GEORGE MASON UNIVERSITY ANTONIN SCALIA LAW SCHOOL

LAW & ECONOMICS CENTER

GEORGE MASON UNIVERSITY LAW AND ECONOMICS CENTER

Symposium on the Legal, Economic, and Regulatory Environment of the Pharmaceutical Industry

Sunday, April 14 – Tuesday, April 16, 2019 | ARLINGTON, VA

Agenda

SUNDAY, APRIL 14

(Registration, Reception, and Dinner held at the Westin Arlington Gateway Hotel)

6:00 – 7:00 pm **Registration and Reception**

Welcoming Remarks:
Henry N. Butler, Dean and Professor of Law, George Mason University Antonin Scalia Law School

Introduction and Overview:
Gregory Conko, Deputy Director, George Mason University Law & Economics Center

7:00 - 8:30 pm **Dinner and Opening Address: The Changing Face of Pharmaceutical Litigation**

Daniel E. Troy, Former General Counsel, GlaxoSmithKline

Response:
George Jepsen, Partner, Shipman & Goodwin LLP, and Former Attorney General of Connecticut

MONDAY, APRIL 15

George Mason University, Founders Hall
(Shuttle leaves Westin for Founders Hall at 6:45am, and 7:15 am)

7:00 – 7:50 am **Breakfast**

8:00 – 9:00 am **Lecture 1: The Economics of Drug Development**

Kenneth Kaitin, Director, Tufts Center for the Study of Drug Development

READINGS: Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," *Journal of Health Economics*, Vol. 47 (2016), pp. 20-33.

Ronald P. Evens and Kenneth I. Kaitin, "The evolution of biotechnology and its impact on health care," *Health Affairs*, Vol. 34, No. 2 (2015), pp. 210-219.

Kenneth A. Getz and Rafael A. Campo, "New benchmarks characterizing growth in protocol design complexity," *Therapeutic Innovation & Regulatory Science*, Vol. 52, No. 1 (2018), pp. 22-28.

Kenneth I. Kaitin, "Editorial. The quest to develop new medicines to treat Alzheimer's disease: Present trends and future prospects," *Clinical Therapeutics*, Vol. 37, No. 8 (2015), pp. 1618-1621.

Agenda

Kenneth I. Kaitin and Joseph A. DiMasi, "Pharmaceutical innovation in the 21st century: New drug approvals in the first decade, 2000-2009," *Clinical Pharmacology and Therapeutics*, Vol. 89 (2011), pp. 183-188.

Christopher-Paul Milne and Kenneth I. Kaitin, "Meeting unmet medical needs: The disparity dilemma," *Pharmaceutical Executive*, Vol. 35, No. 2 (2016), pp. 26-28.

9:15 – 10:45 am **Panel 1: Development, Pricing, and the Market for Pharmaceuticals**

James C. Capretta, Resident Fellow, American Enterprise Institute

Merrill Goozner, Editor Emeritus, *Modern Healthcare*

Charles Silver, Professor, University of Texas School of Law

Aaron Vandervelde, Managing Director, Berkeley Research Group

MODERATOR: Alexander T. Tabarrok, Professor of Economics, George Mason University

READINGS: Jack Scannell, *Four Reasons Drugs Are Expensive, Of Which Two Are False*, Innogen Working Paper No. 114 (October 2015).

11:00 am – 12:00 pm **Lecture 2: The Hatch-Waxman Act and Generic Drugs**

Erika Lietzan, Professor of Law, University of Missouri School of Law

READINGS: Frederick R. Ball and Carolyn A. Alenci, "Generic Drugs: ANDAs, Section 505(B)(2) Applications, Patents, and Exclusivities," Ch. 11 in *Food and Drug Law and Regulation* (Third Edition) David G. Adams et al. eds. (Food and Drug Law Institute, 2015).

12:00 – 1:30 pm **Luncheon Keynote Address: The Social Value of Innovation in the Health Technology Sector**

Thomas J. Philipson, Member, White House Council of Economic Advisors, and Daniel Levin Chair in Public Policy, University of Chicago Harris School of Public Policy Studies

READINGS: Darius N. Lakdawalla, Eric C. Sun, Anupam B. Jena, Carolina M. Reyes, Dana P. Goldman, and Tomas J. Philipson, "An Economic Evaluation of the War on Cancer," *Journal of Health Economics*, Vol. 29 (2010) pp. 333–346. (Skip Subsections 1.1 - 1.3 and Section 2)

1:45 – 3:15 pm **Panel 2: Antitrust Issues and Brand-Generic Disputes** | Founders Hall Auditorium

Sumanth Addanki, Managing Director, NERA Economic Consulting

David A. Balto, Founder, Law Offices of David Balto

Agenda

Markus H. Meier, Acting Director, Federal Trade Commission Bureau of Competition

Christopher M. Holman, Professor, University of Missouri-Kansas City School of Law

MODERATOR: **John M. Yun,** Associate Professor of Law and Director of Economic Education, Global Antitrust Institute, George Mason University Antonin Scalia Law School

READINGS: Michael Gallagher, Eric Grannon, Heather McDevitt, et al., "United States: Pharmaceutical Antitrust," The Antitrust Review of the Americas 2019, White & Case LLP (September 11, 2018), available at https://globalcompetitionreview.com/insight/the-antitrust-review-of-the-americas-2019/1174013/united-states-pharmaceutical-antitrust.

Ravi Gupta, Nilay D. Shah, and Joseph S. Ross, "Generic Drugs in the United States: Policies to Address Pricing and Competition," *Clinical Pharmacology & Therapeutics*, Vol. 105, No. 2 (2019), pp. 329-37.

3:30 – 5:00 pm **Panel 3: Who Really Pays for Drugs and How Much? Marketing, Pricing, and Transparency**

David Hyman, Professor, Georgetown University Law Center

Anupam B. Jena, Ruth L. Newhouse Associate Professor of Health Policy, Harvard Medical School

Richard Manning, Partner, Bates White, LLC

James C. Stansel, Executive Vice President and General Counsel, Pharmaceutical Research and Manufacturers of America

MODERATOR: **Alexander T. Tabarrok,** Professor of Economics, George Mason University

READINGS: Health Strategies Consultancy, *Follow The Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, Kaiser Family Foundation Report No. 7296 (March 2005).

TUESDAY, APRIL 16

George Mason University, Founders Hall
(Shuttle leaves Westin for Founders Hall at 6:45am, and 7:15 am)

7:00 – 7:50 am **Breakfast**

8:00 – 9:00am **Lecture 3: The Regulation of Labeling, Advertising, and Promotion**

Ralph F. Hall, Professor of Practice, University of Minnesota Law School

Agenda

READINGS: Wayne L. Pines, "Regulation of Promotion and Distribution," Ch. 14 in *A Practical Guide to FDA's Food and Drug Law and Regulation* (6th Edition) Kenneth R. Piña and Wayne L. Pines eds. (Food and Drug Law Institute, 2017).

9:15 – 10:45 am

Panel 4: Advertising, Promotion, and the False Claims Act

Kalah Auchincloss, Senior Vice President for Regulatory Compliance and Deputy General Counsel, Greenleaf Health, LLC

James M. Beck, Senior Life Sciences Policy Analyst, Reed Smith, LLP

Candice Deisher, Assistant Attorney General, Virginia Medicaid Fraud Control Unit

Wayne L. Pines, President for Health Care, APCO Worldwide

MODERATOR: **Gregory Conko**, Deputy Director, George Mason University Law & Economics Center

READINGS: Petition for a Writ of Certiorari, *Nathan v. Takeda Pharmaceuticals*, cert. denied (U.S. Mar. 31, 2014) (No. 12-1349). (Read pp. 1-33)

Brief for the United States as Amicus Curiae, *Gilead Sciences v. United States Ex Rel. Jeffrey Campie*, cert. denied (U.S. Nov. 2018) (No. 17-936). (Read pp. 1-23)

11:00 am – 12:30 pm

Panel 5: Labeling, Preemption, and Products Liability

Andrew T. Bayman, Partner, King & Spalding, LLP

Max Kennerly, Partner, Kennerly Loutey, LLC

Jeremy Newman, Associate, Kellogg, Hansen, Todd, Figel & Frederick, PLLC

Rebecca Wood, Partner, Sidley Austin, LLP

MODERATOR: **Michael I. Krauss,** Professor, George Mason University Antonin Scalia Law School

READINGS: Angela M. Higgins, "A Possible Perfect Storm: The Reanimated Innovator-Liability Theory," *DRI For the Defense*, Vol. 60, No. 4 (2018), pp. 60-68.

Petition for a Writ of Certiorari, *Merck Sharp & Dohme Corp. v. Albrecht* (U.S. Aug. 22, 2017) (No. 17-290). (Read pp.1-32)

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Brief in Opposition, *Merck Sharp & Dohme Corp. v. Albrecht* (U.S. Oct. 25, 2017) (No. 17-290). (Read pp. 1-26)

12:30 pm – 2:00 pm **Luncheon Panel Discussion: Daubert, Frye, and the Judge's Role in Evaluating Expert Testimony**

David E. Bernstein, University Professor, George Mason University Antonin Scalia Law School

David Falgman, Chancellor and Dean, University of California Hastings College of the Law

Michael X. Imbroscio, Partner, Covington & Burling LLP

Jason L. Lichtman, Partner, Lieff Cabraser Heimann & Bernstein LLP

MODERATOR: **Hon. David N. Wecht,** Associate Justice, Supreme Court of Pennsylvania

READINGS: David E. Bernstein, "Expert Witnesses, Adversarial Bias, and the (Partial) Failure of the Daubert Revolution," *Iowa Law Review*, Vol. 93, No. 2 (2008), pp. 451-89. (Read pp. 451-79)

David L. Faigman, "The Daubert Revolution and the Birth of Modernity: Managing Scientific Evidence in the Age of Science," *University of California at Davis Law Review*, Vol. 46, No. 3 (2013), pp. 893-930. (Read pp. 909-26)

2:00 pm **Closing Remarks and Adjourn**

Speakers

SUMANTH ADDANKI

Managing Director, NERA Economic Consulting

Dr. Sumanth Addanki specializes in antitrust, intellectual property, and the evaluation of commercial damages. He has analyzed the competitive consequences of numerous mergers in a wide range of industries, including agricultural products, chemicals, consumer products, medical devices, pharmaceuticals, and semiconductors, among many others. He has frequently presented the results of his analyses to US antitrust agencies and courts. In addition, he has addressed liability and damages issues involving allegations of predatory pricing, monopolization, price discrimination, resale price maintenance, tying, and other antitrust violations in a variety of industries. He has considerable experience and expertise in analyzing such questions in the pharmaceutical industry.

KALAH AUCHINCLOSS

Senior Vice President for Regulatory Compliance and Deputy General Counsel, Greenleaf Health, LLC

Kalah Auchincloss has more than a decade of food and drug legal, policy, and regulatory experience at the FDA, on Capitol Hill, and in the private sector. Kalah spent six years at the FDA, most recently, as Deputy Chief of Staff for two FDA Commissioners: Dr. Robert Califf and Dr. Scott Gottlieb. As Deputy Chief of Staff, Kalah worked with senior FDA leadership to manage crises, develop policy decisions, implement communications strategies, and liaise with the Department of Health and Human Services, the White House, and other agencies. Kalah was also a primary point of contact in the immediate Office of the Commissioner for the six FDA Centers and other components of the Commissioner's Office. Prior to that role, Kalah spent time on Capitol Hill as the FDA detailee to the Senate Committee on Health, Education, Labor, and Pensions, working on the 21st Century Cures Act and other FDA-related legislation.

DAVID A. BALTO

Founder, Law Offices of David Balto

David Balto has over 15 years of government antitrust experience as a trial attorney in the Antitrust Division of the Department of Justice and in several senior level positions at the Federal Trade Commission. He was the Policy Director of the Bureau of Competition of the Federal Trade Commission (1998-2001) and attorney advisor to Chairman Robert Pitofsky (1995-1997). In these positions, he was a senior advisor in all aspects of the FTC's merger and non-merger enforcement program. He helped litigate the challenges to the Staples/Office Depot, Drug Wholesalers, and Heinz/Beechnut mergers, the Intel monopolization case, and the challenges to anticompetitive conduct by several pharmaceutical companies. David Balto is nationally known for his expertise in competition policy and is a prolific author on antitrust, consumer protection, financial services, intellectual property, and health care competition.

Speakers

ANDREW T. BAYMAN

Partner, King & Spalding, LLP

Andy Bayman serves a wide range of clients in life sciences and healthcare, including pharmaceutical and medical device manufacturers, as well as automotive and other manufacturers and retailers in product liability and toxic tort cases. He is a partner and the leader of King and Spalding's Trial & Global Disputes practice group. Andy is a trial lawyer who has tried over 20 cases in state and federal courts around the country. Previously, Andy led the firms Life Sciences & Healthcare area of focus. In addition to his work with clients, Andy is serving his third term as a member of the firm's management committee, and has previously served in many other firm leadership positions.

JAMES BECK

Senior Life Sciences Policy Analyst, Reed Smith, LLP

James Beck handles complex personal injury and product liability litigation. He has overseen the development of legal defenses, master briefs, and dispositive motions in numerous multidistrict litigation matters and other mass torts. On the appellate side, he has drafted major appellate briefs in significant product liability and related matters, including numerous amicus curiae briefs. James is a member of the Product Liability Advisory Committee (PLAC) and has sat on PLAC's case selection committee since 1997. He has written over 70 amicus curiae briefs on product liability issues for PLAC. James wrote PLAC's successful amicus brief in the ground-breaking *Tincher v Omega Flex* decision where the Pennsylvania Supreme Court overturned 35 years of product liability precedent. Following *Tincher*, he organized the "Tincher Group" of defense counsel, which has produced scholarship and suggested post-*Tincher* jury instructions in order to prevent the defense win in Tincher from being undercut.

DAVID E. BERNSTEIN

University Professor, George Mason University Antonin Scalia Law School

David E. Bernstein is a George Mason University Foundation Professor at George Mason University Antonin Scalia Law School where he has been teaching since 1995. Bernstein has been writing about expert testimony since 1989, and is a leading expert on Daubert/Rule 702. He is co-editor of *Phantom Risk: Scientific Inference and the Law* (MIT Press 1993) and co-author of *The New Wigmore: Expert Evidence* (2d ed. 2010). Bernstein is also the author of numerous scholarly articles on scientific and expert evidence.

Speakers

JAMES C. CAPRETTA

Resident Fellow, American Enterprise Institute

James C. Capretta is a resident fellow and holds the Milton Friedman Chair at the American Enterprise Institute, where he studies health care, entitlement, and US budgetary policy, as well as global trends in aging, health, and retirement programs. As an associate director at the White House's Office of Management and Budget from 2001 to 2004, he was responsible for all health care, Social Security, welfare, and labor and education issues. Earlier, he served as a senior health policy analyst at the US Senate Budget Committee and at the US House Committee on Ways and Means. Mr. Capretta has an M.A. in public policy studies from Duke University and a B.A. in government from the University of Notre Dame.

GREGORY CONKO

Deputy Director, Law and Ecnomics Center

Gregory Conko manages the Center's day-to-day operations. He has over two decades' experience in non-profit management, research, and advocacy. Prior to joining the LEC, Gregory was Executive Director of the Competitive Enterprise Institute in Washington, DC, where he oversaw that organization's research, communications, and administrative staff. Earlier in his career, he was a Research Associate at the Capital Research Center and a Senior Fellow at the Competitive Enterprise Institute, where his work focused on food and drug regulation, science and environmental policy, and public health issues. He was also a co-founder and Vice President of the Auburn, Alabama-based AgBioWorld Foundation. Gregory received his BA in political science and history from American University and his JD magna cum laude from the George Mason University School of Law, where he was an articles editor of the Journal of Law, Economics & Policy.

CANDICE DEISHER

Assistant Attorney General, Virginia Medicaid Fraud Control Unit

As an experienced health care fraud attorney, Candice Deisher's expertise lies in investigating and prosecuting complex health care fraud *qui tam* cases in federal and state courts on behalf of the Commonwealth of Virginia. Cases include fraud schemes involving off-label marketing, kickbacks, misbranding, managed care, medical device fraud, up-coding, hospice, nursing homes, medical necessity, unbundling, among others. Diesher carries strong knowledge of the federal False Claims Act, the Anti-Kickback Statute, the Virginia Fraud Against Taxpayers Act, and in various government investigation processes.

Speakers

DAVID FAIGMAN

Chancellor and Dean, University of California Hastings College of the Law

David L. Faigman is Chancellor & Dean and John F. Digardi Distinguished Professor of Law at the University of California Hastings College of the Law in San Francisco. He also holds an appointment as professor in the School of Medicine (Dept. of Psychiatry) at the University of California San Francisco. Faigman is the author of numerous articles and essays, published in a wide assortment of journals, including leading law reviews and science journals. He is also the author of three books, *Constitutional Fictions* (Oxford, 2008), *Laboratory of Justice* (Henry Holt & Co. 2004) and *Legal Alchemy* (W.H. Freeman,1999). In addition, he is a co-author/co-editor of the five-volume treatise *Modern Scientific Evidence: The Law and Science of Expert Testimony* (with Cheng, Mnookin, Murphy, Sanders & Slobogin). Faigman was a member of the National Academies of Sciences panel that investigated the scientific validity of polygraphs, a member of the MacArthur Law and Neuroscience Network, and a Senior Advisor to President Obama's Council of Advisors on Science and Technology (PCAST), for its report, *Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature-Comparison Methods.*

MERRILL GOOZNER

Editor Emeritus, Modern Healthcare

Merrill Goozner served as Editor of *Modern Healthcare* from December 2012 to April 2017. As Editor Emeritus, he continues to write a weekly column, participate in *Modern Healthcare* education, events, and awards programs, and provide guidance on coverage related to healthcare transformation issues. Over the course of his four decades in journalism, he served as a foreign, national, and chief economics correspondent for the *Chicago Tribune* and professor of journalism at New York University. He is the author of *The $800 Million Pill: The Truth Behind the Cost of New Drugs* (University of California Press, 2004), and has contributed articles to numerous publications. Goozner earned a master's degree in journalism from Columbia University and a bachelor's in history from the University of Cincinnati, where he received the Distinguished Alumni Award in 2008.

RALPH HALL

Professor of Practice, University of Minnesota Law School

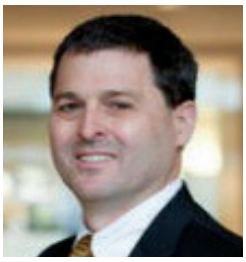
Professor Ralph F. Hall is a professor of practice at the University of Minnesota Law School. He concentrates his teaching, research, and writing in the area of FDA regulation and health care. He is also a principal with Leavitt Partners, a health care policy and consulting firm. At Leavitt Partners, he works with coalitions and clients focused on improving FDA and health care regulation and advancing value based health care. He also serves as CEO of MR3 Medical LLC, a start-up medical device company. He is a frequent speaker on FDA regulatory issues and compliance matters and has testified a number of times before congressional committees. Prior to his association with the University of Minnesota Law School, Professor Hall served in various capacities with Guidant Corporation including Senior Vice President and Deputy General Counsel—Litigation and Compliance and General Counsel of the Cardiac Rhythm Management group.

Speakers

CHRISTOPHER M. HOLMAN

Professor, University of Missouri-Kansas City School of Law

Chris Holman joined the UMKC faculty in 2005, and his primary research focus lies at the intersection of intellectual property and biotechnology. He has published numerous articles in law reviews and scientific publications such as *Science*, *Cell* and *Nature Biotechnology*, and has authored amicus briefs in a number of important biotechnology patent cases at the Supreme Court and Federal Circuit. In 2008 he was awarded the Daniel L. Brenner Faculty Publishing Award for an influential law review article on human gene patent litigation. Professor Holman has taught classes in patent law, copyright law, intellectual property survey, antitrust, biotechnology and pharmaceutical law, and science and technology. He is a faculty advisor for the law school's Intellectual Property Emphasis Area, and helps oversee the IP clinic.



DAVID HYMAN

Professor, Georgetown University Law Center

David A. Hyman is a professor of law at Georgetown University Law Center, where he focuses his research and writing on the regulation and financing of health care. He teaches or has taught health care regulation, civil procedure, insurance, medical malpractice, law and economics, professional responsibility, and tax policy. He is the co-author (with Charles Silver) of *Overcharged: Why Americans Pay Too Much for Health Care* (Cato institute, 2018). His articles have been published in the *Journal of Empirical Legal Studies*, the *Yale Journal of Law & Technology*, the *NYU Journal of Law & Liberty*, and the *Journal of Health Economics*, among others. Prior to joining the Georgetown faculty, Professor Hyman worked at Mayer Brown in Chicago and taught at the University of Maryland, Baltimore and the University of Illinois. He earned his MD, JD, and BA degrees at the University of Chicago.

MICHAEL X. IMBROSCIO

Partner, Covington & Burling LLP

Mike Imbroscio represents clients in the life sciences industry facing complex litigation challenges. He serves as co-chair of Covington & Burlings Product Liability and Mass Tort practice and has been recognized by *Chambers* for his strategic leadership skills and "the wisdom and judgment he brings" to resolving clients' problems. A fierce advocate for increasing the diversity of the legal profession, Mr. Imbroscio leads the firm's diversity and inclusion efforts.

Speakers

ANUPAM B. JENA

Ruth L. Newhouse Associate Professor of Health Policy, Harvard Medical School

Anupam B. Jena, M.D., Ph.D. is the Ruth L. Newhouse Associate Professor of Health Care Policy and Medicine at Harvard Medical School. He is a practicing internist at Massachusetts General Hospital and a Faculty Research Fellow at the National Bureau of Economic Research. As an economist and a physician, Dr. Jena uses 'natural experiments' to help us understand how health care works and what drives physician and patient behaviors. He is the first social scientist to win the NIH Director's Early Independence Award, and he served on the Institute of Medicine Committee on Diagnostic Errors in Health care. His work is frequently featured in the media, including *The New York Times*, *The Washington Post*, *The Wall Street Journal,* NPR, Freakonomics, and others.

GEORGE JEPSEN

Partner, Shipman & Goodwin, LLP, and Former Attorney General of Connecticut

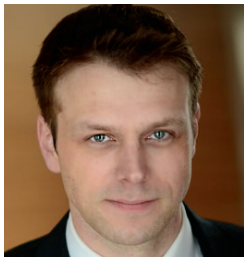
George Jepsen is a partner in Shipman & Goodwin's State Attorneys General Practice Group. He is also Co-Chair of the firm's Data Privacy and Protection Practice Group. George focuses his practice on existing and emerging areas with laws enforced by state attorneys general, including privacy and data protection, financial services, consumer protection, antitrust, and environmental regulation. He collaborates with a multi-disciplinary team of attorneys in related practices to successfully guide clients through complex matters, resolve investigations, and minimize exposure to litigation. George's legal and public service career has spanned more than 30 years. Most recently, he served for eight years as Connecticut's 24th Attorney General.

KENNETH KAITIN

Director, Tufts Center for the Study of Drug Development

Kenneth Kaitin is a Professor at Tufts University School of Medicine and the Director of the Tufts Center for the Study of Drug Development. He is also an Advisory Professor at Shanghai Medical College at Fudan University, and he serves on the faculty of the European Center for Pharmaceutical Medicine at the University of Basel. An internationally recognized expert in drug development science and policy, Dr. Kaitin writes, speaks, and teaches on global trends in pharmaceutical development and regulation, and he has provided public testimony before the U.S. Congress. A former President of the Drug Information Association, Dr. Kaitin is currently Editor-in-Chief of *Expert Review of Clinical Pharmacology*, and he is a consultant to the U.S. Department of Defense on bioterror countermeasures. Dr. Kaitin serves on several public and private company boards of directors. He received his BS from Cornell University and MS and PhD in pharmacology from the University of Rochester.

Speakers



MAX KENNERLY

Partner, Kennerly Loutey, LLC

For more than a decade, Mr. Kennerly has devoted his practice to representing injured plaintiffs. He is listed in Super Lawyers and Best Lawyers in America. Most of his cases involve either (1) a serious injury or wrongful death caused by someone else's negligence or (2) nationwide litigation over defective medications and medical devices. He co-founded his own law firm, Kennerly Loutey LLC. Kennerly has settled cases for multi-million dollar amounts, and has taken to trial and jury verdict a variety of cases, from automotive product liability, to medical malpractice, to workplace safety.

MICHAEL I. KRAUSS

Professor, George Mason University Antonin Scalia Law School

Professor Michael I. Krauss has been teaching torts, remedies, jurisprudence and professional responsiblity at George Mason University since 1987 and also has taught at the law schools of Seattle University, the University of Toronto, and the Université de Sherbrooke in Canada. Born in the United States but raised in Canada, Professor Krauss earned his BA cum laude from Carleton University, his LLB summa cum laude from the Université de Sherbrooke, and his LLM from Yale Law School. He was Columbia University's Law and Economics Fellow in 1981. He is the author of several books, including most recently, *Principles of Products Liability* (Third Edition), published by West Academic.

ERIKA LIETZAN

Professor of Law, University of Missouri School of Law

Erika Lietzan is a law professor at the University of Missouri, where she focuses on food and drug regulation, intellectual property, and administrative law, with a special emphasis on issues at the intersection of pharmaceutical regulation and patent law. Before joining academia, she spent eighteen years in private practice, eight of them as a partner in the food and drug group at Covington & Burling in Washington, DC. She was involved in every major amendment to the Federal Food, Drug, and Cosmetic Act (FDCA) between 1997 and 2014, and was deeply immersed for more than a decade in the development of the Biologics Price Competition and Innovation Act of 2010. Professor Lietzan has been consistently identified by her peers in private practice as a "Best Lawyer in America" in the categories of FDA law (since 2013) and Biotechnology Law (since 2007).

Speakers

JASON L. LICHTMAN

Partner, Lieff Cabraser Heimann & Bernstein, LLP

A partner in Lieff Cabraser's New York office, Jason Lichtman's practice focuses on financial fraud, damages, and appeals. Co-lead counsel in the Whirlpool Front-Loading Washers Litigation and In re VTech child data breach cases, Lichtman also had a lead role representing consumers in the British Airways Fuel Surcharge Litigation that led to a settlement valued at over $42 million and in *qui tam* litigation against several large banks relating to mortgage fraud. He has secured major victories as counsel of record before numerous federal appellate courts. Lichtman played a key role in the settlement of the Imprelis Herbicide Litigation, worked to secure a major settlement with Capital One Bank in the ING Direct Litigation, and helped secure a settlement for Hong Leong Finance (Singapore) over the sale and marketing of certain financial products.

RICHARD MANNING

Partner, Bates White, LLC

Richard Manning has an extensive background providing analysis and thought leadership on issues facing the pharmaceutical, biotechnology, and healthcare industries. Dr. Manning has provided deposition testimony, served as consulting expert, and prepared reports and papers on various matters in healthcare and biopharmaceuticals. His career includes 14 years as an executive at multinational pharmaceutical companies, where he led economic analysis and strategy development to shape practices related to emerging business concerns. Prior to joining Bates White, Dr. Manning was an executive director at Merck & Co., Inc. where he oversaw economic analysis and strategy relative to challenges affecting pricing and reimbursement and intellectual property protection in worldwide markets. Previously, he was a senior director at Pfizer, Inc. for 12 years. In addition, Dr. Manning was a director in the Advisory Strategy Group at Pricewaterhouse Coopers. Dr. Manning was an economics professor at Brigham Young University and a visiting professor in the Graduate School of Business at The University of Chicago.

MARKUS H. MEIER

Assistant Director, Federal Trade Commission Bureau of Competition

Markus is the Assistant Director in charge of the Federal Trade Commission's Health Care Division. He leads an office of thirty-seven lawyers and other professionals who investigate and litigate alleged violations of antitrust law by pharmaceutical companies, physicians, and other health-care providers. From November 2015 to November 2017, Markus served as the Acting Deputy Director and later as the Acting Director of the Bureau of Competition. In this capacity, he helped oversee more than 280 lawyers and other professionals investigating and litigating merger and non-merger cases. Markus joined the FTC in 1990 and became head of the Health Care Division in 2006. In addition to his work at the FTC, Markus has been in private practice, and served as a Special Assistant United States Attorney. He is a graduate of the George Mason University 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.

Speakers

JEREMY NEWMAN

Associate, Kellogg, Hansen, Todd, Figel & Frederick, PLLC

Jeremy Newman is an attorney at Kellogg, Hansen, Todd, Figel & Frederick PLLC; a litigation firm located in Washington, DC. Mr. Newman's law practice focuses on appellate, commercial, product liability, securities, antitrust, telecommunications, insurance, and reinsurance litigation. Mr. Newman has litigated at the United States Supreme Court, the majority of federal appellate courts, as well as many federal and state trial courts, on behalf of both plaintiffs and defendants. Mr. Newman has litigated appellate cases on behalf of plaintiffs regarding the scope of federal preemption of pharmaceutical product liability claims, including the Fosamax (3d Cir. and U.S. Supreme Court) and Incretins (9th Cir.) litigation.

THOMAS J. PHILIPSON

Member, White House Council of Economic Advisors, and Daniel Levin Chair in Public Policy, University of Chicago Harris School of Public Policy Studies

Tomas Philipson is one of three members of the White House's Council of Economic Advisers. He is on leave as the Daniel Levin Professor of Public Policy Studies at the University of Chicago Harris School of Public Policy and the Director of the Health Economics Program of the Becker Friedman Institute at the University. He has published peer-reviewed articles in leading academic journals and has twice won the highest honor of the field of health economics, the Kenneth Arrow Award of International Health Economics Association. He has also held senior positions at the Food and Drug Administration and the Centers for Medicare and Medicaid Services. In addition, he has served on the Key indicator Commission created by the Affordable Care Act, as an advisor to Congress on the 21st Century Cures legislation, and on the steering committee of the Cancer Moon Shot Initiative. He received his undergraduate degree in mathematics at Uppsala University in Sweden and his PhD in economics from the Wharton School at the University of Pennsylvania.

WAYNE L. PINES

President for Health Care, APCO Worldwide

Mr. Pines, President of Healthcare at APCO Worldwide in Washington, DC, is an internationally-known consultant on regulatory, media, and crisis matters involving pharmaceuticals and medical devices. He helps companies address regulatory, media, and advertising/promotional challenges involving the Food and Drug Administration (FDA) or related agencies. Mr. Pines serves on promotional review committees for companies and also helps them navigate the drug development and approval process. Mr. Pines formerly was Associate Commissioner for Public Affairs at the FDA, and was founding president and is now vice president of the Alliance for a Stronger FDA, a coalition seeking to educate Congress and the Administration about FDA funding. He is past chairman and current director of the MedStar Health Research Institute, which oversees research at ten hospitals in the Baltimore-Washington area; and a member of the Executive Committee of the Regional Board of the Anti-Defamation League.

Speakers

CHARLES SILVER

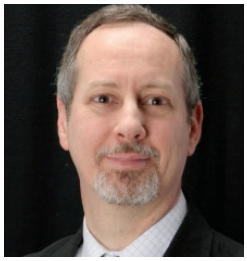
Professor, University of Texas School of Law

Charles Silver holds the Roy W. and Eugenia C. McDonald Endowed Chair in Civil Procedure at the School of Law at the University of Texas at Austin. He has written extensively about group lawsuits (including class actions and other mass proceedings), attorneys' fees (including contractual compensation arrangements, common fund fee awards, and statutory fee awards), and professional responsibility (focusing on lawyers involved in civil litigation on behalf of plaintiffs and defendants). In recent years, as Co-Director of the Center on Lawyers, Civil Justice and the Media at the University of Texas, he has worked with a group of empirical researchers on a series of studies of medical malpractice litigation in Texas. Professor Silver served as Associate Reporter on the *Principles of the Law of Aggregate Litigation*, published by the American Law Institute in 2010. He holds a Bachelor's degree in Political Science from the University of Florida, a Master's degree in Political Science from the University of Chicago, and a JD from Yale Law School.

JAMES STANSEL

Executive Vice President and General Counsel, Pharmaceutical Research and Manufacturers of America

James C. Stansel is Executive Vice President, General Counsel, and Corporate Secretary of the Pharmaceutical Research and Manufacturers of America (PhRMA), where he is responsible for leading a team of lawyers in supporting PhRMA's policy, advocacy, and science priorities and in the development of sound legal policies impacting the pharmaceutical industry. Mr. Stansel previously served as Acting General Counsel of the United States Department of Health & Human Services, where he was the chief legal officer of HHS, including its sub-agencies the Food and Drug Administration, the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention, and the National Institutes of Health. At HHS, he also served as Deputy General Counsel and as Counselor to the Secretary, where he coordinated with the White House and advised the Secretary on the development of health policy.

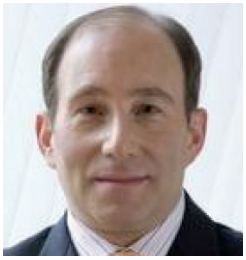


ALEXANDER T. TABARROK

Professor of Economics, George Mason University

Alex Tabarrok is Bartley J. Madden Chair in Economics at the Mercatus Center at George Mason University and a professor of economics at George Mason University. He specializes in patent-system reform, the effectiveness of bounty hunters compared to the police, how judicial elections bias judges, and how local poverty rates impact trial decisions by juries. He also examines methods for increasing the supply of human organs for transplant, the regulation of pharmaceuticals by the FDA, and voting systems. Tabarrok is the coauthor, with Mercatus colleague Tyler Cowen, of the popular economics blog Marginal Revolution and cofounder of the online educational platform Marginal Revolution University. He is the coauthor of *Modern Principles of Economics*, and author of the recent e-book *Launching the Innovation Renaissance*.

Speakers



DANIEL E. TROY

Former General Counsel, GlaxoSmithKline

Dan Troy joined GSK as Senior Vice President & General Counsel in September 2008, and served as a member of GSK's Corporate Executive Team. Previously a Partner at the Washington law firm Sidley Austin LLP, where he represented mainly pharmaceutical companies and trade associations on matters related to the US Food and Drug Administration and government regulations. Dan was formerly Chief Counsel for the FDA, where he served as a primary liaison to the White House and the US Department of Health and Human Services.

AARON VANDERVELDE

Managing Director, Berkeley Research Group

Aaron Vandervelde has over fourteen years of experience providing strategy, health policy, and litigation consulting services to clients in the healthcare industry. He specializes in financial and economic analysis of health policy and provides litigation consulting services related to issues arising from contracts and transactions between healthcare entities and with the federal government. Specifically, he focuses on deriving strategic insight through the integration and analysis of large, complex data sets including claims data, risk adjustment data, internal and external sales data, and publicly available health data. Mr. Vandervelde's practice is focused primarily on clients across the healthcare continuum, including Fortune 500 health insurers, pharmaceutical manufacturers and biotech companies, pharmacy benefit managers (PBMs), and others. He has advised clients in a variety of federal investigations, contract disputes, litigation, and strategic health policy analyses.

DAVID N. WECHT

Associate Justice, Supreme Court of Pennsylvania

David Wecht is an Associate Justice of the Supreme Court of Pennsylvania. Prior to his election in 2015, Wecht had served on the Superior Court of Pennsylvania since 2011, when he was elected to a 10-year term. Before his election to the Superior Court, Wecht served in Allegheny County government, holding elected executive and judicial offices since 1998. Wecht served as Allegheny County's elected register of wills and clerk of orphans' court from 1998 to 2003, and then trial judge from February 2003 until January 2012, working extensively in the civil and family divisions. From 2009 to 2011, he served an administrative judge of the Family Division, where he was credited for implementing several reforms, including a conflict counsel program for juvenile delinquency cases, and a unified family court, in which the same jurist guides a family through its entire experience with the court.

Speakers

REBECCA WOOD
Partner, Sidley Austin LLP

Rebecca ("Becky") Wood is co-leader of Sidley Austin's Food, Drug, and Medical Device Regulatory practice and the D.C. Healthcare and FDA group. Until recently, Becky served as Chief Counsel to the Food and Drug Administration (FDA), where she was the principal legal advisor on major initiatives addressed by the Commissioner and agency leadership. Prior to her government service, Becky had nearly two decades of experience counseling FDA-regulated entities in company-threatening litigation in trial and appellate courts.

JOHN M. YUN
Associate Professor of Law and Director of Economic Education, Global Antitrust Institute, George Mason University Antonin Scalia Law School

Prior to joining the GAI, John M. Yun was the Acting Deputy Assistant Director in the Bureau of Economics, Antitrust Division, at the U.S. Federal Trade Commission. Professor Yun has also served as the Economic Advisor to Commissioner Joshua D. Wright, as well as a staff economist. His experience includes the analysis of horizontal mergers, vertical restraints, and exclusionary conduct. Over an eighteen-year career at the FTC, he has presided over a number of high-profile matters and investigations in various industries including consumer products, retail, intermediate goods, and technology. His research interests include law and economics, antitrust, regulatory policy, and industrial organization, and he has published in academic journals including the *International Journal of Industrial Organization*, *Economic Inquiry, International Review of Law and Economics*, and *Review of Industrial Organization*. Professor Yun received his BA in economics at UCLA and his PhD in economics at Emory University.