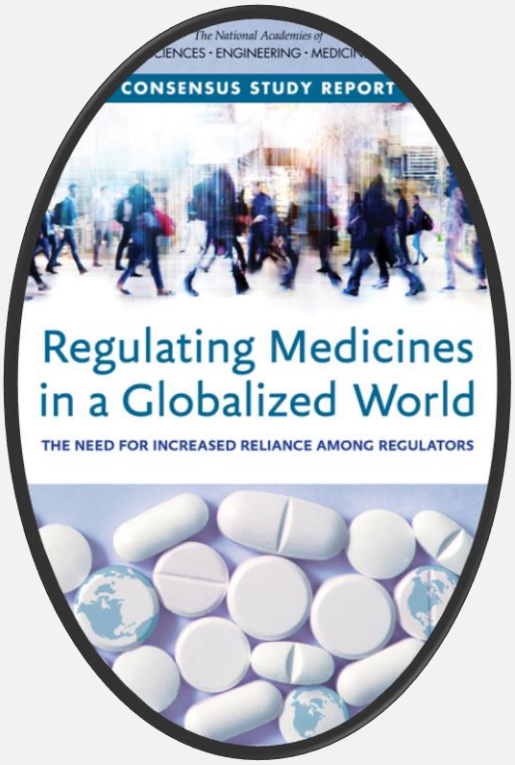
Regulatory Reliance – If not now, when? What are the current barriers?

Friday, September 4

10:30am-12noonEDT /4:30-6pmCEST

Objective: To identify current barriers to greater use of regulatory reliance and to explore potential solutions

Background: This Webinar will focus on the barriers to greater use of regulatory reliance during the pandemic by drawing upon messages from the recently released NASEM report on regulatory reliance that was funded by FDA's Office of Global Policy and Strategy.



DRAFT Agenda

10:30am **Welcome & Background**
Alastair Wood, Fmr Study Chair

Focusing on regulatory reliance as a 21st century best practice, especially during a pandemic when time is of the essence, panelists are asked to respond to the question:

- What do you see as current barriers to greater use of reliance-based regulatory pathways and how might they be overcome?

Webinar Facilitator: Alastair Wood
10:40am **Moderator: Murray Lumpkin**

Guido Rasi, Chair of ICMRA and current Executive Director, EMA

Emer Cooke, Director, Regulation of Medicines and other Health Technologies, WHO; and imminent Executive Director, EMA

Janis Bernat, Director of Biotherapeutics & Scientific Affairs, IFPMA

Mikel Arriola, Fmr Federal Commissioner, COFEPRIS, Mexico

Margaret Hamburg, Fmr Commissioner of Food and Drugs, US FDA

Panel Discussion Questions to Consider

- How can we best remove current barriers to and advocate for greater use of reliance-based regulatory pathways during the current pandemic?
- What needs to change to make this happen?
- Should/could someone/some organization coordinate this? For example, can someone/organization coordinate data on PPE quality-just as a relatively simple example?

Panel Discussion
Moderators: Alastair Wood & Murray Lumpkin
11:20am

- Jeffrey Drazen, Fmr Editor-in-Chief of The New England Journal of Medicine
- Margaret Hamburg, Fmr FDA
- Guido Rasi, ICMRA & EMA
- Emer Cooke, WHO & EMA
- Janis Bernat, IFPMA
- Mikel Arriola, Fmr COFEPRIS, Mexico

12noon Adjourn

Speaker Biographies

Webinar Facilitator

Alastair J. J. Wood, MB, ChB, FRCP, FACP (NAM), was professor of both medicine and pharmacology at Vanderbilt University Medical School and served as assistant vice chancellor for clinical research and associate dean, Vanderbilt Medical School, before being appointed emeritus professor of medicine and emeritus professor of pharmacology in 2006. He was a partner at Symphony Capital LLC, a private equity company investing in the clinical development of novel biopharmaceutical products, from 2006 to 2018. He has also periodically consulted for pharmaceutical companies (AMAG, Sanofi, etc.) in the past 12 months. Dr. Wood has been honored by being elected to the National Academy of Medicine, the American Association of Physicians, and the American Society for Clinical Investigation; is an honorary fellow of the American Gynecological and Obstetrical Society; and was awarded fellowships of the American College of Physicians, the Royal College of Physicians of London, and the Royal College of Physicians of Edinburgh. He was the 2005 recipient of the Rawls-Palmer Award and in 2008 received the honorary degree of doctor of laws, honoris causa, from the University of Dundee. Dr. Wood has served on a number of editorial boards, including that of the New England Journal of Medicine, and was the drug therapy editor of the New England Journal of Medicine from 1985 to 2004. His research has resulted in more than 300 articles, reviews, and editorials. He served on the U.S. Food and Drug Administration's Cardiovascular and Renal Drug Advisory Committee and the Non-Prescription Drug Advisory Committee, which he also chaired. He is currently the Chair of the Burroughs Welcome Fund Regulatory Science Award committee and serves on the board of the Critical Path Institute.

Moderator

Murray Lumpkin, M.D., M.Sc., is the Deputy Director, Integrated Development and Lead for Global Regulatory Systems Initiatives at the Bill and Melinda Gates Foundation since January 2014. These initiatives are focused on working with partners such as the World Health Organization, regulatory regionalization initiatives, and national regulatory authorities to make more efficient and effective (without sacrificing product quality, efficacy, or safety) the regulatory processes through which products must pass in order to be developed, legally marketed, procured, and overseen appropriately after marketing authorization in low- and middle-income countries.

Prior to his appointment at the Gates Foundation, he was at the US FDA for 24 years, as Director of the Anti-infective Drugs Division, then Deputy Center Director at CDER, and finally for 11 years as Deputy FDA Commissioner for International Programs.

Speakers

Mikel Arriola, M.L., M.P.P., was born in Mexico City and has a Law Degree from the Universidad Anahuac del Norte, a master's degree in Public Policy and Public Administration from the London School of Economics and Political Science in London, UK, as well as a master's degree in Law from the University of Chicago, USA. In 2017, he received from the University of Chicago the award for professional merit, becoming the second Mexican citizen to be granted such distinction.

His professional career has unfolded mainly in the public sector. In 2002 he was the Litigation Coordinator of Banrural (Agricultural National Bank). From 2003 to 2005 he served in Rural Financial (Government Financial Fund for Agriculture) where served as Compliance Officer and Corporate Deputy Director of the General Department.

In 2007, he joined the Finance Ministry (SHCP), where he served as Counselor to Minister of Finance, General Director of Revenue Planning of the Deputy Minister of Revenue and, as of 2009, Head of the Tax Legislation Unit of the Deputy Minister of Revenue.

In March 2011 he was appointed Federal Commissioner for Protection against Health Risks of the Ministry of Health (Mexican FDA) and in December 2012 was ratified on office.

On February 8, 2016, the Mexican President announced Mikel as the General Director of the Mexican Social Security Institute (IMSS), a position Mr. Arriola served until December 2017.

In January 2018 he was Candidate for the Mayor of Mexico City, which concluded with the elections which took place on July 1st of the same year, obtaining approximately 800,000 votes.

Nowadays he is a founding partner of VCGA CONSULTORES, as well as a member of the boards of Médica Sur and The North American Speciality Hospital (NASH).

Since 2018 in the National Academies of Science, Engineering and Medicine (NASEM) Mikel is a member of the Committee for the Regulatory Strengthening of Food and Drug Policies in Developing Nations. Furthermore, Mr. Arriola is also Member of the Committee of Experts for the Strengthening of Regulatory Agencies in the Continent of the Pan American Health Organization (PAHO).

Janis Bernat, M.Sc., is the Director of Biotherapeutics & Scientific Affairs at the International Federation of Pharmaceutical Manufacturers & Associations in 2006 to work with the Vaccines Committee and Influenza Vaccine Supply Task Force. She is currently responsible for the policy and technical work in the area of biotherapeutic and biosimilar medicines and leads the organization's regulatory team. Janis holds degrees in agriculture, food science, and mass communications from several US universities. Prior to joining IFPMA, she worked for a US-based multi-national food company in quality assurance and regulatory compliance.

Emer Cooke M.Sc., M.B.A., an Irish national, is currently the Director of the Regulation and Prequalification Department at the World Health Organization (WHO) in Geneva, a position she has held since November 2016. In this role she leads on WHO's global work on health technologies regulation, including prequalification, regulatory systems strengthening and safety activities. Her role also covers assurance of quality, safety, efficacy and performance of health technologies in close conjunction with member states and international partners.

Ms. Cooke has 30 years' experience in international regulatory affairs, 18 years of which were in leadership roles. She worked for the pharmaceutical unit of the European Commission from 1998 to 2002 and at EMA between 2002 and 2016, where she held positions including Head of Inspections and Head of International Affairs.

Ms. Cooke holds a degree in pharmacy from Trinity College, Dublin in Ireland. She has additional Masters degrees in Science and in Business Administration, also from Trinity.

Jeffery Drazen, M.D., was born and raised in Clayton, Missouri, Dr. Drazen majored in applied physics at Tufts University and graduated from Harvard Medical School in 1972. He currently holds the positions of senior physician at the Brigham and Women's Hospital, Distinguished Parker B. Francis Professor of Medicine at Harvard Medical School, professor of physiology at the Harvard School of Public Health and adjunct professor of medicine at the Boston University School of Medicine. He is the recipient of honorary degrees from the University of Ferrara, the University of Athens, the University of Modena, and the University of Paris-Sud.

Dr. Drazen is an elected member of the American Society for Clinical Investigation, the Association of American Physicians, the Interurban Clinical Club and the National Academy of Medicine. He serves on the National Academy of Medicine's Forum on Drug Discovery, Development, and Translation.

An active researcher in the field of pulmonary medicine, Dr. Drazen defined the role of novel endogenous chemical agents in asthma, leading to four licensed pharmaceuticals for asthma, now used by tens of millions of people worldwide.

He has published over 600 papers, editorials and review articles and has edited 12 books, including six editions of Goldman-Cecil Medicine and two of Asthma and COPD.

From 2000 to 2019, Dr. Drazen was editor-in-chief of the New England Journal of Medicine. During his tenure, the Journal published major papers advancing the science of medicine, including the first descriptions of SARS, timely coverage of the Ebola and Zika virus epidemics, and advances in the treatment of cancer, heart disease and lung disease. It has been at the forefront of worldwide efforts to register all clinical trials and to share clinical trial data. The Journal now has over two million unique visitors every week and the highest impact factor of any medical journal publishing original research. He now serves at Editor of NEJM Group.

Margaret Hamburg, M.D., is an internationally recognized leader in public health and medicine, and currently serves as foreign secretary of the National Academy of Medicine and chair of the NTI | bio Advisory Group. She is a former Commissioner of the U.S. Food and Drug Administration (FDA), having served for almost six years. As FDA Commissioner she was known for advancing regulatory science, streamlining and modernizing FDA's regulatory pathways, and globalization of the agency. 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.

As Foreign Secretary of the National Academy of Medicine, the health arm of the National Academy of Sciences, Engineering and Medicine, Hamburg serves as senior advisor on international matters and is the liaison with other Academies of Medicine around the world. She is President-elect of the American Association for the Advancement of Science (AAAS), as well as an elected member of the Council on Foreign Relations and the National Academy of Medicine. Hamburg currently sits on the boards of the Commonwealth Fund, the Simons Foundation, the Urban Institute, the Global Alliance for Vaccines and Immunization, the Parker Institute for Cancer Immunotherapy and the American Museum of Natural History. 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, and the World Dementia Council.

Hamburg earned her B.A. from Harvard College, her M.D. from Harvard Medical School and completed her medical residency at Weill Cornell Medical Center. She is the recipient of multiple honorary degrees and numerous awards.

Guido Rasi, M.D., is currently in his second term as Executive Director of European Medicines Agency (EMA) until November 2020. He has been elected Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) from 1st October 2019 for a term of 3 years.

He was Director-General of the Italian Medicines Agency from 2008 to 2011 and member of the Management Board from 2004 and 2008. He was made full professor of microbiology at the University of Rome 'Tor Vergata' in 2008. From 2005 to 2008, he was Director of Research at the Institute of Neurobiology and Molecular Medicine of the National Research Council (CNR) in Rome. From 1990 to 2005, Prof Rasi worked at the Institute for Experimental Medicine of the National Research Council, Italy. He had a teaching and research experience at the University of California, Berkeley in 1999.

Prof Rasi holds a degree in medicine and surgery, with specializations in internal medicine, allergology and clinical immunology, from the University of Rome. He is the author of numerous scientific publications. He has received many awards and one honorary degree.