

# **Biosimilars: A Decade of Experience and Future Directions**

## **Strategies for Improving Biosimilar Adoption and the Potential Role of Clinical Pharmacology**

University of Maryland Center of Excellence in Regulatory Science and Innovation  
Food and Drug Administration

Public Webinar

April 13, 2022 | 1:00 – 3:30 pm EST

### **Speaker Biographies**

#### **Yow-Ming Wang, PhD**

Associate Director for Biosimilars and Therapeutic Biologics; Office of Clinical Pharmacology, US Food and Drug Administration

Dr. Yow-Ming Wang is currently the Associate Director for Biosimilars and Therapeutic Biologics in the Office of Clinical Pharmacology at the FDA. She leads the Therapeutic Biologics Program which has a mission to promote scientific and regulatory excellence in biologic product development through developing clear policies, enhancing excellence in review, facilitating knowledge sharing, and building collaboration & outreach.



#### **Gary Lyman, MD, MPH, FACP, FRCP (Edin), FASCO**

Professor; Cancer Prevention Program, Public Health Sciences Division and Clinical Research Division, Fred Hutchinson Cancer Research Center Senior Lead; Health Care Quality and Policy, Hutchinson Institute for Cancer Outcomes Research

Professor of Medicine and Adjunct Professor; Public Health and Pharmacy, University of Washington and Duke University School of Medicine

Dr. Lyman is Professor of Public Health Science and Clinical Research at the *Fred Hutchinson Cancer Research Center* where he is also Senior Lead of Healthcare Quality and Policy at the Hutchinson Institute for Cancer Outcomes Research. He also is Professor of Medicine and Adjunct Professor of Public Health and Pharmacy at the *University of Washington* and at the *Duke University School of Medicine*.

Dr. Lyman is an Executive Officer for the *SWOG Cancer Research Network* with responsibility for Immunotherapy, Cancer Care Delivery & Symptom Management and QOL studies and is supporting SWOG's involvement in the NCI *ComboMATCH* and SWOG's leading effort in the forthcoming NCI *ImmunoMatch* along with related efforts on immune-related adverse events. He is a member of the Board of Directors of *The Hope Foundation for Cancer Research*. Dr. Lyman has published more than 600 professional articles in the medical literature along with more than 20 medical texts and over 70 book chapters. He has been listed by *Web of Science* among the top 1% of cited investigators for the past four years with nearly 77,000 citations. Dr. Lyman has published extensively on biosimilars and advised the American Society of Clinical Oncology, the National Comprehensive Cancer Network, and other professional organizations on their role in clinical oncology. Dr. Lyman is a founding member of *COVID-19 and Cancer Consortium* which represents the largest global registry of patients with cancer and confirmed COVID-19.

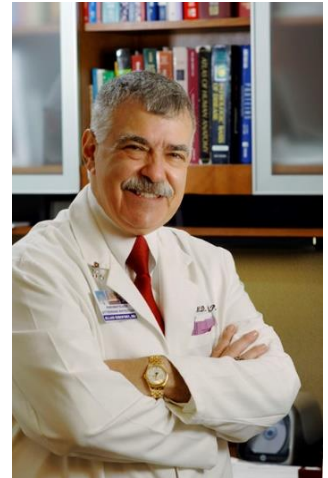


**Allan Gibofsky, MD, JD, MACR, FACP, FCLM**

Professor of Medicine; Weill Cornell Medical College  
Attending Physician and Rheumatologist; New York Presbyterian Hospital,  
Memorial Sloan Kettering Cancer Center, and Hospital for Special Surgery, Co-  
Director of the Clinic for Inflammatory Arthritis and Biologic Therapy

Dr. Gibofsky received his undergraduate degree from Brooklyn College of the City University of New York, his M.D. from Weill Medical College of Cornell University, and his law degree from Fordham University. He did his internship in Pathology, followed by a residency in Medicine at New York Hospital. He completed a fellowship in Rheumatology/Immunology jointly at Hospital for Special Surgery and at The Rockefeller University. Dr. Gibofsky has authored numerous papers and text chapters, primarily on the immunogenetics of rheumatic diseases, and legal aspects of medical practice. He is known for his research and publications on mechanisms of host-microbe interactions in rheumatology, and, in particular for his basic and clinical studies on rheumatic fever as well as for his work on therapeutic strategies in the treatment of inflammatory rheumatic diseases.

Dr. Gibofsky is a Jonas Salk Scholar of the City University and was named Alumnus of the Year by Brooklyn College. Currently Secretary-Treasurer of The New York Rheumatism Association, Dr. Gibofsky is past Chair of the Medical & Scientific Committee of the New York Chapter of The Arthritis Foundation and received their Physicians' Leadership Award. He also served as a member of the local and national Arthritis Foundation Board of Trustees and was Chair for Professional Education. Dr. Gibofsky is past-Chair of the Arthritis Advisory Committee to the US Food and Drug Administration and continues as a Special Consultant to the Agency. He is a past President of the American College of Legal Medicine and is past Chair of the American Board of Legal Medicine. Dr. Gibofsky is a past-President and Master of The American College of Rheumatology.



## **Gary Lichtenstein, MD, FACP, FACG, AGAF**

Director of the Inflammatory Bowel Disease Center and Professor of Medicine: Gastrointestinal Division, Department of Medicine, University of Pennsylvania Hospital and University of Pennsylvania School of Medicine



Dr. Lichtenstein earned his medical degree from the Mount Sinai School of Medicine, in New York, New York. He then completed his internship and residency in Internal Medicine at Duke University Medical Center, in Durham, North Carolina. He also served a fellowship in Gastroenterology at the Hospital of the University of Pennsylvania of the University of Pennsylvania School of Medicine. His current research interests encompass investigational therapies for the treatment of ulcerative colitis and Crohn's disease as well his research has had a significant focus on the safety of current and future medical therapy. He has also focused his research on the natural history of disease. Dr. Lichtenstein has received numerous research grants focusing on these areas and has served as the national/ international principal investigator evaluating novel agents for therapeutic trials in the treatment of Ulcerative Colitis and Crohn's disease.

A Fellow of the American Gastroenterological Association, the American College of Physicians, and the American College of Gastroenterology, Dr. Lichtenstein has been listed in "Best Doctors in America" (inflammatory bowel disease) and has served as Medical Secretary for the American Board of Internal Medicine, Gastroenterology Section. He holds membership and committee positions in many professional societies at a national level, including the American Gastroenterological Association where he has served as chair of the clinical practice committee and a member of the Nominations Committee and currently serves as a member of the grant review committee. He is currently a member of the National Scientific Advisory Committee of the Crohn's Colitis Foundation where he serves as chair of the Professional membership committee, has served as chair of the membership committee of the Clinical Research Alliance, and has served on the national grants review committee. He has served on numerous other committees in the ACG, ASGE, AGA, and Crohn's Colitis Foundation.

Dr. Lichtenstein has received numerous awards including the National Scientific Achievement Award from the national Crohn's and Colitis Foundation of America (CCFA) for his clinical work and research. He is the 2020 recipient of the AGA's top academic clinician award- the AGA Distinguished Clinician Award in Academic Practice. He has received the award for the top specialist in the University of Pennsylvania Health system- the Louis A. Duhring Award. He is the recipient of the Christina and Marie Lindback award- the top teaching award in the entire University of Pennsylvania. He has received the medical school teaching award the "Penn Pearls Award". He has received the Department of Medicine house staff teaching award- the "Donald B. Martin Teaching Award". He has received the Gastroenterology Division teaching award - the Sidney Cohen Teaching Award. He is listed in "The Best Doctors in America" - Inflammatory Bowel Disease and in Philadelphia Magazine-Listed among top Gastroenterologists for elderly in Philadelphia and Listed among top Gastroenterologists in Philadelphia (Special Focus: Inflammatory Bowel Disease). He is the recipient of the CCFA- Physician of the Year Award: Philadelphia and Delaware Valley Chapters.

In addition to having served on the Editorial Board of the journals *Gastroenterology*, *American Journal of Gastroenterology*, *Inflammatory Bowel Diseases*, *World Journal of Gastroenterology*, and *Digestive Diseases and Sciences*, Dr. Lichtenstein serves as a former writer of Selected Summaries in the journal *Gastroenterology* and served as the section editor of Selected Summaries and the section editor of Print and Media Review in *Gastroenterology* for a 5 year term. He is the journal founder and the executive editor of the journal *Gastroenterology and Hepatology now in press for 16 years* and has served as Associate editor for numerous journals including *Therapeutic Advances in Gastroenterology* and *American Journal of Gastroenterology* as well he has served as Assistant Editor-in-Chief of the *World Journal of Gastroenterology*. An invited lecturer at the local, national, and international levels, Dr. Lichtenstein is the author or coauthor of more than 150 primary research articles, 280 chapters, editorials and reviews and he has presented over 350 abstracts and edited 32 books. He has lectured at a national and an international level at over 500 invited conferences, lectures, symposiums, and institutional grand rounds. Dr. Lichtenstein's work is frequently cited, and his H index is 81 and i-10 index is 261.

## **Zachary Bloomgarden, MD, MACE, FASPC**

Clinical Professor; Department of Medicine, Icahn School of Medicine at Mount Sinai  
Editor; Journal of Diabetes

Dr. Bloomgarden is a clinician in private practice with an international reputation for writing and lecturing on diabetes, having authored more than 650 articles. He is Clinical Professor in the Department of Medicine of the Icahn School of Medicine at Mount Sinai and is Editor of the Journal of Diabetes. He served on the Board of the American Association of Clinical Endocrinologists, the Journals Managing Subcommittee of the Endocrine Society, and the Editorial Board of Diabetes Care, has been principal investigator in numerous studies, and is a reviewer for many journals, including Diabetes Care, Endocrine Practice, the Journal of Clinical Endocrinology and Metabolism, the Medical Letter on Drugs and Therapeutics, the Lancet, Lancet Diabetes and Endocrinology, JAMA Internal Medicine, the Annals of Internal Medicine, BMC Cardiovascular Disorders, BMJ Open Diabetes Research & Care, Arteriosclerosis, Thrombosis, and Vascular Biology, the Journal of the American College of Cardiology, the American Journal of Epidemiology, and Pediatrics. In 2012, Dr. Bloomgarden was awarded the title of Master of the American College of Endocrinology. He has been listed for many years in the "Castle Connolly Guide: The Best Doctors New York Metro Area" and the New York Times "SuperDoctors."



Dr. Bloomgarden's interests span the overall field of diabetes. He has carefully followed the development of therapeutic approaches over the past two decades, and for many years wrote a renowned monthly commentary in Diabetes Care, entitled "Perspectives on the News," focusing on this and other aspects of clinical care. Currently, as the Editor of the Journal of Diabetes, he writes frequent commentaries addressing various aspects of treatment. He is interested in the epidemiology of diabetes with particular focus on cardiovascular disease, and has paid particular attention to questions of safety of therapeutic approaches and, even more important, to the potential for cardiovascular and microvascular benefit of diabetes treatment. He also is a frequent commentator on novel technologies, including continuous glucose monitoring and insulin pump treatment, with attention to closed loop approaches, and has addressed novel treatment approaches including insulin treatment modalities, incretin-based treatments, and inhibitors of glucose transport.

## **Raymond Cross, MD, MS, AGAF, FACG**

Professor of Medicine; Division of Gastroenterology and Hepatology,  
University of Maryland, Baltimore  
Director; Inflammatory Bowel Disease Program, University of Maryland  
School of Medicine  
Co-Director; Digestive Health Center, University of Maryland Medical Center

Dr. Cross received his undergraduate degree from Washington and Jefferson College and his medical degree from the University of Pittsburgh School of Medicine. He completed his postgraduate training in Internal Medicine and Gastroenterology at the University of Maryland and Baltimore VA Medical Center. In addition, Dr. Cross obtained a Master of Science degree in Clinical Research at the University of Maryland School of Medicine.

Dr. Cross has authored over 100 journal articles, reviews, and book chapters. His research interests include application of telemedicine in the care of patients with IBD, disparities, outcomes research and clinical trials. He is Co-Chair of the Clinical Research Alliance, Research & Investigator Engagement Lead for SPARC IBD, past Chair of the Clinical Grants Review Committee and Patient Education Committee for the Crohn's and Colitis Foundation and Scientific Co-Director of the Corevitas Registry.



### **Sarah Yim, MD**

Director; Office of Therapeutics Biologics and Biosimilars, Center for Drug Evaluation and Research, US Food and Drug Administration

Sarah Yim, M.D. has been the Director of the Office of Therapeutic Biologics and Biosimilars, in CDER's Office of New Drugs (OND) since 2019. She has been with FDA since 2005 in various roles, including 2 years as Director of the Division of Clinical Review in the Office of Generic Drugs, and 11 years in various roles in rheumatology regulatory review. She received her undergraduate degree from Stanford University, her Doctor of Medicine degree from the Uniformed Services University of Health Sciences, and completed a postdoctoral fellowship in rheumatology at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), at the National Institutes of Health.



### **Qin Sun, PhD**

Therapeutic Biologics Program Biologics Lead; Office of Clinical Pharmacology, Center for Drug Evaluation and Research, US Food and Drug Administration

Dr. Qin Sun is the Therapeutic Biologics Program (TBP) biologics lead in the Office of Clinical Pharmacology (OCP), CDER, FDA. Her key job functions include guide and support reviews and policy development for new molecular entity (NME) biologics or biosimilar products. In addition, Qin is PI or co-PI for biologics related research projects. Qin joined FDA in 2016. Before that, she worked at Pharmaceutical Product Development (PPD) from 2015 to 2016, and at Bristol-Myers Squibb from 2008 to 2014. Qin received her Ph.D. from University of Virginia. Her work experience extends from drug discovery to drug development, and finally to regulatory review, focusing on biologics and biosimilars currently.



### **Sophie Shubow, PhD**

Project and Program Manager; Office of Clinical Pharmacology, Center for Drug Evaluation and Research, US Food and Drug Administration

Sophie Shubow is a project and program manager in the Office of Clinical Pharmacology (OCP) in FDA's Center for Drug Evaluation and Research (CDER). Before joining OCP, she conducted research on tumor angiogenesis for France's National Institute of Health and Medical Research (INSERM) before moving to project management and communications positions in the biopharmaceutical industry and the US Department of Health and Human Services. She holds a Ph.D. in Cell and Molecular Biology from the University of Bordeaux, France, and a Master's in Project Management from ESCP business school.



**James Polli, PhD**

Professor and Ralph F. Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics, University of Maryland School of Pharmacy

James Polli is Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption. His two main research interests are 1) maximizing oral bioavailability through formulation and chemical approaches and 2) developing public quality standards for oral dosage forms. He has served as advisor to 21 Ph.D. graduates. He is co-Director of the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI; [www.cersi.umd.edu](http://www.cersi.umd.edu)) and the Center for Research on Complex Generics (CRCG; [www.complexgenerics.org](http://www.complexgenerics.org)), each an FDA-funded collaborative agreement with the Agency. He is Director of the online M.S. in Regulatory Science program ([www.pharmacy.umd.edu/regulatoryscience](http://www.pharmacy.umd.edu/regulatoryscience)).

He is a fellow of the American Association for Pharmaceutical Scientists and until recently served as an editor of its flagship journal *Pharmaceutical Research* for 12 years. He is a member of the University of Maryland General Clinical Research Center Advisory Committee and the University of Maryland institutional review board (IRB). He is a member of the Scientific Advisory Board of Simulations Plus.

**Maureen A. Kane, PhD**

Associate Professor; Department of Pharmaceutical Sciences; University of Maryland School of Pharmacy  
Executive Director; University of Maryland School of Pharmacy Mass Spectrometry Center.

She received a B.S. in Chemistry from Canisius College (Buffalo, NY), a Ph.D. in Analytical Chemistry from the University at Buffalo, State University of New York, and completed postdoctoral training at the University of California, Berkeley. The Kane Lab focuses on elucidating disease mechanisms towards identifying new therapeutic targets and informing on mechanism(s) of action of current drug candidates using a combination of mass spectrometry-based techniques including quantitative LC-MS/MS, targeted metabolomics, lipidomics, proteomics, and mass spectrometry imaging.

