Gregory Daniel, PhD, MPH is a Clinical Professor in Duke's Fuqua School of Business and Deputy Director in the Duke-Robert J. Margolis Center for Health Policy at Duke University. Dr. Daniel directs the DC-based office of the Center and leads the Center's pharmaceutical and medical device policy portfolio which includes developing policy and data strategies for improving development and access to innovative pharmaceutical and medical device technologies. This includes post-market evidence development to support increased value, improving regulatory science and drug development tools, optimizing biomedical innovation, and supporting drug and device payment reform. Dr. Daniel is also a Senior Advisor to the Reagan-Udall Foundation for the FDA and Adjunct Associate Professor in the Division of Pharmaceutical Outcomes and Policy at the UNC Eshelman School of Pharmacy. Previously, he was Managing Director for Evidence Development & Biomedical Innovation in the Center for Health Policy and Fellow in Economic Studies at the Brookings Institution and Vice President, Government and Academic Research at HealthCore (subsidiary of Anthem, Inc). Dr. Daniel’s research expertise includes utilizing electronic health data in designing research in health outcomes and pharmacoepidemiology, comparative effectiveness, and drug safety and pharmacoepidemiology. Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes from the University of Arizona, as well as an MPH, MS, and BS in Pharmacy all from The Ohio State University.

Jennifer Dudinak, PharmD is Vice President Global Regulatory Affairs Oncology and Head, Pharma Regulatory Therapeutic Teams at GlaxoSmithKline. Her primary strategic focus is to lead global regulatory therapeutic teams across the R&D portfolio and Franchises to deliver innovative global regulatory strategies and drive development and implementation of policies and strategies for optimization of drug development. Dr. Dudinak has worked across all phases of drug development, including small molecules and biologics, for over 20 years. She has held multiple senior leadership roles in regulation across a variety of disease areas (e.g. oncology, virology, immuno-inflammation, ophthalmology) with an emphasis on precision medicine and development of novel approaches to advance regulatory pathways. Dr. Dudinak has overseen numerous global regulatory filings and approvals in her career, including NCEs, combination therapies and medicines with companion diagnostics. Dr. Dudinak received a Bachelor of Pharmacy and Doctorate of Pharmacy from Rutgers University. Jennifer joined GSK from Roche/Genentech where she served for over 15 years. Prior to that, she practiced in community, retail and hospital pharmacy as well as a founding member of Heart to Hearts, a non-profit women’s wellness organization with the aim to empower women through education.
Anne-Virginie Eggimann, MSc joined bluebird bio, Inc. to lead the Regulatory Science function in 2011. In her role as Vice President, she is responsible for global regulatory strategy and focuses on innovative pathways to accelerate the development of bluebird bio’s gene therapy products for the treatment of rare diseases and oncology indications. Prior to joining bluebird bio, Anne-Virginie was an Executive Director at Voisin Consulting, leading projects involving the design and implementation of regulatory strategies for medicinal products, with a particular focus on rare diseases and advanced therapies. Her experience spans from early development through commercialization, including lead roles on the registration of several orphan drugs, and regulatory expertise on both sides of the Atlantic. Anne-Virginie holds a Master of Science in Environmental Health Sciences from the UCLA School of Public Health, as well as a BS in Chemical Engineering from the California Institute of Technology.

Jarno Hoekman, PhD is an assistant professor based at the Innovation Studies Group of Utrecht University in The Netherlands. Jarno holds a PhD in Economics of Innovation and Technical Change from Eindhoven University of Technology. He also conducted postdoctoral research in the field of pharacoequipepidemiology at the University Medical Center Groningen and spent time at the Science Policy Research Unit (SPRU) at University of Sussex, United Kingdom. In his academic research, Dr. Hoekman examines the relationship between pharmaceutical regulation and innovation, particularly focusing on the emergence of new technologies (e.g. gene- and cell-based therapies) and enactment of new policies (e.g. expedited pathways). He also studies the global diffusion of standards in the pharmaceutical sector and their influence on the production of regulatory science and patient access to medicines. Dr. Hoekman’s research has been published in leading scientific journals in the field of pharmacology (e.g. Clinical Pharmacology & Therapeutics, Drug Discovery Today) and science, technology and innovation studies (e.g. Research Policy, Technological Forecasting and Social Change) as well as in national and European policy reports. Dr. Hoekman has received a personal VENI grant for excellent researchers from the Dutch Research Council for his work on pharmaceutical risk regulation and is involved in collaborative research projects conducted within the context of the Utrecht WHO Collaborating Centre for Pharmaceutical Policy & Regulation.
Kay Holcombe is currently Senior Vice President for Science Policy at BIO, the Biotechnology Innovation Organization. She works with the BIO CEO and Board, and BIO’s health policy, reimbursement, government affairs, and alliance development staff to formulate, develop, and advance BIO principles, programs, and strategies relating to science policy matters that are of interest to and affect BIO member companies. Kay served as the lead negotiator for BIO in the PDUFA and BsUFA negotiations with FDA. Prior to BIO, as Senior Policy Advisor and Vice President for Government Relations at Sanofi-Genzyme, Kay worked with government relations and regulatory affairs staff, and with principals of Genzyme and Sanofi, to develop and implement corporate policies and appropriate responses to government initiatives in the regulatory and health policy arenas. She worked with members of Congress and their staffs as well as with officials in the Food and Drug Administration and other agencies whose actions had impact on the corporation and the biopharmaceutical industry. Before joining Genzyme in 2006, Kay spent 8 years as Executive Vice President of Policy Directions Inc., a government relations firm specializing in strategic planning and legislative and regulatory advocacy regarding health care and related issues. She represented a variety of clients in the pharmaceutical and biotechnology, food, and consumer products industries, providing strategic advice and assistance and advocacy at federal regulatory and funding agencies and in the U.S. Congress. Kay was selected as a founding member of the board of the congressionally mandated Reagan-Udall Foundation and still serves in that capacity, and is a member of the board of the National Blood Clot Alliance. She received her BS in chemistry education from the University of Illinois and her M.S. in chemistry from the University of Virginia. She graduated with honors and was elected to Phi Beta Kappa, Phi Kappa Phi, and Iota Sigma Pi.

David Joy, JD joined FDA in 2008 as a regulatory counsel in CDER’s Office of Regulatory Policy. He currently serves as the Director of the Division of Regulatory Policy IV in that office. In 2014, he was detailed to FDA’s Europe Office as a senior policy analyst. Prior to joining FDA, Mr. Joy was a partner with Keller and Heckman LLP, an international law firm based in Washington, DC. His practice focused on food and drug regulatory matters with emphasis on food additives, food labeling and advertising, dietary supplements, health claims, food packaging materials, antimicrobials, food safety, and international trade. Mr. Joy spent a year assigned to Keller and Heckman’s Brussels office where he focused on the developing food and drug law of the European Union. He received a BS in chemistry from the University of Maryland and a JD from George Washington University.
Emil Kakkis, MD, PhD is currently President and Chief Executive Officer of Ultragenyx Pharmaceutical where he leads a team developing multiple rare and ultra-rare disease treatments. Over the last 22 years Dr. Kakkis is best known for his work developing novel treatments for rare diseases and working on policy issues affecting rare disease treatment development. He began his work developing an enzyme replacement therapy (Aldurazyme) for the rare disorder MPS I, with minimal funding and support. After joining BioMarin in 1998, Dr. Kakkis guided the development and approval of two more treatments for rare disorders, MPS VI and PKU, and has contributed to the development of multiple other rare disease therapeutics there. Dr. Kakkis went on to found Ultragenyx in 2010 to focus on developing as many rare and ultrarare disease therapeutics. The company went public in January 2014 (RARE; NASDAQ). Since its founding, Ultragenyx has grown to more than 300 employees developing treatments for six rare and ultrarare diseases. Dr. Kakkis is also Founder and President of the non-profit EveryLife Foundation for Rare Diseases, dedicated to the acceleration of biotech innovation for rare diseases through practical and scientifically sound improvements to development strategies and regulatory policy. Dr. Kakkis graduated from Pomona College, magna cum laude and received the Vaile prize for his biology research. He received combined M.D. and Ph.D. degrees from the UCLA Medical Scientist Program and received the Bogen prize for his research on graduation. He completed both a Pediatrics residency and Medical Genetics Training Fellowship at Harbor-UCLA Medical Center from 1989-1993 and from 1993 to 1998, was an assistant professor of Pediatrics at Harbor-UCLA Medical Center where he initiated the enzyme therapy program for MPS I. Dr. Kakkis is board certified in both Pediatrics and Medical Genetics.

Saima Khan, PhD is Vice President, Worldwide Regulatory Strategy for Pfizer Innovative Health – Neuroscience & Pain. Dr. Khan has over 25 years pharmaceutical industry experience with Smith Kline Beecham, Elan Pharma and Pfizer in research and regulatory strategy roles, and 5 years academic research experience at the Royal London and St Bartholomew’s School of Medicine, London, UK. Dr. Khan has held regulatory positions at global, regional and country-level, spanning early to late stage development in the areas of drug, biologics, devices, and combination products across various therapy areas including pain, neuroscience, cardiovascular, gastro-intestinal, genitourinary, and global consumer product switch strategies. Additionally, Dr. Khan has been a reviewer for the TOPRA regulatory affairs journal, and is a manuscript reviewer for the Journal of Clinical Pharmacology & Therapeutics. Dr. Khan received her PhD in neuroscience from the Royal London & St Bartholomew’s School of Medicine, London, sponsored by the Wellcome Foundation, and a BSc (Hons) degree in biochemistry from the University of London.
Mark McClellan, MD, PhD is the Robert J. Margolis Professor of Business, Medicine, and Policy, and Director of the Duke-Margolis Center for Health Policy at Duke University with offices at Duke and in Washington DC. The new Center will support and conduct research, evaluation, implementation, and educational activities to improve health policy and health, through collaboration across Duke University and Health System, and through partnerships between the public and private sectors. It integrates the social, clinical, and analytical sciences to integrate technical expertise and practical capabilities to develop and apply policy solutions that improve health and the value of health care locally, nationally, and worldwide. Dr. McClellan is a doctor and an economist, and his work has addressed a wide range of strategies and policy reforms to improve health care, including such areas as payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and more effective drug and device innovation. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership. He also has a highly distinguished record in public service and in academic research. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, Medicare and Medicaid payment reforms, the FDA’s Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA, is a member of the National Academy of Medicine and chairs the Academy’s Leadership Council for Value and Science-Driven Health care, co-chairs the guiding committee of the Health Care Payment Learning and Action Network, and is a research associate at the National Bureau of Economic Research. He has also previously served as a member of the President’s Council of Economic Advisers and senior director for health care policy at the White House, and as Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. He was previously an associate professor of economics and medicine with tenure at Stanford University, and has twice received the Kenneth Arrow Award for Outstanding Research in Health Economics.

Jay Siegel, MD is Chief Biotechnology Officer and Head of Scientific Strategy and Policy for Johnson & Johnson (J&J). Dr. Siegel is part of the R&D leadership and is actively engaged at the national and international levels in policy development with regard to scientific and regulatory issues, working with WHO, FDA, EMA, BIO, EFPIA, NASEM, and other organizations in the development and implementation of policy. He currently serves on the Executive Committees and the Boards of Directors of the Biotechnology Innovation Organization and the Alliance for Regenerative Medicine. Dr. Siegel joined Johnson & Johnson in 2003 as President of Centocor Research & Development, Inc., and subsequently served as J&J Group President of R&D for Biotechnology, Immunology and Oncology. The groups he led were responsible for the successful discovery and development of several pharmaceutical products including STELARA® (ustekinumab), SIMPONI® (golimumab), SYLVANT® (siltuximab), and most indications for REMICADE® (infliximab). Dr. Siegel later served as Head of Global Regulatory Affairs and head of the Biotechnology Center of Excellence (now Janssen BioTherapeutics) for Janssen, the pharmaceutical companies of Johnson & Johnson.
Mark Stewart, PhD is a senior science policy analyst at Friends of Cancer Research (Friends). Friends is an advocacy organization based in Washington, DC that drives collaboration among partners from every healthcare sector to power advances in science, policy, and regulation that speed life-saving treatments to patients. During the past 20 years, Friends has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible. Prior to joining Friends, Dr. Stewart worked at the National Academies of Sciences, Engineering, and Medicine. At the Academies, he assisted with a congressionally-mandated study that resulted in the report titled Ovarian Cancers: Evolving Paradigms in Research and Care. This report identified gaps in ovarian cancer knowledge and care, and provided recommendations to overcome these gaps. Dr. Stewart also helped workshops for the National Cancer Policy Forum. He has served on several committees, including the Associate Member Council of the American Association for Cancer Research (AACR) and the North Central Alabama Race for the Cure Committee. During his tenure on the Associate Member Council, Mark served as the 2015-2016 Chair and helped direct efforts to ensure the unique needs of early-career investigators were known and addressed through resources and programming at AACR. He continues to advocate for sustained biomedical research funding to maintain a predictable funding environment to allow for continued innovation and novel discoveries in cancer research. Dr. Stewart received his PhD in cancer biology from the University of Alabama at Birmingham and was a recipient of NCI’s Ruth L. Kirschstein National Research Service Predoctoral Award.

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