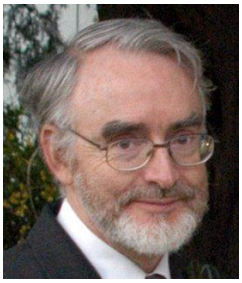
**Observational Medical Outcomes Partnership (OMOP) Symposium**
**June 28, 2012 – Panelists**
**Bethesda North Marriott & Conference Center | North Bethesda, MD 20852, USA**

**Michael Berkwits, MD, MSCE, Deputy Editor, *Annals of Internal Medicine*, Adjunct Associate Professor of Medicine, Perelman School of Medicine at the University of Pennsylvania**

Dr. Berkwits received his medical education and training at the University of Illinois in Chicago, University of Michigan in Ann Arbor, and University of Pennsylvania, and previously held editorial positions at the Journal of General Internal Medicine and The Merck Manuals. As an Annals Editor, he is responsible for promoting high standards of research reporting and for developing innovations to communicate and disseminate evidence on new electronic platforms. In 2011, he became Secretariat of the International Committee of Medical Journal Editors (ICMJE).

**Stephen Evans, BA MSc C Stat FRCP (Edin) FISPE, Professor of Pharmacoepidemiology, London School of Hygiene & Tropical Medicine**



Dr. Evans is Professor of Pharmacoepidemiology at The London School of Hygiene and Tropical Medicine, and Immediate Past-President of the International Society of Pharmacoepidemiology. After training in physics and chemistry he worked in statistics and computing at The London Hospital and Medical College for 25 years, then Head of Epidemiology at the UK Medicines Control Agency.

He is currently a co-opted member of the Pharmacovigilance (Drug Safety) Working Party at the European Medicines Agency and a member of the WHO Global Advisory Committee on Vaccine Safety. He was a statistical advisor to the British Medical Journal for 20 years and is an Associate Editor of the Journal of Pharmacoepidemiology and Drug Safety.

**Ralph I. Horwitz, MD, MACP, Senior Vice President for Clinical Evaluation Sciences and Senior Advisor to the Chairman of Research and Development, GlaxoSmithKline**

Dr. Horwitz is Senior Vice President for Clinical Evaluation Sciences and Senior Advisor to the Chairman of Research and Development at GlaxoSmithKline, and Harold H. Hines, Jr. Professor Emeritus of Medicine and Epidemiology at Yale University. Dr. Horwitz trained in internal medicine at institutions (Royal Victoria Hospital of McGill University and the Massachusetts General Hospital). These experiences as a resident unleashed a deep interest in clinical research training which he pursued as a fellow in the Robert Wood Johnson Clinical Scholars Program at Yale under the direction of Alvan R.Feinstein.

He joined the Yale faculty in 1978 and remained there for 25 years as Co-Director of the Clinical Scholars Program and later as Chair of the Department of Medicine. Before joining GSK, Dr. Horwitz was Chair of Medicine at Stanford and Dean of Case Western Reserve Medical School. He is an elected member of the Institute of Medicine of the National Academy of Sciences; the American Society for Clinical Investigation; the American Epidemiological Society; and the Association of American Physicians (he was President in 2010). He was a member of the Advisory Committee to the NIH Director (under both Elias Zerhouni and Francis Collins). Dr. Horwitz served on the American Board of Internal Medicine and was Chairman in 2003. He is a Master of the American College of Physicians.

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**Sharon-Lise T. Normand, PhD, Professor of Health Care Policy, Harvard Medical School, and Professor, Department of Statistics, Harvard School of Public Health**

Dr. Normand's research focuses on the development of statistical methods for health services and outcomes research, primarily using Bayesian approaches, including causal inference, provider profiling, item response theory, latent variables analyses, multiple informants analyses, and evaluation of medical devices in randomized and non-randomized settings. Serving on several task forces for the American Heart Association and the American College of Cardiology, was a consultant to the US FDA's Circulatory System Devices Advisory Panel after serving a four-year term on the panel, is a member of the Medicare Evidence Development and Coverage Advisory Committee, and is Director of Mass-DAC, a data coordinating center that monitors the quality of all adult cardiac surgeries and coronary interventions in all Massachusetts' acute care hospitals.

She has served on several editorial boards including *Biometrics*, *Statistics in Medicine*, *Health Services and Outcomes Research Methodology*, *Psychiatric Services*, and *Cardiovascular Quality and Outcomes*. She was the 2010 President of the Eastern North American Region of the International Biometrics Society and is Vice Chair of the Patient Centered Outcomes Research Institute's Methodology Committee. She earned her Ph.D. in Biostatistics from the University of Toronto, holds a Master's of Science as well as a Bachelor of Science degree in Statistics, and completed a post-doctoral fellowship in Health Care Policy at Harvard Medical School. She is a Fellow of the American Statistical Association, a Fellow of the American College of Cardiology, a Fellow of the American Heart Association, and an Associate of the Society of Thoracic Surgeons. In 2011, Dr. Normand was awarded the American Statistical Association Health Policy Statistics Section's Long Term Excellence Award.

**Robert T. O'Neill, PhD, Senior Statistical Advisor, CDER, FDA**

Dr. O'Neill is currently the Senior Statistical Advisor to CDER in the Office of Translational Sciences in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration. Up until June, 2011, Dr. O'Neill was the Director of the Office of Biostatistics which provides biostatistical and scientific computational leadership and support to all programs of CDER. Prior to October 1998 he was Director of the Office of Epidemiology and Biostatistics, responsible also for the post-market safety surveillance of new drugs.

In 1989-1990, Dr. O'Neill was a visiting professor at the Department of Research, University Medical School, Basel, Switzerland, where he developed and presented numerous lectures and created a course series Topics in Therapy Evaluation and Review (TITER) for European pharmaceutical scientists, which was the model for the European Course in Pharmaceutical Medicine (ECPM), a degree granting graduate program. He is a fellow of the American Statistical Association (1985), a member of several professional societies, a past Member of the Board of Directors of the Society for Clinical Trials, the 2002 recipient of the Marvin Zelen Leadership Award in Statistical Science, and the 2004 Lowell Reed Lecture Awardee from the American Public Health Association.

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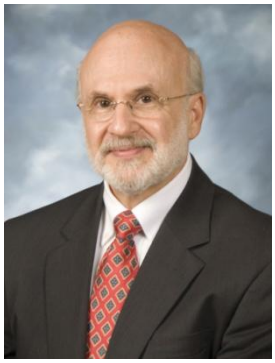
**Stephen P. Spielberg, MD, PhD, Deputy Commissioner for Medical Products and Tobacco, US Food and Drug Administration**



Dr. Spielberg is Deputy Commissioner for Medical Products and Tobacco of the US Food and Drug Administration. A pediatrician and pharmacologist, Spielberg was most recently the Marion Merrell Dow Chair in Pediatric Pharmacogenomics, and Director of the Center for Personalized Medicine and Therapeutic Innovation at Children's Mercy Hospital in Kansas City. Previously, he served as Dean of Dartmouth Medical School and Vice President for Health Affairs at Dartmouth College in Hanover, NH.

From 1997-2003, Dr. Spielberg was Johnson and Johnson's Vice President for Pediatric Drug Development and, prior to that, was Executive Director at Merck and Co.'s Research Laboratories. During that time, he was Chairman of the Pediatric Task Force at PhRMA, the drug industry's trade association. He received his bachelor's degree in biology from Princeton University, and an MD and PhD (Pharmacology) from the University of Chicago.

**Miriam Sturkenboom, PhD, Professor in Pharmacoepidemiology, Department of Medical Informatics, Erasmus University Medical Center**

Dr. Sturkenboom is a professor in pharmacoepidemiology at the department of Medical Informatics of the Erasmus University Medical Center in the Netherlands. She has a PhD from the Faculty of Mathematics and Physics in Groningen (cum laude), a pharmacy degree and a Master in Epidemiology from the Harvard School of Public Health. Her research group focuses on knowledge discovery from data collected in routine health care. Her research interest is to study drug and vaccine safety in large populations through the creation of national and most importantly international networks of databases.

Successful projects with respect to international data linkage are EU-ADR, SOS, ARITMO, ARPEC, SAFEGUARD, GRIP, and the VAESCO European Vaccines Safety Datalink. She is past president of the International Society of Pharmacoepidemiology and holds advisory roles in several organizations/institutions. Miriam Sturkenboom has published over 200 journal articles in peer-reviewed journal articles in the field of (pharmaco)epidemiology.

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**Alexander M. Walker, MD, DrPH, Principal, World Health Information Science Consultants, LLC**

Dr. Walker is Principal of World Health Information Science Consultants, a US-based firm that conducts research in the safety of drugs, devices, vaccines, and medical procedures. He is a former professor and Chair of the Department of Epidemiology at the Harvard School of Public Health. Dr. Walker's current and recent work includes post-marketing safety studies for recently approved drugs, natural history of disease studies, studies of the impact of drug labeling and warnings on prescribing behavior, and determinants of drug uptake and discontinuation. Additional areas of research and expertise include health effects of chemicals used in the workplace and statistical methods in epidemiology.

Dr. Walker received an MD degree from Harvard Medical School in 1974, and a doctorate of Public Health in Epidemiology from the Harvard School of Public Health in 1981. Dr. Walker is on the editorial board of Pharmacoepidemiology and Drug Safety. Dr. Walker Board served as President in 1995-1996 of the International Society for Pharmacoepidemiology, and was a member of that group's Board of Directors from 2005-2011. He was a statistical consultant for the New England Journal of Medicine from 1992 through 1996 and a Contributing Editor of The Lancet from 1999 through 2001. From 2000 through 2007, he served as Senior Vice President for Epidemiology at Ingenix, a US-based medical information company. Dr. Walker has written or contributed to over 250 peer-reviewed articles in drug safety, epidemiology and occupational health, and is the author of a book of essays, Observation and Inference: An Introduction to the Methods of Epidemiology.