic biology. His goals are civilization-scale flourishing and renewal of liberal democracies. Prof. Endy helped launch new undergraduate majors in bioengineering at both MIT and Stanford and the iGEM — a global genetic-engineering “Olympics” enabling thousands of students annually. His past students lead companies like Ginkgo Bioworks and Octant. He is married to Christina Smolke, CEO of Antheia the essential medicine company. He has financial interests in several synthetic biology companies. Endy served on the US National Science Advisory Board for Biosecurity (NSABB), the Committee on Science Technology & Law (CSTL), the International Union for the Conservation of Nature’s (IUCN) Synthetic Biology Task Force and, briefly, the Pentagon’s Defense Innovation Board (DIB). He currently serves on the World Health Organization’s (WHO) Advisory Committee on Variola Virus Research (ACVVR), the Defense Science Board (DSB) Emerging Biotechnologies Task Force, and the Organization for Economic Co-operation & Development (OECD) Synthetic Biology Task Force. He also serves on the boards of the BioBricks, iGEM, and BioBuilder Educational Foundations, public benefit charities advancing open source biotechnologies and bioengineering education. Esquire magazine recognized Drew as one of the 75 most influential people of the 21st century.

## Diane E. Griffin

### Member

Diane E. Griffin M.D., Ph.D., is University Distinguished Service Professor and former Chair of the W. Harry Feinstone Department of Molecular Microbiology and Immunology at Johns Hopkins Bloomberg School of Public Health. Dr. Griffin is a virologist recognized for her work on the pathogenesis of viral infections. She is known particularly for her studies on measles and alphavirus encephalomyelitis that have delineated the role of the immune response in virus clearance, vaccine-induced protection from infection, tissue damage and immune suppression. She has over 400 publications and has received the Rudolf Virchow Medal from the University of Wurzburg, the Wallace Sterling Award from Stanford University, the FASEB Excellence in Science Award and the Maxwell Finland Award from the National Foundation for Infectious Diseases. Dr. Griffin graduated from Augustana College with a B.A. in biology and from Stanford University School of Medicine with an M.D. and Ph.D., followed by residency in internal medicine. She was a postdoctoral fellow in virology and infectious diseases at Johns Hopkins University School of Medicine. She has been president of the American Society for Virology and the American Society for Microbiology and is currently Vice President of the National Academy of Sciences and US Chair of the US-Japan Cooperative Medical Sciences Program. She serves on vaccine advisory committees for GSK and Takeda Pharmaceuticals and has received research funding from Merck and Gilead Biosciences in addition to the NIH. She is an elected member of the National Academy of Medicine, American Academy of Microbiology, Association of American Physicians, and the American Philosophical Society.

# Noreen A. Hynes

## Member

Noreen A. Hynes, M.D., M.P.H., is currently Associate Professor at Johns Hopkins University (JHU) Schools of Medicine and Public Health with appointments in Infectious Diseases (Department of Medicine) and Public Health (Departments of International Health; Environmental Health & Engineering; and Population/Family/Reproductive Health) and serves as the Research Director and Associate Medical Director of the Johns Hopkins Hospital Biocontainment Unit. Dr. Hynes spent over 30 years working in the U.S. Government including the Peace Corps, Department of State, Department of Health and Human Services (HHS), and the Office of the Vice President of the U.S. She has worked both internationally and domestically providing medical care, working with and at state/county/local health departments, teaching (bedside and classroom), and undertaking research (laboratory-based, vaccine [Ebola, dengue, COVID-19] and therapeutic randomized clinical trials [COVID-19 ACTT], implementation science (COVID-19), and disease surveillance. Since 1997, she has increasingly focused on high consequence pathogens, particularly Category A agents including as a Deputy Assistant Secretary in the Office of Public Health Preparedness and Response (now ASPR)/Director of OPHEMC (the Office of Public Health Emergency Medical Countermeasures), now BARDA, and created the OPHEMC Enterprise. In the latter setting, Dr Hynes ran an \$8 billion program develop and acquire medical countermeasures (MCM) for the Strategic National Stockpile (SNS) including smallpox MCMs (live, replicating smallpox vaccine [ACAM2000], live non-replicating smallpox vaccine [MVA-BN/Jynneos], ST-246 (tecovirimat/Tpoxx], anthrax MCM, and pandemic influenza MCM. Dr. Hynes is trained as a physician and has completed a residency in internal medicine and a fellowship in infectious diseases at Harvard's Massachusetts General Hospital; a master of public health at JHU; field epidemiology as an Epidemic Intelligence Service officer at CDC; and a diploma in tropical medicine and hygiene from the Royal College of Physicians/London School of Tropical Medicine and Hygiene. She has received numerous awards including the HHS Secretary's Award for outstanding Service, the US Public Health Service's Distinguished Service Medal, and the Leadership Program for Women Faculty at JHU. Dr. Hynes has published over 100 journal articles and book chapters.

# Richard Kennedy

## Member

Richard Kennedy, Ph.D., is a Professor of Medicine and Co-Director of Mayo Clinic's Vaccine Research Group. He has over 150 peer-reviewed publications. He is the Deputy Editor-in-Chief of *Vaccine: X*, an Associate Editor at *Vaccine*, and an Associate Editor for *Frontiers in Immunology*. He is a member of the American Association of Immunologists and the American Society for Microbiology. He has served as a reviewer for dozens of NIH study sections and has participated in numerous national and international review panels. Dr. Kennedy has multiple R01 grants from NIH funding his work on viral vaccine immunology. Dr. Kennedy has also received foundation and industry funding to study adverse events after COVID-19 vaccination and to develop peptide-based vaccines for COVID-19, respectively. His research emphasis is on understanding the factors driving the tremendous diversity in human immune responses to vaccines against viral pathogens including: influenza, measles, mumps, rubella, SARS-CoV-2, smallpox, varicella, and zika. Dr. Kennedy has authored the smallpox and vaccinia chapter in the textbook *VACCINES*, has served as an advisor for the WHO Global Advisory Committee on Vaccine Safety in 2015, wrote the report "Emergency Stockpiling and Future use of Smallpox Vaccines" for that Committee, and served as an external advisor for the WHO Strategic Advisory Group of Experts- Monkeypox Working Group in 2022. Dr. Kennedy is also a member of the Joint Scientific Committee for Phase 1 Clinical Trials for the Queen Mary Hospital (The University of Hong Kong) and Prince of Wales Hospital (The Chinese University of Hong Kong).

## Kent E. Kester

### Member

Kent E. Kester, M.D., is currently Vice President, Translational Medicine, at IAVI. During a 24-year career in the US Army, he worked extensively in clinical vaccine development and led multiple research platforms at the Walter Reed Army Institute of Research, the U.S. Department of Defense's largest and most diverse biomedical research laboratory with a major emphasis on emerging infectious diseases, an institution he later led as its Commander. His final military assignment was as the Associate Dean for Clinical Research in the School of Medicine at the Uniformed Services University of the Health Sciences (USUHS). During his military service, Dr. Kester was appointed as the lead policy advisor to the US Army Surgeon General in both Infectious Diseases and in Medical Research & Development. More recently, he served as the head of translational medicine and biomarkers at Sanofi Pasteur. Dr. Kester holds an undergraduate degree from Bucknell University and an M.D. from Jefferson Medical College, completing his internship and residency in internal medicine at the University of Maryland and a research fellowship in infectious diseases at the Walter Reed Army Medical Center. Currently a member of the Department of Veterans Affairs Health Services Research & Development Service Merit Review Board, the National Academy Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats, and the CEPI Scientific Advisory Committee, he previously chaired the Steering Committee of the NIAID/USUHS Infectious Disease Clinical Research Program, and has served as a member of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), the FDA Vaccines & Related Biologics Products Advisory Committee (VRBPAC), the NIAID Advisory Council, and the CDC Office of Infectious Diseases Board of Scientific Counselors. He is the Vice Chair of the National Academy of Medicine Forum on Microbial Threats. Board-certified in both internal medicine and infectious diseases, Dr. Kester holds faculty appointments at USUHS and the University of Maryland; and is a fellow of the American College of Physicians, the Royal College of Physicians of Edinburgh, the Infectious Disease Society of America, and the American Society of Tropical Medicine and Hygiene. He is a member of the clinical faculty at the University of Maryland Shock Trauma Center in Baltimore and the Wilkes-Barre VA Medical Center in Wilkes-Barre, PA. He has ownership of (former employee) stock in a pharmaceutical company that does not work in the area of smallpox and related vaccines.

## **Anne W. Rimoin**

### **Member**

Anne Rimoin, Ph.D., is a Professor of Epidemiology and Gordon-Levin Endowed Chair in Infectious Diseases and Public Health at the UCLA Fielding School of Public Health. She is the Director of the Center for Global and Immigrant Health and the Director/Founder of the UCLA-DRC Health Research and Training Program. She is a globally recognized expert on infectious diseases, global health, disease surveillance systems, and vaccination. Dr. Rimoin has been leading studies of emerging and vaccine preventable diseases for more than two decades. Her work has contributed to the fundamental understanding of the epidemiology of human Mpox, long term immunity to Ebolavirus in survivors and durability of immune response to Ebolavirus vaccines in health workers. Her current research portfolio includes studies of Congo Crimean hemorrhagic fever (CCHF), COVID-19, Ebolavirus, Nipahvirus, Marburg, Mpox and vaccine preventable diseases of childhood. She is considered one of the world's leading subject matter experts on the epidemiology of mpox and participated on the World Health Organization (WHO) International Health Regulations Emergency Committee on the multi-country outbreak of Mpox and the WHO Strategic Advisory Group of Experts on Immunization (SAGE) Working Group on Smallpox and Mpox. She has been recognized for her achievements in the fields of Epidemiology and Global Health with the Middlebury College Alumni Achievement Award (2017), induction as a Fellow of the American Society of Tropical Medicine and Hygiene (2019), and the Johns Hopkins Alumni Association Global Achievement Award (2021). Dr. Rimoin earned her B.A. at Middlebury College, M.P.H. at UCLA, and Ph.D. at Johns Hopkins University. She started her career in global public health in as a Peace Corps Volunteer in Benin, West Africa in the Guinea Worm Eradication Program.

# Oyewale Tomori

## Member

Oyewale Tomori, D.V.M., Ph.D., is a past President of the Nigerian Academy of Science with experience in virology, disease prevention, and control. He was a researcher at the University of Ibadan from 1971 to 1994. He later served as the pioneer Vice-Chancellor of the Redeemer's University in Nigeria from 2004 to 2011. From 1994 to 2004, he was the virologist for the WHO-AFRO, establishing the African Regional Polio Laboratory Network. In 1981, he was recognized by the US-CDC for contributions to Lassa fever research. In 2002, he received the Nigerian National Order of Merit, the country's highest award for academic and intellectual attainment and national development. Dr. Tomori has served or continues to serve on numerous advisory committees, at national and global levels, including (national) - Lassa Fever Steering Committee, Laboratory Technical Working Group, Expert Group on Polio Eradication and Routine Immunization, Advisory Committee on Covid19 Response, and (international)- WHO SAGE, WHO-AFRO Polio Certification Committee, WHO Yellow Fever Disease Committee, , WHO TAG on COVID-19 Vaccine Composition (TAG-CO-VAC), GAVI Board, U.S. NAS Global Health Risk Framework Commission, and WHO-AFRO Laboratory Planning and Quality Monitoring Adviser. He is a member of US-NAM He has authored/co-authored over 160 scientific publications. Dr. Tomori currently serves as a non-executive Chair of the Board of Directors of BioVaccines Nigeria Limited (BVNL), a joint special purpose vehicle company set up between the Federal Government of Nigeria (FGN) and the May & Baker Company, a private pharmaceutical company, set up to manufacture locally, vaccines for childhood vaccinations in Nigeria. The Board provides guidance and policy oversight to the Management of BVNL. It is a non-remunerative position. Dr. Tomori is one of the 3 representatives of the FGN in the BVNL Board.

## Henry H. Willis

### Member

Henry H. Willis, Ph.D., M.S., is a senior policy researcher at the RAND Corporation and a professor of policy analysis at the Pardee RAND Graduate School. He previously served as deputy director of the RAND Homeland Security Division and director of the division's Strategy, Policy, and Operations Program and Infrastructure, Immigration, and Security Operations Program. Willis is a recognized expert in risk analysis and management. Recent work analyzes biosecurity risks and biodefense capabilities; food, energy, and water security; climate and natural disaster risks; critical infrastructure resilience; national preparedness to chemical, biological, nuclear, and radiological attacks; and prevention of global catastrophic and existential risk. Through his work he testified before Congress; served on several committees of the National Academy of Sciences; advised government agencies across the United States, Europe, Australia, and the United Arab Emirates; and published dozens of journal articles, reports, and op-eds on applying risk analysis to homeland security policy. Willis is a member of the Council on Foreign Relations and serves on the Science and Governance Committees of the Society for Risk Analysis. His work in homeland security policy evolved from his work on program evaluation at the White House Office of Management and Budget and infrastructure design as a water and wastewater engineer. He earned his Ph.D. in engineering and public policy at Carnegie Mellon University, M.S. in environmental engineering from the University of Cincinnati, and B.A. in chemistry from the University of Pennsylvania.

## Matthew K. Wynia

### Member

Matthew Wynia, M.D., M.P.H., is Board certified in Internal Medicine and Infectious Diseases, with additional training in public health and health services research. He led the Institute for Ethics at the American Medical Association for 15 years and founded its Center for Patient Safety before moving in 2015 to become the Director of the University of Colorado's Center for Bioethics and Humanities (CBH). The CBH is involved in the education for every health professions student at CU, facilitates clinical ethics case consultation for hospitals on the Anschutz Medical Campus, and carries out a research agenda to better understand the complex ethical challenges facing medicine and society. The Center also runs the annual Aspen Ethical Leadership Program and several major community engagement programs, including the annual Holocaust Genocide Contemporary Bioethics program and the Hard Call® podcast series. Dr. Wynia has led national projects on issues including public health and disaster ethics; ethics and quality improvement; communication, team-based care and engaging patients as members of the team; and medicine and the Holocaust. He has delivered more than 2 dozen named lectures and visiting professorships and is the author of more than 160 published articles, co-editor of several books, and co-author of a book on fairness in health care benefit design. He is a Fellow of the Hastings Center, past president of the American Society for Bioethics and Humanities (ASBH), and past-chair of the Ethics Forum of the American Public Health Association (APHA) and the Ethics Committee of the Society for General Internal Medicine (SGIM).

# Zhilong Yang

## Member

Zhilong Yang, Ph.D., is an Associate Professor in the Department of Veterinary Pathobiology, School of Veterinary Medicine & Biomedical Sciences at Texas A&M University. He has been working on large DNA viruses for over 21 years, including over 15 years on poxviruses. His current research focuses on understanding how poxviruses replicate in their infected host cells, antiviral discovery, and poxvirus utility development. He is a member of American Society for Virology, as well as a member of American Society for Microbiology. He obtained his B.S. and M.S. degrees from Nankai University, Ph.D. degree from University of Nebraska-Lincoln, and received postdoc training in the Laboratory of Viral Diseases at the National Institute of Allergy and Infectious Diseases.