



American Society for Quality ([www.asq.org](http://www.asq.org)) – Washington D.C. and Maryland Metro, Section 509 ([www.asq509.org](http://www.asq509.org))

**Biomed/Biotech Special Interest Group Meeting**

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**“Oncology Biopharmaceuticals and Preclinical Development - Evolving Regulatory Challenges”**

Presented by

**Michael Orr, PhD, DABT**

Senior Pharmacologist

Division of Biologic Oncology Products, Office of Oncology Drug Products,  
Center for Drug Evaluation and Review (CDER), FDA

and

**“Working with the FDA to Test A New Vaccine - Regulatory Science 101 for Basic Researchers”**

Presented by

**Stuart Shapiro, MD, PhD**

NIAID Program Officer & Team Leader

Center for HIV/AIDS Vaccine Immunology (CHAVI; [www.chavi.org](http://www.chavi.org))  
Vaccine Discovery Branch, Vaccine Research Program  
Division of AIDS, NIAID, NIH, DHHS

**May 28, 2009 (Thursday) Evening**

**6:00 PM – Networking and Pizza and soft drink with a door prize**

**6:15 - 9:10 PM – Program**

**9:10 – 9:15 PM – Door-prize drawing and networking**

***Open and free to the public***

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**Location:**

**Kelly’s Deli Conference Center, 7519 Standish Place, Rockville, MD 20855**

**Driving directions:**

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 conference room is on the first floor with its entrance opposite to the left side of building main entrance.

**For headcount purpose, please register by Thursday noon, May 28, 2009.**

**Registration Website: <http://www.asq509.org/ht/d/DoSurvey/i/35817>**

For registration problems or further information contact **Dr. George Chang**, Co-Chair of

Biomed/Biotech SIG, at [gchang2008@yahoo.com](mailto:gchang2008@yahoo.com) or call **240-793-8425**.

## 5/28/09 Event Speakers' Bios:

**Michael S. Orr, PhD, DABT** ([michael.orr@fda.hhs.gov](mailto:michael.orr@fda.hhs.gov)), is currently a **Pharmacology and Toxicology Reviewer in the Division of Biologic Oncology Products, Office of Oncology Drug Products, CDER, FDA**. He is responsible for thorough scientific evaluation of non-clinical data at various stages of the products life-cycle and collaboratively works with the review team members to promote the development of safe and effective therapeutic proteins, drug-protein conjugate products, and small molecule oncology products. Previously at the FDA (2005-2007), he worked for two years in the Office of Clinical Pharmacology, CDER in which he played a dual role as both a Genomic Reviewer and Clinical Pharmacology Reviewer for small molecule oncology products.

Prior to joining the FDA, Dr. Orr worked his way up from a Staff Scientist to a Director in the Department of Toxicogenomics and acquired approximately 6 years of industry experience in the fields of toxicology, molecular toxicology, and toxicogenomics.

Dr. Orr received his PhD in Pharmacology and Toxicology from the Medical College of Virginia/Virginia Commonwealth University (1996) and his BS in Biochemistry from Texas A&M University (1991). Dr. Orr performed his postdoctoral training in the Department of Molecular Pharmacology at the National Cancer Institute, the National Institutes of Health (NCI/NIH) from 1996 to 1999. In 2004 he became a Diplomat of the American Board of Toxicology. Dr. Orr is a full member of the Society of Toxicology, American Association for Cancer Research, and Councilor for the NCAC-SOT. Dr. Orr is an author and/or co-author on 21 publications.

**Stuart Z. Shapiro, MD, PhD** ([sshapiro@niaid.nih.gov](mailto:sshapiro@niaid.nih.gov)), is currently a **Medical/Program Officer in the Vaccine Discovery Branch of the Vaccine Research Program, Division of AIDS (DAIDS), NIAID/NIH**. His primary assignment is scientific/clinical research/program involvement and Government oversight in the conduct and operation of the Center for HIV/AIDS Vaccine Immunology (CHAVI), a large NIH-funded extramural center for basic research in HIV/AIDS vaccine discovery. He was the Program Officer for CHAVI during its competition and has been its NIAID Scientific Coordinator since the Center was awarded in July, 2005.

Dr. Shapiro obtained his B.A. degree in Biochemistry from the University of California at Berkeley (1969), and his Ph.D. (Molecular Biology; thesis research on retrovirus protein synthesis) and M.D. degrees in 1977 from Albert Einstein College of Medicine of Yeshiva University. He underwent medical internship training at Los Angeles County Harbor General Hospital after which he was a postdoctoral fellow and then a core Staff Scientist in tropical parasitic disease vaccine development for eight years at the International Laboratory for Research on Animal Diseases (ILRAD) in Nairobi, KENYA. He continued in parasitic disease vaccine research as an Assistant Professor of Veterinary Microbiology & Immunoparasitology and taught in courses on Immunology, Parasitology, and African Health Problems at the University of Illinois (Urbana-Champaign) from 1987 to 1993. After his first wife was diagnosed with AIDS, Dr. Shapiro made a major shift in his career to work on HIV/AIDS vaccine development. He joined the Division of Viral Products, Office of Vaccines, CBER/FDA in 1993 as a laboratory-based reviewer and Senior Staff Fellow in Retrovirology (HIV/AIDS). In 1998, following 4 years at the FDA, Dr. Shapiro made a brief foray into industry as the sole proprietor of a regulatory affairs consultancy and vaccine design company.

With his experiences at the FDA and his own company, Dr. Shapiro came to work in DAIDS in September 1999 very aware of the difficulties vaccine developers face in getting their products into clinical trials. In his early years at DAIDS he authored a review (Shapiro, S.Z., VACCINE 2002; 20: 1261-1280) that attempts to explain to academic HIV/AIDS vaccine researchers, in plain English, what the FDA wants from them; he received an NIH Plain Language Award in 2001 for this review (as well as the distinction of being the only scientist to publish his cheesecake recipe in the journal VACCINE). When he started work at DAIDS, Dr. Shapiro's efforts focused on management of grants and contracts designed to facilitate the transition of new vaccine designs into early-phase clinical trials. He thought then, perhaps a bit naively as most others in the field, that all that was required was to get more candidate HIV/AIDS vaccines into clinical testing and we would see something that worked and could run with it. However, since coming to work in DAIDS, more than a dozen new vaccine modalities have entered clinical trials and none have performed well. Thus in recent years Dr. Shapiro has shifted his work within DAIDS to more of a focus on basic research that will inform novel HIV/AIDS vaccine design (and other prevention strategies). Dr. Shapiro's commitment to work on HIV/AIDS is as much a life choice as a career choice; and he believes that one can express/advance one's personal values through working in Science as well as collect a paycheck.

