

Advancing Structured Benefit-Risk Assessment in FDA Review

The Duke-Margolis Center for Health Policy • Washington, DC

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Biographies

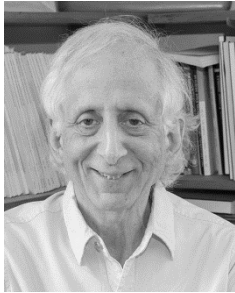
Steven Anderson is currently the Director of the Office of Biostatistics and Epidemiology (OBE) at the FDA Center for Biologics Evaluation and Research (CBER). He provides leadership for all CBER statistical, epidemiological and benefit-risk assessment programs. Previously, Dr. Anderson had been the Deputy Director for OBE since 2005. In 2001, he was hired by CBER as the Associate Director for Risk Assessment to establish a program in quantitative risk assessment for biologic products including vaccines, blood products and others. Since his arrival at FDA he has led numerous important risk assessment projects and epidemiological studies. He led the first studies at FDA using Centers for Medicare & Medicaid Services (CMS) data to estimate blood utilization and address important blood product safety questions of regulatory concern. He has conducted collaborative studies using the FDA Sentinel system and CMS data to evaluate the safety of blood products and vaccines and worked to integrate use of these data systems into CBER's regulatory processes to improve biologic product safety evaluations and surveillance. Dr. Anderson earned a Master's Degree in Public Policy (MPP) at Georgetown University and while there developed the first quantitative risk assessment for antimicrobial resistant pathogens. Dr. Anderson received his PhD in Biology from the University of Cincinnati where he worked on biochemistry, drug resistance and ion pumps, pathogenicity and genomics of unique tropical disease pathogens. He has published a number of articles in biologic product safety, risk assessment, epidemiology, pharmacoepidemiology, infectious diseases, biologics safety, and genomics and protein structure/targeting.



Gregory Daniel 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 pharmacoconomics, 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.



Sara Eggers supports FDA’s Center for Drug Evaluation and Research in the areas of decision support and analysis, contributing to the development and implementation of initiatives regarding human drug benefit-risk assessment, patient-focused drug development, risk evaluation and mitigation strategies, and other efforts. Before joining FDA in 2011, she conducted research and consulting in the area of decision science, stakeholder engagement, and risk communication. She has a Ph.D. in Engineering and Public Policy, with an emphasis on decision science, from Carnegie Mellon University.



Baruch Fischhoff is the Howard Heinz University Professor in the departments of Institute for Politics and Strategy and of Engineering and Public Policy at Carnegie Mellon University. A graduate of the Detroit Public Schools, he holds a BS in mathematics and psychology from Wayne State University and an MA and PhD in psychology from the Hebrew University of Jerusalem. He is a member of the National Academy of Sciences and of the National Academy of Medicine. He is past President of the Society for Judgment and Decision Making and of the Society for Risk Analysis, and recipient of its Distinguished Achievement Award. He was founding chair of the Food and Drug Administration Risk Communication Advisory Committee and recently chaired the National Research Council Committee on Behavioral and Social Science Research to Improve Intelligence Analysis for National Security and currently co-chairs the National Research Council Committee on Future Research Goals and Directions for Foundational Science in Cybersecurity and the National Academy of Sciences Sackler Colloquium on “The Science of Science Communication.” He is a former member of the Eugene, Oregon Commission on the Rights of Women, Department of Homeland Security’s Science and Technology Advisory Committee, the World Federation of Scientists Permanent Monitoring Panel on Terrorism, and the Environmental Protection Agency Science Advisory Board, where he chaired the Homeland Security Advisory Committee. He is a Fellow of the American Psychological Association, the Association for Psychological Science (previously the American Psychological Society), the Society of Experimental Psychologists, and the Society for Risk Analysis. He has co-authored or edited eleven books, *Acceptable Risk* (1981), *A Two-State Solution in the Middle East: Prospects and Possibilities* (1993), *Elicitation of Preferences* (2000), *Risk Communication: A Mental Models Approach* (2002), *Intelligence Analysis: Behavioral and Social Science Foundations* (2011), *Risk: A Very Short Introduction* (2011), *Communicating Risks and Benefits: An Evidence-Based Guide* (2011), *Judgment and Decision Making* (2011), *Risk Analysis and Human Behavior* (2011), *The Science of Science Communication* (2013), and *Counting Civilian Casualties* (2013).



Richard Forshee leads the Analytics and Benefit-Risk Assessment Team for the Office of Biostatistics and Epidemiology in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. He works on a wide range of issues related to the risks and benefits of blood and blood products, vaccines, and human cell and tissue products. Before joining the FDA, he was the Director of the Center for Food, Nutrition, and Agriculture Policy at the University of Maryland, College Park.



Brett Hauber is a Senior Economist and the Vice President of Health Preference Assessment at RTI-HS and an Affiliate Associate Professor in the Department of Pharmacy at the University of Washington. He has more than 20 years of academic, research, and government experience in health and environmental economics. He specialized in health preference studies. Although much of his work involved discrete-choice experiments, he has extensive experience in multiple preference elicitation methods. He has studied the theoretical and empirical relationships among various health preference methods. The majority of Dr. Hauber's work has involved the elicitation of benefit-risk preferences of patients and other health care

decision makers and applying these results to endpoint development and benefit-risk evaluations. Dr. Hauber led a number of studies that have been included in regulatory submissions. Dr. Hauber regularly teaches courses on conjoint analysis and discrete-choice experiments. He was a member of to the Patient-Centered Benefit-Risk Steering Committee of the Medical Device Innovation Consortium (MDIC) and was the principal investigator for developing the Catalog of Methods for Assessing Patient Preferences for Benefits and Harms of Medical Technologies for MDIC. He is currently a member of the scientific advisory board for the IMI-PREFER project and an advisor to a number initiatives led by industry and patient-advocacy organizations to incorporate patient preferences in regulatory and reimbursement decision making in multiple disease areas. He was the chair of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Conjoint Analysis–Statistical Analysis, Reporting, and Conclusions (CA-SARC) task force and was previously a member of the ISPOR task force that developed the ISPOR Checklist for Good Research Practices in Conjoint Analysis. Dr. Hauber's research has been published in numerous health outcomes research and medical journals.



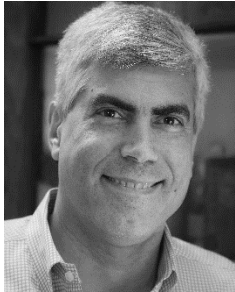
Telba Irony is the Deputy Director of the Office of Biostatistics and Epidemiology at the Center for Biologics in the FDA. She is an expert on Bayesian clinical trials and has been a leading proponent for the use of Bayesian methods, decision analysis and patient-preference in the regulatory setting. Prior to joining the Center for Biologics, Telba led the Decision Analysis initiative at the Center for Devices in the FDA, which involved Bayesian clinical trials, benefit-risk assessments, patient preference surveys, and decision tools. Dr. Irony received her Ph.D. from the University of California, Berkeley and joined the FDA to implement the use of Bayesian Statistics in medical device clinical trials. She was instrumental in writing

the guidance documents on Bayesian statistics, benefit – risk determinations, and on submission of patient preference information for medical devices. In 2014, Telba received the FDA Excellence in Analytical Science Achievement Award for spearheading innovative regulatory science studies culminating in the release of novel guidance documents, supporting complex policy decision making and changing the submission review paradigm. Telba is a fellow of the American Statistical Association and an elected member of the International Statistical Institute.



Laura Lee Johnson is the Acting Director of the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research's (CDER) Division of Biometrics III and the Clinical Outcome Assessment liaison for CDER's Office of Biostatistics. She provides guidance on design, logistics, implementation, and analysis of research studies ranging from person reported outcome (PRO) measure qualification to safety and randomized studies of all sizes. She works across CDER and other parts of FDA on patient focused drug development initiatives. Prior to working at the FDA she spent over a decade at the U.S. National Institutes of Health (NIH) working on and overseeing clinical research and research support programs. At NIH she

contributed to programs such as the CTSAs, PROMIS, and the NIH Collaboratory. She has been involved with numerous projects developing, validating, and using clinical outcome assessments in both patient care and research and received several NIH Director's Awards and an FDA award for her work involving clinical trials in various populations, health related quality of life, and teaching. She has co-authored several articles and book chapters across a variety of disciplines and served on NIH and PCORI review and methods panels. Among her many activities Dr. Johnson serves on the FDA-NIH Interagency Clinical Outcome Assessments Working Group, the IMI PREFER Scientific Advisory Board, co-directs the NIH Principles and Practice of Clinical Research course, and volunteers with the Montgomery County Maryland Science Fair. Dr. Johnson received her Ph.D. in Biostatistics from the University of Washington.



Bennett Levitan is Senior Director, Benefit-risk Assessment, Department of Epidemiology at Janssen R&D, Pharmaceutical Companies of Johnson & Johnson. He introduced state of the art patient-focused benefit-risk assessment to Johnson & Johnson and has led numerous teams in preparation of benefit-risk assessments for regulatory submissions and health authority advisory meetings. He has co-led cross-disciplinary teams to implement processes to support growing regulatory requirements for patient-focused benefit-risk assessment both during development and post-approval. Bennett has published widely on both theoretical and pragmatic aspects in benefit-risk and patient preference studies and is a frequent speaker on

these topics in national and international conferences. He co-led development of the PhRMA Benefit Risk Action Team (BRAT) Framework for drug benefit-risk assessment and the Medical Device Innovation Consortium (MDIC) Patient Centered Benefit-Risk Project. Bennett serves on several committees that inform policy on benefit-risk methods including the IMI PREFER project on patient preference assessment and use, the ISPE Benefit Risk Assessment, Communication and Evaluation (BRACE) team, the CTTI Patient Groups & Clinical Trials work stream, the PCORI Advisory Panel on Patient Engagement and the PhRMA Patient-Focused Drug Development Work Group. Bennett received his B.Sc. (Electrical Engineering) from Columbia University in New York and his M.D.-Ph.D. (Bioengineering) from the University of Pennsylvania and was a postdoctoral fellow at the Santa Fe Institute.



Theresa Mullin serves as Director of OSP, whose mission is to transform and modernize drug regulatory operations, playing a lead role in a number of CDER's strategic initiatives including the human drugs international program, data standardization, business informatics, lean management, development of benefit-risk and other decision support tools, program analysis, and major user fee negotiations. Having led successful negotiations for the previous 3 cycles of reauthorization, Dr. Mullin is currently serving as FDA's lead negotiator for the 2017 reauthorization of the Prescription Drug User Fee Act (PDUFA), a program that currently provides more than \$800 million per year in fee funding for new drug

review. She is also serving as FDA's lead negotiator for the 2017 reauthorization of the Biosimilar User Fee Act (BsUFA). Dr. Mullin leads the FDA Patient Focused Drug Development Initiative, an effort begun in 2012 to better incorporate the patient's voice in drug development. She also heads the FDA delegation to the International Council on Harmonization, the primary venue for international harmonization of drug regulatory standards. Before joining CDER in September 2007, Dr. Mullin was Assistant Commissioner for Planning in the FDA Office of Commissioner, where she served as Director of the Office of Planning. Since joining FDA Dr. Mullin has received numerous awards including the Senior Executive Service Presidential Rank Award for Distinguished Service in 2011, and the Presidential Rank Award for Meritorious Service in 2006. In addition, she has recently been named as one of the 2016/2017 recipients of the US Food and Drug Law Institute's Distinguished Service & Leadership Award. Before joining FDA, Dr. Mullin was a Senior

Manager with The Lewin Group, specializing in health care consulting, and prior to that, Principal Scientist at Decision Science Consortium, specializing in decision research and analysis. Dr. Mullin received her B.A., *magna cum laude*, in Economics from Boston College, and Ph.D. in Public Policy Analysis from Carnegie-Mellon University.



Lawrence Phillips is an Emeritus Professor of Decision Science at the London School of Economics, and a Director of Facilitations Limited. He works as a process consultant helping key players in organisations facing difficult decisions that must balance uncertainty and multiple conflicting objectives. His publications explore how people manage uncertainty and risk, how culture affects the concept of uncertainty, and how groups can out-perform even their best members. His extensive experience with managers and executives in the private, public and voluntary sectors is the subject of numerous case studies that show the positive effects of structured approaches to making decisions. His most recent research has

focused on the harm of psychoactive drugs and the benefit-risk of prescription drugs. In November 2005, the Decision Analysis Society of INFORMS (Institute for Operational Research and Management Science) awarded Dr Phillips its highest honour, the Frank P. Ramsey medal for distinguished contributions to decision analysis.

Peter Stein earned his medical degree from University of Pennsylvania and trained at Yale-New Haven Hospital in internal medicine, and in endocrinology and metabolism. He was on faculty at Yale in the Section of Endocrinology and served as the associate program director for the Primary Care Residency Program. Subsequently, Peter was the section chief for endocrinology and the program director for internal medicine residency program at the Medical College of Georgia. Peter joined Bristol-Myers Squibb in 1999, subsequently working at Merck, Janssen, and finishing his career in industry at Merck as Vice-president for late-stage development in Diabetes and Endocrinology. During his industry career, Peter led development programs for several currently approved diabetes medications, and has worked on a wide range of programs from discovery through early and late clinical development. He is a clinical associate professor at the Robert Wood Johnson Medical School, where he maintained a practice in endocrinology for many years. Peter joined FDA in late 2016 as the Deputy Director, Office of New Drugs, CDER.