FDA/FTC Workshop on a Competitive Marketplace for Biosimilars
March 9, 2020
FDA Headquarters, Silver Spring, MD

Speaker Bios

Stephen M. Hahn
Commissioner of Food and Drugs - Food and Drug Administration

Dr. Hahn's bio can be found on the FDA internet site at the following link - https://www.fda.gov/about-fda/fda-organization/stephen-hahn.

Joseph J. Simons
Chairman, Federal Trade Commission

Mr. Simons' bio can be found on the FTC internet site at the following link - https://www.ftc.gov/about-ftc/biographies/joseph-j-simons.

Murray Aitken
Executive Director, IQVIA Institute for Human Data Science

Murray Aitken is a senior vice president of IQVIA and Executive Director of the IQVIA Institute for Human Data Science. The Institute undertakes independent research for publication, drawing upon the resources of IQVIA, and focuses on improving understanding of critical healthcare issues around the world, including the role of medicines in patient care, the disruptive impact of technology, productivity in research and development, and the value of information in improving decision-making.

In his role, Murray directs the research agenda and co-authors reports, while also engaging externally with a broad range of healthcare decision-makers in the public and private sectors. Reports by the Institute are widely cited by policy-makers, referenced in peer-reviewed research, and covered by the media.

Prior to joining IQVIA (formerly IMS Health and QuintilesIMS) in 2001, Murray was a partner at McKinsey & Company, based in the Los Angeles, Seoul and New Jersey offices.

Murray holds an MBA, with distinction, from Harvard University and a Master of Commerce degree from the University of Auckland in New Zealand.

Meredyth Andrus
Attorney, Health Care Division, Bureau of Competition, FTC

Meredyth Smith Andrus is an attorney in the Health Care Division of the Federal Trade Commission, Bureau of Competition. Ms. Andrus has taken a prominent role in numerous investigations and prosecutions in the pharmaceutical industry. Prior to joining the FTC, Ms. Andrus was an Assistant Attorney General in the Antitrust Division of the Maryland Office of the Attorney General. She has been in antitrust enforcement for over thirty years, primarily in the health care field. Before joining the government, she practiced commercial litigation with Semmes Bowen & Semmes in Baltimore.

She earned her JD in 1985 from Cornell Law School, her BA in 1978 from Cornell University, and her MFA in dance in 1981 from Sarah Lawrence College. She is admitted to the bar of the State of Maryland, the U.S. District Court for the District of Maryland, the U.S. Court of Appeals for the Fourth Circuit, and the U.S. Supreme Court.

Michele Andwele
Editorial Director for Health Content, Arthritis Foundation

Michele I. Andwele is the Editorial Director for Health Content at the Arthritis Foundation, the largest nonprofit advocacy organization representing the needs of adults and children with arthritis and related conditions. In this role, Ms. Andwele oversees the content strategy and development of patient education across multiple media including web, print and in-person communication. A 25-year health communication veteran, Ms. Andwele provided consulting and program development services for nonprofit and faith-based organizations as well as health care companies before joining the Foundation in 2013. Her insights and expertise have guided patient education campaigns in the areas of heart disease, musculoskeletal health, HIV/AIDs, diabetes, periodontal disease, Alzheimer's disease and health disparities. Ms. Andwele has a Bachelor's degree in Communications from Florida International University and a marketing MBA from Barry University.

Sameer Awsare
Associate Executive Director, The Permanente Medical Group

Dr. Sameer Awsare is an Associate Executive Director for The Permanente Medical Group in charge of Pharmacy, Adult and Family Medicine, Mental Health, Risk Adjusted Coding, Revenue Cycle, Outside Medical Services, Pain Management and the Opioid Initiative.

Dr. Awsare joined the Permanente Medical Group in 1993. In addition to his clinical responsibilities, he has served in a number of other roles. He is involved in resident teaching and was the Chair of the Hospital Ethics Committee. He has also been involved in Medicare coding and compliance at the medical center level. He was the Chief of medicine at our Campbell facility. He had been a member of TPMG Board of Directors from 1997-2014, and served as its secretary from 2000 to 2006. He also served as Chair of the board's Governance Committee and the Vice Chair of the board from 2006 - 2014. He is currently the Secretary and Chair of the Governance Committee of the Mid-Atlantic Permanente Medical Group Board.

Dr. Awsare is board certified in Internal Medicine. He received his BS in Biology, and his MD from the University of California, Irvine. He has served on the voluntary clinical faculty at the Stanford University of School of Medicine. Dr. Awsare is a fellow of the American College of Physicians.

Armine Black
Attorney, Health Care Division, Bureau of Competition, FTC

Armine Black is an attorney in the Health Care Division of the FTC's Bureau of Competition. Since joining the Commission, they have worked on a variety of pharmaceutical investigations and litigations, including investigations related to biosimilar products. Armine attended Columbia Law School and Brown University.

Alex Brill
Resident Fellow, American Enterprise Institute

Alex Brill is a resident fellow at the American Enterprise Institute, where he studies health policy, tax policy, and other public finance matters. Alex is also the founder and CEO of Matrix Global Advisors, an economic policy consulting firm. Previously, Alex was the policy director and chief economist for the House Committee on Ways and Means, where he worked from 2002 to 2007, and also served on the staff of the White House Council of Economic Advisers.

Alex has been studying the economics of biosimilars for more than a decade, beginning with assessing the appropriate duration of market exclusivity for reference biologics before a U.S. biosimilar pathway was established. In recent years, he has studied the economic viability of the U.S. biosimilars market and examined ways to incentivize biosimilar utilization. Alex has testified before the FTC and the House Judiciary Committee on biosimilars, modeled various aspects of the economics of biosimilars, and written extensively on the topic.

Alex has testified numerous times before Congress on other issues and has written and consulted on small-molecule drug competition, drug pricing, Part B reimbursement, and generic drug labeling requirements, among other topics.

Molly Burich
Director of Public Policy, Boehringer Ingelheim

Molly Burich, MS, is the Head of Public Policy at Boehringer Ingelheim, Inc. In her role she leads the public policy team at Boehringer with specific focus on biosimilars, oncology, pipeline products as well as reimbursement across the existing and pipeline portfolio for Boehringer Ingelheim. Ms. Burich has held previous positions in federal and state government affairs, public policy and reimbursement across other organizations including Otsuka Pharmaceuticals, Xcenda, an Amerisource Bergen company and Avalere Health. Ms. Burich holds a master of science in public service management with an emphasis in public policy from DePaul University and a bachelor of arts in political science from the University of Northern Colorado.

Michael Carrier
Distinguished Professor, Rutgers Law School

Michael A. Carrier is Distinguished Professor at Rutgers Law School, where he specializes in antitrust and IP law. He is co-author of the leading IP/antitrust treatise, *IP and Antitrust Law: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, the author of *Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law*, and the editor of *Critical Concepts in Intellectual Property Law: Competition*. He has written more than 120 book chapters and articles in leading law reviews, has been quoted more than 2000 times in the media, and has been cited in courts including the U.S. Supreme Court. Professor Carrier has testified before the FDA, FTC, National Academies, Senate Judiciary Committee, and House Energy & Commerce Committee; is a past chair of the Executive Committee of the Antitrust and Economic Regulation section of the Association of American Law Schools (AALS); and served on the 2016 ABA Antitrust Section's Presidential Transition Task Force.

Dominic Cirincione
Regulatory Counsel, Office of Prescription Drug Promotion, CDER, FDA

Dominic (Dom) Cirincione is a Regulatory Counsel in FDA's Office of Prescription Drug Promotion (OPDP). He regularly provides advice and regulatory counseling on policy and compliance matters to both OPDP reviewers and OPDP management. Since joining FDA in 2010, he has held several roles within the FDA's Office of the Commissioner, including in the Office of External Affairs and Office of Legislation, and within CDER's Office of Medical Policy. Dom received his B.A. and M.P.P. from the University of Maryland, Baltimore County (UMBC) and J.D. from the University of Maryland Carey School of Law

Richard L. Cleland
Assistant Director, Division of Advertising Practices, Bureau of Consumer Protection, FTC

Mr. Cleland joined the Federal Trade Commission's Division of Advertising Practices in 1991. In 1996, Mr. Cleland was appointed Assistant to the Director of the Bureau of Consumer Protection and, in 1998, he was appointed Assistant Director of the Division of Service Industry Practices. He currently serves as Assistant Director of the Division of Advertising Practices. His primary area of expertise is the advertising and marketing of health-related products and services.

Hillel P. Cohen
Executive Director, Scientific Affairs, Sandoz

Dr. Hillel P. Cohen PhD is Executive Director of Scientific Affairs at Sandoz Inc., helping explain the principles of biosimilars and biosimilar policies to the healthcare community, patient advocacy groups, and other stakeholders. He has published and given presentations in the areas of biosimilar education, switching, interchangeability, totality-of-evidence, naming and safety. Hillel is Co-Chair of the Education Committee of the Biosimilars Forum and is a member of the Education Committee of the Biosimilars Council (a division of the Association for Affordable Medicines). Prior to joining Sandoz he held multiple positions at Novartis Vaccines, including Head of Regulatory Affairs for North and Latin America and well as Head of Global Labeling. Dr. Cohen received a BA from New York University and a PhD in Biology from Dartmouth.

Antara Dutta
Economist, Bureau of Economics, FTC

Antara Dutta is an Economist at the Federal Trade Commission's Bureau of Economics. She has over ten years of antitrust experience in the government and private sector, spanning a wide range of industries including healthcare and multiple issues such a mergers, intellectual property and anticompetitive conduct. At the FTC, Dr. Dutta has been a lead economist on a large number of antitrust investigations, including those in the biologics or related industries, and was on the FTC teams that challenged the mergers of hospital systems Cabell-St. Mary's in West Virginia and Penn State-Pinnacle in Pennsylvania. She was previously an Assistant Professor of Economics at Georgetown University. Dr. Dutta is an Assistant Editor of the Antitrust Law Journal.

Alison Falb
Regulatory Counsel, Office of Therapeutic Biologics and Biosimilars, CDER, FDA

Alison Falb is a Regulatory Counsel in CDER's Office of Therapeutic Biologics and Biosimilars, which oversees the development and implementation of regulatory policy related to biosimilar, interchangeable, or other therapeutic biologic products. Prior to joining the Office of Therapeutic Biologics and Biosimilars, Ms. Falb was a Senior Advisor at the Center for Medicare and Medicaid Innovation (CMMI) at the Centers for Medicare & Medicaid Services where she led policy development for specialty care and episode-based payment models under the MACRA statute and designed and implemented alternative payment models including the Oncology Care Model (OCM). She earned her J.D., cum laude, from Fordham University School of Law and her B.A. in psychology from Brown University.

Catherine B. Gray
Staff Director, Office of Prescription Drug Promotion, CDER, FDA

Catherine Gray leads the Advertising and Promotion Policy Staff in the Office of Prescription Drug Promotion (OPDP) at the FDA. Her diverse team of professionals focuses on the challenging and evolving policy issues pertaining to the promotion of prescription drugs. She oversees policy development, social science research and operational support to the full office as it realizes its mission to protect the public health. Her over twenty years of experience include roles in clinical pharmacy and the pharmaceutical industry. She completed Fellowships through the Rutgers University Pharmaceutical Industry Post-Doctoral Fellowship program and the Partnership for Public Service Excellence in Government Fellowship program.

Inma Hernandez
Assistant Professor of Pharmacy and Therapeutics, University of Pittsburgh School of Pharmacy

Hernandez earned her PharmD from the University of Navarra (Spain), and her PhD in Health Services Research and Policy from the University of Pittsburgh. She currently serves as Assistant Professor of Pharmacy and Therapeutics and Associate Director of the Center for Pharmaceutical Policy and

Prescribing at the University of Pittsburgh. Her research has focused on evaluating clinical and economic outcomes of oral anticoagulant agents, and the application of statistical, epidemiological, and econometric methods to administrative databases. She has also made important contributions to studying pharmaceutical pricing. She has published over 50 peer-reviewed scientific manuscripts.

Sarah Ikenberry
Senior Communication Advisor, Office of Therapeutic Biologics and Biosimilars, CDER, FDA

Sarah Ikenberry is a Senior Communication Advisor at the Office of Therapeutic Biologics and Biosimilars (OTBB) in the Food and Drug Administration's (FDA) Center for Evaluation and Research (CDER). She provides communication advice and support to senior leaders and the agency about communicating strategic priorities, initiatives, and educational information about biosimilar and interchangeable products. Sarah previously worked in CDER's Office of Communications where she planned and implemented strategic communication strategies and marketing activities about high-priority, complex CDER policy matters and public health and regulatory issues related to drug products. While there, she also helped develop and launch FDA's first campaign about biosimilar and interchangeable products. Sarah has a Master of Arts in Communication from Johns Hopkins University.

Elizabeth Jex
Attorney Advisor, Office of Policy Planning, FTC

Elizabeth Jex is an attorney advisor specializing in biopharmaceutical health policy in the Federal Trade Commission's Office of Policy Planning. She is a career staff attorney with 30 years of experience in public service, twenty years performing biopharmaceutical merger review and ten years performing advocacy work on healthcare competition. Ms. Jex has received several team and individual awards at the FTC, including the prestigious Paul Rand Dixon Award (2009) for her expertise in the pharmaceutical industry and antitrust; the Janet D. Steiger Awards for the Remedies Study Report (2017) and Global Competition Hearings (2019). She has also served as a Special Assistant United States Attorney for the Eastern District of Virginia. Ms. Jex is a graduate of Williams College (1983) and obtained her Juris Doctor from Georgetown University Law Center (1987).

Cheryl Koehn
Founder & President, Arthritis Consumer Experts

Cheryl Koehn lives with rheumatoid arthritis and over her 30 years since diagnosis has become a national patient community leader, educator, patient research partner and published author. Ms. Koehn has dedicated her life to helping others living with arthritis. She is the Founder and President of Arthritis Consumer Experts, Canada's first national, patient-led organization that provides science-based information and education programs in both official languages to people with arthritis. She served as Co-Chair of the Summit on Standards for Arthritis Prevention and Care, was a volunteer member of the management committee of Canada's first federally funded arthritis research institute (the Canadian Arthritis Network), was a consumer representative Board Member of the Arthritis Alliance of Canada and today serves as the patient representative on the Canadian Institutes of Health Research Standing Committee on Ethics.

As one of the world's leading arthritis advocates, Ms. Koehn represents ACE by providing our members' perspectives on arthritis health and policy issues to governments, private payers, employers, healthcare professionals, and media. She is a frequently invited speaker at national and international arthritis and health-related conferences. Ms. Koehn is the lead consumer representative on two global initiatives: the RA NarRAtive, a panel comprised of 39 healthcare providers and patient group leaders from 17 countries, and the Global RA Network, a coalition of 24 RA patient-led organizations from North America, Europe and South America.

Ms. Koehn is also an active patient research partner participating in numerous current research projects in Canada and internationally:

- ICON - Walk10Blocks (CIHR) – Lead, Knowledge User Group
- PRECISION (CIHR) – Lead, Consumer Core
- EQUIP-TJR (Vancouver Coastal Health Research Institute) – Co-Investigator and Organizational Partner
- OPERAS (CIHR) – Collaborator and Organizational Partner
- ANSWER 1 & 2 – Collaborator and Organizational Partner
- CIHR Project Grant (evaluation of multidisciplinary rheumatology nursing care for people with complex rheumatic diseases) – Co-Investigator
- Making it Work (CIHR) – Key consumer informant

In her leadership role at Arthritis Consumer Experts, Ms. Koehn has led the development of numerous information and education innovations to the arthritis community, including the ArthritisID and Arthritis ID PRO iPhone apps, Arthritis Broadcast Network blog, the annual JointHealth™ Arthritis Medications Report Card and Canada's Best Workplaces for Employees Living with Arthritis Award, among many others.

Along with co-authors Dr. John Esdaile and Taysha Palmer, Cheryl Koehn authored Rheumatoid Arthritis: PLAN TO WIN, published by Oxford University Press.

Ms. Koehn lives in Vancouver, British Columbia, where she enjoys ocean swimming, cycling, and walking her faithful dog, Molly.

Disclosure: Cheryl Koehn is a full-time employee of Arthritis Consumer Experts. Their financial disclosures and guiding principles can be found here https://jointhealth.org/about-principles.cfm?locale=en-CA

Elizabeth Pepinsky
Health Science Policy Analyst, Office of Prescription Drug Promotion, CDER, FDA

Elizabeth Pepinsky is a Health Science Policy Analyst in FDA's Office of Prescription Drug Promotion, where she focuses on guidance and policy development. Prior to joining OPDP, she served as a Regulatory Counsel in FDA's Center for Tobacco Products. Ms. Pepinsky received her B.S. from Wake Forest University and her J.D. from the University of Baltimore School of Law.

Andreas Schick
Director, Economics, Office of Program and Strategic Analysis, CDER, FDA

Andreas Schick serves as the director of economics for the Office of Program and Strategic Analysis in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). In this role, he serves as a leading authority on economic matters related to the FDA's strategic initiatives and policies. In his time at the FDA, Andreas has managed and carried out analysis and research in a range of topics, including the corona virus, drug shortages, drug pricing, drug safety, and the public health impact of abuse-deterrent opioids, and the cost-benefit of abuse-deterrent opioids. Andreas holds a PhD in economics from the Ohio State University and a bachelor's degree in Mathematics and Economics from Binghamton University.

Lowell Schiller
Principal Associate Commissioner for Policy, FDA

Lowell Schiller serves as the Principal Associate Commissioner for Policy of the Food and Drug Administration. In this role, Mr. Schiller is responsible for overall leadership of FDA's Office of Policy, manages agency-wide processes for the development of regulations and guidance, and provides leadership and support on a broad range of policy issues.

Mr. Schiller previously served as the Senior Counselor to the Commissioner of Food and Drugs and as FDA's Acting Chief Counsel. Prior to joining FDA, Mr. Schiller served as Senior Counsel to Chairman Lamar Alexander on the Senate Committee on Health, Education, Labor, and Pensions (HELP). On the HELP Committee, he handled presidential nominations to public health agencies and other positions within Committee jurisdiction, conducted congressional investigations and other oversight, and helped draft legislation including the 21st Century Cures Act. Earlier in his career, Mr. Schiller was a litigator in private practice specializing in appeals, dispositive motions, and federal agency disputes, with a focus on matters involving federal health laws including the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

Previously, Mr. Schiller clerked for the Honorable Jane R. Roth of the United States Court of Appeals for the Third Circuit. He earned his law degree cum laude from Harvard Law School and his undergraduate degree summa cum laude from Princeton University.

David R. Schmidt
Assistant Director, Office of Applied Research and Outreach, Bureau of Economics, FTC

David Schmidt is the Assistant Director of the Office of Applied Research and Outreach in the Federal Trade Commission's Bureau of Economics. He has published research in the fields of healthcare competition, econometrics, game theory, and experimental economics. He also has contributed to FTC staff reports on generic drugs, and pharmacy benefit managers. He earned his Ph.D. from the California Institute of Technology and served on the faculty of the Department of Economics at Indiana University.

Christine M. Simmon
Senior Vice President, Policy & Strategic Alliances and
Executive Director, Biosimilars Council

Christine Simmon joined the Association for Accessible Medicines in 2012 as the Senior Vice President of Policy & Strategic Alliances, and in 2015 was named Executive Director of AAM's Biosimilars Council.

In her current role, Christine is responsible for leading policy development and issues management for AAM, directing the Biosimilars Council, and building relationships with strategic partners in the health care sector, including patient advocacy groups.

Christine had previously served as Vice President of Policy, Public Affairs & Development at AAM from 2002-2006. Before rejoining the association, she was the Senior Director of Public Policy for CVS Caremark, where she was the policy lead for the integrated retail, convenient care clinic and PBM enterprise at both the state and federal levels. Previously, Christine was a Senior Policy Analyst at BlueCross BlueShield Association, where she helped position the insurer as a leading voice on pharmaceutical cost and safety issues.

Christine received her J.D. from Georgetown University Law Center and her B.A. in American Studies from Georgetown University.

Surya Singh, M.D.
President & Owner
Singh Healthcare Advisors, LLC
Adjunct Instructor of Medicine, Harvard Medical School

As a senior advisor and consultant to non-profits, private corporations, and publicly traded companies, Dr. Singh provides expertise and guidance on healthcare issues with broad impact. While he frequently provides senior executives with counsel on their overall business strategy, he topically focuses on the adoption of novel therapies, acceleration of value-based reimbursement, predictive analytics and the use of artificial intelligence, and the clinical application of genomic sequencing.

Previously, Dr. Singh was Corporate Vice-President and Chief Medical Officer at CVS Health Specialty, where he was responsible for specialty client & clinical strategy, product innovation, analytics, clinical program management, and drug safety/pharmacovigilance. In this role, he oversaw a multifaceted team of clinicians and analysts, led several strategic initiatives, partnerships, and acquisitions for the company, and played a key senior management role during a time of unprecedented business growth.

Before CVS Health, Dr. Singh was Chief Medical Officer and Head of Product Development and Strategy at Proventys, (acquired by McKesson Corporation), Chief Medical Officer and SVP of Clinical Operations at D2Hawkeye (now part of Verisk Health) and was a healthcare strategy consultant at McKinsey and Company.

Dr. Singh is licensed and board certified in internal medicine and is an Adjunct Instructor of Medicine at Harvard Medical School. He lives in Lexington, Massachusetts with his wife (a practicing gastroenterologist), and their three sons.

Eva Temkin
Acting Director for Policy, Office of Therapeutic Biologics and Biosimilars, CDER, FDA

Eva Temkin is the Acting Director for Policy in the Office of Therapeutics and Biologics within FDA's Center for Drug Evaluation and Research. In this role, she oversees the development and implementation of regulatory policy related to biosimilar, interchangeable, and therapeutic biologic products. In addition, Ms. Temkin is the agency lead for FDA's Biosimilar Action Plan, which outlines the Administration's plans for encouraging innovation and competition among biologics and the development of biosimilars. Prior to joining the Office of Therapeutic Biologics and Biosimilars, Ms. Temkin was Associate Chief Counsel for Drugs in FDA's Office of Chief Counsel, where she served as counsel to CDER on complex issues relevant to drug development and approval. Previously, Ms. Temkin was a litigator at the law firms of Cravath, Swaine & Moore LLP and Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP and a law clerk in the United States District Court for the Eastern District of New York. She earned her J.D. from New York University School of Law, where she was the NYU Law and Economics Fellow, and her B.A. in economics, cum laude, from the University of Michigan.

Rebecca Tushnet
Frank Stanton Professor of First Amendment Law, Harvard Law School

Rebecca Tushnet is the inaugural Frank Stanton Professor of First Amendment Law at Harvard Law School. Her work focuses on copyright, trademark, and advertising law. Her blog, tushnet.blogspot.com, is one of the top intellectual property blogs, and her writings may be found at tushnet.com. She is also an expert on the law of engagement rings.

Randall Weinsten
Attorney, Health Care Division, Bureau of Competition, FTC

Randall ("Randy") Weinsten graduated from Carnegie Mellon in 2005 (Phi Beta Kappa, University Honors, College Honors) with a degree in business administration and an additional major in philosophy. After college he served as a Coro Fellow in Local Democracy, developing and testing deliberative polling initiatives and researching citizen engagement in local policy issues. Randy then attended law school at Duke University, graduating magna cum laude, where he also earned a master's degree in philosophy. After Duke, Randy spent four years at a large international law firm practicing antitrust and also worked on a number of pro bono matters. He left private practice for the Federal Trade Commission in 2014, where he leads investigations into anticompetitive conduct in the healthcare industry and works on high profile litigation.