SESSION 1

Karen Bijwaard, MS, RAC, MB(ASCP), joined the FDA's Office of In Vitro Diagnostics and Radiological Health (OIR) in April 2005 as a Scientific Reviewer in the Division of Immunology and Hematology Device evaluation (DIHD) and then in the Division of Molecular Genetics and Pathology (DMGP) when it was created in April 2014. She is a Master Reviewer specializing in Molecular Acquired and Hereditary Hematological Disorders. In her current position as a Senior Reviewer, she reviews submissions for molecular pathology, genetics, companion diagnostic In Vitro Devices (IVDs) and diagnostic software/instrumentation. She is the DMGP product specialist for cell-free/circulating-tumor DNA assays and medical device instrumentation and software and the leader of the IVD Instrumentation and Software Policy Group in CDRH. She is a consultant to other divisions in OIR and the Centers for Biologics and Drugs. She is also a member in a number of genetics/genomics committees and working groups in FDA.

Ms Bijwaard is certified by ASCP as Technologist in Molecular Biology and received her Regulatory Affairs Certification from the Regulatory Affairs Professional Society in 2009. She has been an active member of the Assoc. for Molecular Pathology since 1996. In addition, she is active in CLSI and has served as a Subcommittee member and Advisor on several new and revised guidelines. Ms. Bijwaard received her undergraduate degrees in Animal Science and Biology from VA Tech in Blacksburg, VA and her Masters Degree in Pathology from Georgetown University in Washington, DC. Prior to joining OIR, she had extensive laboratory experiences in the area of molecular diagnostics. Previously she has worked as a medical technologist in the Molecular Diagnostics Laboratory (MDL) in the Dept. of Pathology at Georgetown University. In 1996, she joined the MDL at the Armed Forces Institute of Pathology as a medical technologist where she continued to perform and created new molecular assays until 2003, after which she worked in the Laboratory of Immunology at NIH/NIAID.

Bridget Foltz, M.S., is a policy analyst in the Office of Good Clinical Practice (OGCP), the focal point within FDA for good clinical practice and human subject protection issues arising in human research trials regulated by the Agency. She has been with FDA for over 15 years holding previous positions in the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER). Bridget has prior experience in both the pharmaceutical and device industries. She has an M.S. in Biotechnology from Johns Hopkins University.

Soma Kalb, Ph.D., is the director of the Investigational Device Exemption (IDE) Program in FDA's Center for Devices and Radiological Health. She has been with the Agency since 2005, originally splitting her time between doing laboratory research at the Office of Science and Engineering Laboratories and reviewing postmarket device performance in the Office of Surveillance and Biometrics. In 2007, she transitioned to the Office of Device Evaluation, where she performed premarket device reviews in the Division of Cardiovascular Devices. She assumed her current role in 2013, where she oversees IDE Program policy and operations. She holds a Bachelor's Degree in Electrical Engineering from the University of Maryland, a Master's in Biomedical Engineering from the Johns Hopkins University, and a Ph.D. in Biomedical Engineering from Duke University.

Elektra Papadopoulos, M.D., M.P.H., is the associate director for the Clinical Outcome Assessments (COA) Staff in the Office of New Drugs, Center for Drug Evaluation and Research, FDA. The COA Staff contributes to a culture that ensures the patient voice is integrated into drug development through COAs, including patient-reported outcome measures, that are meaningful to patients, valid, reliable and sensitive to change. The COA Staff work collaboratively to provide consultation for COAs used across all stages of drug development and therapeutic areas, manages the COA Drug Development Tool Qualification Program to develop and qualify COAs for unmet public health needs, and provides education and outreach to advance the science of COA development and implementation in drug development.

Patroula Smpokou, M.D., FACMG, is a lead medical officer (team leader) in the Division of Gastroenterology and Inborn Errors Products (DGIEP) at FDA's Center for Drug Evaluation and Research where she is involved in leading the clinical review of products (small molecule drugs and biologics) intended for the treatment of rare genetic diseases called inborn errors of metabolism (IEM). She is board certified in general pediatrics and in clinical genetics and previously practiced clinical genetics at Children's National Health System in Washington, DC where she also held an academic appointment as Assistant Professor of Pediatrics at The George Washington University School of Medicine & Health Sciences. She has clinical experience in the diagnosis and management of patients with various genetic syndromes, congenital birth defects, and inborn errors of metabolism as well as in prenatal genetic counseling. Her current work encompasses the clinical review and regulation of medical products investigated for the chronic treatment of IEM and also includes engagement with external stakeholders including industry, academia, and patient groups to facilitate and accelerate drug development for rare diseases with unmet needs.

Leonard Sacks, M.D., received his medical education in South Africa, moving to the USA in 1987, where he completed fellowships in immunopathology and Infectious Diseases. He worked as an attending physician in Washington DC and South Africa and he joined the FDA in 1998 as medical reviewer in the Office of New Drugs. Subsequent positions included acting director of the Office of Critical Path Programs and associate director for clinical methodology in the Office of Medical Policy in the Center for Drug Evaluation and Research. In this capacity he has led efforts to support the use of electronic technology in clinical drug development. Besides his involvement in the design and analysis of clinical trials, he maintains a special interest in tuberculosis and other tropical diseases and has published and presented extensively on these topics. He is board certified in Internal Medicine and Infectious Diseases and holds an academic appointment as Associate Clinical Professor of Medicine at George Washington University.

Robert Temple, M.D., serves as CDER's Deputy Center Director for Clinical Science and also Acting Deputy Director of the Office of Drug Evaluation I (ODE-I). He has served in this capacity since the office's establishment in 1995.

Dr. Temple received his medical degree from the New York University School of Medicine in 1967. In 1972 he joined CDER as a review Medical Officer in the Division of Metabolic and Endocrine Drug Products. He later moved into the position of Director of the Division of Cardio-Renal Drug Products.

In his current position, Dr. Temple oversees ODE-1 which is responsible for the regulation of cardio-renal, neuropharmacologic, and psychopharmacologic drug products. Dr. Temple has a long-standing interest in the design and conduct of clinical trials. He has written extensively on this subject, especially on choice of control group in clinical trials, evaluation of active control trials, trials to evaluate dose-response, and trials using “enrichment” designs.

SESSION 2

Jon Mark Hirshon, M.D., Ph.D., M.P.H., FACEP, FAAEM, FACPM, is dedicated to improving access to high quality acute care in the United States and across the globe. He is a professor in the Department of Emergency Medicine and in the Department of Epidemiology and Public Health at the University of Maryland School of Medicine, where he treat's patients and teaches students and residents. He is the former director of the Charles McC. Mathias, Jr. National Study Center for Trauma and EMS and is currently the Senior Vice-Chairman of the University of Maryland, Baltimore's Institutional Review Board. Additionally, he is the Vice-President of the American College of Emergency Physicians. Dr. Hirshon is a federally funded researcher and teacher who has been the principal investigator/program director on over $8 million in federal research and training grants and contracts and has been co-investigator on numerous other funded projects. As part of his international work through a National Institutes of Health Fogarty International Center grant, he and his dedicated teams have trained over 1200 physicians from Egypt and multiple other countries in the Middle East in acute care related topics including the clinical care of trauma patients, disaster preparedness and response, and injury research methods. Dr. Hirshon is Board Certified in both Emergency Medicine and Preventive Medicine and has authored over 100 articles and chapters on various topics related to improving acute care, including the need to place acute care on the global health agenda and articles on improving emergency department operations.

Bridget Foltz, M.S. (See biography - Session 1)

SESSION 3

Kassa Ayalew, M.D., M.P.H., is a branch chief for the Good Clinical Practice Assessment Branch of the Division of Clinical Compliance Evaluation in the Office of Scientific Investigation in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). He oversees verification of the integrity of efficacy and safety data submitted to the FDA in support of new drug and biologic applications and the protection and assurance of the rights and welfare of human research subjects. Dr. Ayalew obtained his M.D. from Haile Selassie University Medical Faculty in Addis Ababa, Ethiopia(also called Addis Ababa University Medical Faculty). He then worked as an assistant professor in the Department of Pediatrics at the Gondar University of Medical Sciences in Ethiopia and completed post-graduate training in pediatrics and child health at Leipzig University in Germany. He also completed a pediatrics residency at the Long Island College of Hospital (State University of New York) followed by a fellowship program at Children's National Medical Center/George Washington University.

Dr. Ayalew is a Pediatrics Infectious Disease physician and holds an active license to practice medicine in Virginia. He serves as a pediatrician at Inova Fair Oaks Hospital where he provides clinical services in pediatrics and pediatric infectious diseases. He has given numerous didactic lectures and case presentations and has published article in peer review journals. He holds several awards and credentials from the FDA, where he has over 18 years of regulatory medicine and work experience.

Su-Young Choi, Pharm.D., Ph.D., is currently a clinical pharmacology reviewer of anti-viral products in the Office of Clinical Pharmacology (OCP), Center for Drug Evaluation and Research (CDER), FDA. She is responsible for reviewing clinical pharmacology aspects of regulatory submissions for antiviral drugs. She is also actively involved in guidance development working groups and research projects for various anti-viral products.

Dr. Choi obtained her Pharm.D. and Ph.D. at the University of Illinois at Chicago. Her research background is identifying the molecular mechanism behind altered pharmacokinetics of drugs during pregnancy, including antiviral drugs. She has published multiple articles and given presentations on antiviral drug interactions, pharmacokinetic changes in specific populations, and physiologically based pharmacokinetic modeling of antiviral drugs.

Joseph G. Toerner, M.D, M.P.H., He is currently deputy director for safety in the Division of Anti-Infective Products. During his time at FDA he has held medical reviewer, team leader, and deputy director positions in review division in CDER and CBER. He joined FDA in 1998 as a medical reviewer after spending four years as a clinician-educator and as assistant professor of medicine at University of California, San Diego. He received his undergraduate degree from the University of Dayton, his M.D. from Case Western Reserve University and his M.P.H. degree from Johns Hopkins School of Public Health. He completed training in Internal Medicine at CWRU University Hospitals of Cleveland/Cleveland Veterans Administration Medical Center and completed fellowship training in Infectious Diseases at Georgetown University Medical Center.

Yuliya Yasinskaya, M.D., is a medical team leader in the Division of Anti-Infective Products, Office of Antimicrobial Products, Center for Dug Evaluation and Research, Office of New Drugs. She has Medical Degree from Khabarovsky State Medical University, Russia. She has joined the FDA in 2005 as a Medical Officer after completion of her fellowship training as pediatric infectious disease physician at NIH/Childrens National Medical Center. As a Medical Team Leader, she oversees a diverse application portfolio of products targeting various bacterial and fungal pathogens, agents of bioterrorism, as well as parasitic diseases (INDs, NDAs, BLAs) and is an active member of many Agency committees.

SESSION 4

Cynthia Kleppinger, M.D., is currently a senior medical officer in the Good Clinical Practice Assessment Branch, Division of Clinical Compliance Evaluation, Office of Scientific Investigations, Center for Drug Evaluation and Research at the US Food and Drug Administration. In this capacity, she directs, and may participate in, onsite inspections of clinical investigators, sponsors, monitors, and contract research organizations in collaboration with FDA's field organization to monitor clinical drug product studies and initiate administrative and regulatory corrective measures as necessary.

Since joining CDER in 2008, Dr. Kleppinger has also held the positions of team leader for the Policy and Planning Team and Team Leader for International Policy in the Office of Scientific Investigations. Work included launching and then overseeing the collaborative FDA-European Medicines Agency Good Clinical Practice Initiative as well as issues relating to capacity building, bilateral agreements, and international standards development and harmonization.

Prior to her work at CDER, Dr. Kleppinger was a Clinical Reviewer for 4 years in the Division of Vaccines and Related Products Applications, Center for Biologics Evaluation and Research/FDA. She also spent 3 ½ years at Science Applications International Corporation-Frederick, overseeing clinical trials as Director of the Clinical Safety Office in the Division of Intramural Research at the National Institute of Allergy and Infectious Diseases/National Institutes of Health. Preceding that job, she was a Senior Medical Officer and Project Coordinator in the Center for the Clinical Trials Network at the National Institute on Drug Abuse at the NIH. She also has over 16 years as an active practicing clinician in academia, private practice, family and emergency medicine.

SESSION 5

Susan Ellenberg, Ph.D., is professor of biostatistics, Department of Biostatistics, Epidemiology and Informatics, Perelman School of Medicine at the University of Pennsylvania. Her research has focused on practical problems and ethical issues in designing, conducting and analyzing data from clinical trials. At Penn, in addition to her teaching and administrative duties she serves as senior statistician for several multicenter clinical trials, directs the Biostatistics Core of the Penn Center for AIDS Research and chairs the organizing committee for the annual Penn conference on statistical issues in clinical trials.

Prior to her appointment at Penn, Dr. Ellenberg held positions of increasing responsibility in the federal government, including service as Director of the Office of Biostatistics and Epidemiology in the Center for Biologics Evaluation and Research (CBER) at the U.S. Food and Drug Administration, and as the first Chief of the Biostatistics Research Branch in the Division of AIDS, National Institute of Allergy and Infectious Diseases.

Dr. Ellenberg is a Fellow of the American Statistical Association, the Society for Clinical Trials and the American Association for the Advancement of Science, and is an elected member of the International Statistical Institute. A second edition of her book, Data Monitoring Committees in Clinical Trials: A Practical Perspective, co-authored with Drs. Thomas Fleming and David DeMets, is in preparation.

SESSION 6

Susan Ellenberg, Ph.D. (See biography - Session 5)

Erika E. Englund, Ph.D., is a senior chemist at the FDA in the Division of New Drug Products, and is currently acting CMC Lead in the Division of Anti-infective Products. She joined the FDA in 2013, and has assessed INDs, NDAs, NDA supplements, consults, and other submissions during this time. She also served as a subject matter expert in domestic and foreign inspections. She earned her Ph.D. in organic chemistry from the University of Pittsburgh in 2008.

Brenda Gehrke, Ph.D., currently reviews pharmacology and toxicology data in Investigational New Drug applications (INDs) and marketing applications for malignant and benign hematology drugs. Since 2008, Brenda has been a pharmacologist at the FDA in the Office of Hematology and Oncology Products. She was a post-doctoral fellow at the National Institute on Drug Abuse from 2004-2008 and attended graduate school at the University of Kentucky and received her Ph.D. in Experimental Psychology in 2004.

Sue Lim, M.D., is the director of the Scientific Review Staff with the Therapeutic Biologics and Biosimilars Staff at FDA. In this role, she provides scientific oversight and advice on the development and approval of therapeutic biologics and biosimilar products and is also involved in policy development and implementation as it pertains to biosimilar products. Dr. Lim was previously a Medical Officer with the FDA's Division of Anti-Infective Products. Prior to the FDA, Dr. Lim served as an Infectious Diseases physician and Associate Hospital Epidemiologist at the University Health Network in Toronto, Canada. She received her M.D. from the University of Toronto where she also completed her residency in Internal Medicine and subspecialty training in Infectious Diseases and served as a Lecturer in the Faculty of Medicine. She has a Master of Science degree in Health Policy, Management and Evaluation from the University of Toronto.

Shirley K. Seo, M.D., is currently the director of the Division of Clinical Pharmacology III in the Office of Clinical Pharmacology at the FDA. She obtained her PhD in pharmaceutics at the University of Texas at Austin where her research focus was in drug metabolism and pharmacology. Shirley began her career at the FDA in 2004 as a reviewer in the Office of Generic Drugs. In 2007, she became a reviewer in the Office of Clinical Pharmacology and in 2012, she was selected as a team leader for one of the antiviral teams. In her previous role as a team leader and currently as division director, Shirley has been involved in IND and NDA analysis and review, interpreting regulations, and providing guidance on drug development programs. Her areas of scientific and regulatory interest include: complex drug interactions, pediatric clinical pharmacology and drugs being developed under the Animal Rule. Shirley also has a passion for mentoring.

SESSION 7

Michelle Anantha, MSPAS, PA-C, RAC, is a Good Clinical Practice (GCP) compliance reviewer in FDA/CDER's Office of Scientific Investigations (OSI). Her work focuses on review of significant and serious GCP inspectional findings and taking the appropriate regulatory action. Michelle received her undergraduate degree from the University of Pittsburgh and graduate degree from DeSales University. She is also a certified Physician Assistant and holder of the Regulatory Affairs Certification (RAC – US). Michelle practiced as physician assistant and worked as a pharmaceutical sales representative before joining CDER's Office of Prescription Drug Promotion. She joined OSI five years ago and hopes to continue making a positive impact on the conduct of human prescription drug clinical trials.

Jiping Chen, M.D., Ph.D., M.P.H., is the chief, Epidemiologic Evaluation and Research Branch 1, in the Division of Epidemiology, OSB, in the Center for Devices and Radiological Health (CDRH) at the U.S. Food and Drug Administration.

Joshua Chetta, Ph.D., is temporarily serving as the acting IDE program director in the Clinical Trials Program in FDA's Office of Device Evaluation. Josh earned his undergraduate degree in Biology from the University of Chicago, and a doctorate in Bioengineering from the University of Maryland. He spent a few years as a post-doctoral fellow at the NIH's Clinical Center before joining CDRH in 2014 as a premarket reviewer. He first joined the Clinical trials Program as part of an inter-Office team tasked with identifying needs and developing tools and resources for staff to help CDRH implement the Real World Evidence Guidance Document.

Donald W. Fink, Ph.D., is in the Cell Therapies Branch, Division of Cellular and Gene Therapies, Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER), FDA. He possesses 25-years of regulatory review experience.

Presently, Dr. Fink is engaged primarily in regulatory activities pertaining to investigational products comprised of or derived from stem cells. He oversees an extensive portfolio of applications that includes hematopoietic, mesenchymal, cord blood, placenta-derived, and pluripotent stem cell-derived cellular products. His current appointment is as Expert Regulatory Biologist with specific expertise in human pluripotent stem cells (PSC). Dr. Fink has organized an FDA advisory committee meeting on the topic of cellular replacement therapies for neurological disorders focused on stem cell-based treatments and has served on the planning committee for an NIH/FDA co-sponsored workshop regarding PSC-based products in clinical translation. He acts as the coordinator for an intra-OTAT working group that monitors development of cellular products derived from PSCs and has served as FDA liaison to both the NIH Stem Task Force and the International Society for Stem Cell Research Task Force on Clinical Translation of Stem Cells. Dr. Fink is a co-founder and co-chair of an FDA-NIH interagency working group that includes extramural program officers from the National Institute of Neurological Disorders and Stroke (since 2002) established to promote cross-agency dialogue with the objective of facilitating clinical translation of cellular and gene transfer-based treatments. Dr. Fink has given numerous presentations and authored or co-authored several book chapters describing FDA's approach for evaluation of stem cell-based therapies.

Lieutenant Commander Eithu Z. Lwin has served as a regulatory health project manager at the Food and Drug Administration, in the Division of Transplant and Ophthalmology Products for the past 4.5 years. She manages multidisciplinary review teams and oversees all aspects of

administrative and regulatory review processes of drug application from initial submission throughout the product lifecycle, including approval and post-marketing safety. She is also pursuing Juris Doctor (J.D.) degree at the University of Maryland Francis King Carey School of Law. Prior to joining the FDA, LCDR Lwin served as a clinical pharmacist at the Indian Health Service at an isolated hardship location, Chinle, AZ. At Chinle Comprehensive Health Care Facility, she rotated at various pharmacy settings including outpatient pharmacy, inpatient pharmacy, and pharmacy-operated clinics. She received her Doctor of Pharmacy from the Massachusetts College of Pharmacy and Health Sciences University in Boston, MA. In addition, she is a Certified Diabetes Educator.

Judit Milstein, D.Sc., was born in raised in Buenos Aires, Argentina, were she received her degree in organic chemistry (Licensed) from the University of Buenos Aires. Judit immigrated to the United States in 1985 and became a U.S. Citizen in 1986. Judit joined the Center for Drug Evaluation and Research as a consumer safety officer in 1999 in the Division of Anesthetic, Critical Care and Addiction Drug Products. She joined the Division of Anti-Infective Drug Products in 2001 as a Regulatory Health Project Manager and she became a supervisor in the Division of Transplant and Ophthalmology Products in 2005. Before joining the agency, Judit worked as an organic chemist at Procter and Gamble in Cincinnati, OH, and at NABI in Rockville, MD.

Nadezda Radoja, Ph.D., works in the Division of Epidemiology, Office of Surveillance and Biometrics in the Center for Devices and Radiological Health (CDRH) at the U.S. Food and Drug Administration.

Allen Wensky, Ph.D., is a biologist, pharmacology/toxicology reviewer in the Office of Tissues and Advanced Therapies (OTAT), Pharmacology and Toxicology Branch in FDA's CBER. He joined OTAT (formerly Office of Cellular Tissues and Gene Therapies) in October 2008 and currently serves as a senior pharmacology/toxicology reviewer. He is responsible for the critical review of preclinical data packages for gene and cellular therapy products at multiple stages during the development program of these novel investigational products. Dr. Wensky obtained his Ph.D. degree at New York University in the Department of Pathology where he investigated the role of T cell subsets in autoimmune disease pathogenesis. He subsequently spent four years at the University of California, Berkeley investigating the molecular mechanisms of apoptosis and its relationship to the immune response to pathogens. Prior to his PhD, Dr. Wensky worked in a small biotechnology firm in the San Francisco/Bay area engaged in development of novel therapies for various autoimmune diseases.

Rachel Witten M.D., FAAP, is a senior medical officer in the Division of Clinical Evaluation and Pharmacology/Toxicology in the Office of Tissues and Advanced Therapies at the FDA's Center for Biologics Evaluation and Research. Dr. Witten's reviews cover a wide range of gene and cell therapy products across different therapeutic areas, which among others, include rare and orphan diseases. Dr. Witten actively participates in scientific and regulatory working groups within and outside the FDA, teaches clinical courses for new investigators, participates in writing guidances on rare diseases and gene therapy, and organizes relevant workshops at the FDA.

SESSION 8

Michelle Anantha, MSPAS, PA-C, RAC (See biography – Session 7)

Pat Furlong is the founding president and CEO of Parent Project Muscular Dystrophy (PPMD), the largest nonprofit organization in the United States solely focused on Duchenne muscular dystrophy (Duchenne). Their mission is to end Duchenne. They accelerate research, raise their voices in Washington, demand optimal care for all young men, and educate the global community. Duchenne is the most common fatal, genetic childhood disorder, which affects approximately 1 out of every 3,500 boys each year worldwide. It currently has no cure.

When doctors diagnosed her two sons, Christopher and Patrick, with Duchenne in 1984, Pat didn't accept "there's no hope and little help" as an answer. Pat immersed herself in Duchenne, working to understand the pathology of the disorder, the extent of research investment and the mechanisms for optimal care. Her sons lost their battle with Duchenne in their teenage years, but she continues to fight—in their honor and for all families affected by Duchenne.

In 1994, Pat, together with other parents of young men with Duchenne, founded PPMD to change the course of Duchenne and, ultimately, to find a cure. Today, Pat continues to lead the organization and is considered one of the foremost authorities on Duchenne in the world.

SESSION 9

Mark Avigan, M.D., CM, is associate director for Critical Path Initiatives in the Office of Pharmacovigilance and Epidemiology at the Food and Drug Administration. As a clinical hepatologist with expertise both in drug safety science and cellular regulation, he has served as an expert consultant at FDA on the evaluation of risk surrounding drug-induced liver injury during the life-cycle of drugs and biological agents. With an earlier faculty appointment at the Georgetown University School of Medicine and then service as Director of the Division of Drug Risk Evaluation at FDA, he has been a long-standing member of the Drug Safety Oversight Board at the agency's Center for Drug Evaluation and Research. Dr. Avigan has authored or co-authored more than 130 scientific publications, book chapters and professional meeting abstracts.

Leonard Sacks, M.D. (See biography – Session 1)

Edward Sausville, M.D., Ph.D., F.A.C.P., is a clinical professor of medicine and adjunct professor, Department of Pharmacology & Experimental Therapeutics, University of Maryland School of Medicine and the Deputy Director of the Marlene & Stewart Greenebaum Comprehensive Cancer Center.

Dr. Sausville graduated from Albert Einstein College of Medicine in 1979 with the MD and a PhD in Pharmacology. After residency in Internal Medicine at Brigham & Women's Hospital and a Medical Oncology Fellowship at NCI, he remained on the staff of the NCI in the U.S. Public Health Service through 2004. In that capacity, he served as attending physician in the NIH Clinical Center, leading Phase I and II trials in solid tumors and lymphoma. Also at NCI, he led the Developmental Therapeutics Program, NCI's preclinical drug and biological agent discovery and development program. Under his management, more than 30 agents passed into clinical trials under NCI or corporate sponsorships, including Velcade® (ultimately approved for myeloma), Romidepsin® (approved for cutaneous lymphoma), among others. He served on the US FDA Biological Response Modifiers Advisory Committee from 1999-2002. After joining the University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center (UMGCCC) in 2004, he was associate center director for Clinical Research through 2017. In that role he supervised research staff management of ~150 therapeutic and ~100 non-therapeutic clinical trials, implementing an electronic database protocol management system across UMGCCC's protocol portfolio, and restructuring UMGCCC's data safety monitoring process to synchronize with Institutional Review Board(IRB) review. He serves as an active Phase I clinical investigator, and is UMGCCC deputy director and chief ad interim of the Division of Hematology / Oncology. He served as Principal Investigator of UMGCCC's K12 Paul Calabresi Clinical Oncology Training Program. He is a member of the University of Maryland, Baltimore IRB, and co-chairs the University of Maryland Medical Center's Chemotherapy sub-Committee of its Pharmacy & Therapeutics Committee. Outside UMGCCC, Dr. Sausville had the privilege to chair the Data and Safety Monitoring Board for NCI's National Lung Screening Trial, which reported in 2011 the value of spiral CT screening to detect early lung cancers, having enrolled more than 50,000 patients nationwide. He is co-editor-in-chief of Cancer Chemotherapy and Pharmacology, among other editorial roles, and is a current member of the National Cancer Institute Experimental Therapeutics (NExT) Program's Special Emphasis

Panel.

Alan R. Shuldiner, M.D., vice president, Regeneron Genetics Center, Regeneron Pharmaceuticals, Inc., received his undergraduate degree in chemistry from Lafayette College, and his medical degree from Harvard Medical School. He completed residency training in internal medicine at Columbia Presbyterian Hospital, and his postdoctoral fellowship in Endocrinology and Metabolism in the Diabetes Branch at the National Institutes of Health. Dr. Shuldiner served on the fac, Culty at Johns Hopkins University in Baltimore and at the University of Maryland School of Medicine where he was the John Whitehurst Endowed Professor of Medicine, and served as Associate Dean and founding director of the Program for Genetics and Genomic Medicine, and Head of the Division of Endocrinology, Diabetes and Nutrition.

Dr. Shuldiner's major research interests lie in the molecular biology and genetics age-related diseases including of diabetes, obesity, osteoporosis, and cardiovascular disease, common disorders that contribute significantly to mortality, morbidity, and functional loss. He also works on the pharmaco- and nutri-genomics of these disorders. He is best known for his research in the Old Order Amish, a homogeneous founder population ideal for genetic studies. Dr. Shuldiner has authored more than 400 original articles in leading journals and 70 reviews and book chapters. He is the recipient of a number of awards including the prestigious Paul Beeson Physician Faculty Scholar award, Ellison Medical Foundation Senior Scholar award, University of Maryland Founders Day Researcher of the Year award, and Grant R.Wilkinson Distinguished Lectureship.

In September 2014, Dr. Shuldiner became Vice President of the Regeneron Genetics Center where he continues to work in discovery and translational genomics, applying high-throughput sequencing and analytical approaches to glean insights into human biology and to identify and validate novel drug targets for diseases of unmet need. He founded the DRIFT Program, which focuses on special and founder population genetic discovery and clinical translation.

Shari L. Targum, M.D., M.P.H., F.A.C.C., is the chief of General Medicine Branch 1, Division of Clinical Evaluation and Pharmacology/Toxicology, Office of Tissue and Advanced Therapies in the Center for Biologics Evaluation and Research, US FDA.

Dr. Targum is an internist and cardiologist with over 15 years of experience at the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research. She is currently a Branch Chief in the Division of Clinical Evaluation and Pharmacology-Toxicology in the Center for Biologics Evaluation and Research. She has earned numerous FDA awards.

In addition to FDA activities, she holds medical staff privileges at the Washington, DC VA Medical Center, where she treats patients and supervises medical students, residents and cardiology fellows.

Dr. Targum graduated from New York University Medical School and earned an M.P.H. at the Johns Hopkins Bloomberg School for Public Health. She completed a residency in internal medicine at Bellevue Hospital and a cardiology fellowship at the Mount Sinai Medical Center in

New York City. She is a Fellow of the American College of Cardiology and a Fellow of the American College of Physicians.