



American Society for Quality (www.asq.org) – Washington DC and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group (SIG) Meeting

“Conversation on New Cancer Drugs - Development, Approval, and Access”

To be presented by

Anthony J. Murgo, MD, MS, FACP
(anthony.murgo@fda.hhs.gov)

Associate Director for Regulatory Sciences

Office of Hematology Oncology Products

Center for Drug Evaluation and Research (CDER)

US Food and Drug Administration (FDA)

Thursday, February 28, 2013

6:00 – 6:20 PM – Networking; Pizza/drink

6:20 – 8:30 PM – Program (intermission at 7:40 pm)

8:30 – 8:45 PM – Door-prizes drawing; Networking

Online Registration site: <http://www.asq509.org/ht/d/DoSurvey/i/35817>

Open to Public –

\$5: [non-ASQ members to cover pizza/drink cost;](#)

Free: [ASQ Members, MJ-DC Members, veterans, senior citizens, students, interns, residents, postdocs, FDA Commissioner’s Fellows, and current job-seekers](#)

Location: Kelly’s Deli Conference Center, 7519 Standish Place, Rockville (Derwood, for GPS user), MD 20855

Registration Deadline: Please register by **Thursday noon, February 28, 2013.**

Question: Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG, ASQ509; gchang2008@yahoo.com or 240-793-8425 (cell).

Driving directions: By Cars: From I-270 (N or S bound): Take Exit 9A and exit from the FIRST right exit; turn left (east) onto Shady Grove Dr.; turn right (south) onto Rockville Pike (**Route 355**); turn left (east) onto East Gude Dr.; turn left (north) immediately onto Crabb’s Branch Dr.; turn left (west) immediately onto Standish Place. The first building on your right side is 7519 Standish Place; open parking). **The venue is on the first floor with its entrance opposite to the left side of building main entrance.** **By Metro trains:** Off from Red Line **Shady Grove Station**, and take RideOn **Route 59 TOWARD ROCKVILLE** and get off from “**Calhoun Place**” stop. Standish Place is next to the Bus stop. Our venue is within 2 min of walking distance from the stop.

Summary: Improved knowledge of cancer biology along with advances in biotechnology has created a number of opportunities and challenges. Increasing emphasis is placed on the development of **targeted therapeutics**. In the past, the majority of oncology drugs were considered cytotoxic because they were not directed specifically against a patient's tumor. Historically, pharmaceutical companies, for the most part, steered away from developing and marketing drugs for the treatment of cancer, especially for those indications that are relatively rare such as brain and pediatric cancer. But the tide has changed with greater opportunities for success in developing more **personalized or precision therapy**.

There is the opportunity to develop **biomarkers** that distinguish those patients who are likely to benefit from those who are not. There is the opportunity to improve the **efficiency** of drug development by using **predictive biomarkers** to enrich for patients more likely to respond, achieving larger, clear-cut treatment effects, with smaller, and more successful clinical trials. But the path of targeted drug development is often not straight-forward and requires a carefully thought-out scientific and regulatory strategy. Maneuvering along the path of **targeted drug development** can be particularly challenging when the therapeutic area is crowded or when two or more new agents are used in combination or when the development and use of the therapeutic product depends on a biomarker.

Accelerating the development of promising new oncology drugs and making them available as soon as possible is in the public interest. But moving too fast and taking unjustified shortcuts can be counter-productive. One way to avert delays and improve chances for success is to consult FDA as early as possible and throughout the development process.

Presenter's Bio: Anthony J. Murgo, MD, MS, FACP

Dr. Anthony J. Murgo is currently **Associate Director for Regulatory Science** in the FDA Office of Hematology and Oncology Products. Dr. Murgo has many years of experience in teaching and research in both academia and government service. Dr. Murgo received his MD in conjunction with a MS (Pathology and Immunology) in 1975 from the State University of New York Downstate Medical Center. He completed a medical residency at Maimonides Medical Center in Brooklyn and a fellowship in Hematologic Oncology at Memorial Sloan-Kettering Cancer Center in New York City. Dr. Murgo is board certified in Internal Medicine and Medical Oncology and is a Fellow of the American College of Physicians.

Dr. Murgo was also on the faculty of West Virginia University School of Medicine where he was **Professor of Medicine** in the Section of Hematology/Oncology until 1989, at which time he joined the FDA Center for Drug Evaluation and Research (CDER) as a **Medical Officer** in the Division of Oncologic Drug Products. In 1996 he continued in government service at the NIH National Cancer Institute (NCI), where he held several leadership positions at the NCI, including **Acting Chief** of the Investigational Drug Branch in the Cancer Therapy Evaluation Program, **Head of Early Clinical Trials Development** in the Division of Cancer Treatment and Diagnosis, and **Adjunct Investigator** and **Head** of the Developmental Therapeutics Section in the Center for Cancer Research, Medical Oncology Branch. At the NCI, Dr. Murgo was responsible for developing and conducting early phase clinical trials at the NIH Clinical Center.

Dr. Murgo returned to the FDA CDER in January 2009 in his present position as **Associate Director for Regulatory Science**. He is also **Adjunct Professor** of Medicine at the Uniformed Services University of the Health Sciences and a **Visiting Physician** and **Clinical Investigator** at the NIH Clinical Center. Dr. Murgo co-edited four books and is an author of more than 130 articles and book chapters.

This event is cosponsored by the Monte Jade Science and Technology Association of Greater Washington (www.MonteJadeDC.org).