SPEAKER BIOS

Draft as of 10/3/18

CONCURRENT SESSION 1A
DRUGS I

Grail Sipes, JD

Deputy Center Director for Regulatory Policy, CDER, FDA

Grail Sipes is the Deputy Center Director for Regulatory Policy at FDA's Center for Drug Evaluation and Research (CDER). In this position, Ms. Sipes is responsible for broad policy matters and issues in all areas related to human drugs. She serves as advisor to the Center Director and FDA officials on matters impacting drug policy development, execution, and long-range program goals. This Includes input on industry positions and proposals, precedent cases and other aspects of consumer protection and public health, proposed legislation, and implementation of regulations and standards related to drugs.

Previously, Ms. Sipes was the director of CDER's Office of Regulatory Policy (ORP). In that role, she managed the development of new regulations and policies applicable to FDA's regulation of human pharmaceuticals. She joined FDA in 2011 as a senior regulatory counsel in ORP. Before coming to FDA, she was in legal practice as a partner with Covington & Burling, LLP. Earlier in her career, she served with the NYC Human Resources Administration as a budget manager for foster care and preventive services for children. She also was an associate at Oliver, Wyman & Co., a strategy consulting firm in the financial services industry.

Ms. Sipes earned a bachelor's degree from Yale University with distinction in literature, and her juris doctor degree from Harvard Law School.

Erika Lietzan, JD, MA

Associate Professor of Law, University of Missouri School of Law

Erika Lietzan is an Associate Professor at the University of Missouri School of Law. She researches, writes, and teaches primarily in the areas of food and drug regulation, intellectual property, and administrative law. Before joining the University of Missouri in 2014, she was a partner in the food and drug group at Covington & Burling. In practice, she handled a wide range of complex legal problems and broader legislative and regulatory policy questions affecting FDA-regulated companies. She is an elected member of the American Law Institute. She has also been 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).

Kurt Karst, JD (AUWCL '01)

Director, Hyman, Phelps & McNamara, P.C.

Kurt R. Karst provides regulatory counsel to pharmaceutical manufacturers on Hatch-Waxman patent and exclusivity, drug development, pediatric testing, and orphan drugs. He helps clients develop strategies for product lifecycle management, obtaining approval, managing post-marketing issues, and defining periods of exclusivity. As the co-founder and primary author of Hyman, Phelps & McNamara's FDA Law Blog, Mr. Karst often leads the response to new rules and regulations, sharing his interpretation with the broader legal community.

Mr. Karst's knowledge of FDA precedents and timely analysis of developments helps clarify and shape the industry's understanding of Hatch-Waxman, in particular. He is a prolific writer, contributing to the blog and publishing articles in major legal journals. Mr. Karst has co-authored and contributed to several text books, including *Generic and Innovator Drugs: A Guide to FDA Approval Requirements*; *Pharmaceutical, Biotechnology, and Chemical Inventions*; *Fundamentals of US Regulatory Affairs*; and FDLI's *Drug and Biologic Approvals: The Complete Guide for Small Businesses-FDA Financial Assistance and Incentives*.

Mr. Karst clerked for Hyman Phelps & McNamara while attending law school and served as articles editor for the *American University Law Review*. Before joining the firm, Mr. Karst lobbied for F. Hoffmann-La Roche Inc. In 1995, he was awarded a Fulbright Scholarship for post-graduate studies in Germany.

Dmitry Karshtedt, JD, PhD, MA

Associate Professor of Law, George Washington University School of Law

Dmitry Karshtedt's primary research interest is in patent law. His legal scholarship has been or will be published in the *Vanderbilt Law Review*, *Washington University Law Review*, and *Iowa Law Review*. He was cited in three of the leading patent law casebooks and a casebook on intellectual property. Professor Karshtedt's academic work has won several awards, including the Samsung-Stanford Patent Prize and the scholarship grant for judicial clerks sponsored by the University of Houston Law Center Institute for Intellectual Property and Information Law.

Before going into law, Professor Karshtedt completed a Ph.D. in chemistry from U.C. Berkeley and worked as a staff scientist for a semiconductor materials startup. He is a co-author on five scientific publications and a co-inventor on ten U.S. patents. Professor Karshtedt received his law degree from Stanford Law School, where he served as the Senior Symposium Editor for the *Stanford Law Review*. Professor Karshtedt practiced in the Patent Counseling and Innovation Group at Wilson Sonsini Goodrich & Rosati and clerked for the Honorable Kimberly A. Moore on the U.S. Court of Appeals for the Federal Circuit. Immediately prior to starting his position at GW, Professor Karshtedt was a Fellow at the Center for Law and the Biosciences at Stanford Law School.

James N. Czaban, JD

Partner, Chair, FDA and Medical Products Regulatory Practice Group, DLA Piper LLP (US)

Jim has nearly three decades of private practice experience involving governmental regulation of pharmaceutical, biotechnology, food, medical device and health care related companies, guiding clients at all stages of a product's lifecycle, from product development, marketing applications, advertising and promotional compliance, good manufacturing practices, and pre- and post-approval compliance matters. Chambers USA described Jim as "one of only a few people who really do think outside the box," and the lawyer to turn to "if you are looking for innovation and someone to break new ground." He has also been recognized by "DC Super Lawyers" for both Food & Drug law and Constitutional Law, by Who's Who Legal/Life Sciences for both regulatory and transactional work, and by Euromoney's LMG Life Sciences as a "Life Sciences Star" for FDA law.

Mr. Czaban is known for his leadership on complex legal, regulatory and policy issues implicated by competitive pressures within the pharmaceutical and biotechnology industries under the Hatch-Waxman Amendments, biosimilars laws, and the patent laws, and is a seasoned litigator in matters involving FDA and other governmental agencies. His practice also encompasses matters involving the Federal Trade Commission (FTC), the Drug Enforcement Administration (DEA), the Department of Justice (DOJ) and state health regulatory agencies. He regularly advises companies, banks, private equity firms, venture capitalists and other entities involved in corporate, commercial, and financial transactions involving life sciences companies.

Jim writes and speaks prolifically on FDA regulatory issues in both academic and private sector settings. He has twice received the Burton Award for Distinguished Legal Writing, on the topics of

Biosimilars legislation and Precision Medicine. He serves on the Editorial Board of the Journal of Precision Medicine (for which he writes a regular column, "The Legal Genome") and on the Bloomberg Law Advisory Board for Pharmaceuticals and Life Sciences. Jim has volunteered thousands of hours of service to the Food & Drug Law Institute (FDLI), serving on numerous FDLI committees, as co-author for three FDLI legal treatises, as moderator or speaker at dozens of FDLI conferences, and as author of multiple FDLI-published articles and monographs. Jim is a graduate of the University of California, Berkeley, and the University of Virginia School of Law.

CONCURRENT SESSION 1B
FOOD AND ANIMAL PRODUCTS

Stuart Pape, JD

Shareholder, Practice Chair, Polsinelli

Stuart Paper is a shareholder and Practice Chair at Polsinelli. He is widely recognized as one of the country's preeminent FDA lawyers. In his practice, he helps clients understand and face challenges presented by regulations imposed by FDA, US Department of Agriculture (USDA), state and local regulators, and similar health and safety regulatory bodies worldwide. He assists clients in obtaining approval of new food ingredients, pharmaceuticals, and medical devices; advises on labeling and advertising of regulated products; defends clients in enforcement proceedings initiated by regulatory bodies; and helps clients develop sound strategies in the face of challenges from NGOs. Mr. Pape served in various positions in the Office of the Chief of Counsel at the FDA, including as Associate Chief Counsel for food as well as executive assistant to FDA Commissioner Donald Kennedy. Mr. Pape is a 1970 graduate of the University of Virginia and a 1973 graduate of its School of Law.

Laurie J. Beyranevand, JD

Associate Dean for Academic Affairs, Director, Center for Agriculture and Food Systems, and Professor of Law, Vermont Law School

Laurie J. Beyranevand is the Associate Dean for Academic Affairs and Professor of Law at Vermont Law School. In addition, she serves as the Director of the Center for Agriculture and Food Systems.

Professor Beyranevand received a BA from Rutgers College in 1999 and a JD from Vermont Law School in 2003. She clerked in the Environmental Division of the Vermont Attorney General's Office and also served as a law clerk to the Honorable Marie E. Lihotz in New Jersey. Prior to joining the faculty at Vermont Law School, Professor Beyranevand was a Staff Attorney at Vermont Legal Aid where she represented adults and children in individual cases and class action litigation involving health law issues. In that capacity, she appeared in state and federal court, as well as before administrative adjudicative bodies, and served as an appointed member of the Human Rights Committee.

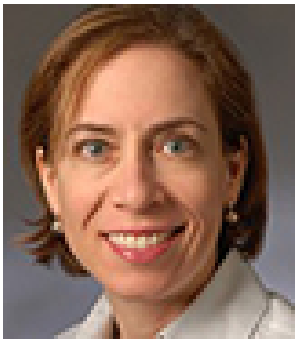
Professor Beyranevand developed Vermont Law School's first food law and policy course and has been closely involved in the Center for Agriculture and Food Systems since its formation. Professor Beyranevand has published a number of scholarly articles and book chapters that focus on the connections between human health and the food system. Her work has been cited in petitions to major federal agencies, books, blogs, and articles, and she has been quoted in Politico, Mother Jones, the Christian Science Monitor, Climate Wire, and E & E Greenwire among others.

She is an appointed member of the Academic Programs Committee for the Food and Drug Law Institute, the Co-Chair of the Outreach Committee of the Academy of Food Law and Policy, and a Committee Member of the Agriculture and Food Law Section of the American Association of Law

Schools. She is admitted to the New York and Vermont State Bars, as well as the U.S. District Court, District of Vermont.

Diana Winters, JD, PhD, MA

Assistant Director of Scholarship, Resnick Program for Food Law & Policy, University of California Los Angeles School of Law



Diana R. H. Winters is the Assistant Director of Scholarship at the Resnick Program for Food Law & Policy at UCLA Law. Her research interests lie in food law and she writes about the interaction between federal and local law and the judicial review of regulation. Winters was an Associate Professor at Indiana University McKinney School of Law from 2012 to 2018. Before that she was the Health Law Scholar Visiting Assistant Professor at Boston University School of Law and an Assistant Solicitor General at the New York Attorney General's Office. Winters holds a J.D. from New York University, a Ph.D. and M.A. from Harvard University, and a B.A. from Brown University.

Jeannie Perron, DVM, JD

Partner, Covington & Burling LLP

Jeannie Perron is a member of the firm's Food and Drug Practice Group, resident in the Washington, DC Office.

In addition to being an attorney, Dr. Perron also holds a degree in veterinary medicine and has practiced as a veterinarian. She specializes in food and drug law, with a sub-specialty in animal food and drug law. In this capacity, she represents companies that manufacture feed, feed ingredients, drugs, biologics and medical devices for animals, as well as clients in related industries. Her specialties also include advising clients and providing representation on matters before the United States Department of Agriculture arising under the Animal Welfare Act.

Her clients are animal research companies, pharmaceutical companies, and animal dealers and exhibitors.

Another specialized area of practice relates to the importation of animal-derived ingredients and products. Dr. Perron advises clients on USDA regulations and procedures in this area and assists clients in securing the required permits and certifications.

In addition to these other practice areas, Dr. Perron also advises clients in the regulation of dietary supplements, over-the-counter drugs, cosmetics for humans, and import and export of products regulated by the United States Food and Drug Administration as well as those having animal or microbially-derived ingredients regulated by USDA.

Joanna Sax, JD, PhD

E. Donald Shapiro Professor of Law, California Western School of Law

Professor Sax's research is at the nexus of law and science. Her articles address ways to incentivize the advancement of science and protect scientific inquiry and innovation. Professor Sax analyzes and questions policies that create barriers to basic science research, mostly by focusing on NIH-funded research. In addition to basic research, she has a strong interest in the translation of advances in basic science. In this vein, Professor Sax is widely recognized for her work on food policy, particularly FDA regulation of dietary supplements and genetically engineered food.

Professor Sax combines her education with her legal background in her research and teaching. She has a JD and PhD in Cell and Molecular Biology from the University of Pennsylvania. After law school, Professor Sax was an associate at Morgan, Lewis & Bockius, LLP, and is admitted to practice in California and the Ninth Circuit. Professor Sax served as Associate Dean for Research and Faculty Development at California Western for the 2014-15 and 2015-16 academic years. In fall 2016, she was a visiting faculty member at the James E. Rogers College of Law - University of Arizona.

While Professor Sax's core teaching interests mirror her research, she also enjoys teaching first-year students. In 2015, she authored an innovative online casebook for contracts published by ChartaCourse, which provides an interactive online environment at an attractively low cost to students.

Sarah Roller, JD, RD, MPH

Partner, Chair, Food and Drug Law Practice, Kelley Drye & Warren LLP

Sarah Roller is a partner in the Washington, D.C. office of Kelley Drye & Warren LLP and chair of the firm's Food and Drug Law practice. For nearly 30 years, Ms. Roller's practice has focused on the representation of U.S. and global companies and industry trade organizations that are involved in the development, manufacture, packaging, labeling, marketing and retail sale of foods, beverages, dietary supplements and other health products. She represents companies in proceedings before FDA, USDA, FTC, TTB and state governmental bodies, and serves as regulatory counsel in litigation matters involving product safety, labeling and advertising regulation. Ms. Roller is a Registered Dietitian and received her Bachelor of Science from the University of Wisconsin-Madison and her Master of Public Health from the University of Minnesota. She received her Juris Doctor from The George Washington University. Ms. Roller has been recognized nationally as a leading practitioner by *Chambers USA* and selected as one of *The Best Lawyers in America*.

CONCURRENT SESSION 1C
MEDICAL PRODUCTS: CROSS-CUTTING ISSUES I

Elizabeth Jungman, JD, MPH

Director of Public Health Programs, Pew Charitable Trusts

Elizabeth Jungman directs Pew's work on public health, overseeing initiatives related to the innovation of antibiotics and the safety of prescription drugs, over-the-counter medicines, and other consumer health care products.

Before joining Pew, Jungman was a senior health policy adviser with the U.S. Senate Committee on Health, Education, Labor, and Pensions, where she played a key role in drafting and negotiating the Food and Drug Administration Safety and Innovation Act of 2012 and other health- and drug-related legislation, including pandemic preparedness, drug compounding, and supply chain security measures. Previously, she was in private legal practice, counseling clients on a broad range of FDA regulatory matters and other health care issues. Jungman serves on FDA's Pharmacy Compounding Advisory Committee.

She has a bachelor's degree in biology from Harvard College, a master's in public health from Johns Hopkins University, and a Juris Doctor from Georgetown University.

Ralph Hall, JD

Professor of Practice, University of Minnesota Law School

Ralph Hall is a principal and works in association with the Washington, D.C., office. In this role, Ralph provides consulting services to clients in the areas of FDA statutes and regulations, regulatory compliance, as well as health care policy and legislation, and particularly the application of those regulatory systems to the medical device industry.

Ralph's rich background with drug and medical device regulation and corporate compliance matters makes him one of the nation's foremost experts. Ralph previously served as counsel at Faegre Baker Daniels where he provided legal services, including FDA-related matters, corporate compliance, the design and implementation of multiple cross-disciplinary, corporate legal strategies, corporate law department organization and management, and general corporate counseling. Ralph has also served as General Counsel for Guidant CRM and Chief Compliance Officer for Guidant.

Ralph furthermore serves as a Professor of Practice at the University of Minnesota Law School. He received his B.A. from Indiana University and his juris doctorate from the University of Michigan where he was a Weymouth Kirkland Scholar.

Daniel Kracov, JD

Partner and Co-Chair, Live Sciences and Healthcare Regulatory Practice, Arnold & Porter LLP and Adjunct Professor of Law, American University Washington College of Law

Dan Kracov is co-chair of the Life Sciences and Healthcare Regulatory practice, which was recently named the top Healthcare practice in the country by *Law360*. For decades, he has been one of the foremost Food and Drug Administration lawyers in the country, and his expertise in critical regulatory matters has been widely recognized by *Chambers*, the *Legal Times*, *Best Lawyers in America*, and other publications. A particular focus of his practice is assisting pharmaceutical, biotechnology, medical device and diagnostic companies, including start-up companies, trade associations, and large manufacturers, negotiate challenges relating to the development, approval and marketing of FDA-regulated products. He also has extensive experience in matters relating to foods, dietary supplements and cosmetics.

In addition to day-to-day counseling on regulatory strategies and concerns, Mr. Kracov regularly handles product and compliance-related government and internal investigations, the development of global corporate compliance programs, and due diligence in financings, mergers and acquisitions. He has a widely recognized experience in biomedical public policy matters, including Congressional investigations and advising on FDA-related legislation.

Rachel Sachs, JD, MPH

Associate Professor of Law, Washington University Law School

Professor Rachel Sachs is a scholar of innovation policy whose work explores the interaction of intellectual property law, food and drug regulation, and health law. Professor Sachs' scholarship has or will have appeared in journals including the *Michigan Law Review*, the *Minnesota Law Review*, the *New England Journal of Medicine*, and the *Journal of the American Medical Association*. Prior to joining Washington University, Professor Sachs was an Academic Fellow at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics and a Lecturer in Law at Harvard Law School. She also clerked for the Honorable Richard A. Posner of the U.S. Court of Appeals for the Seventh Circuit. She received her J.D. *magna cum laude* from Harvard Law School and a Master of Public Health from the Harvard School of Public Health. She received her A.B. in Bioethics from Princeton University.

Gail H. Javitt, JD, MPH

Member of the Firm, Epstein Becker Green

Gail H. Javitt is a Member of the Firm in the Health Care and Life Sciences practice, in the Washington, DC, office of Epstein Becker Green. Ms. Javitt provides strategic FDA regulatory advice for leading medical device, diagnostics, pharmaceutical, biological products, human cellular, and tissue-based products (HCT/Ps), and dietary supplement companies throughout the product life cycle and has successfully resolved disputes at both the pre- and post-market stage. She also has significant experience advising clinical laboratories on FDA and CLIA requirements for laboratory developed tests.

Ms. Javitt's services include: Providing premarket strategic advice to clients interested in bringing innovative medical technologies to market Advising on the NDA, 510(k), and PMA review pathways and the regulatory implications of post-market product modifications. Counseling clients on clinical trial (GCP) compliance, including the responsibilities of sponsors and investigators, IRB engagement, and the submission of investigational device exemption (IDE) and investigational new drug (IND) submissions. Preparing client communications to FDA, including requests for designation, Citizen Petitions, and comments to proposed regulations and guidance documents, and representing clients in engagements with the agency. Providing post-market compliance counseling, including medical device reporting and corrections and removals, and assisting clients in resolving Form 483 inspectional observations and Warning and Untitled Letters.

Ms. Javitt's experience prior to joining Epstein Becker Green includes serving as counsel in a major Washington, DC, FDA Regulatory practice and as a law and policy director at the Genetics and Public Policy Center, part of Johns Hopkins University. At the Center, she was responsible for developing policy options to guide the development and use of reproductive and other genetic technologies. Earlier in her legal career, Ms. Javitt clerked for the Honorable Gary Taylor of the U.S. District Court for the Central District of California.

In addition, Ms. Javitt has published and spoken widely on issues at the intersection of law and science, including FDA regulation of genetic testing, precision medicine, and next-generation sequencing. Her academic experience has included serving as a faculty member at the Berman Institute of Bioethics at Johns Hopkins University and as an adjunct professor at the Georgetown University Law Center, American University's Washington College of Law, and the University of Maryland School of Law. She was previously a Greenwall Fellow in Bioethics and Health Policy, a collaborative effort between Johns Hopkins University and Georgetown University.

WELCOMING REMARKS

Lewis Grossman, JD, PhD

Professor of Law, American University Washington College of Law

Lewis Grossman is Professor of Law at the Washington College of Law, where he has taught since 1997 and where he served as Associate Dean for Scholarship from 2008 to 2011. During academic year 2017-18, Professor Grossman served as a Law and Public Affairs (LAPA) Fellow at Princeton University. He teaches and writes in the areas of American legal history, food and drug law, health law, and civil procedure. He has also been a Visiting Professor of Law at Cornell Law School. Professor Grossman's scholarship has appeared in the Cornell Law Review, Law and History Review, Yale Journal of Health Policy, Law & Ethics, and Administrative Law Review, among others. He has made recent contributions to volumes published by Oxford University Press and Columbia University Press. He is the co-author of Food and Drug Law: Cases and Materials (with Peter Barton Hutt and Richard A. Merrill) and of a widely used supplement to the first-year civil procedure course titled A Documentary Companion to A Civil Action (with Robert G. Vaughn). Professor Grossman is currently at work on a book titled Choose Your Medicine: Freedom of Therapeutic Choice in American Law and History, which will be published by Oxford University Press. He has served as a member or legal consultant on three committees of the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine (formerly the Institute of Medicine).

Amy Comstock Rick, JD

President and Chief Executive Officer, Food and Drug Law Institute

Amy Comstock Rick is the President and Chief Executive Officer of the Food and Drug Law Institute, having joined in August, 2014. Prior to joining FDLI, Ms. Rick was the Chief Executive Officer of the Parkinson's Action Network (PAN) from 2003-2014. PAN is a Washington D.C.-based national nonprofit focused on educating the public and government leaders on better policies for research and therapy development and an improved quality of life for people living with Parkinson's disease. Ms. Rick has also served as the President of the Coalition for the Advancement of Medical Research, on the Boards of Directors of Research!America, the National Health Council, and the American Brain Coalition. Before joining PAN, she was the Senate-confirmed Director of the U.S. Office of Government Ethics from 2000-2003 and the Associate Counsel to the President in the White House Counsel's Office from 1998-2000. Ms. Rick began her federal service as a career attorney at the U.S. Department of Education in 1989 and became the Assistant General Counsel for Ethics in 1993. Prior to her government service, Ms. Rick was an associate attorney at the law firm of Beveridge & Diamond. She received a Bachelor of Arts degree from Bard College and a Juris Doctor degree from the University of Michigan.

Sylvia Mathews Burwell

American University President and former Secretary of Health and Human Services

Sylvia M. Burwell is American University's 15th president and the first woman to serve as president. A visionary leader with experience in the public and private sectors, President Burwell brings to American University a commitment to education and research, the ability to manage large and complex organizations, and experience helping to advance solutions to some of the world's most pressing challenges. Burwell served as the 22nd Secretary of the United States Department of Health and Human Services (HHS) from 2014 to 2017. During her tenure, the Department shepherded the implementation of the Affordable Care Act, pioneered groundbreaking advances in research and innovation, and expanded critical services for children and families. Previously, she was the Director of the Office of Management and Budget (OMB), where she worked with Congress to negotiate a two-year budget deal following the 2013 government shutdown. Her prior government experience includes Deputy Director of the Office of Management and Budget, Deputy Chief of Staff to the President, Chief of Staff to the Secretary of the Treasury, and Special Assistant to the Director of the National Economic Council. President Burwell served 11 years at the Bill and Melinda Gates Foundation, including roles as the Chief Operating Officer and President of the Global Development Program. After the Gates Foundation, she was the President of the Walmart Foundation, where she led efforts to fight hunger in America, empower women around the world, and leverage Walmart's presence in local communities to reach millions of people. She earned a bachelor's degree in Government from Harvard University and a BA in Philosophy, Politics and Economics from the University of Oxford as a Rhodes Scholar.

PLENARY SESSION 1
A DISCUSSION WITH FORMER FDA COMMISSIONERS

Robert M. Califf, MD

Vice Chancellor for Health Data Science, Donald F. Fortin, M.D. Professor of Cardiology, Professor of Medicine, Director of Duke Forge, Duke University School of Medicine & Advisor, Verily Life Sciences

Robert M. Califf, MD, MACC, is vice chancellor for health data science and director of Duke Forge, the Center for Actionable Health Data Science at Duke Health, Donald F. Fortin, MD Professor of Cardiology in the Duke University School of Medicine, Chair of the Board of the People Centered Research Foundation, and an advisor for Verily Life Sciences, a member of the Alphabet family of companies formed by Google. He served in the administration of President Barack Obama as Deputy Commissioner for Medical Products and Tobacco in the U.S. Food and Drug Administration (FDA) from 2015-106, and as Commissioner of Food and Drugs from 2016-2017.

Prior to joining the FDA, Dr. Califf was a professor of medicine and vice chancellor for clinical and translational research at Duke University. He was founding director of the Duke Clinical Research Institute. A nationally and internationally recognized expert in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf has led many landmark clinical trials and is one of the most frequently cited authors in biomedical science, with 1,250 publications in the peer-reviewed literature. Dr. Califf is a member of the National Academy of Medicine (formerly the Institute of Medicine [IOM]). Dr. Califf has served on numerous IOM committees, and was a member of the FDA Cardiorenal Advisory Panel and FDA Science Board's Subcommittee on Science and Technology. Dr. Califf has also served on the Board of Scientific Counselors for the National Library of Medicine, as well as on advisory committees for the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Environmental Health Sciences, and the Council of the National Institute on Aging.

He has led major initiatives aimed at improving methods and infrastructure for clinical research, including the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by the FDA and Duke. He also served as the principal investigator for Duke's Clinical and Translational Science Award and the NIH Health Care Systems Research Collaboratory coordinating center, and as co-PI of the National Patient-Centered Clinical Research Network (PCORnet). He currently serves as chair of the board of the People-Centered Research Foundation, a not-for-profit organization that is supporting and extending the work of PCORnet.

Dr. Califf is a graduate of Duke University School of Medicine. He completed a residency in internal medicine at the University of California, San Francisco and a fellowship in cardiology at Duke.

Margaret Hamburg, MD

President, American Association for the Advancement of Science and Foreign Secretary of the National Academy of Medicine

Dr. Hamburg is an internationally recognized leader in public health and medicine, and currently serves as foreign secretary of the National Academy of Medicine and chair of the NTI | bio Advisory Group. She is a former Commissioner of the U.S. Food and Drug Administration (FDA), having served for almost six years. As FDA Commissioner she was known for advancing regulatory science, streamlining and modernizing FDA's regulatory pathways, and globalization of the agency. Before joining FDA, Dr. Hamburg was founding vice president and senior scientist at the Nuclear Threat Initiative, a foundation dedicated to reducing nuclear, chemical and biological threats. Previous government positions include Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Health Commissioner for New York City, and Assistant Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health.

As Foreign Secretary of the National Academy of Medicine, the health arm of the National Academy of Sciences, Engineering and Medicine, Dr. Hamburg serves as senior advisor on international matters and is the liaison with other Academies of Medicine around the world. She is President of the American Association for the Advancement of Science (AAAS), as well as an elected member of the Council on Foreign Relations and the National Academy of Medicine. Dr. Hamburg currently sits on the boards of the Commonwealth Fund, the Simons Foundation, the Urban Institute, the Global Alliance for Vaccines and Immunization, the Parker Institute for Cancer Immunotherapy and the American Museum of Natural History. She is chair of the Joint Coordinating Group for the Coalition for Epidemic Preparedness and Innovation, and a member of the Harvard University Global Advisory Council, the Global Health Scientific Advisory Committee for the Gates Foundation, the Harvard Medical School Board of Fellows, and the World Dementia Council.

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

David Kessler, MD, JD

Professor, University of California San Francisco

David A. Kessler, M.D., J.D., is Professor of Pediatrics and Epidemiology and Biostatistics at the School of Medicine, University of California, San Francisco (UCSF). He was Dean of the School of Medicine and the Vice Chancellor for Medical Affairs at UCSF from 2003 through 2007 and Dean of the Yale University School of Medicine from 1997 until 2003. Dr. Kessler, who served as Commissioner of the United States Food and Drug Administration from November 1990 until March 1997, was appointed by President Bush and reappointed by President Clinton. From 1984 until his FDA appointment, David Kessler was the medical director of the Hospital of the Albert Einstein College of Medicine in the Bronx, New York, where he held teaching appointments in the Department of Pediatrics and in the Department of Epidemiology and Social Medicine. From 1986 until 1990, Dr. David Kessler

also taught food and drug law at the Columbia University School of Law in New York. He was a consultant to the United States Senate Labor and Human Resources Committee from 1981 until 1984. Dr. Kessler is the author of *A Question of Intent* and of *The End of Overeating: Taking Control of the Insatiable American Appetite*.

Andrew C. von Eschenbach, MD

President, Samaritan Health Initiatives

Andrew C. von Eschenbach, M.D. currently serves as President of Samaritan Health Initiatives, Inc. and as an Adjunct Professor at University of Texas MD Anderson Cancer Center. From September of 2005 to January 2009 he served as Commissioner of Food and Drugs where he championed an agenda to modernize the FDA by process improvement of the regulatory pathway for drugs and medical devices and by fostering creative projects, including FDA's Critical Path Initiative (designed to bring modern tools of science to the product development process); work plans like the FDA's Food Protection Plan; and most especially the nurturing of the workforce through initiatives, such as an Agency-wide fellowship program and development of a new integrated campus for the Agency in White Oak, Maryland. Under his leadership, the FDA experienced dramatic increases in resources enabling implementation of many new programs designed to strengthen the FDA in its mission to protect and promote public health. He has emphasized FDA's role in working with external partners to assure quality throughout the entire life cycle of the products it regulates.

Dr. von Eschenbach joined FDA after serving for four years as Director of the National Cancer Institute (NCI) at the National Institutes of Health where he set an ambitious goal to eliminate the suffering and death due to cancer by rapid acceleration and integration of the discovery-development-delivery continuum. While at NCI, he committed resources to ensure the application to oncology of nanotechnology, genomics, proteomics, bioinformatics, and other emerging technologies. At the time of his appointment by President Bush to serve as Director of NCI, he was President-Elect of the American Cancer Society. Dr. von Eschenbach entered government service after an outstanding career over three decades as a physician, surgeon, oncologist and executive that included numerous leadership roles from Chairman of the Department of Urologic Oncology to Executive Vice President and Chief Academic at the University of Texas M.D. Anderson Cancer Center in Houston, an institution world renowned for the magnitude and excellence of its clinical and research cancer programs. An internationally renowned cancer specialist and author of more than 300 scientific articles and studies, Dr. von Eschenbach has served in numerous leadership roles, including serving as one of the founding members of the National Dialogue on Cancer. He has received numerous professional awards and honors. In 2006, Dr. von Eschenbach was named one of Time magazine's "100 most influential people to shape the world," and in both 2007 and 2008, he was selected as one of the Modern Healthcare/Modern Physician's "50 Most Powerful Physician Executives in Healthcare."

Dr. von Eschenbach earned a B.S. from St. Joseph's University in his native Philadelphia and his medical degree from Georgetown University School of Medicine in Washington, D.C. He served as a Lt. Commander in the U.S. Navy Medical Corps. After completing a residency in urologic surgery at Pennsylvania Hospital in Philadelphia, he was an instructor in urology at the University of Pennsylvania School of Medicine. He completed a Fellowship in Urologic Oncology at the University of Texas M.D. Anderson Cancer Center.

Lewis Grossman, JD, PhD

Professor of Law, American University Washington College of Law

Lewis Grossman is Professor of Law at the Washington College of Law, where he has taught since 1997 and where he served as Associate Dean for Scholarship from 2008 to 2011. During academic year 2017-18, Professor Grossman served as a Law and Public Affairs (LAPA) Fellow at Princeton University. He teaches and writes in the areas of American legal history, food and drug law, health law, and civil procedure. He has also been a Visiting Professor of Law at Cornell Law School. Professor Grossman's scholarship has appeared in the Cornell Law Review, Law and History Review, Yale Journal of Health Policy, Law & Ethics, and Administrative Law Review, among others. He has made recent contributions to volumes published by Oxford University Press and Columbia University Press. He is the co-author of Food and Drug Law: Cases and Materials (with Peter Barton Hutt and Richard A. Merrill) and of a widely used supplement to the first-year civil procedure course titled A Documentary Companion to A Civil Action (with Robert G. Vaughn). Professor Grossman is currently at work on a book titled Choose Your Medicine: Freedom of Therapeutic Choice in American Law and History, which will be published by Oxford University Press. He has served as a member or legal consultant on three committees of the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine (formerly the Institute of Medicine).

PLENARY SESSION 2
A DISCUSSION WITH FORMER FDA CHIEF COUNSELS

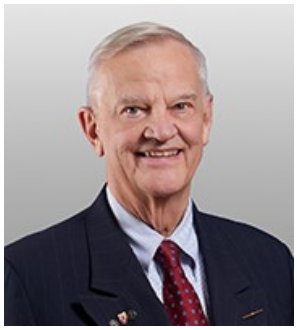
Richard Cooper, JD, MA

Senior Counsel, Williams & Connolly, LLP

Richard Cooper is a Senior Counsel at Williams & Connolly LLP, Washington, DC. He has contributed articles to professional journals, co-edited a book on food and drug law, co-taught that subject at Georgetown University Law Center, and served on advisory committees of the Institute of Medicine (now the National Academy of Medicine) and National Research Council, as chairman of the editorial boards of the Food and Drug Law Journal and the Business Crimes Bulletin, and on the executive committee and other committees at Williams & Connolly LLP. He was FDA Chief Counsel during 1977-1979, and previously was a senior member of the Office of Energy Policy and Planning, Executive Office of the President. He was a Rhodes Scholar, President of the Harvard Law Review, and a law clerk to Justice William J. Brennan, Jr., U.S. Supreme Court. He received a B.A. summa cum laude from Haverford College, a B.A., First Class with Congratulations, from Oxford University, and a J.D. summa cum laude from Harvard Law School.

Peter Barton Hutt, LLB, LLM

Senior Counsel, Covington & Burling LLP



Peter Barton Hutt is a Senior Counsel in the Washington, D.C. law firm of Covington & Burling LLP specializing in food and drug law. He graduated from Yale College and Harvard Law School and obtained a Master of Laws degree in Food and Drug Law from NYU Law School. Mr. Hutt served as Chief Counsel for the Food and Drug Administration during 1971-1975. He is the co-author of the casebook used to teach Food and Drug Law throughout the country, and has published more than 175 book chapters and articles on food and drug law and health policy. Beginning in 1994 he has taught a full course on this subject each year during Winter Term at Harvard Law School and in 1998 he taught the same course during Spring Term at Stanford Law School. Mr. Hutt has been a member of the Institute of Medicine (now the National Academy of Medicine) since it was founded in 1971. He serves on academic, philanthropic, and venture capital advisory boards, and the boards of startup biotechnology companies. He recently served on the Working Group on Innovation in Drug Development and Evaluation of President Obama's Council of Advisors on Science Technology (PCAST),. The Panel on the Administrative Restructuring of the National Institutes of Health, and the Working Group to Review Regulatory Activities Within the Division of AIDS of the National Institute of Allergy and Infectious Diseases, and was a consultant to the FDA Science Board Subcommittee to review the agency's science needs in order to perform its regulatory mission.

Gerald Masoudi, JD

Chief Legal Officer, JUUL Labs

Jerry Masoudi serves as Chief Legal Officer of JUUL, Inc., a role he has held since July 2018. He previously served as Executive Vice President, General Counsel and Corporate Secretary of Celgene Corporation. He served as Chief Counsel (2007-09) and Principal Deputy/Acting Chief Counsel (2004-05) of the U.S. Food and Drug Administration (FDA). In addition to his time working for the FDA, from 2009-15 Mr. Masoudi was a partner and co-chair of the food and drug practice at the Washington, D.C. office of Covington & Burling LLP, where he advised FDA-regulated companies on a wide range of regulatory and litigation matters. Mr. Masoudi also served as Deputy Assistant Attorney General in the Antitrust Division of the U.S. Department of Justice, where he was responsible for international, policy and appellate matters. Mr. Masoudi also practiced for a decade as a litigator at Kirkland & Ellis LLP and Bartlit Beck Herman Palenchar & Scott.

Mr. Masoudi earned a B.A. in economics from Amherst College in 1990 and a J.D. with High Honors from the University of Chicago Law School in 1993.

Daniel Troy, JD

Senior Vice President & General Counsel, GlaxoSmithKline

Since 2008, Dan has been Senior Vice President & General Counsel and a member of the Corporate Executive Team of GSK. He will be leaving GSK as of the end of the year. As General Counsel, he is responsible for leading the company's legal department in protecting GSK's intellectual property, managing litigation, supporting business development transactions, as well as risk management.

Before joining GSK, he was a Partner at the Washington law firm Sidley Austin LLP, where he represented pharmaceutical companies and trade associations on matters related to the US Food and Drug Administration (FDA) and government regulations. Dan was formerly Chief Counsel for the FDA.

Dan holds a bachelor's degree in Industrial and Labor Relations from Cornell University and a juris doctor degree from Columbia University School of Law, where he was a member of the Law Review and a Kent Scholar. After graduation from law school, he was a law clerk for the US Circuit Court of Appeals for the District of Columbia Circuit. He was the 2012 CPR Corporate Leadership Award recipient and, in 2013, was named a 'Legend in the Law' at the Burton Awards.

I. Glenn Cohen, JD

James A. Attwood and Leslie Williams Professor of Law, Harvard Law School
Faculty Director, Petrie-Flom Center for Health Law Policy, Biotechnology & Bioethics

Prof. Cohen is one of the world's leading experts on the intersection of bioethics (sometimes also called "medical ethics") and the law, as well as health law. He also teaches civil procedure. From Seoul to Krakow to Vancouver, Professor Cohen has spoken at legal, medical, and industry conferences around the world and his work has appeared in or been covered on PBS, NPR, ABC, CNN, MSNBC, Mother Jones, the *New York Times*, the *New Republic*, the *Boston Globe*, and several other media venues.

He was the youngest professor on the faculty at Harvard Law School (tenured or untenured) both when he joined the faculty in 2008 (at age 29) and when he was tenured as a full professor in 2013 (at age 34), though not the youngest in history.

Prof. Cohen's current projects relate to big data, health information technologies, mobile health, reproduction/reproductive technology, research ethics, organ transplantation, rationing in law and medicine, health policy, FDA law, translational medicine, and to medical tourism – the travel of patients who are residents of one country, the "home country," to another country, the "destination country," for medical treatment.

He is the author of more than 100 articles and chapters and his award-winning work has appeared in leading legal (including the Stanford, Cornell, and Southern California Law Reviews), medical (including the *New England Journal of Medicine*, *JAMA*), bioethics (including the *American Journal of Bioethics*, the *Hastings Center Report*), scientific (*Science*, *Cell*, *Nature Reviews Genetics*) and public health (the *American Journal of Public Health*) journals, as well as Op-Eds in the *New York Times* and *Washington Post*.

Cohen is the author, co-author, editor, or co-editor of 12 books. They include: *Health Care Law and Ethics* (Aspen, 2018); *Big Data, Health Law, and Bioethics* (Cambridge University Press, 2018); *Specimen Science* (MIT Press, 2017); *Nudging Health: Health Law and Behavioral Economics* (John Hopkins University Press, 2016) *The Oxford Handbook of U.S. Health Care Law* (Oxford University Press, 2016); *FDA in the Twenty-First Century: The Challenges of Regulating Drugs and New Technologies* (Columbia University Press, 2015); *Identified Versus Statistical Lives: An Interdisciplinary Perspective* (Oxford University Press, 2015); *Patients with Passports: Medical Tourism, Law, and Ethics* (Oxford University Press, 2014); *Human Subjects Research Regulation: Perspectives on the Future* (MIT Press, 2014); *The Globalization of Health Care: Legal and Ethical Issues* (Oxford University Press, 2013).

For his law school teaching he was awarded the HLS Student Government Teaching and Advising Award in 2017. He also sometimes teaches courses at Harvard College and Harvard Medical School. For the public he created the free online Harvard X class “Bioethics: The Law, Medicine, and Ethics of Reproductive Technologies and Genetics,” which was nominated by Harvard for the Japan Prize. More than 25,000 students have taken the course in its first two runs alone. You can also watch his Tedx talk, Are There Non-Human Persons? Are There Non-Person Humans?

Prior to becoming a professor he served as a law clerk to Judge Michael Boudin of the U.S. Court of Appeals for the First Circuit and as a lawyer for U.S. Department of Justice, Civil Division, Appellate Staff, where he handled litigation in the Courts of Appeals and (in conjunction with the Solicitor General’s Office) in the U.S. Supreme Court. In his spare time (where he can find any!) he still litigates, having authored an amicus brief in the U.S. Supreme Court for leading gene scientist Eric Lander in

Association of Molecular Pathology v. Myriad, concerning whether human genes are patent eligible subject matter, a brief that was extensively discussed by the Justices at oral argument. Most recently he submitted an amicus brief to the U.S. Supreme Court in Whole Women's Health v. Hellerstedt (the Texas abortion case, on behalf of himself, Melissa Murray, and B. Jessie Hill).

Cohen was selected as a Radcliffe Institute Fellow for the 2012-2013 year and by the Greenwall Foundation to receive a Faculty Scholar Award in Bioethics. He is also a Fellow at the Hastings Center, the leading bioethics think tank in the United States. He recently finished his role as one of the key co-investigators on the multi-million dollar Football Players Health Study at Harvard which is committed to improving the health of NFL players. He co-leads the Regulatory Foundations, Ethics, and Law Program of Harvard Catalyst | The Harvard Clinical and Translational Science Center program. He also leads the Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL). He is also one of three editors-in-chief of the *Journal of Law and the Biosciences*, a peer-reviewed journal published by Oxford University Press and serves on the editorial board for the *American Journal of Bioethics*. He served on the Steering Committee for Ethics for the Canadian Institutes of Health Research (CIHR), the Canadian counterpart to the NIH, and currently serves and on the Ethics Committee for the American Congress of Obstetricians and Gynecologists (ACOG).

CONCURRENT PANEL 2A
DRUGS II

David Horowitz, JD

Partner, Hogan Lovells

David Horowitz joined Hogan Lovells as a Partner in the Pharmaceuticals/Biotech practice group in 2017 after a 25-year career at the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS), in several senior legal, regulatory, and policy positions. As Deputy General Counsel at HHS (2010-2016), David oversaw and coordinated legal services in support of FDA, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and international and emergency preparedness programs, including serving as the Department focal point for all legal matters relating to the Ebola crisis.

During his 18-year tenure at FDA — which included five years as head of the Office of Compliance for drugs— David played a leadership role in major initiatives, including the modernization of FDA's approach to pharmaceutical manufacturing quality and the agency's efforts to develop and implement a more scientific, risk-based approach to inspection and enforcement. David started his career at FDA's Office of the Chief Counsel, where he served as Assistant Chief Counsel for Enforcement and Associate Chief Counsel for Drugs, working on various issues related to drug approval, GMPs, drug importation, OTC drugs, and pharmacy compounding. Before moving to HHS, David served as Assistant Commissioner for Policy, leading the Office of Policy in the FDA Commissioner's office.

Over the course of his career at HHS and FDA, David acquired expertise in FDA law and policy, with particular emphasis on pharmaceuticals, compliance, and the application of administrative law. He also developed a deep understanding of the institutions, structures, procedures, and cultures through which regulatory policy and compliance decisions are considered, developed, and implemented across all branches of government. David obtained his bachelor's degree, *magna cum laude*, from Brown University and his law degree from University of Virginia School of Law.

Lars Noah, JD

Professor of Law, Stephen C. O'Connell Chair, University Term Professor, University of Florida Levin School of Law

Lars Noah is a Professor of Law at the University of Florida, where he has taught courses in Administrative Law, Medical Technology, Public Health Law, and Torts, among other subjects. Professor Noah has published more than sixty scholarly articles on a wide range of subjects as well as a casebook that focuses on the regulation of pharmaceuticals and medical devices: Law, Medicine, and Medical Technology (Foundation Press 4th ed. 2017). He has served as a visiting professor at Georgetown, Texas, Vanderbilt, George Washington, U.C. Hastings, and Washington & Lee, and he has worked with expert committees at the National Academy of Sciences and the National Institutes of Health. Before entering academia

in 1994, Professor Noah clerked for Chief Judge Abner J. Mikva on the U.S. Court of Appeals for the D.C. Circuit and then practiced law for three years at Covington & Burling in Washington, D.C.

David C. Spangler, JD

Senior Vice President, Policy, and General Counsel and Secretary, Consumer Healthcare Products Association

David Spangler directs CHPA's legal affairs and international affairs, and oversees association policy initiatives. He has particular expertise in regulatory matters. Spangler joined CHPA in 1984 as a legislative analyst. He subsequently served in a number of roles for the association in the president's office, project management, international affairs, and, after completing law school in 1995, the association's legal department. Spangler was named a vice president in 1997, and a senior vice president in 2006. His responsibilities were expanded to include the legal function in 2011. Spangler serves on the board of directors of the World Self-Medication Industry. He is a member of the District of Columbia Bar as well as the American Society of Association Executives. He authored the chapter on OTC medicines in "Modern Pharmaceutical Industry: A Primer" (Jacobsen and Wertheimer, eds., 2009) and is on the editorial board for the Food and Drug Law Institute's Policy Forum. Spangler earned his Certificate in Organizational Management in 1991 from the U.S. Chamber of Commerce's Institute for Organization Management. Education: A.B., Miami University (Ohio); J.D., George Washington University National Law Center.

Elizabeth McCuskey, JD

Professor, University of Toledo College of Law & School of Population Health

Liz McCuskey directs the University of Toledo's Health Law program and co-directs the University's JD/MD and JD/MPH joint-degree programs. Her research investigates the roles of civil justice and preemption jurisprudence in health care regulation and reform. Her articles on health care preemptions, waivers, and regulatory reforms have appeared in law reviews and peer-reviewed publications including the Ohio State Law Journal, Temple Law Review, Journal of Legal Medicine, and Journal of Health Law & Policy. She was selected as a 2016 Health Law Scholar by the American Society for Law, Medicine, & Ethics and received the University President's Award for Outstanding Contribution in Scholarship in 2018.

Professor McCuskey teaches courses on Food & Drug Law, Health Law, Antitrust in Health Care Markets, and Civil Procedure. She holds a joint appointment in the University of Toledo's School of Population Health and is an adjunct of St. Louis University's Center for Health Law Studies. She earned her bachelor's and law degrees from the University of Pennsylvania and practiced law with Drinker, Biddle, & Reath LLP in Philadelphia.

Brian Wolfman, JD

Associate Professor of Law, Director Appellate Court Immersion Clinic, Georgetown University Law Center

Professor Wolfman re-joined the Georgetown Law faculty in 2016 as the Director of the new full-time, semester-long Appellate Clinic. He was previously a Professor of the Practice of Law and Co-Director of Stanford Law School's Supreme Court Litigation Clinic. Before that, from 2009 to 2014, Professor Wolfman served as Director of the Civil Rights section of Georgetown Law's Institute for Public Representation, a student clinic that handles complex trial court and appellate litigation focused on civil rights and other public-interest litigation. While at Georgetown, he also taught the standard doctrinal course on Federal Courts and the Federal System and a course on appellate courts. Before Georgetown, he spent nearly 20 years at the national public interest law firm Public Citizen Litigation Group, serving the last five years as the Group's Director. Earlier in his career, he conducted trial and appellate litigation as a staff lawyer at a rural poverty law program in Arkansas. Professor Wolfman has handled a broad range of litigation, including cases involving health and safety regulation, class action governance, court-access issues, federal preemption, consumer law, public-benefits law, and government transparency. He has argued six cases before the Supreme Court (winning five), and he has litigated hundreds of cases before federal and state appellate and trial courts around the country. He directed Public Citizen's Supreme Court Assistance Project, which helps "underdog" public-interest clients litigate before the U.S. Supreme Court. He has testified before Congress and federal rules committees on a range of issues, and he was an Advisor to the American Law Institute's Principles of the Law of Aggregate Litigation. Since 2004, he has taught an intensive Appellate Courts Workshop during the January Term at Harvard Law School. Professor Wolfman has authored articles on a variety of subjects, often on the intersection of state tort law and federal preemption doctrine and on class actions.

CONCURRENT PANEL 2B
MEDICAL PRODUCTS: CROSS-CUTTING ISSUES II

Theresa Mullin, PhD

Associate Director for Strategic Initiatives, CDER, FDA

Theresa Mullin, Ph.D., serves as CDER's Associate Director for Strategic Initiatives. She oversees areas of strategic interest to external stakeholders. She leads the Patient-Focused Drug Development (PFDD) initiative, which includes work related to the FDA Reauthorization Act (FDARA) and implementation of the 21st Century Cures Act. She also leads CDER's International Program. Dr. Mullin previously served as director of CDER's Office of Strategic Program (OSP) for almost a decade. Under her leadership, the office became a critical part of CDER's sustained effort to modernize drug regulatory operations. Before joining CDER in 2007, Dr. Mullin was Assistant Commissioner for Planning in FDA's Office of the Commissioner. Dr. Mullin received her bachelor's degree., magna cum laude, in economics from Boston College, and she has a Ph.D. in public policy analysis from Carnegie-Mellon University. Dr. Mullin received the Senior Executive Service Presidential Rank Award for Meritorious in 2006 and for Distinguished Service in 2011.

Jordan Paradise, JD

Georgia Reithal Professor of Law, Loyola University Chicago School of Law

Jordan Paradise researches and publishes on the intersection of law, science, and technology. Her primary focus is in the life science realm, examining legal and policy issues in the development and regulation of pharmaceuticals, medical devices and innovations in medicine. Recent interests span nanotechnology, synthetic biology, precision medicine, gene editing, and electronic cigarettes. Her publications have appeared in both peer-reviewed and legal publications.

Previously, Professor Paradise served as the Schering-Plough Professor of Law at Seton Hall University School of Law in New Jersey where she was a faculty member of both the Center for Health & Pharmaceutical Law & Policy and the Gibbons Institute for Law, Science & Technology. From 2005-2009, she was the Associate Director of Research & Education for the Joint Degree Program in Law, Health & the Life Sciences and the Consortium on Law and Values in Health, Environment & the Life Sciences at the University of Minnesota Law School. She was also an adjunct associate professor of law, a research associate in the Center for Bioethics, and the faculty editor-in-chief of the *Minnesota Journal of Law, Science & Technology* during her time at the University of Minnesota.

Marc M. Boutin, JD

Chief Executive Officer, National Health Council

Marc Boutin is the chief executive officer of the National Health Council, the only organization that brings together all segments of the health community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 diverse national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient advocacy organizations, which control its governance and policy-making process. Other members include professional and membership associations, nonprofit organizations with an interest in health, and representatives from the pharmaceutical, generic drug, health insurance, device, biotechnology, and communication industries. Boutin has been a leading voice for greater patient involvement at every stage of the continuum, starting with the development of new drugs, to regulatory oversight of health care delivery, to shared decision-making at the point of care. Under his leadership, the NHC has convened a broad range of stakeholders to create and effectively implement pragmatic strategies and public policy that address diverse issues, such as enhancing patient engagement, advancing the development of new treatments, and developing a better health delivery system to meet the needs of people with chronic conditions.

Boutin has a long history of Board and Committee service. Currently he serves as a member of the AdaptSmart International Advisory Board, NEST Governing Committee and Subcommittee Charter, Patient-Centered Research Foundation, Patient Focused Medicines Development (PFMD), MDIC Patient-Centered Benefit-Risk Steering Committee/Patient Engagement Steering Committee, PhRMA Stakeholder Advisory Committee. Boutin is a former civil rights litigator. He received his bachelor of economics degree in international politics/law from the University College of Wales, Aberystwyth, United Kingdom and his JD from Suffolk University Law School in Boston, Massachusetts.

Patricia Zettler, JD

Professor of Law, Georgia State University College of Law

Patricia J. Zettler, associate professor of law, has expertise in the regulation of medicine, medical products, and tobacco products, with an emphasis on the U.S. Food and Drug Administration (FDA). She is a faculty member of the Center for Law, Health & Society, and teaches Torts, Health Law: Quality & Access, and Food and Drug Law.
Zettler's scholarship has appeared or is forthcoming in various legal and medical journals, such as the Indiana Law Journal, Ohio State Law Journal, BostonCollege Law Review, Food and Drug Law Journal, Yale Journal of Health Policy Law and Ethics,Journal of Law and the Biosciences, JAMA Internal Medicine, EMBO Molecular Medicine, American Journal of Bioethics Neuroscience, and Public Health Reports. She also regularly writes about FDA-related issues at Objective Intent, the FDA law and policy blog that she co-founded, as well as at the Yale Journal on Regulation's blog, Notice & Comment, and Stanford's Law and the Biosciences Blog.

Zettler's work has earned her recognition, including being selected as a 2015 Health Law Scholar by the American Society of Law, Medicine & Ethics and as the 2018 winner of the Patricia T. Morgan

Award for Outstanding Scholarship among the College of Law faculty. She also advises various groups and organizations on FDA law and policy. Among other things, she served as a consultant to the National Academies of Sciences, Engineering, and Medicine's Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse from 2016 to 2017, and has served on the editorial advisory board for the Food and Drug Law Journal since 2015.

Before joining Georgia State Law in 2015, she was a fellow at the Center for Law and the Biosciences at Stanford Law School. Prior to her fellowship, she served as an associate chief counsel in the FDA's Office of Chief Counsel. In that role, she advised the FDA and the Department of Health and Human Services on various issues including drug safety, human subjects protection, expanded access to investigational drugs, over-the-counter drugs, dietary supplements, prescription drug advertising and promotion, incentives for developing antibiotics and advisory committees. In addition to her legal background, Zettler has bioethics experience through work at the Program in Medical Ethics at the University of California San Francisco and at the Department of Bioethics at the National Institutes of Health.

Zettler graduated with distinction from Stanford Law School in 2009. She received a B.A. in psychology, with distinction and departmental honors, from Stanford University in 2002, where she played on the varsity lacrosse team.

Geoffrey Levitt, JD

Senior Vice President and Associate General Counsel for Regulatory, Environmental and Global Supply, Pfizer, Inc.

Mr. Levitt is Senior Vice President and Associate General Counsel for Regulatory, Environmental and Global Supply at Pfizer, where he is responsible for managing global legal support for regulatory, medical, safety, clinical research, manufacturing and environmental operations. Mr. Levitt has published and lectured extensively on regulatory law. He is a past member of the editorial board of the Food and Drug Law Journal and a current member of the editorial board of the FDA Advertising and Promotion Manual. Mr. Levitt is past Chairman of the Board of the Food and Drug Law Institute and received the Institute's 2009 Distinguished Service and Leadership Award. He has also served as Chair of the PhRMA Law Section Executive Committee and is a current member of the Board of the Friedreich's Ataxia Research Alliance. He earned his J.D. from Harvard Law School and his B.A. from Columbia University.

CONCURRENT PANEL 2C
OTHER FDA PRODUCT AREAS: TOBACCO AND COSMETICS

Linda Katz, MD, MPH

Director, Office of Cosmetics and Colors Acting Chief Medical Officer, Center for Food Safety and Applied Nutrition, FDA

Dr. Linda Katz has held a variety of positions at the FDA. Since 2002 she has been the Director for the Office of Cosmetics and Colors (OCAC). In this position, she establishes the priorities and missions of OCAC, focusing on cosmetic safety, compliance, policy and legislative issues, as well as certification of color additives, and broad reaching cosmetic and colors research, in the areas of nanotechnology, photoxicity and percutaneous absorption, tattoo-related safety issues among others. From September 2012 through March 2013 Dr. Katz was the Acting Deputy Director for Operations at in FDA's Center for Food Safety and Applied Nutrition (CFSAN). She also has served as Chief Medical Officer CFSAN since 2007 where she is responsible for addressing safety and medical concerns for CFSAN regulated products. She has had numerous presentations and publications, including those related specifically to cosmetic and food issues.

Prior to assuming leadership of OCAC, she began her FDA career in the Center for Drug Evaluation and Research (CDER), holding position as Deputy Director in the Division of Over-the-Counter Drug Products, Deputy Director in the Division of Dermatologic and Dental Drug Products, and Team Leader and Acting Director in the Pilot Drug Evaluation Staff (division responsible for anti-rheumatic drugs, anesthetic drugs and drugs of abuse).

Dr. Katz received her B.A. magna cum laude in biology from the University of Pennsylvania, her M.D. from the University of Connecticut, and a M.P.H. in epidemiology from the University of Michigan School of Public Health. She completed her internship and residency in Internal Medicine, and fellowship in Rheumatology, at the George Washington University Medical Center, in Washington, D.C. She is a Fellow in the American College of Physicians and a Fellow Member of the American College of Rheumatology and was board certified in Internal Medicine in 1985and in Rheumatology in 1994. In addition, Dr. Katz maintains an academic appointment, as Associate Clinical Professor of Medicine, at The Uniformed Services University of the Health Sciences. Dr. Katz taught and treated patients at Walter Reed Military Medical Center for 25 years.

Marie Boyd, JD

Professor of Law, University of South Carolina School of Law

Professor Boyd's research focuses on the regulation of products within the Food and Drug Administration's jurisdiction. Her current research explores the relationship between law and culture in the context of the regulation of insects as human food and the regulation of cosmetics. Her scholarship has been published in the *Yale Law and Policy Review*, the *Cardozo Law Review*, and the *Pace Law Revie*w. She teaches Food and Drug Law, Food Law and Policy, Administrative Law, and Tort Law. Professor Boyd previously served as a Visiting Assistant Professor at the University of South Carolina School of Law. Prior to joining the University of South Carolina School of Law, Professor Boyd practiced law with Covington & Burling LLP in Washington, DC. At Covington, she advised companies on the federal and state regulation of drugs, biologics, medical devices, foods, and dietary supplements. She also advised and represented low-income DC residents in a variety of civil contexts ranging from family matters to landlord-tenant disputes through the Neighborhood Legal Services Program. Professor Boyd earned an A.B. in Chemistry from Harvard University and a J.D. from Yale Law School.

Alexandra Gerber, JD

Vice President, Assistant General Counsel, Revlon, Inc.

Alexandra (Alex) Gerber is vice president, assistant general counsel for Revlon, one of the top 20 beauty companies in the world, with product offerings in color cosmetics, skincare, hair care and fragrances under brands such as Revlon, Elizabeth Arden, Colorsilk, American Crew, Almay and Mitchum, to name a few. In her role as chief legal advisor to the Revlon marketing and regulatory teams, Ms. Gerber advises on a wide variety of issues that include marketing, advertising, talent, product and claims development, technology, quality, safety and all product-related regulatory matters. Alexandra started her career in Chicago with the intellectual property firm Laff, Whitesel, Conte & Saret. She then joined the firm Darby & Darby in Manhattan as a litigator specializing in trademarks, copyright and unfair competition. Prior to joining Revlon, Alex was part of the Colgate-Palmolive Company legal department, serving in various legal roles advising on marketing, advertising and intellectual property matters.

Micah Berman, JD

Associate Professor, Ohio State University, Moritz College of Law and College of Public Health

Micah Berman is an associate professor of public health and law at The Ohio State University's College of Public Health and Michael E. Moritz College of Law. His research explores the intersection between public health research and legal doctrine, and he is a co-author of *The New Public Health Law: A Transdisciplinary Approach to Practice and Advocacy*. He is currently funded by the National Cancer Institute to conduct research that supports the FDA's regulation of tobacco, and by the Ohio Department of Medicaid to evaluate the impact of Ohio's Medicaid expansion. Prior to joining Ohio State, Berman established and directed the Public Health and Tobacco Policy Center, which is now affiliated with Northeastern University School of Law. Under his leadership, the Center developed innovative model ordinances and provided policy support to state and local public health programs. Previously, he taught at Capital University Law School and directed the Ohio Tobacco Public Policy Center.

Professor Berman has also served as a senior advisor to the FDA's Center for Tobacco Products and as a member of the NIH's Council of Public Representatives. Before discovering his passion for public health, Berman was a trial attorney with the U.S. Department of Justice's Antitrust Division and an associate with the law firm Stinson Morrison Hecker LLP (now Stinson Leonard Street LLP). He received a JD with distinction from Stanford Law School and a BA with highest honors in Public Policy from Brandeis University.

Azim Chowdhury, JD, MBA

Partner, Keller and Heckman LLP

Azim Chowdhury is a regulatory and public policy attorney with a focus on vapor, nicotine and tobacco product regulation. He is a Partner in Keller and Heckman's nationally-ranked food and drug law practice.

Mr. Chowdhury advises domestic and foreign corporations in matters of Food and Drug Administration (FDA) and international regulatory compliance. In particular, he has developed expertise in tobacco and vapor product regulation relating to the implementation of the Family Smoking Prevention and Tobacco Control Act, and spearheaded the Tobacco and E-Vapor practice at Keller and Heckman. Specifically, Mr. Chowdhury has experience representing tobacco, e-cigarette and e-liquid manufacturers, distributors, retailers, suppliers and trade associations in matters of FDA, state and global regulatory compliance. He also assists corporations in establishing clearances for food and drug additives in the U.S., Canada, and European Union, with an emphasis on indirect additives used in food-contact materials.

Mr. Chowdhury is also a frequent contributor to the Food and Drug Law Institute's (FDLI) *Update* Magazine, has served on the Editorial Advisory Board of the *Food and Drug Law Journal*, and has authored and edited numerous articles and publications, including *Tobacco Regulation and Compliance: An Essential Resource, FDA Regulation of Tobacco: A Comprehensive Guide – An FDLI Primer* and *Tobacco and Nicotine Delivery: Regulation and Compliance, 2nd Edition*. He frequently speaks at industry conferences and events, was featured in *U.S. News and World Reports Best Lawyers*

Edition(2016) and was named one of "10 Names to Know in the Vape World" in the October 2015 issue of *Vape Magazine*.

Mr. Chowdhury also has an active pro bono practice through Keller and Heckman's Pro Bono Program, and has been featured in the *Baltimore Sun* for successfully obtaining asylum in the United States for a family who fled their home country of El Salvador because of violence they faced from an international gang.

Prior to entering private practice, he served as a judicial law clerk on the Court of Special Appeals of Maryland. Mr. Chowdhury received a B.A. and B.S. from Johns Hopkins University, a MBA from the University of Maryland Robert H. Smith School of Business, and a JD, *cum laude*, from the University of Maryland School of Law.

CONCURRENT PANEL 3A
MEDICAL DEVICES

Bakul Patel, MSEE, MBA

Associate Center Director for Digital Health
Office of the Center Director, Center for Devices and Radiological Health, FDA

Bakul Patel is Associate Director for Digital Health, at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel leads regulatory policy and scientific efforts at the Center in areas related to emerging and converging areas of medical devices, wireless and information technology. This includes responsibilities for mobile health, health information technology, cyber security, medical device interoperability, and medical device software.

Mr. Patel is the FDA liaison between the Federal Communications Commission (FCC) and the Office of the National Coordinator (ONC). Since its inception in 2013, Bakul chairs the International Medical Device Regulators Forum (IMDRF) "software as a medical device" working group, a global harmonization effort.

Before joining FDA, Mr. Patel held key leadership positions working in the telecommunications industry, semiconductor capital equipment industry, wireless industry and information technology industry. His experience includes Lean Six Sigma, creating long and short-term strategy, influencing organizational change, modernizing government systems, and delivering high technology products and services in fast-paced, technology-intensive organizations.

Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.

W. Nicholson Price, JD, PhD

Assistant Professor of Law, University of Michigan Law School

Nicholson Price is an assistant professor of law. He teaches and writes in the areas of intellectual property, health law, and regulation, particularly focusing on the law surrounding innovation in the life sciences. He previously was an assistant professor of law at the University of New Hampshire School of Law, an academic fellow at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, and a visiting scholar at the University of California, Hastings College of the Law. Previously, he clerked for the Hon. Carlos T. Bea of the U.S. Court of Appeals for the Ninth Circuit. He received a JD and a PhD in biological sciences from Columbia University and an AB in biological sciences from Harvard College.

Jeffrey N. Gibbs, JD

Director, Hyman, Phelps & McNamara, P.C. and Chair, FDLI Board of Directors

Jeffrey N. Gibbs is a Director in the Washington, D.C. law firm of Hyman, Phelps & McNamara, P.C. Before entering private practice, he was an Associate Chief Counsel for Enforcement at the Food and Drug Administration. Jeff also served as a Special Assistant United States Attorney in the District of Columbia in the Civil Division. He is currently Chairman of FDLI's Board of Directors and was previously FDLI's General Counsel.

Jeff has assisted in vitro diagnostic and medical device companies with a variety of regulatory issues, including FDA product approval, pre-submissions, regulatory strategy, product labeling, clinical studies, promotional and marketing programs, product appeals and enforcement actions. He received FDLI's Distinguished Service and Leadership Award in 2013, and LMG Life Science's Star Award in 2016. Jeff previously served on the Human Subjects Review Board of George Mason University, and has written and spoken extensively on a wide variety of FDA regulatory topics, and has taught medical device law at the University of Maryland and George Washington University.

Jeff graduated from Princeton University and New York University School of Law.

Nathan Cortez, JD

Associate Dean for Research, Gerald J. Ford Research Fellow, Adelfa Botello Callejo Endowed Professor of Law in Leadership and Latino Studies, Southern Methodist University Dedman School of Law

Professor Cortez teaches and writes in the areas of health law, administrative law, and food and drug law. His research focuses on emerging markets in health care and biotechnology, including mobile health, digital health, big data, machine learning, and artificial intelligence. His scholarship explores government information policy, how to regulate innovation under aging regulatory frameworks, the First Amendment constraints on FDA regulation, and alternative modes of regulation.

Professor Cortez frequently presents his research around the world to professional societies, industry, and regulators. He has given academic talks at Colorado, Harvard, North Carolina, the University of Paris, Radboud University (Netherlands), Stanford, Texas, Wisconsin, and Yale. He also provides frequent commentary to the media, including the Chicago Tribune, CNN, the Los Angeles Times, the New York Times, NPR, the Washington Post, and WIRED.

Professor Cortez is also a frequent peer reviewer and referee for leading law reviews and medical journals, including Health Affairs, The Lancet, The New England Journal of Medicine, and the Yale Law Journal. He recently served as a consultant for the Administrative Conference of the United States (ACUS), advising agencies such as the FDA, FTC, and CFPB on government data policy. He is a member of the SMU Center for Global Health Impact, advises health care technology start-ups for the business accelerator Health Wildcatters, and works with the Surgical Safety Network.

Before joining the SMU faculty, Professor Cortez practiced with the Washington D.C. law firm Arnold & Porter, as part of its pharmaceutical, health care, and biotechnology practice. He represented clients in health care regulatory matters, with a special emphasis on health care fraud and abuse, FDA enforcement, privacy, and the Medicare and Medicaid programs. He received his B.A from the University of Pennsylvania and his J.D. from Stanford.

Wade Ackerman, JD

Partner and Co-Lead of Covington's Digital Health Initiative, Covington & Burling LLP

Wade Ackerman is a partner in Covington's FDA Regulatory group and serves as one of the leaders of the Firm's cross-practice Digital Health Initiative. Wade provides clients with strategic FDA regulatory and policy advice. Until 2016, he served as Senior FDA Counsel to the Senate Health Education, Labor & Pensions (HELP) Committee where he handled all FD&C Act legislation and other FDA issues. While in that role, he negotiated the recent 21st Century Cures Act, including changes to FDA's authorities over digital health software. Prior to the Senate, Wade worked in FDA's Office of Chief Counsel (OCC) for over five years. Wade currently serves on the Board of Directors of the California Life Sciences Association (CLSA) and is a member of the Board of Trustees of the Keck Graduate Institute, one of the Claremont Colleges. He also serves on the Legal Council of the Williams Institute, a think tank at UCLA Law dedicated to research on sexual orientation and gender identity law and public policy. Wade is a graduate of Harvard Law School and earned a Bachelor's degree in Biology from the University of Illinois at Urbana-Champaign.

CONCURRENT PANEL 3B
BIOLOGICAL PRODUCTS

Peter Marks, MD, PhD

Director, Center for Biologics Evaluation and Research, FDA

Peter Marks received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women's Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in January 2016.

Yaniv Heled, JSD, LLM, LLB

Associate Professor of Law, Co-Director, Center for Intellectual Property Law, Georgia State University College of Law

Yaniv Heled's research focuses on legal and ethical aspects of biomedical technologies. He has written on such topics as the regulation of biologics and biosimilars, stem cells, human reproductive tissue, DNA sequencing and testing, and more. Notable recent scholarship includes his article, "Follow-On Biologics Are Set Up to Fail," which explains why there is not going to be meaningful competition in biologics under current market and regulatory conditions. In another article, "Why Healthcare Companies Should (Be)come Benefit Corporations," Heled and co-authors, Liza Vertinsky and Cass Brewer, make the case for requiring companies involved in the provision of healthcare products and services to incorporate (or re-incorporate) as benefit corporations, a relatively new type of business entity which is required to consider not only corporate profits but also public health.

Heled is on the faculty of Georgia State University's Center for Law, Health & Society and is the Co-Director of the Georgia State University Center for Intellectual Property Law. He teaches the courses: Patent Law, Family Law, Law & Biotechnology, Policy & Ethics, and Different & Unusual Forms of Intellectual Property.

Prior to joining Georgia State Law, Heled practiced intellectual property law with Goodwin Procter LLP in New York.

Heled earned a J.S.D. from Columbia University School of Law. His doctoral dissertation focused on the regulation of novel biomedical technologies. In addition, Heled holds an LL.M. from Columbia, where he was a Harlan Fiske Stone Scholar, and an LL.B. and undergraduate Diploma in Biology, magna cum laude, from Tel Aviv University.

Michael Werner, JD

Partner, Co-Leader, Healthcare & Life Sciences Team, Holland & Knight LLP

Michael Werner is a Washington, D.C., public policy and regulatory attorney and a co-leader of Holland & Knight's Healthcare & Life Sciences Team. Mr. Werner has almost three decades of healthcare law, lobbying, regulatory and reimbursement experience in Washington. He focuses on issues affecting FDA-regulated entities, including biotechnology and pharmaceutical companies developing and manufacturing prescription and over-the-counter (OTC) drugs, biosimilars, cosmetics, dietary supplements and digital-health technologies. His specific areas of knowledge include FDA regulations regarding product approval, marketing and distribution; Medicare, Medicaid and commercial insurance reimbursement; regulation and reimbursement of cell therapy, gene therapy, tissue engineering and regenerative medicine products; the Physician Sunshine Act; human subject protection issues such as institutional review board (IRB) review and informed consent; as well as conflicts of interest and other bioethics issues arising from research and uses of new technologies.

Mr. Werner is the co-founder and senior policy counsel of the Alliance for Regenerative Medicine, the leading global organization representing the cell therapy, gene therapy, tissue engineering and regenerative medicine sector. The Alliance's mission is to advocate for federal funding, regulatory and reimbursement policies to advance the field.

Before joining Holland & Knight, Mr. Werner was president of The Werner Group, a Washington-based firm that provided lobbying, regulatory and bioethics consulting services for biotechnology and pharmaceutical companies, physicians, health plans, investors, and patient advocacy groups. Prior to founding The Werner Group, he was chief of policy for the Biotechnology Innovation Organization (BIO), representing more than 1,000 biotechnology companies in the U.S. and other countries. In that role, Mr. Werner was responsible for nearly all major issues affecting biotech companies, including drug evaluation and review by the FDA, CMS policies and reimbursement, Medicare, intellectual property, stem cell research and other bioethics issues.

Mr. Werner is a heavily sought-after speaker for meetings and conferences, and the author of more than 60 published articles. He is a frequent media commentator and has appeared in The New York Times, The Wall Street Journal, Science, Scientific American, The Washington Post, BIOWorld, Congressional Quarterly and The Baltimore Sun, as well as on many TV and radio news programs. He co-authored "Life Sciences Compliance: A Pre-Market and Post-Market Roadmap," published by Bloomberg BNA in 2014.

Myrisha Lewis, JD

Assistant Professor of Law, Howard University School of Law

Myrisha Lewis is an Assistant Professor of Law at the Howard University School of Law. Professor Lewis earned a law degree from Columbia Law School and an A.B. in Government from Harvard College. During law school, she was a case law editor of the Columbia Journal of European Law. Professor Lewis primarily teaches health law and health law-related courses. Prior to joining the Howard faculty, she was a Visiting Assistant Professor at the IIT Chicago-Kent College of Law. Before joining the Chicago-Kent faculty in 2015, she spent approximately four years as an attorney at the U.S. Nuclear Regulatory Commission in Rockville, Maryland. There, she filed pleadings on behalf of agency staff, advised legal and technical staff on federal rulemakings and statutes, and reviewed staff analyses of new nuclear power reactor licenses and designs. While employed by the U.S. Nuclear Regulatory Commission, Professor Lewis also completed a seven-month detail as a Special Assistant U.S. Attorney for the District of Columbia, where she prosecuted domestic violence cases. Professor Lewis' research considers how health law, family law, and criminal law respond to scientific innovations. Her research and teaching interests include health law, family law, administrative law, and bioethics. Her work has been published in the Cardozo Law Review, Wisconsin Journal of Law, Gender and Society, Charleston Law Review, Nevada Law Journal, and William and Mary Journal of Women and the Law. A forthcoming article will be published by the Utah Law Review.

Professor Lewis is a member of the New York Bar and speaks French and Spanish.

Chad Landmon, JD

Partner, Chair, Intellectual Property and FDA Practice Groups, Axinn, Veltrop & Harkrider LLP

Chad Landmon is a partner at Axinn, Veltrop & Harkrider LLP, where he chairs the FDA and IP Practice Groups. Chad has nearly 20 years of experience in food and drug law and patent litigation and counseling, with an emphasis on pharmaceuticals, biologics and human tissue products. His FDA matters involve client counseling and petitioning FDA and litigating issues relating to the Biologics Price Competition and Innovation Act (BPCIA), including the requirements for the demonstration of biosimilarity and the patent resolution provisions, and the Hatch-Waxman Act, including marketing exclusivities, patent listing, certification and notification requirements, bioequivalence, labeling and other issues. Chad is regularly engaged by clients to litigate cases involving FDA issues, including serving as lead counsel in a case that has been described as the first time a court has ever ordered FDA to approve an Abbreviated New Drug Application. His patent litigation practice is national in scope and concentrates on the life sciences industry. By coupling his patent litigation experience with his FDA expertise, Chad enables clients to develop and execute on patent and FDA strategies to bring products to market in the most efficient and profitable manner. He has litigated a wide variety of FDA and Paragraph IV cases in numerous jurisdictions, including cases involving blockbuster drugs. With a practice that also includes matters involving the intersection of the antitrust and patent laws, such as issues arising from the settlement of patent and marketing exclusivity

disputes, Chad frequently speaks and writes about issues relating to the BPCIA, the Hatch-Waxman Act and litigation in the life sciences industry.

CONCURRENT PANEL 3C
BEYOND TRADITIONAL DRUG REGULATION

Henry T. Greely, JD

Director, Center for Law and the Biosciences; Professor (by courtesy) of Genetics, Stanford School of Medicine; Chair, Steering Committee of the Center for Biomedical Ethics; and Director, Stanford Program in Neuroscience and Society.

Henry T. Greely (BA '74) specializes in the ethical, legal, and social implications of new biomedical technologies, particularly those related to neuroscience, genetics, or stem cell research. He frequently serves as an advisor on California, national, and international policy issues. He is chair of California's Human Stem Cell Research Advisory Committee, a member of the Advisory Council of the NIH's National Institute for General Medical Sciences, a member of the Committee on Science, Technology, and Law of the National Academies, a member of the Neuroscience Forum of the Institute of Medicine, and served from 2007-2010 as co-director of the Law and Neuroscience Project, funded by the MacArthur Foundation. Professor Greely chairs the steering committee for the Stanford Center for Biomedical Ethics and directs both the law school's Center for Law and the Biosciences and the Stanford Program in Neuroscience and Society. In 2007 Professor Greely was elected a fellow of the American Association for the Advancement of Science. Before joining the Stanford Law School faculty in 1985, Greely was a partner at Tuttle & Taylor, served as a staff assistant to the secretary of the U.S. Department of Energy, and as special assistant to the general counsel of the U.S. Department of Defense. He served as a law clerk to Justice Potter Stewart of the U.S. Supreme Court and to Judge John Minor Wisdom of the Court of Appeals for the Fifth Circuit. Greely is also a professor (by courtesy) of genetics at Stanford School of Medicine. He received the University's Richard W. Lyman Prize in 2013.

Rebecca Eisenberg, JD

Robert and Barbara Luciano Professor of Law, University of Michigan Law School

Rebecca S. Eisenberg, the Robert and Barbara Luciano Professor of Law, specializes in patent law and the regulation of biopharmaceutical innovation. She teaches courses about patent law, trademark law, international intellectual property law, and FDA law, and runs workshops about intellectual property and student scholarship. She has written and lectured extensively about the role of intellectual property in biopharmaceutical research, publishing in leading law reviews and scientific journals. She spent the 1999–2000 academic year as a visiting professor of law, science, and technology at Stanford Law School and the spring of 2012 as a visiting scholar at the Berkeley Center for Law & Technology. Professor Eisenberg has played an active role in public policy debates concerning the role of intellectual property in biopharmaceutical research, advising the National Institutes of Health and the National Academies of Science. She is a graduate of Stanford University and Boalt Hall School of Law at the University of California, Berkeley, where she was articles editor of the *California Law Review*. Following law school

she served as law clerk for the Hon. Robert F. Peckham of the U.S. District Court for the Northern District of California and then practiced law as a litigator in San Francisco. She joined the Michigan Law faculty in 1984.

D. Kyle Sampson, JD

Partner, King & Spalding LLP

Kyle Sampson focuses on Food and Drug Administration regulatory, compliance and enforcement issues. As a partner in our FDA and Life Sciences practice, Kyle represents companies in the full range of regulatory and enforcement issues.

Kyle advises food, drug, biologics, medical device, cosmetics and dietary supplement companies on FDA compliance, regulatory and enforcement matters. His practice also includes strategic advice and compliance counseling, enforcement, litigation and transactional matters.

Kyle has engaged in extensive public service in every branch of the federal government. He served in the White House as Associate Counsel to the President; at the Department of Justice as a Special Assistant U.S. Attorney and as Counselor and Chief of Staff to two attorneys general; and in the U.S. Senate as Counsel to the Senate Judiciary Committee.

Craig Konnoth, JD, MPhil

Associate Professor of Law, University of Colorado School of Law

Professor Konnoth's work lies at the intersection of health law and policy, bioethics, civil rights, and technology. His papers consider how health privacy burdens are created and distributed, how medical discourse is used both to enable and harm civil rights and autonomy, and how technology can be used to improve health outcomes. He has examined these issues in in contexts as diverse as religion and biblical counseling, consumer rights and transparency, FDA regulation, and collection of individual data. His publications have appeared in the Yale Law Journal, the Hastings Law Journal, the Penn Law Review, the Iowa Law Review, the online companions to the Penn Law Review & the Washington & Lee Law Review, and as chapters in edited volumes. Before arriving at the University of Colorado, Craig was a Sharswood and Rudin Fellow at Penn Law School and NYU Medical School, where he taught health information law, health law, and LGBT health law and bioethics. Before that he was the Deputy Solicitor General and the Inaugural Earl Warren Fellow at the California Department of Justice where he litigated primarily before the United States Supreme Court, and also before the California Supreme Court and the Ninth Circuit Court of Appeals. Cases involved the contraceptive mandate in the Affordable Care Act, Sexual Orientation Change Efforts, Facebook privacy policies, and cellphone searches. Before moving into government, Craig was the R. Scott Hitt Fellow in Law & Policy at the Williams Institute at UCLA Law School, where he focused on issues affecting same-sex partners, long term care, and Medicaid coverage issues, and drafted HIV rights legislation. He holds a J.D. from Yale, and an M.Phil. from the University of Cambridge. He clerked for Judge Margaret McKeown of the Ninth Circuit Court of Appeals.

Peter Pitts

President, Center for Medicine in the Public Interest; Visiting Professor, Université Paris Descartes Medical School; Visiting Lecturer, École Supérieure des Sciences Économiques et Commerciales; Former Associate Commissioner, US Food and Drug Administration

Peter Pitts is President of the Center for Medicine in the Public Interest. A former member of the United States Senior Executive Service, Peter was FDA's Associate Commissioner for External Relations, serving as senior communications and policy adviser to the Commissioner. He supervised FDA's Office of Public Affairs, Office of the Ombudsman, Office of Special Health Issues, Office of Executive Secretariat, and Advisory Committee Oversight and Management. He served on the agency's obesity working group and counterfeit drug taskforce and as a Special Government Employee (SGE) consultant to the FDA's Risk Communications Advisory Committee.

Specific areas of global policy expertise include FDA policy and process, healthcare technology assessment and reimbursement issues, real world evidence, social media, off label-communications, pharmacovigilance, patient-focused drug development, abuse-deterrent opioids, biosimilar development, Rx-to-OTC switching, risk management plans, GMP policies, pharmacy education programs, drug safety, Critical Path, personalized medicine, clinical trial transparency, IP protection, FDA reform, drug importation, counterfeiting, genetically modified food issues, food safety and security, recalls, nutritional labeling.

His comments and commentaries on health care policy issues regularly appear in *The New York Times, The Los Angeles Times*, *The Washington Post, The Wall Street Journal*, *The Financial Times*, *Health Affairs*, *Time*, *Newsweek*, *The Boston Globe*, *The Washington Times*, *The Chicago Tribune*, *The San Francisco Examiner*, *Investor's Business Daily*, *The Baltimore Sun*, *The Economist*, *The Lancet*, *Nature Biotechnology*, *The Journal of Life Sciences the BBC World Service*, *Fox News*, *CNBC*, *Bloomberg*, *The PBS NewsHour*, *NBC Dateline*, *The Daily Show with John Stewart*, among others.

He has given healthcare policy presentations throughout Europe, Canada, and the United States, as well as in Russia, China, Hong Kong, Taiwan, India, the Philippines, Malaysia, Saudi Arabia, Lebanon, Oman, Israel, Turkey, The United Arab Emirates, Kuwait, Qatar, Jordan, Kenya, South Africa, Egypt, Algeria, Ukraine, Thailand, Japan, Brazil, Mexico, Vietnam, Indonesia, Singapore, Panama, Costa Rica, Argentina, and Columbia.

He is a Visiting Professor at the Université Paris Descartes Medical School, a Visiting Lecturer at the École Supérieure des Sciences Économiques et Commerciales (Paris and Singapore), and has served as an adjunct professor at Indiana University's School of Public and Environmental Affairs and Butler University.

His book, *Become Strategic or Die*, is widely recognized as a cutting edge study of how leadership, in order to be successful over the long term, must be combined with strategic vision and ethical practice. He is the editor of Coincidence or Crisis, a discussion of global prescription medicine counterfeiting and Physician Disempowerment: A Transatlantic Malaise.

CLOSING REMARKS

Mitch Zeller, JD (AUWCL '82)

Director, Center for Tobacco Products, FDA

As director of the Center for Tobacco Products, Mitch Zeller leads FDA's efforts to reduce disease and death from tobacco use and bring previously unavailable information about its dangers to light. Zeller is dedicated to carrying out CTP's charge to reduce the harm from all tobacco products across the entire population—with a focus on how and why people start, stop, or start using these products again.

Mitch Zeller, J.D., became director of the FDA's Center for Tobacco Products in March 2013. The mission of CTP—established by enactment of the 2009 Family Smoking Prevention and Tobacco Control Act—is "to make tobacco-related death and disease part of America's past, not America's future, and, by doing so, ensure a healthier life for every American family."

"Today, FDA has an unprecedented opportunity to use the tools in the Tobacco Control Act," Zeller said. "Product regulation is a powerful component of a comprehensive strategy to reduce the death and disease from tobacco use. We will marshal the science to support new policies to help combat the leading cause of preventable disease and death in the United States," he added. Zeller, a graduate of Dartmouth College and the American University Washington College of Law, has been working on FDA issues for more than 30 years. He began his career as a public interest attorney in 1982 at the Center for Science in the Public Interest (CSPI). In 1988, Zeller left CSPI to become counsel to the Human Resources and Intergovernmental Relations Subcommittee of the House of Representatives Government Operations Committee where he conducted oversight of enforcement of federal health and safety laws.

In 1993, Zeller joined the staff of then-FDA Commissioner Dr. David Kessler, M.D. What began as a two-week assignment by Kessler in 1994 to examine the practices of the tobacco industry led to his serving as associate commissioner and director of FDA's first Office of Tobacco Programs. Instrumental in crafting the agency's 1996 tobacco regulations, Zeller also represented FDA before Congress, federal and state agencies. Zeller also served as an official U.S. delegate to the World Health Organization (WHO) Working Group for the Framework Convention on Tobacco Control. In 2000, Zeller left FDA to continue his work for tobacco control as executive vice president of the American Legacy Foundation. His responsibilities there included marketing, communications, strategic partnerships, and creating the foundation's first Office of Policy and Government Relations.

In 2002, Zeller joined Pinney Associates where, as senior vice president, he provided strategic planning and communications advice on domestic and global public health policy issues involving the treatment of tobacco dependence and the regulation of tobacco products and pharmaceuticals. He returned to FDA in 2013 after his time at Pinney Associates.