To Test or Not to Test – That is the Question:
DPD Deficiency and Weighing Potential Harms

Thursday, January 16 | 9am – 3pm ET
Bethesda Marriott, 5151 Pooks Hill Rd, Bethesda, MD 20814

Workshop Co-Chairs (Alphabetically by Last Name)

Jennifer Gao, MD, U.S. Food & Drug Administration
Session 2 Moderator

Dr. Gao is a medical oncologist, Associate Director for Education in the Oncology Center of Excellence (OCE), and Acting Associate Director for Clinical Review Policy in the Office of Oncologic Diseases at the U.S. Food & Drug Administration (FDA). She received her undergraduate degree from Harvard University and spent a year in Bonn, Germany, as a J. William Fulbright Fellow before completing her medical degree at the Alpert Medical School of Brown University. Dr. Gao pursued her internal medicine internship and residency training at Massachusetts General Hospital, followed by a fellowship in medical oncology at the National Cancer Institute (NCI), where she also served as Chief Fellow. In 2016, Dr. Gao joined the FDA as an oncologist on the breast cancer team. She served as the Acting Breast Team Lead before assuming her current position in OCE in 2019. She currently leads OCE's educational initiatives under Project Socrates and co-leads Project Renewal, OCE's public health initiative aimed at updating product labeling of older oncology drugs. She is also involved in the OCE Equity Program, focusing on Asian American, Native Hawaiian, and other Pacific Islander patients with cancer.

Patricia M. LoRusso, DO, PhD (hc), FAACR, Yale Cancer Center
Opening Speaker, Session 3 Panelist, Closing Speaker

Dr. LoRusso serves as the Amy and Joseph Perella Professor of Medicine at the Yale School of Medicine and as the Associate Cancer Center Director for Experimental Therapeutics at Yale Cancer Center. She also currently serves as President of the American Association for Cancer Research. Dr. Patricia LoRusso has been a practicing academic medical oncologist performing clinical/translational research in early phase clinical trials for over 30 years, spending the first 25 years at Wayne State University/Karmanos Cancer Institute in Detroit, MI and transitioning to Yale University/Yale Cancer Center in 2014. She has had continuous NIH/NCI funding for 28 years and has long been a proponent of cooperative and team science, receiving collaborative grants through the NIH, Stand Up to Cancer, the Department of Defense, and the Komen Foundation. She has been involved in service disciplines at the NCI as a member of various study sections and steering committees, including the Investigational Drug Steering Committee and the Board of Scientific Counselors. Having experienced at a young age the death of her own parents from cancer, Dr. LoRusso understands the urgent need for new cancer discoveries to increase the potential for longevity and quality of life. She advocates not only for cancer researchers and clinicians, but more importantly patients and caregivers.

Speakers and Panelists (Alphabetically by Last Name)

Sam Abdelghany, PharmD, MHA, BCOP, Smilow Cancer Center at Yale New Haven

Session 1 Presenter and Panelist

Dr. Abdelghany is the Executive Director of Oncology Pharmacy Services at Smilow Cancer Hospital at Yale New Haven Health. He currently serves on various committees regarding healthcare and research at Yale, including the Yale Cancer Center Protocol Review Committee, Yale University Science and Safety Committee, and the Yale University Institutional Review Board (IRB). Sam's current areas of research interest include real-world data within the context of cancer therapies for oncology economic and outcomes research. Dr. Abdelghany received his Doctor of Pharmacy degree from the University of Connecticut School of Pharmacy and completed a residency in Oncology at Yale New Haven in 2001. He also received a Master of Health Care Administration degree from Ohio University.

Jill Bates, PharmD, MS, BCOP, CPT, FASHP, U.S. Department of Veterans Affairs

Session 1 Panelist, Session 2 Panelist

Dr. Bates is the Deputy Executive Director of the National Pharmacogenomics Program for the Department of Veterans Affairs (VA) and a Professor at the UNC Eshelman School of Pharmacy. In a previous role as National PHASER Pharmacy Program Manager at the VA, she helped lead the rollout of a nationwide comprehensive pharmacogenomic testing program for Veterans which optimizes the use of nearly 40 medications across disease areas through genetic testing. She has been a longstanding and active member of both the American Society of Health-System Pharmacists (ASHP) and Hematology/Oncology Pharmacy Association (HOPA), where she has held multiple leadership and committee member positions such as Chair of ASHP's Council on Therapeutics. Dr. Bates received her doctorate in pharmacy from the University of Illinois at Chicago and completed a research-based masters in biochemistry and biophysics from Northern Illinois University. She completed her oncology pharmacy residency at Duke University.

Evan Bryson, PharmD, BCOP, U.S. Food & Drug Administration

Session 1 Presenter and Panelist

Dr. Bryson is a clinical pharmacologist and clinical analyst in FDA's Oncology Center of Excellence (OCE). He supports the OCE's Project Renewal, a public health initiative that aims to update the labeling for certain older oncology drugs to ensure information is clinically meaningful and scientifically up to date. He received his PharmD from Presbyterian College School of Pharmacy and completed his hematology/oncology pharmacy residency at the Winship Cancer Institute of Emory University. His main interests include precision medicine and regulatory science.

Robert Diasio, MD, Mayo Clinic Cancer Center

Session 1 Presenter and Panelist

Dr. Diasio is currently Director Emeritus of the Mayo Clinic Cancer Center. He held the Director position for 14 years between 2006 and 2020. At Mayo Clinic he has held the position of William J. and Charles H. Mayo Professor, as well as Consultant and Professor in the Departments of Molecular Pharmacology & Experimental Therapeutics and Oncology. Dr. Diasio is the author of more than two hundred and fifty manuscripts and invited reviews and has received continuous NCI funding for more than 30 years. He has served on the editorial boards of various journals including *Cancer Research*, *Journal of clinical Oncology*, *Clinical Cancer Research*, and the *Journal of the National Cancer Center*, in addition to being inducted as a member of the American Society for Clinical Investigation, the American Association of Physicians, and the American Association for the Advancement of Science. Dr. Diasio's clinical interest continues to be in gastrointestinal oncology, with particular expertise in the predictive and prognostic role of genomic biomarkers. His basic research interest has focused mainly on the area of cancer pharmacogenetics/pharmacogenomics, having initially characterized dihydropyrimidine dehydrogenase (DPD) deficiency and subsequently developing genomic tests to predict DPD deficiency. Dr. Diasio received his undergraduate degree from the University of Rochester and his M.D. from Yale University School of Medicine.

Ravin Garg, MD, Johns Hopkins School of Medicine & Maryland Oncology Hematology

Fireside Chat Panelist, Session 2 Panelist

Dr. Garg is an Assistant Professor of Oncology at Johns Hopkins School of Medicine and a practicing medical oncologist at Maryland Oncology Hematology. He received his MD from the University of Chicago Pritzker School of Medicine, completed his residency at the University of Michigan-Ann Arbor, and finished his training with a hematology-oncology fellowship at MD Anderson Cancer Center. As an expert in medical education, a passion for and excellence in teaching have been central to Dr. Garg's career as demonstrated by extensive teaching service and awards received, including the founding of a leading Heme/Onc board exam review service. He maintains professorship at Johns Hopkins, where he staffs the fellows' clinic, conducts case-based weekly morning reports, and gives board review lectures, meanwhile balancing his private medical practice in Annapolis, MD.

Daniel Hayes, MD, FACP, FASCO, University of Michigan Rogel Cancer Center

Session 2 Panelist and Speaker, Session 3 Panelist

Dr. Hayes is the Stuart B. Padnos Professor of Breast Cancer Research at the University of Michigan Rogel Cancer Center. Dr. Hayes received undergraduate, master's and medical degrees from Indiana University, followed by residency in internal medicine at the University of Texas Southwestern Medical School and fellowship in medical oncology at Harvard's Dana Farber Cancer Institute. Dr. Hayes' expertise lies in experimental therapeutics and biomarkers for breast cancer, particularly focusing on biomarker development and validation. He has been instrumental in establishing international guidelines for the use of biomarker tests, including criteria for clinical utility. Dr. Hayes has long been active in the American Society of Clinical Oncology (ASCO), serving on its Board of Directors and for a three-year term as President. He is a fellow of ASCO and the American College of Physicians, a past Komen Scholar, an emeritus of the Breast Cancer Research Foundation, and a member of the Association of American Physicians and American Clinical and Climatologic Association. He was the recipient of the ASCO Gianni Bonadonna Award in Breast Cancer (2007), the ASCO Allen Lichter Visionary Leadership Award (2021), the Susan G. Komen Brinker Award for Scientific Distinction in Clinical Research (2023), and Indiana University Medical School's Distinguished Alumni Award (2024).

Daniel Hertz, PharmD, PhD, University of Michigan College of Pharmacy

Session 2 Speaker and Panelist

Dr. Hertz is an Associate Professor at the University of Michigan College of Pharmacy. He received his PharmD from Rutgers University, and his PhD from University of North Carolina under Dr. Howard McLeod. Dr. Hertz's research focuses on developing individualized treatment strategies for patients with cancer and translating them into clinical practice. He has particular interest in the development of biomarkers of taxane-induced peripheral neuropathy and dihydropyrimidine dehydrogenase (DPD) deficiency pharmacogenetic testing. He serves as a medical advisor to the Advocates for Universal DPD/DPYD Testing (AUDT).

Paul Kluetz, MD, U.S. Food & Drug Administration

Fireside Chat Moderator, Closing Speaker

Dr. Kluetz is a medical oncologist and the Deputy Director of the Oncology Center of Excellence at the U.S. FDA. In addition to assisting in the strategic and operational oversight of the OCE, he has a broad interest in trial design and endpoint selection to expedite drug development and define clinical benefit in oncology trials. Some of his initiatives include creation of the OCE's patient-focused drug development program and expansion and direction of OCE's efforts to advance real-world evidence, decentralized trial design and digital health technology. He is also active in regulatory review of oncology products and

oversees important oncology drug labeling initiatives. Dr. Kluetz remains clinically active, caring for patients and supervising medical residents at the Georgetown University Hospital.

Karen Merritt, Advocates for Universal DPD/DPYD Testing (AUDT)

Fireside Chat Panelist, Session 3 Panelist

Karen Merritt is a passionate and dedicated patient advocate who turned her personal tragedy into a mission to save lives. After losing her mother in 2014 due to fatal toxicity from her first infusion of 5-FU chemotherapy, a result of not being tested for DPD (dihydropyrimidine dehydrogenase) deficiency beforehand, Karen committed herself to raising awareness about the importance of pretesting for DPD deficiency before the administration of fluoropyrimidine-based chemotherapy. Karen is a founding member of Advocates for Universal DPD/DPYD Testing (AUDT), an organization focused on promoting mandatory pretesting to ensure patient safety and prevent chemotherapy-induced toxicities & fatalities. She actively engages with healthcare professionals and institutions to emphasize the need for personalized cancer care that includes pretreatment DPD testing. In addition to her work with AUDT, Karen serves as a Patient Representative for ClinGen PGx Working Group and the Standardizing Laboratory Practices in Pharmacogenomics (STRIPE) Collaborative Community. Her role in these groups reflects her commitment to improving clinical practices and standardizing testing protocols for better patient outcomes.

Sheheryar Muhammad, PharmD, BCCCP, BCCP, BCPS, CACP, U.S. Food & Drug Administration

Session 3 Presenter and Panelist

Dr. Muhammad earned his PharmD from the University of Maryland School of Pharmacy and went on to complete a post-graduate year 1 pharmacy residency at the University of Pittsburgh Medical Center. He is board-certified in critical care pharmacy, cardiology pharmacy, and pharmacotherapy. He is currently a Drug Utilization Team Lead in the Division of Epidemiology II (DEPI-II) within the Office of Surveillance and Epidemiology (OSE) at the U.S. Food and Drug Administration (FDA). During his tenure at the FDA, he has played a pivotal role in numerous reviews. He has received the FDA Commissioner's Special Citation awards for his work on COVID-19 and respiratory syncytial virus therapeutics. He has also received several Honor Awards at FDA for his work on the evaluation of various safety issues. Prior to joining the FDA, he practiced as a clinical pharmacy specialist in Critical Care/Acute Care. He has precepted many pharmacy and medical trainees over the years and currently holds an appointment as an Adjunct Clinical Assistant Professor at the Howard University College of Pharmacy in Washington D.C.

Michael Pacanowski, PharmD, MPH, U.S. Food & Drug Administration

Fireside Chat Panelist, Session 1 Moderator

Dr. Pacanowski is the Director of the Division of Translational and Precision Medicine within the FDA Office of Clinical Pharmacology. The Division works to support the development and approval of safe and effective drug products for rare diseases, as well as to overall improve the practice of precision medicine, through regulatory review, regulatory science research, policy development, and education/outreach. Dr. Pacanowski received his Pharm.D. from the University of the Sciences and his M.P.H. from the University of Florida. Dr. Pacanowski came to the FDA in 2008 after completing residency in clinical pharmacology at Bassett Healthcare in Cooperstown, NY and a clinical research fellowship in cardiovascular pharmacogenomics at the University of Florida.

Richard Pazdur, MD, U.S. Food & Drug Administration

Opening Speaker

Dr. Pazdur is the director of FDA's Oncology Center of Excellence (OCE), which leverages the combined skills of FDA's regulatory scientists and reviewers with expertise in drugs, biologics, and devices to expedite the development of novel cancer products. In this role, Dr. Pazdur leads the effort to develop and execute an integrated regulatory approach to enhance cross-center coordination of oncology product clinical review. Prior to joining FDA in 1999, Dr. Pazdur was professor of medicine at The University of Texas M.D. Anderson Cancer Center. From 1982 to 1988, he served on the faculty of Wayne State University. He received his bachelor's degree from Northwestern University, his M.D. from Loyola Stritch School of Medicine, and completed clinical training at Rush-Presbyterian St. Luke's Medical Center and University of Chicago Hospitals and Clinics. Dr. Pazdur has published more than 600 articles, book chapters, and abstracts. He was recognized in Fortune's 2015 list of "50 World's Greatest Leaders." In 2016, he was named to Massachusetts General Hospital Cancer Center's "The One Hundred" list. In 2017, he was chosen as one of "The Bloomberg 50." In 2019, he was named one of OncLive's "Giants of Cancer Care." He has received numerous awards from professional societies including the American Society of Clinical Oncology, American Association for Cancer Research, National Coalition for Cancer Survivorship, LUNGevity Foundation, American Society for Clinical Pharmacology and Therapeutics, National Organization for Rare Disorders, Reagan-Udall Foundation for the FDA, and the FDA Alumni Association.

Bill (William) Pierce, PharmD, MPH, BCPS, U. S. Food & Drug Administration

Session 3 Moderator

Dr. Pierce is a clinical pharmacist who has served with the FDA for over 20 years in multiple roles. He currently works in the FDA's Oncology Center of Excellence (OCE) as the Senior Advisor of Oncology Labeling and Policy. In this role, he creates and executes best labeling practices to produce consistent, high quality, data-driven FDA-approved oncology drug information. This is accomplished through development of drug labeling guidance and policies, multidisciplinary consensus building, and negotiation with pharmaceutical manufacturers to ensure the safe and effective use of oncology drug and biological products. Prior to his current position, he was the FDA Associate Director for Labeling and an FDA Clinical Reviewer for oncology drug and biological products. Dr. Pierce received his Doctor of Pharmacy from the University of Connecticut, completed residency training at Yale-New Haven Hospital, and has a master's in public health (MPH) from the University of Massachusetts-Amherst.

Victoria Pratt, PhD, Agena Bioscience

Session 1 Presenter and Panelist, Session 3 Panelist

Dr. Pratt is a board-certified medical and clinical geneticist with extensive experience in the clinical laboratory industry and the Director of Scientific Affairs for Pharmacogenetics at Agena Bioscience. She is a past president of the Association for Molecular Pathology (AMP) and led a recent collaborative effort across AMP and various clinical genetics consortiums to create consensus recommendations for *DPYD* genotyping assays. She has served on the American Medical Association's Current Procedural Terminology Molecular Advisory Work Group, the Center for Medicare and Medicaid Service's Advisory Panel on clinical Diagnostic Laboratory Tests, the U. S. Secretary of Health and Human Services' Advisory Committee on Genetics, Health, and Society, among other influential committees. Her current academic interests include pharmacogenetic testing, molecular pathology coding, regulatory science, and reimbursement. She received her PhD in Medical and Molecular Genetics from Indiana University School of Medicine.

Asal Sayas, White House Office of Science and Technology Policy

Session 2 Panelist, Patient Perspective Speaker

Asal Sayas was most recently a Senior Advisor on the Health Outcomes Team in the White House Office of Science and Technology Policy and a Senior Advisor on President Biden's Cancer Moonshot. As part of these roles, she worked on advancing two clear goals that the President Biden and First Lady Jill Biden set: To prevent more than 4 million cancer deaths by 2047 and to improve the experience of people who are impacted by cancer. Asal began her career in policy working as a congressional aide in both the U.S. House of Representatives and the U.S. Senate. After leaving Capitol Hill Asal joined amfAR (The Foundation for AIDS Research), where she works

on domestic and global HIV policy. Asal believes that good policy is achieved when we allow people at the center of the experience to lead.

Robert Schuck, PharmD, PhD, U.S. Food & Drug Administration

Session 3 Panelist

Dr. Schuck is the Deputy Director of the Division of Translational and Precision Medicine (DTPM) in the Office of Clinical Pharmacology (OCP) at the FDA. DTPM is a multidisciplinary team consisting of translational scientists with clinical pharmacology, human genomics, epidemiology, and molecular biology expertise. The division focuses on regulatory review, research, and policy development in the areas of pharmacogenomics, biomarker qualification, drugs for rare diseases and inborn errors of metabolism, and genetically targeted therapies. Dr. Schuck has been at the FDA in various capacities since 2013. He received his PharmD from University of Michigan, and his PhD from UNC-Chapel Hill.

D. Max Smith, PharmD, PhD, MedStar Health

Session 1 Panelist

Dr. D. Max Smith, PharmD, BCPS is a Clinical Pharmacogenomics Specialist at MedStar Health and Assistant Professor at Georgetown University Medical Center. Dr. Smith earned a PharmD at the University of Toledo and is a board-certified pharmacotherapy specialist. At the University of Florida, he completed a PGY-1 hospital residency and completed a PGY-2 residency and fellowship specializing in pharmacogenetics. His overarching research interest is studying implementation and clinical outcomes from the application of pharmacogenetic information in prescribing decisions. In his current role, he facilitates implementation and oversight of clinical pharmacogenetic testing throughout MedStar Health. He also provides an electronic PGx consult service throughout MedStar Health.

Alan Venook, MD, University of California San Francisco

Session 2 Presenter and Panelist

Dr. Alan Venook is the Madden Family Distinguished Professor of Medical Oncology and Translational Research at UCSF and is the Shorenstein Associate Director for Program Development at the Helen Diller Family Comprehensive Cancer Center at UCSF. He was the founding Chairman of the NCI's Hepatobiliary Task Force, chaired the GI Committee of the Alliance for Clinical Trials in Oncology from 2010 -2016, and was an Associate Editor of the Journal of Clinical Oncology from 2010 - 2015. Dr. Venook earned his medical degree at UCSF, completed a residency in internal medicine at the University of California, Davis, and fellowship in hematology and oncology at UCSF. Afterwards, he served in the Commissioned Corps of the U.S. Public Health Service for two years. He has been a UCSF faculty member since 1988. Dr. Venook's expertise lies in the regional treatment of tumors in the liver and the development of new therapies for colorectal and liver cancers. It was his observation from data in a clinical advanced colorectal cancer study that helped define "sidedness", the phenomenon that colon cancers arising in the right colon are biologically different than those that arise on the

left side. Recently, his research group has turned its focus to understanding the interactions between immunotherapy and the microbiome as well as the marked increase in colorectal cancer in young adults.

Christina Wu, M.B., B.Ch., MD, Mayo Clinic Arizona

Session 3 Presenter and Panelist

Dr. Christina Wu is Professor in the Department of Internal Medicine, Division of Hematology/Oncology at Mayo Clinic Arizona. She is a board-certified medical oncologist and specializes in the treatment of gastrointestinal cancers. Her research focuses on colorectal cancers and drug development. Dr. Wu holds professional memberships with American Society of Clinical Oncology, NRG Oncology, and Academic and Community Cancer Research United (ACCRU). She received her MD degree from Trinity College Dublin, completed residency at the University of Massachusetts, and completed heme/onc fellowship at Georgetown University.