2015 SCIENCE WRITERS SYMPOSIUM
FDA PARTICIPANTS
FRIDAY, SEPTEMBER 18, 2015, 9 AM TO 5 PM ET

Brian Baker, M.S., M.S., P.E.
Director, Winchester Engineering and Analytical Center (WEAC),
Office of Regulatory Affairs (ORA)
Mr. Baker oversees an extensive research portfolio at WEAC, located in the Greater Boston area. There he leads more than 100 engineers, scientists, and staff working on priority medical product and food program areas, and he has established myriad award-winning scientific collaborations with federal, state, academic and industry partners during his 8-year tenure. Mr. Baker was selected as the FDA "Engineer of the Year" in 2011 and is a retired U.S. Army Corps of Engineers' Lieutenant Colonel. He holds master of science degrees in civil engineering and political science from MIT, where he served as department head from 2000–2005. He has obtained Professional Engineer (P.E.) licensure in Virginia and Rhode Island.

Steven R. Bauer, Ph.D.
Chief of the Cellular and Tissue Therapies Branch (CTTB),
Division of Cellular and Gene Therapies (DCGT) in the Office of Cellular, Tissue, and Gene Therapies (OCTGT),
Center for Biologics Evaluation and Research (CBER)
As the Chief of CTTB, Dr. Bauer supervises CBER scientific staff engaged in review of cell-based biological therapies, policy development in emerging areas of cellular therapies, and research relevant to their use in clinical trials. His current research focuses on mesenchymal stem cell biology and stromal cell-hematopoietic cell interactions that influence development of lymphocytes. He received his Ph.D. in biochemistry from the University of Maryland in 1986. From 1986 through 1991, Dr. Bauer was a scientific member of the Basel Institute for Immunology in Basel, Switzerland. In 1991, he joined CBER's Division of Cellular and Gene Therapies.

Ksenia Blinova, Ph.D.
Staff Fellow, Division of Biomedical Physics, Office of Science and Engineering Laboratories (OSEL), Center for Devices and Radiological Health (CDRH)
Dr. Blinova leads an Induced Pluripotent Stem Cell and Electrophysiology Core Facility. It was established within OSEL to foster collaborative regulatory research supporting review and assessment of FDA-regulated products based on human induced-pluripotent stem cells, including lab-developed in vitro diagnostic tests, stem cell based combination products, high-throughput cardiotoxicity and neurotoxicity screening of new drugs, and patient-specific precision medicine. Dr. Blinova received her Ph.D. in physics and mathematics from Moscow State University and completed a postdoctoral fellowship at the National Heart, Lung, and Blood Institute and FDA Commissioner's Fellowship Program at the FDA.

Luciana Borio, M.D.
Acting Chief Scientist
As Acting Chief Scientist, Dr. Borio is responsible for leading and coordinating the FDA's cross-cutting scientific and public health efforts. Since 2011, she has served as the assistant commissioner for counterterrorism policy and director of the Office of Counterterrorism and Emerging Threats (OCET) in the Office of the Chief Scientist at FDA. In this capacity, she provided leadership, coordination, and oversight for FDA's national and global health security, counterterrorism, and emerging threat portfolios and led the MCMi. Dr. Borio received her medical degree from The George Washington University and continues to practice medicine at Johns Hopkins Hospital.

Conrad Choiniere, Ph.D.
Director of the Division of Population Health Science,
Office of Science, Center for Tobacco Products
Dr. Choiniere has been with FDA for 12 years. In his current role, he oversees a broad research program that encompasses social science, epidemiology, evaluation and statistics, and he is the lead scientist for FDA's modified risk tobacco products program. He previously spent six years at the Center for Food Safety and Applied Nutrition, where he focused on the assessment of the impacts of marketing FDA-regulated products on consumer perceptions, beliefs, attitudes, and behaviors.

Eugene Civillico, Ph.D.
Health Physicist, Center for Devices and Radiological Health
Since 2013, Dr. Civillico has led the Functional Performance and Device Use Laboratory in Dr. Victor Krauthamer's Division of Biomedical Physics. His current projects include the development of test platforms for nerve- and muscle-interfacing upper limb prosthetics, and the study of population variability in noninvasive brain measurements with potential diagnostic utility. He received his Ph.D. in Neuroscience from the University of Pennsylvania School of Medicine in 2006, where his doctoral research focused on sensory neurophysiology. Following postdoctoral training in cerebellar physiology at Princeton University, he worked in central nervous system drug discovery for Otsuka Pharmaceutical Company before joining CDRH's Office of Science and Engineering Laboratories (OSEL) in 2011.

LT James Coburn
Research Engineer, Center for Devices and Radiological Health
LT Coburn began his career as a Mechanical Engineer at Brown University Graduate School performing clinically-directed experimental orthopedic research. He then built a foundation in tissue engineering through a research fellowship at the National University of Ireland, Galway. He is now a principle investigator of collaborative 3D printing-based interdisciplinary research projects in the Functional Performance and Device Use Laboratory and a co-founder of the FDA Additive Manufacturing Working Group. His research strives to incorporate patient-based needs and variability into medical device research and development, especially with regard to 3D printing of innovative medical products.

Matthew Di Prima, Ph.D.
Materials Scientist, Center for Devices and Radiological Health
Dr. Di Prima's areas of research are investigating how the additive manufacturing process can alter material properties, the interplay between corrosion and durability testing, and explant analysis. He also is the head of the Additive Manufacturing Working Group, which is spearheading efforts across the Agency to address how this technology affects medical devices and other regulated medical products. Efforts include guidance and standards development, device review harmonization, and performing regulatory science with the intent to foster innovative and high-quality products while maintaining safety and effectiveness. He received his doctorate in materials science and engineering from the Georgia Institute of Technology.

Sara Eggers, Ph.D.
Operations Research Analyst, Office of Strategic Programs,
Center for Drug Evaluation and Research
Dr. Eggers supports the center 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 the FDA in 2011, she conducted research and consulting focused on decision research, stakeholder engagement, and risk communication. She has a Ph.D. in engineering and public policy from Carnegie Mellon University.

Darón I. Freedberg, Ph.D.
Principal Investigator, Center for Biologics Evaluation and Research
Dr. Freedberg has research experience in nuclear magnetic resonance (NMR) and conformational analysis, and he is currently working on new methods for structure and dynamics studies of oligo- and polysaccharides at the FDA. He has been using cutting-edge NMR spectroscopy for the past 25 years to study the structures of carbohydrates, proteins and organic molecules, and he has published 48 papers over his research career. He earned his doctoral degree from the University of California, Los Angeles (UCLA), and completed postdoctoral research at the National Institutes of Health.

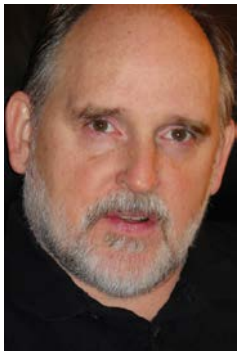
Beth F. Fritsch, R.Ph., M.B.A.
Deputy Director, Office of Health and Constituent Affairs,
Office of External Affairs
CAPT Fritsch provides policy advice to the Acting Commissioner and other senior FDA staff on issues of cross-cutting agency, departmental and national importance incorporating the perspectives of patients with serious and life-threatening diseases and health professionals. She joined the FDA and the United States Public Health Service (USPHS) in 2000 and previously worked for the Center for Drug Evaluation and Research (CDER) Office of Generic Drugs. In addition to her pharmacy degree from the University of Pittsburgh, CAPT Fritsch earned a master of business administration degree from the Johns Hopkins University and a certificate of public health from Georgetown University.

Brandon D. Gallas, Ph.D.
Research Physicist, Center for Devices and Radiological Health
Dr. Gallas currently works in the Division of Imaging, Diagnostics, and Software Reliability in the Office of Science and Engineering Laboratories within CDRH. His research is driven by his regulatory work reviewing imaging devices and the reader studies that support them. He designs, executes, and analyzes reader studies. In addition to publishing the results of his work, he also publishes software to help frontline scientists. He also investigates novel study designs and analysis methods in pursuit of least burdensome methods. He earned his Ph.D. in applied mathematics from the University of Arizona.

Suzanne Junod, Ph.D.
Historian, FDA History Office, Office of Communications, Office of External Affairs
Dr. Junod started her work as a historian at the FDA in 1984. She assumes primary responsibility for the history of foods and food regulation, medical devices and radiological health regulation, as well as other FDA-related fields. Her research interests include food and food additive safety, medical device regulation, women's health, and early agency legal history. She received her Ph.D. in the history of medicine from Emory University and has published in a diverse number of fields related to FDA history and the history of public health.

Gerardo Kaplan, Ph.D.
Principal Investigator at the Lab of Emerging Pathogens,
Center for Biologics Evaluation and Research
Dr. Kaplan joined CBER in 1991 and was tenured in 1998 due to his scientific contributions in hepatitis A virus (HAV) biology and regulatory work in hepatitis virus vaccines. At CBER, he discovered the HAV cellular receptor 1 (HAVCR1), the first identified member of a family of molecules that have a significant role modulating asthmatic, autoimmune, graft-versus-host disease, anti-viral, and anti-cancer immune responses. He continues his research in viral immunology and contributes to blood safety regulatory policy issues. He received his doctorate in biological sciences from the University of Buenos Aires, Argentina, and completed postdoctoral training at Columbia University.

Naomi Kruhlak, Ph.D.
Lead, Chemical Informatics Program, Center for Drug Evaluation and Research
Dr. Kruhlak develops and applies (quantitative) structure-activity relationship ((Q)SAR) models to support regulatory review decisions. She is currently the lead for the Division of Applied Regulatory Science's Chemical Informatics Program and is the principal investigator on three FDA/CDER Research Collaboration Agreements with commercial (Q)SAR software vendors. She has published 29 peer-reviewed articles describing data standardization, transformation, and classification for modeling purposes, as well as the creation and refinement of (Q)SAR models with chemical interpretability. She has extensive experience in the technical aspects of (Q)SAR modeling as well as their application in a regulatory context. Dr. Kruhlak holds a Ph.D. in chemistry from the University of Calgary, Canada.



Mark A. KuKuruga
Manager, CBER Flow Cytometry Core, Office of Vaccines Research and Review, Center for Biologics Evaluation and Review
Mr. KuKuruga manages the flow cytometry and cell sorting core facility established for CBER investigators in 2012. He was formerly a Strategic Applications Specialist for Flow Cytometry, BD Biosciences, and formerly directed core facilities at Medical Schools and Comprehensive Cancer Centers for the University of Michigan and Wayne State University Medical School/Karmanos Cancer Center. He has 35 years of experience and provides flow cytometry and cell sorting consultation and training, and operations support for FDA investigators.

William B. Mattes, Ph.D.
D.A.B.T., Director, Division of Systems Biology,
National Center for Toxicological Research
Dr. Mattes leads a division that tackles problems of drug and food safety using cutting-edge molecular technology, with an eye toward how molecular, cellular and tissue systems respond to treatments. The division's research has resulted in ultra-sensitive tools for microbial detection, novel molecular modeling approaches, in vitro systems for understanding liver, cardiac, and developmental toxicity, and new measures of liver toxicity. Dr. Mattes received his Ph.D. in Biological Chemistry from the University of Michigan and completed postdoctoral fellowships at the Johns Hopkins University as well as the National Cancer Institute.

Tod J. Merkel, Ph.D.
Principal Investigator, Laboratory of Respiratory and Special Pathogens,
Center for Biologics Evaluation and Research
Dr. Merkel brings more than 25 years of experience in infectious disease research and related disciplines and 15 years of vaccine regulatory experience to the study of bacterial pathogenesis and the evaluation of new vaccines. He has extensive experience developing and using animal models of bacterial infections, including murine and non-human primate models of Pertussis, murine models of Staphylococcal infection, and murine models of Anthrax. Dr. Merkel received his Ph.D. from the University of Virginia and postdoctoral training at NIH.

Tina M. Morrison, Ph.D.
Regulatory Advisor of Computational Modeling, Center for Devices and Radiological Health
Dr. Morrison leads the Regulatory Review of Computational Modeling Task Force at CDRH, which has developed guidance documents on the use of modeling and simulation in the regulatory evaluation of medical devices. She also is a scientific reviewer on medical device premarket submissions in cardiovascular devices. She is dedicated to advancing regulatory science through modeling and simulation because she believes the future of medical device design and evaluation, and thus enhanced patient care, lies with computation and enhanced visualization. Dr. Morrison received her doctoral degree in theoretical and applied mechanics from Cornell University in 2006 and studied cardiovascular biomechanics as a postdoctoral fellow at Stanford University.

Kathryn O'Callaghan
Acting Associate Center Director for Science and Strategic Partnerships,
Center for Devices and Radiological Health
Ms. O'Callaghan oversees an extensive program portfolio at CDRH, supporting a number of priority strategic partnership and regulatory science programs, including the Network of Experts, the Medical Device Development Tools (MDDT) Qualification Program, the Critical Path research program, and a variety of scientific and medical fellowship programs. She directs the center's initiatives for patient engagement and the science of patient input, including efforts on patient preferences and patient-reported outcomes (PROs). She also oversees a variety of cross-center working groups dedicated to improving diversity of clinical data and study participation, advancing pediatric device development, and developing and qualifying broadly applicable tools like PROs and computer models.

Stephen Ostroff, M.D.
Acting Commissioner of Food and Drugs
As the top official of the FDA, Dr. Ostroff is committed to strengthening programs and policies that enable the agency to carry out its mission to protect and promote the public health. Before his current post, he served as the FDA's chief scientist since January 2014. He previously served as deputy director of the National Center for Infectious Diseases at the Centers for Disease Control and Prevention (CDC), where he was also acting director of CDC's Select Agent Program. Dr. Ostroff graduated from the University of Pennsylvania School of Medicine in 1981 and completed residencies in internal medicine at the University of Colorado Health Sciences Center and preventive medicine at CDC.

Elektra J. Papadopoulos, M.D., M.P.H.,
Acting Associate Director Clinical Outcome Assessments Staff,
Office of New Drugs, Center for Drug Evaluation and Research
Dr. Papadopoulos currently serves as a member of the Clinical Outcome Assessments (COA) staff (formerly SEALD). This group provides advice on the development and implementation of clinical outcome assessments, including PROs, for use in trials to support medical product approval and labeling claims. She has participated in the development of guidance for the regulatory qualification of clinical outcome assessments and is the FDA co-chair of the FDA-NIH Clinical Outcome Assessments Working Group. She is a board certified dermatologist with experience in the review and design of clinical trials. Dr. Papadopoulos has served as an FDA Medical Officer since 2001, first in CBER, and subsequently in the Division of Dermatology and Dental Products in CDER, before joining SEALD in 2007.

Patrick Regan, Ph.D., Analytical Branch Director,
Winchester Engineering and Analytical Center, Office of Regulatory Affairs
As Branch Director, Dr. Regan has directed efforts to support FDA's strategic initiatives by leveraging technology through the development of academic, state, federal and private industry collaborations. His group is heavily involved in the exploration and expansion of new analytical technologies in the foodborne pathogens, chemistry and radionuclide areas. He has been with the FDA for more than 30 years. In his role as scientist, his Ph.D. work focused on the development and application of molecular techniques for the detection of human enteric viruses in the environment.

Karen Riley, M.P.H., Deputy Director for Strategy, Office of External Affairs
Ms. Riley provides strategic advice on communicating to the FDA's various stakeholders and provides editorial guidance for speeches, blogs, talking points, and other written material. She also planned and implemented the three prior science writers symposia. Before joining the FDA in 2006, she was a Washington-based journalist for 20 years, initially covering the economy, taxes, and trade and then covering health care and the FDA. She received her master's degree from the Johns Hopkins Bloomberg School of Public Health and an A. B. in Economics from Cornell University.

Maria Rios, Ph.D.
Senior Scientist, Center for Biologics Evaluation and Research
Dr. Rios focuses her research on the use of molecular biological techniques in transfusion medicine and blood safety. During the last 11 years, she has studied the potential threat of arboviruses (West Nile, dengue, and chikungunya viruses) to transfusion safety. She also performs regulatory reviews of product applications, policy development, and other activities related to blood safety and the impact of arboviruses on public health. She has published numerous scientific papers and served as member of editorial boards for a variety of scientific journals. She received her doctorate in molecular biology from the Escola Paulista de Medicina, Sao Paulo Brazil, and completed postdoctoral training at the New York Blood Center.

Steven Rubin, Ph.D.,
Acting Chief, Laboratory of Method Development,
Center for Biologics Evaluation and Research
Dr. Rubin directs a research program focused on the establishment of methods to assure viral vaccine safety and development of assays to support the evaluation of vaccine efficacy. As a regulatory scientist, he is a primary reviewer for Investigational New Drug submissions and Product License Applications for pediatric viral vaccines and participates in vaccine manufacturing facility inspections. He is an internationally recognized scientist for mumps virology and has contributed to several guidance documents for industry. He has authored more than 80 peer-reviewed scientific journal articles and book chapters, including seminal chapters in *Field's Virology*. Dr. Rubin received a master's degree in molecular biology from the Johns Hopkins University, and a Ph.D. in molecular virology from the Queen's University in the United Kingdom.

Vahan Simonyan, Ph.D.
Lead Scientist, High-Performance Integrated Virtual Environment (HIVE),
Center for Biologics Evaluation and Research
Based on technology developed by Dr. Simonyan and donated to the U.S. government, the FDA launched the HIVE initiative within CBER. The regulatory compliant R&D IT platform is capable of handling peta-scale data from sequencing project, post-market analytics, clinical and preclinical data analysis. Dr. Simonyan is an author on more than 50 scientific peer-reviewed journals and conference proceedings in areas including physics, chemistry, quantum chemistry, nanotechnology, and bioinformatics. He formerly served as a scientist for Moscow State University, Institute of Organic Chemistry, University of Hannover, University of Pittsburgh, and National Institutes of Health/National Center for Biotechnology Information.

John P. Swann, Ph. D.
Historian, FDA History Office, Office of Communications, Office of External Affairs
Dr. Swann has worked at the FDA since 1989. His research interests concern the pharmaceutical industry, regulation, dietary supplements, and obesity and its therapeutics. He has primary responsibility for all areas concerning the history of drugs, biologics, and their regulation, as well as other aspects of agency history. Prior to joining the FDA, he earned a joint Ph.D. at the School of Pharmacy and the Department of History of Science at the University of Wisconsin in 1985, spent a year as a postdoctoral fellow at the Smithsonian Institution, and collaborated on a centennial history of the University of Texas Medical Branch.

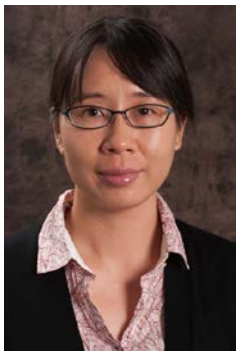
David Strauss, M.D., Ph.D.
Senior Advisor for Translational and Experimental Medicine,
Center for Drug Evaluation and Research
Dr. Strauss served as a Medical Officer in CDRH from 2010–2015. He built a large translational regulatory science research group and led research involving clinical biomarkers, personalized medicine, induced pluripotent stem cells, computational models, meta-analyses of premarket clinical trials and postmarket outcomes and comparative effectiveness studies. He has published more than 75 peer-reviewed journal articles or book chapters and has received multiple awards, including being recognized as one of Forbes 30 under 30 in Science and Healthcare. Dr. Strauss recently joined CDER but continues to work closely with CDRH on induced pluripotent stem cell research and other regulatory science activities.

Lisa Turner
Associate Commissioner for External Affairs
Ms. Turner comes to FDA after leaving the U.S. Department of Agriculture's Food and Nutrition Service where she served as the Agency's first Chief Communications Officer. She is the former president of The Turner Group, Ltd, a full service campaign consulting firm where her portfolio spanned more than 20 years as a political strategist electing candidates, advising philanthropists and restructuring organizations. Her work embodies external and internal communications, strategic and innovative leadership as well as designing and implementing original progressive infrastructures for long term political change.

Alice Welch, Ph.D.
Director, FDA Technology Transfer Program, Office of the Chief Scientist
Dr. Welch oversees management of a large, diverse technology portfolio comprising inventions from all parts of the FDA. The Technology Transfer Program engages with external partners, who license FDA inventions for development and commercialization, and helps FDA researchers establish partner collaborations. It also develops and updates related policies. Dr. Welch received a Ph.D. in cellular and molecular physiology from Tufts University School of Medicine and completed a postdoctoral fellowship at the American Red Cross Holland Laboratory.

Cristin Welle, Ph.D.
Neuroscientist, Division of Biomedical Physics, Center for Devices and Radiological Health
As the principal investigator of the Neural Implant Lab in the Division of Biomedical Physics within CDRH, Dr. Welle directs a team of scientists in the development of test platforms to evaluate the long-term safety and reliability of neural interface devices in small animal model systems. She also provides subject matter expert consulting reviews for neurological device submissions to the Office of Device Evaluation and participates in internal and external efforts to facilitate the regulatory process for neural technology, including working groups, conference planning committees, and peer-review panels for the U.S. Department of Veterans Affairs (VA), the Defense Advanced Research Projects Agency (DARPA), and the FDA. She served as a project lead for the FDA Public Workshop on Brain-Computer Interface (BCI) Devices for Patients with Paralysis and Amputation held in November 2014. Dr. Welle received her Ph.D. in neuroscience from the University of Pennsylvania in 2010.

Carolyn A. Wilson, Ph.D.
Associate Director for Research, Center for Biologics Evaluation and Research
Dr. Wilson ensures that CBER's research is relevant, high quality, and provides CBER with the appropriate scientific expertise, tools, and data to support regulatory decision-making and policy development. Her responsibilities include leading FDA's Genomics Working Group and CBER's Medical Counter-Measure Regulatory Science Initiative. She still maintains her laboratory program studying retroviruses, which are either used as vectors for gene therapy clinical trials or are of concern in the xenotransplantation setting. Dr. Wilson joined the Division of Cellular and Gene Therapies (DCGT) at the Center for Biologics Evaluation and Research of the FDA in 1993. As a researcher-reviewer in DCGT, she reviewed investigational new drugs (INDs) and developed policy and guidance documents in two novel product areas: gene therapy and xenotransplantation. Dr. Wilson holds a Ph.D. in genetics from The George Washington University.



Meijun Ye, Ph.D., Postdoctoral Fellow
Division of Biomedical Physics, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health

Dr. Ye joined the neural implant lab in the Division of Biomedical Physics in the Center for Devices and Radiological Health in 2013. As an electrophysiologist, she investigates the use of electroencephalogram (EEG) electrodes for the detection of traumatic brain injury at the FDA. The goal is to contribute to the scientific knowledge base for the development of medical products for the diagnosis and treatment of brain injury, as well as regulatory review. Dr. Ye received her Ph.D. in neuroscience from the University of Arkansas for Medical Sciences and completed a postdoctoral research fellowship at Yale University.