The National Academies of
SCIENCES • ENGINEERING • MEDICINE

The Food and Drug Administration's Emergency Use Authorization:
Lessons Learned from the Past to Guide the Future
A Workshop

Committee Member Biographies

CHAIR

William B. Schultz, JD, is a Partner at Zuckerman Spaeder LLP. Formerly, he served as General Counsel of the Department of Health and Human Services between March 2011 and June 2016 (Acting General Counsel, March 2011-April 2013), where he was legal counsel to two HHS Secretaries on all legal matters and managed an office of 500 lawyers with attorneys at 8 offices and in 10 regions across the country. The Office of General Counsel is responsible for all litigation where HHS is a party, for ensuring that regulations and policy decisions are consistent with the law, for reviewing legal issues involving appropriations, and for ensuring that ethical rules are followed.

From 2001 until March 2011, Schultz was also a Partner at Zuckerman Spaeder LLP, where he represented nonprofit organizations, state and local governments, individuals, generic drug companies and small biotechnology companies. From 1999 through 2000, Schultz was Deputy Assistant Attorney General at the U.S. Department of Justice, where he was responsible for overseeing all Civil Division appellate litigation and the Department's Tobacco Litigation Team. From 1994 to 1998, he was the Deputy Commissioner for Policy for the Food and Drug Administration, where he was the principal advisor to the Commissioner on all significant policy issues and was responsible for development and management of all regulations. From 1989 to 1994, he was the Counsel to the Subcommittee on Health and the Environment (Rep. Henry A. Waxman, Chairman), Committee on Energy and Commerce, U.S. House of Representatives, where he worked on health care, FDA, tobacco and trade legislation, and was responsible for drafting and negotiating the Nutrition Labeling and Education Act, the Safe Medical Devices Act and the Prescription Drug User Fees Act. From 1976 to 1989, he was an attorney with the Public Citizen Litigation Group, where he litigated law reform cases on state and federal constitutional law, antitrust and administrative law, voting rights, product liability, nuclear power, and food and drug law, and where he argued dozens of appellate cases, including several in the U.S. Supreme Court.

Schultz began his career as a law clerk to Judge William B. Bryant, U.S. District Court, District of Columbia. For almost 10 years, he was an adjunct professor at Georgetown University Law Center, where he taught civil litigation and food and drug law. He received his B.A. from Yale University and his J.D. from the University of Virginia School of Law.

MEMBERS

Rogerio Paulo Pinto de Sa Gaspar, PhD, is Director of the Department of Regulation and Prequalification at the World Health Organization (WHO) in Geneva, Switzerland.

Originally from Portugal, Dr. Gaspar obtained his PhD in Pharmaceutical Sciences from the Catholic University of Louvain Belgium in 1991, after a graduation as pharmacist from the University of Coimbra Portugal.

He worked as a Full Professor at the Faculty of Pharmacy University of Lisbon until the end 2020, where he was Head of Department and President of the School Council. He was previously leading the Nanomedicine Drug Delivery Systems research group within the Research Institute for Medicines (iMedUL), which he cofounded in 2007), before moving in 2017 to the Institute of Bioengineering and Biosciences where he was until now researcher and part of the Scientific Board.

He has also taken leadership and participation roles in different activities both at the EU-Japan MRA, training in GMPs and Quality Management System for ASEAN National Regulatory Authorities, both public and private sector in Portugal, President of the Portuguese Society of Pharmaceutical Sciences (SPCF, 2016-2020) and both at the Executive Committee of the European Federation of Pharmaceutical Sciences (EUFEPS, 2009-2013 and 2016-2020, including Vice-President (VP) 2011-2012 and 2018-2020) and leadership of the EUFEPS Regulatory Science Network (2010-2019) as well as VP of International Pharmaceutical Federation (FIP) Special Interest Group (SIG) in Regulatory Science (2011-2014). Other participation in international collaboration, merging scientific domains and regulatory science, include several countries in the Americas, Africa and Europe.

Dr. Gaspar was previously a member of the management board of EMA and VP of the management board at Portugal's NRA (INFARMED). In Portugal, he was responsible for the redrawing and installation of the national Official Medicines Control Laboratory (OMCL) and also lead the first ISO 9001 certification for INFARMED (Inspection and Licensing procedures). He had also a relevant participation in activities against medicines counterfeiting and from 2000-2002 lead the participation of Portugal within International Narcotics Control Board (INCB) (UN, Vienna).

Rogerio Gaspar has participated in past National Academies activities, including as an invited speaker for "Nanotechnology and Oncology" workshop, organized with by the Institute of Medicine of the National Academies in 2010.

Julie L. Gerberding (NAM), MD, is Executive Vice President and Chief Patient Officer at Merck & Co., Inc., where she is responsible for global public policy, communications, patient engagement, corporate social responsibility, and other functions. She joined Merck in 2010 as president of vaccines and was instrumental in increasing access to the company's vaccines to people around the world.

Previously, Dr. Gerberding was Director of the U.S. CDC, where she led the agency through SARS and over 40 emergency responses to public health crises. She serves on the Boards of Cerner Corporation and MSD Wellcome Trust Hilleman Laboratories, a non-profit that develops new technologies for developing countries. She also co-chairs the CSIS Commission on Strengthening America's Health Security.

Dr. Gerberding received her undergraduate and M.D. degrees from Case Western Reserve University and a Masters of Public Health at the University of California, Berkeley. She completed her internship and residency in Internal Medicine and fellowship in Clinical Pharmacology and Infectious Diseases at the University of California, San Francisco, where she is currently an Adjunct Associate Professor of Medicine.

Margaret "Peggy" A. Hamburg (NAM), MD, is an internationally recognized leader in public health and medicine, who currently serves as VP for Biological Programs and Policy at the Nuclear Threat Initiative (NTI) where she also sits a member of the NTI Board. She previously served as Foreign Secretary of the National Academy of Medicine, acting as senior advisor on international matters and liaison with other Academies of Medicine around the world. In addition, she recently completed terms as Chair/President of the American Association for the Advancement of Science (AAAS). Dr. Hamburg is a former Commissioner of the U.S. Food and Drug Administration (FDA), where she served for almost six years. Before joining FDA,

Hamburg was founding vice president and senior scientist at the Nuclear Threat Initiative. Previous government positions include Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Health Commissioner for New York City, and Assistant Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health.

Hamburg currently sits on a range of boards, including the Commonwealth Fund, the Simons Foundation, the Urban Institute, the Global Alliance for Vaccines and Immunization, The Nature Conservancy and the Lasker Foundation, the American Museum of Natural History and Alnylam Pharmaceuticals. She is chair of the Joint Coordinating Group for the Coalition for Epidemic Preparedness and Innovation, and a member of the Harvard University Global Advisory Council, the Global Health Scientific Advisory Committee for the Gates Foundation, the Harvard Medical School Board of Fellows (Chair) , and the World Dementia Council. She currently co-chairs the WHO Expert Advisory Group on Human Genome Editing and Global Governance.

Dr. Hamburg is an elected member of the Council on Foreign Relations, the American Academy of Arts and Sciences and the National Academy of Medicine, and recipient of multiple other honors, honorary degrees and awards. She earned her B.A. from Harvard College, her M.D. from Harvard Medical School and completed her medical residency at Weill Cornell Medical Center.

Agnes Saint-Raymond, MD, is Head of the International Affairs Division at the European Medicines Agency. She worked as a paediatrician in several paediatric Hospitals in Paris, France, from 1982 to 1990 then in pharmaceutical industry (1990-1995), and then the French Medicines Agency as Head of one of the Pharmaco-Toxico-Clinical Evaluation Units (1995-1999) and was an expert at the EMA.
In Jan 2000 she joined the European Medicines Agency (EMA) where she led the Department in charge of Orphan Medicines, Scientific Advice, the Small & Medium-sized Enterprises Office, and Paediatric Medicines until Sept 2013. She was responsible for implementing the EU legislations on orphan then paediatric medicines.

In 2013, she became Head of the Portfolio Board Division, providing oversight of projects for EMA. Since November 2016, she is also the EMA Head of the International Affairs Division.

Nirav D. Shah, MD, JD, is the Director of the Maine Center for Disease Control and Prevention. Previously, he served as the Director of the Illinois Department of Health.

Earlier in his career, Dr. Shah served as the Chief Economist of the Ministry of Health of Cambodia, during his tenure as a Henry Luce Scholar. In Cambodia, he worked on a variety of public health programs aimed at reducing corruption in the health care system. In particular, he designed a system that reduced the number of administrative steps required to transfer funds from the central Ministry to rural hospitals, thereby reducing opportunities for corruption and graft. Dr. Shah completed both his medical and law degrees at University of Chicago. After graduating from college, he studied economics at Oxford University.

Joshua M. Sharfstein (NAM), MD, is Vice Dean for Public Health Practice and Community Engagement and Professor of the Practice at the Johns Hopkins Bloomberg School of Public Health. He earned his M.D. from Harvard Medical School in 1996. He oversees the Office of Public Health Practice and Training and is director of the Bloomberg American Health Initiative. He also holds a faculty appointment in the Department of Health Policy and Management. Previously, he served as the Secretary of the Maryland Department of Health and Mental Hygiene, the Principal Deputy Commissioner of the U.S. Food and Drug Administration, as Commissioner of Health for Baltimore City, and as health policy advisor for Congressman Henry A. Waxman. He is the author of *The Public Health Crisis Survival Guide: Leadership and Management in*

Trying Times (2018) and co-author of *The Opioid Epidemic: What Everyone Needs to Know* (2019), both from Oxford University Press.

David C. Vladeck, JD, LLM, is A.B. Chettle, Jr. Professor of Law at Georgetown University Law Center. He teaches federal courts, civil procedure, directs a civil litigation clinic, and teaches a practicum, along with MIT, that puts law students together with graduate computer science students to work together on technology policy. He is also the faculty director of the law school's Center on Privacy and Technology. From 2009-2013, he served as the Director of the Federal Trade Commission's Bureau of Consumer Protection, where he supervised the Bureau's lawyers, investigators, paralegals and support staff in carrying out the Bureau's work to protect consumers from unfair, deceptive or fraudulent practices. Before joining the Law Center faculty, Professor Vladeck spent over 25 years with Public Citizen Litigation Group, handling and supervising complex litigation and arguing several cases before the U.S. Supreme Court and more than sixty cases before federal courts of appeal and state courts of law resort. He is a Trustee of the Natural Resources Defense Council, a Senior Fellow of the Administrative Conference of the United States, an elected Member of the American Law Institute, and a member of the board of the National Consumer Law Center.