



**FDA-AACR Workshop**

**To Test or Not To Test – That Is The Question: DPD Deficiency And Weighing Potential Harms**

Bethesda Marriott Pooks Hill

January 16 | 9:00 AM – 3:00 PM ET

**Workshop Co-Chairs**

**Jennifer Gao, MD**, U.S. Food and Drug Administration

**Patricia LoRusso, DO, PhD (hc), FAACR**, Yale Cancer Center

**AGENDA**

**9:00 AM INTRODUCTION**

9:00 AM **Welcome & Introduction**  
Richard Pazdur, MD, U.S. Food and Drug Administration

9:05 AM **Workshop Overview**  
Patricia LoRusso, DO, PhD (hc), FAACR, Yale Cancer Center

**9:10 AM FIRESIDE CHAT**

- **Paul Kluetz, MD**, U.S. Food and Drug Administration
- **Michael Pacanowski, PharmD, MPH**, U.S. Food and Drug Administration
- **Karen Merritt**, Advocates for Universal DPD/DPYD Testing
- **Ravin Garg, MD**, Maryland Oncology Hematology

**9:40 AM BREAK**

**9:55 AM SESSION 1: CURRENT LANDSCAPE – DPD DEFICIENCY TESTS AND FDA PRODUCT LABELING**

9:55 AM **Moderator Introduction**  
Michael Pacanowski, PharmD, MPH, U.S. Food and Drug Administration

10:00 AM **The Importance of Dihydropyrimidine Dehydrogenase in 5-FU Treatment**  
Robert Diasio, MD, Mayo Clinic

10:05 AM **AMP's Recommendations for Clinical DPYD Genotyping Allele Selection**  
Victoria Pratt, PhD, Agena Bioscience

10:10 AM **Fluoropyrimidine and DPD Deficiency: A Regulatory History of FDA Labeling**  
Evan Bryson, PharmD, BCOP, U.S. Food and Drug Administration

**10:20 AM PANEL DISCUSSION**

**Additional Panelists**

- **Sam Abdelghany, PharmD, MHA, BCOP**, Smilow Cancer Hospital at Yale New Haven
- **D. Max Smith, PharmD, BCPS**, MedStar Health & Georgetown University
- **Jill Bates, PharmD, MS, BCOP, CPT, FASHP**, Department of Veterans Affairs

**11:05 AM BREAK**

**11:15 AM SESSION 2: CURRENT LANDSCAPE – CLINICAL CONSIDERATIONS AND EVIDENCE****11:15 AM Moderator Introduction**

**Jennifer Gao, MD**, U.S. Food and Drug Administration

**11:20 AM When Should a Tumor Biomarker be Applied in the Clinic?**

**Daniel Hayes, MD, FACP, FASCO**, The University of Michigan

**11:25 AM Clinical Utility of Pre-treatment for *DPYD* Testing**

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

**11:30 AM Guidelines and Diagnostics: Details Matter**

**Alan Venook, MD, FASCO**, The University of California, San Francisco

**11:35 AM PANEL DISCUSSION****Additional Panelists**

- **Asal Sayas**, Former White House Office of Science and Technology Policy
- **Jill Bates, PharmD, MS, BCOP, CPT, FASHP**, Department of Veterans Affairs
- **Ravin Garg, MD**, Maryland Oncology Hematology

**12:30 PM LUNCH BREAK (ON YOUR OWN)****1:30 PM SESSION 3: FUTURE DIRECTION – WHERE DO WE GO FROM HERE?****1:30 PM Moderator Introduction**

**William Pierce, PharmD, MPH, BCPS**, U.S. Food and Drug Administration

**1:35 PM Current State of *DPYD* Genotype Testing at Mayo Clinic**

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

**1:40 PM PANEL DISCUSSION****Additional Panelists**

- **Robert Schuck, PharmD**, U.S. Food and Drug Administration
- **Patricia LoRusso, DO, PhD (hc), FAACR**, Yale Cancer Center
- **Karen Merritt**, Advocates for Universal DPD/DPYD Testing
- **Alan Venook, MD**, The University of California, San Francisco
- **Victoria Pratt, PhD**, Agena Bioscience

**2:40 PM PATIENT PERSPECTIVE**

**2:40PM Asal Sayas**, Former White House Office of Science and Technology Policy

**2:50 PM CLOSING REMARKS**

**2:50 PM Paul Kluetz, MD**, U.S. Food and Drug Administration

**2:55 PM Patricia LoRusso, DO, PhD (hc), FAACR**, Yale Cancer Center