Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics

SPEAKER BIOS

Introductory Remarks:

Svetlana Gans serves as the FTC's Chief of Staff, overseeing all agency operations. She advises the Acting Chairman on FTC competition and consumer protection policy and enforcement matters including mergers, conduct investigations, privacy, data security, and advertising. She creates, executes, and oversees strategic initiatives to advance the Chairman's priorities to promote the agency's consumer protection and competition mission. She serves as the Chairman's liaison to the White House, other federal and state agencies, members of Congress and Congressional committees, and other stakeholders, and is on several agency task forces including the Economic Liberty Team, Regulatory Reform and Streamlining Team, and Healthcare Competition Team.

Keynote Remarks:

The Honorable Maureen K. Ohlhausen was sworn in as a Commissioner of the Federal Trade Commission on April 4, 2012 and was designated to serve as Acting FTC Chairman by President Donald Trump in January 2017. Prior to joining the Commission, she was a partner at Wilkinson Barker Knauer, LLP, where she focused on FTC issues, including privacy, data protection, and cybersecurity. Ohlhausen previously served at the Commission for 11 years, most recently as Director of OPP from 2004 to 2008, where she led the FTC's Internet Access Task Force. She was also Deputy Director of that office. From 1998 to 2001, Ohlhausen was an attorney advisor for FTC Commissioner Orson Swindle, advising him on competition and consumer protection matters. She started at the FTC General Counsel's Office in 1997. Before coming to the FTC, Ohlhausen spent five years at the U.S. Court of Appeals for the D.C. Circuit, serving as a law clerk for Judge David B. Sentelle and as a staff attorney. Ohlhausen also clerked for Judge Robert Yock of the U.S. Court of Federal Claims from 1991 to 1992. Ohlhausen graduated with distinction from Antonin Scalia Law School, George Mason University in 1991 and graduated with honors from the University of Virginia in 1984. Ohlhausen was on the adjunct faculty at the Antonin Scalia Law School, George Mason University, where she taught privacy law and unfair trade practices. She served as a Senior Editor of the *Antitrust Law Journal* and a member of the American Bar Association Task Force on Competition and Public Policy. She has authored a variety of articles on competition law, privacy, and technology matters.

The Honorable Scott Gottlieb, M.D., was sworn in as the 23rd Commissioner of Food and Drugs on May 10, 2017. Dr. Gottlieb is a physician, medical policy expert, and public health advocate who previously served as the FDA's Deputy Commissioner for Medical and Scientific Affairs and before that, as a senior advisor to the FDA Commissioner. He also worked on implementation of the Medicare drug benefit as a Senior Adviser to the Administrator of the Centers for Medicare and Medicaid Services, where he supported policy work on quality improvement and the agency's coverage process, particularly as it related to new medical technologies. In 2013 Dr. Gottlieb was appointed by the Senate to serve on the Federal Health Information Technology Policy Committee, which advises the Department of Health and Human Services on healthcare information technology. Dr. Gottlieb was previously a Resident Fellow at the American Enterprise Institute, and a Clinical Assistant Professor at the New York University School of Medicine in Manhattan, where he also practiced medicine as a hospitalist physician. He completed a residency in internal medicine at the Mount Sinai Medical Center in New York, New York and is a graduate of the Mount Sinai School of Medicine and of Wesleyan University, in Middletown, Connecticut, where he studied Economics.

Panel 1: Generic Drug Competition: Understanding Demand, Price and Supply Issues

Michael A. Carrier is Distinguished Professor at Rutgers Law School. He is the 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 95 book chapters and articles, has been quoted more than 1,000 times in the media, and has been cited in courts including the U.S. Supreme Court. Professor Carrier has testified before the U.S. Senate Judiciary Committee, FDA, and National Academies; is a member of the Board of Advisors of the American Antitrust Institute; 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.

Chester "Chip" Davis, Jr., J.D., is the President and Chief Executive Officer of the Association for Accessible Medicines, the nation's leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals and suppliers of other goods and services to the generic drug industry. Prior to joining AAM, Chip most recently served as Executive Vice President for Advocacy and Member Relations at the Pharmaceutical Research and Manufacturers of America (PhRMA), where he was responsible for leading PhRMA's federal, state and international government relations and advocacy efforts, in addition to member company recruitment and retention. Prior to joining PhRMA, he was Vice President of Corporate External Relations for AstraZeneca, where he oversaw the company's government relations, strategic alliances, community relations and employee volunteer efforts. He was a member of AstraZeneca's Corporate Affairs Leadership team and Vice-Chairman of the company Political Action Committee. Chip earned an undergraduate degree in Accounting from the University of Delaware, and a Juris Doctor from the University of Baltimore School of Law. He is a licensed attorney in Maryland, Virginia and the District of Columbia.

Aharon "Ronny" Gal, Ph.D., is the Senior Analyst at Bernstein covering Global Specialty Pharmaceuticals & Biotechnology. Prior to joining Bernstein in 2004, Ronny spearheaded Canon's business development in life sciences. He also spent six years with the Boston Consulting Group, advising clients in the pharmaceuticals and healthcare delivery industries. Ronny was awarded a Ph.D. from the Massachusetts Institute of Technology and holds a BSc from Emory University. Ronny has been a top analyst in *Institutional Investor*'s All-America Research Team survey for the past eight years; ranking either No. 1 or No. 2 in his sector.

Aaron S. Kesselheim, M.D., J.D., M.P.H., is an Associate Professor of Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital. Within the Division, Aaron created and leads the Program On Regulation, Therapeutics, And Law (PORTAL, www.PORTALresearch.org), an interdisciplinary research core focusing on intersections among prescription drugs and medical devices, patient health outcomes, and regulatory practices and the law. With 3 full-time faculty members, 5 post-docs, and numerous student affiliates, PORTAL is now the largest, independent academic center focusing on these issues in the country. Author of over 300 publications in the peer-reviewed medical and health policy literatures, Aaron has testified before Congress on pharmaceutical policy, medical device regulation, generic drugs, and modernizing clinical trials, is a member of the FDA Peripheral and Central Nervous System Advisory Committee, and served on a National Academies of Science, Engineering and Medicine consensus committee on addressing the opioid epidemic. His work has been funded by the Greenwall Faculty Scholar in Bioethics Program, the Commonwealth Fund, the Robert Wood Johnson Foundation, the Laura and John Arnold Foundation, the Engelberg Foundation, the FDA, and AHRQ. Aaron is a core faculty member at the HMS Center for Bioethics, where he co-teaches a course on health policy, law, and bioethics and organizes a monthly policy and ethics seminar series. Aaron also serves as the Irving S. Ribicoff Visiting Associate Professor of Law at Yale Law School, where he teaches a yearly course on Food and Drug Administration Law. He is the editor-in-chief of the *Journal of Law, Medicine, and Ethics.*

Stephen W. Schondelmeyer, Pharm.D, Ph.D., a professor of Pharmaceutical Economics in the College of Pharmacy, is an expert in the practice of pharmaceutical care and its role in the healthcare system. He has unique knowledge and 40 years of experience in policy analysis related to prescription drug reimbursement; drug benefit plans; pricing patterns of brand, generic, and specialty products; and generic product evaluation and drug product selection. His research projects have included prescription drug reimbursement under Medicaid, Medicare and other programs; pharmaceutical prices and the role of patents and other exclusivities; and the dynamics of pharmaceutical competition. He has conducted research for many sponsors including the Centers for Medicare and Medicaid Services, the U.S. Special Committee on Aging, and the Food and Drug Administration.

Suzanne Munck is Chief Counsel for Intellectual Property for the United States Federal Trade Commission and Deputy Director of its Office of Policy Planning, where she leads teams addressing cutting-edge policy issues. Ms. Munck has significant litigation experience managing IP issues that arise during the FTC's enforcement efforts in the ICT and healthcare sectors. In recognition of her work, Ms. Munck has received the Commission's Paul Rand Dixon and Janet D. Steiger Awards. Before joining the FTC, she was an antitrust and IP litigator in Los Angeles. She received her BA in mathematics from Bryn Mawr College and graduated from the University of Minnesota Law School, where she was a managing editor of the Minnesota Law Review.

Maarika Kimbrell, J.D., M.S. serves as Deputy Chief of Staff to the Commissioner of the Food and Drug Administration. Prior to joining the Office of the Commissioner, Ms. Kimbrell served as the Director of the Division of Legal and Regulatory Support within the Office of Generic Drug Policy and held other positions within the Office of Generic Drug Policy. Before joining FDA, Ms. Kimbrell practiced for over a decade as an attorney in private practice with a focus on intellectual property licensing and other corporate transactions on behalf of clients in the life sciences industry both at Covington & Burling LLP in Washington DC and Morrison & Foerster LLP in San Francisco, CA.

Panel 2: Understanding Intermediaries: Pharmacy Benefit Managers

Robert E. Andrews is the CEO of the Health Transformation Alliance. Rob led the Government Affairs practice at Dilworth Paxson law firm for two years before joining the HTA. Rob served as a Member of the U.S. House of Representatives for nearly 24 years. Upon his departure from the House, President Obama praised Rob's service as "an original author of the Affordable Care Act...and a vital partner in its passage and implementation," and cited his "tenacity and skill" in representing the people of New Jersey.

Jennifer Bryant serves as Senior Vice President, Policy and Research for the Pharmaceutical Research and Manufacturers of America (PhRMA), the national association representing the country's leading pharmaceutical research and biotechnology companies. At PhRMA, she oversees development of public policy related to Medicare, Medicaid and health care reform, as well analysis and policy development related to changes in the health care delivery system. She oversees a broad portfolio of economic and policy research, with a focus on better understanding how medicines are used and valued, and the impact of appropriate medication use on health care costs. Prior to joining PhRMA, Ms. Bryant was Vice President at The Lewin Group, a national health care consulting firm. Previously, she held positions at Blue Cross Blue Shield Association, Blue Cross Blue Shield of Florida, New York Hospital-Cornell Medical Center, and the State of New York. Ms. Bryant graduated magna cum laude from Harvard College and received her MBA from the Harvard Graduate School of Business Administration.

Adam J. Fein, Ph.D., is the president of Pembroke Consulting, Inc., a management advisory and business research firm based in Philadelphia. He also is the CEO of Pembroke's Drug Channels Institute, a leading management educator for and about the pharmaceutical industry. Dr. Fein is one of the country's foremost experts on pharmaceutical economics and the drug distribution system. Top manufacturers call on Dr. Fein's insights and judgment to create successful commercial strategies and make better strategic decisions in our evolving healthcare environment. Dr. Fein's popular and influential Drug Channels website (DrugChannels.net) is the go-to source for definitive and comprehensive industry analysis, delivered with a witty edge. He has published hundreds of academic and industry articles, and is regularly quoted in such national publications as *The Wall Street Journal*, *The New York Times*, *Fortune*, *Drug Benefit News,* and many others. Dr. Fein earned his doctoral degree from the Wharton School of Business at the University of Pennsylvania and a B.A., *summa cum laude*, from Brandeis University. He lives in Philadelphia with his wife and their two children.

Mark Merritt is President and CEO of the Pharmaceutical Care Management Association, the national association representing America's pharmacy benefit managers, which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D. Mr. Merritt took the helm of PCMA in March 2003 and quickly raised the industry's profile. He is repeatedly ranked as one of the most effective trade association CEOs in America and has been inducted into the U.S. Chamber of Commerce's elite "Association Committee of 100," representing America's top trade association executives. In recognition of his aggressive advocacy for lower cost prescription medications, the Generic Pharmaceutical Association (GPhA), which represents the world's leading generic drug manufacturers, honored Mr. Merritt with its prestigious "Outstanding Contribution" award. Prior to PCMA, Mr. Merritt served as a senior strategist with America's Health Insurance Plans and the Pharmaceutical Research and Manufacturers of America (PhRMA) as well as with the presidential campaigns of current U.S. Senator Lamar Alexander and former Senator Robert Dole. Mr. Merritt has also served as a Fellow at Harvard University's John F. Kennedy School of Government, where he lectured on the intersection between public policy and the news media. He holds both an MA and BA from Georgetown University.

Susan Pilch is the Vice President of Policy and Regulatory Affairs for the National Community Pharmacists Association and has worked at NCPA since 2009. Prior to this position she worked as a multi-state lobbyist representing primary wholesale pharmaceutical distributors as well as served as Director of state legislative and regulatory advocacy for another health-related professional association. Susan began her career in the health policy/legislative arena immediately following her graduation from law school when she worked for the Maryland House of Delegates Judiciary Committee.

Neeraj Sood, Ph.D., is Professor & Vice Dean for Research at the USC Sol Price School of Public Policy at the University of Southern California. Dr. Sood is on the editorial boards of leading journals in his field including the *Journal of Health Economics* and *Health Services Research*. He is a research associate at the National Bureau of Economic Research (NBER) – the nation's premier economic research organization, faculty at the USC Schaeffer Center, and board member of the American Society of Health Economists. He has published more than 100 book chapters and papers in leading journals including *JAMA*, *Health Affairs*, *BMJ*, *Quarterly Journal of Economics* and *Journal of Health Economics* and his work has also been featured in several media outlets such as the *New York Times*, *Washington Post*, *U.S. News and World Report*, and *Scientific American*. He has testified frequently on health policy issues, participated in expert panels for the National Academies of Sciences, Engineering and Medicine and led projects funded by prominent national and international agencies such as the National Institutes of Health, National Science Foundation and World Bank. Dr. Sood was the finalist for the 16th and 21st Annual NIHCM Health Care Research Award, recognizing outstanding research in health policy. He was also the 2009 recipient of the Eugene Garfield Economic Impact Prize, recognizing outstanding research demonstrating how medical research impacts the economy. Prior to joining USC, Dr. Sood was a senior economist at RAND and Professor at the Pardee RAND Graduate School. Dr. Sood would like to acknowledge the contributions of the Schaeffer Center for Health Policy & Economics and by Amgen through a contract with Precision Health Economics.

David R. Schmidt, Ph.D., is the Assistant Director of the Office of Applied Research and Outreach in the FTC's Bureau of Economics, and was previously a staff economist in one of the antitrust shops in the Bureau. His research has focused on antitrust analysis, healthcare, game theory and experimental economics. He has contributed to FTC staff reports on generic drugs, and pharmaceutical benefit managers. He earned his undergraduate degrees at Indiana University, and his Ph.D. from the California Institute of Technology. He has also served on the faculty of the Department of Economics at Indiana University.

Panel 3: Understanding Intermediaries: Group Purchasing Organizations

Anthony Barrueta is senior vice president of Government Relations for Kaiser Foundation Health Plan, Inc. in Oakland, California. He oversees Kaiser Permanente's legislative and regulatory policy efforts, leading a team of legislative advocates and policy professionals in Oakland, Sacramento and Washington, D.C. He oversees development of Kaiser Permanente's public policy positions in collaboration with senior leadership throughout the organization to ensure that Kaiser Permanente maintains a common voice in support of the interests of the organization, its members and the communities it serves. Prior to joining Kaiser Permanente in 1994, Barrueta was in private law practice in Washington, D.C., specializing in legislative and regulatory advocacy on behalf of health plans, pharmacy benefit management companies, and health-related trade associations. A native of Washington D.C., Barrueta received a bachelor's degree in history from Boston College in 1987 and his law degree from the University of Texas at Austin in 1991. He is licensed to practice law in California and the District of Columbia. He serves on the board of the Public Health Institute and is the chair-elect for 2018. He is also a member of the boards of directors of the Alliance of Community Health Plans and California Latino Economic Institute, and serves on the Statewide Leadership Council for the Public Policy Institute of California.

Todd Ebert, R.Ph., President and CEO of Healthcare Supply Chain Association (HSCA), is a nationally recognized supply chain leader, a group purchasing industry expert, and a registered pharmacist with more than 30 years of healthcare experience. Ebert joined HSCA in 2015 from Amerinet, Inc., a national healthcare solutions organization and HSCA member, where he had served as President and CEO since 2007. After joining Amerinet from Intermountain Healthcare in 1991, Ebert served in a series of leadership roles including Vice President of Amerinet's pharmacy program; President of Amerinet's private-label company, Amerinet Choice, LLC; Executive Vice President for Contracting Operations and Purchasing Program Development Units; President of Operations; and as President and Chief Operating Officer. Prior to Amerinet, Ebert gained extensive experience in several other sectors of the healthcare industry. He is a former vice president and general manager of a specialty healthcare product logistics company; a director of hospital and retail pharmacy; and has owned and operated a nursing home clinical pharmaceutical consulting company. Internationally, Ebert has provided pharmaceutical consulting to foreign government officials and healthcare providers. Ebert is a former Chair of HSCA and is the immediate past Chair of the Healthcare Industry Supply Chain Institute (HISCI). He is often requested as a guest speaker for industry events on subjects ranging from pharmacy to group purchasing trends. Ebert holds bachelor's degrees in pharmacy and business management from the University of Utah and a Master of Science degree in pharmacy administration. He is a registered pharmacist.

Erin R. Fox, Pharm.D, is Senior Director of Drug Information and Support Services at University of Utah Health, and Associate Professor (Adjunct), at the Department of Pharmacotherapy, University of Utah College of Pharmacy. The University of Utah Drug Information Service provides content for the American Society of Health-System Pharmacists (ASHP) Drug Shortage Resource Center with some financial support from Vizient. Erin serves as a media resource and advocate for changes to improve the ongoing drug shortage situation and rising drug costs. In December 2015, Erin testified for the Senate Aging Committee regarding the impact of sudden price increases on health systems. Erin is recognized as an expert in drug shortages and has received the ISMP Cheers Award and ASHP Award of Excellence for her work on drug shortages. Erin has also received the ASHP Award of Excellence for raising awareness about the problem of increasing drug prices. Erin would like to acknowledge that Vizient, Inc. provides funding to the University of Utah Drug Information Service (UUDIS) for the provision of drug shortage information. This funding represents less than 5% of the UUDIS budget.

Hal Singer, Ph.D., is a principal at Economists Incorporated. He is also a senior fellow at the George Washington's Institute for Public Policy, and an adjunct professor at Georgetown's McDonough School of Business. Dr. Singer is co-author of the e-book The Need for Speed: A New Framework for Telecommunications Policy for the 21st Century (Brookings Press 2013), and co-author of the book Broadband in Europe: How Brussels Can Wire the Information Society (Kluwer/Springer Press 2005). He has published several book chapters and his articles have appeared in dozens of legal and economic journals. Dr. Singer has testified before Congress on the interplay between antitrust and sector-specific regulation. His scholarship and testimony has been widely cited by courts and regulatory agencies. In several antitrust cases concerning class certification, the district court's order favorably cited Dr. Singer's testimony. In agency reports and orders, his writings have been cited by the Federal Communications Commission, the Federal Trade Commission, and the Department of Justice. Although his consulting experience spans several industries, Dr. Singer has particular expertise in the media industry. He recently advised the Canadian Competition Bureau on a large vertical merger in the cable television industry. He has served as consultant or testifying expert for several media companies, including Apple, AT&T, Bell Canada, Google, Mid-Atlantic Sports Network, NFL Network, Tennis Channel, and Verizon. Dr. Singer earned M.A. and Ph.D. degrees in economics from the Johns Hopkins University and a B.S. *magna cum laude* in economics from Tulane University.

Stephanie Trunk is a partner in the Health Law Group at Arent Fox LLP in Washington, D.C. Ms. Trunk counsels pharmaceutical and device manufacturers, distributors and their customers, including pharmacy benefit managers, on regulatory, reimbursement and compliance matters. Her practice extends to counseling on drug pricing and government price reporting, HIPAA and privacy matters, counseling on Medicare Part D, developing corporate compliance programs, representing clients in contract negotiations and providing transactional support to her clients. Prior to joining Arent Fox LLP, Ms. Trunk was in-house counsel to a pharmacy benefit management company. Ms. Trunk is the author of numerous chapters on health law treatises including a chapter on Controlling Fraud, Waste and Abuse in the Medicare Part D Program in the ABA/BNA's *Health Care Fraud and Abuse: Practical Perspectives*. She received a J.D. with Highest Honors from the George Washington University Law School in 2003 where she was elected to the Order of the Coif and a member of the George Washington Law Review. Ms. Trunk also has as a graduate certificate in health management from the George Washington University School of Public Health (2003) and she received a B.S. in Accounting Summa Cum Laude from the University of Maryland in 1997.

Markus Meier is the Assistant Director in charge of the Federal Trade Commission's Health Care Division in Washington, D.C. He leads an office of thirty-five lawyers and other professionals who investigate and litigate alleged violations of antitrust law by pharmaceutical companies, physicians, and other health-care providers. Since November 2015, Markus also has been serving as the Acting Deputy Director of the FTC's Bureau of Competition, helping to oversee more than 280 lawyers and other professionals investigating and litigating merger and non-merger cases. Markus joined the FTC in1990 and became head of the Health Care Division in 2006. In addition to his work at the FTC, Markus has been in private practice, where he worked on antitrust litigation and represented clients before the FTC and Department of Justice. He has served as a Special Assistant United States Attorney prosecuting criminal cases in the Eastern District of Virginia. And he was a resident advisor to the Indonesian Competition Commission in Jakarta in 2001. Before joining the FTC, Markus served as an officer in the United States Army. He is a graduate of the George Mason School of Law, has a master's degree in public administration from Old Dominion University, and a bachelor's degree from the University of Virginia.

Discussion: Potential Next Steps to Encourage Entry and Expand Access through Lower Prices

Rena M. Conti, Ph.D., is associate professor at the University of Chicago, departments of pediatrics and public health sciences. Her research applies economic methods to analyze the incentives driving prescription drug development, adoption and price. Her focus has been primarily on "specialty" drugs, particularly cancer, because this area is at the epicenter of the key policy conundrum: the tradeoff between providing incentives for innovative activity versus ensuring access and affordability. Dr. Conti is a 2007 graduate of Harvard University's Interfaculty Initiative in Health Policy, concentration: economics. She would like to acknowledge the support of the NCI, the Commonwealth Fund and the American Cancer Society.

David Mitchell, 67, is a patient with an incurable—but treatable—blood cancer called multiple myeloma. He was diagnosed in 2010. He relapsed in 2014. He depends on drugs for his survival, and expects to be in continuous treatment until he dies. Myeloma is smart and finds its way around drugs, so David is a strong supporter of innovation and new drugs to extend his life, and the lives of other patients. But he says drugs don't work if people can't afford them. David has 40 years of experience working on health care and public health policy as a communications specialist. He has worked to reduce teen smoking, increase use of seat belts, to fight drunk driving and improve child health and safety. He helped build and run for more than 30 years GMMB—a cause-oriented, public policy communications firm in Washington, DC. He retired in 2016 to focus his full energy and attention on helping bring about policy change to lower drug costs. You can follow him on Twitter here. Email him at david@patientsforaffordabledrugs.org

FTC Staff:

Katie Ambrogi, Attorney Advisor, Office of Policy Planning

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

Elizabeth Jex, Attorney Advisor, Office of Policy Planning

Gabrielle Koenig, Legal Intern, Health Care Division, Bureau of Competition

Kelly Signs, Deputy Assistant Director, Office of Policy and Coordination, Bureau of Competition

Kari Wallace, Attorney, Mergers I, Bureau of Competition

Randy Weinsten, Attorney, Health Care Division, Bureau of Competition