

**DAY 1: Tuesday, March 16, 2010**

7:30 a.m. **Registration in Grand Foyer**

8:00 a.m. **Continental Breakfast in Grand Foyer**

9:00 a.m. **FDA Welcome**

Courtney Harper, Ph.D., Director, Division of Chemistry and Toxicology Devices, Center for Devices and Radiological Health, Silver Spring, Maryland

9:05 a.m. **Opening Remarks**

Jeffrey E. Shuren, M.D., J.D., Director, Center for Devices and Radiological Health

**Session 1: Clinical Accuracy Requirements for Blood Glucose Meters**

9:15 a.m. **Moderator's Introduction of Session 1**

William L. Clarke, M.D., University Of Virginia School Of Medicine, Charlottesville, Virginia

9:25 a.m. **FDA Perspective: FDA Evaluation of Point of Care Blood Glucose Meters**

Patricia Bernhardt, M.T.(ASCP), Office of in Vitro Diagnostic Device Evaluation and Safety

9:50 a.m. **Analytical Performance of Blood Glucose Meters: State of the Art**

Mitchell Scott, Ph.D., Washington University School of Medicine, St. Louis, Missouri

10:15 a.m. **Clinical Perspective: Clinical Need for Tighter Performance Requirements**

David B. Sacks, M.D., M.B., Ch.B., Harvard Medical School and Brigham and Women's Hospital, Boston, Massachusetts

10:40 a.m. Break in Grand Foyer

11:00 a.m. **Clinical Perspective: Clinical Needs Relative to Insulin Dosing**

Marc Breton, Ph.D., University of Virginia, Charlottesville, Virginia

11:25 a.m. **Industry Perspective: Tighter Performance Criteria for Blood Glucose Meters; Are They Needed?**

Steve Brotman, M.D., J.D., Advanced Medical Technology Association (AdvaMed)



11:50 a.m. **Industry Perspective: Tighter Performance Criteria Are Achievable and Appropriate**

Barry Ginsberg, M.D., Ph.D., Diabetes Consultants, Wyckoff, New Jersey

12:15 p.m. Lunch on your own

1:30 p.m. **Session 1 Panel Discussion**

Added panel members: David C. Klonoff, M.D., F.A.C.P., Mills-Peninsula Health Services, San Mateo, California; Ellen H. Ullman, MSW, Close Concerns, Boca Raton, Florida; Alberto Gutierrez Ph.D., and; Courtney Harper, Ph.D.

**Session 2: Blood Glucose Meter Performance, Interferences and Limitations**

2:30 p.m. **Moderator's Introduction of Session 2**

Gary L. Myers, Ph.D., Division of Laboratory Sciences at the Centers for Disease Control and Prevention, Atlanta, Georgia

2:40 p.m. **FDA Perspective: Public Health Notification: Potentially Fatal Errors with GDH-PQQ Glucose Monitoring Technology**

Courtney Harper, Ph.D.

3:05 p.m. Break in Grand Foyer

3:20 p.m. **Analytical Interferences and Physiological Limitations of Blood Glucose Meters**

Ken Ervin, Ken Ervin Consulting Services, Brentwood, California

3:45 p.m. **Industry Perspective: Barriers to Overcoming Interferences and Limitations**

Alan Cariski, M.D., J.D., FACP, FACE, LifeScan, Inc.  
Mike Flis, Roche

4:10 p.m. **Session 2 Panel Discussion**

5:00 p.m. **Day 1 Closing Remarks**

Courtney Harper, Ph.D.



**DAY 2: Wednesday, March 17, 2010**

8:00 a.m. **Continental Breakfast in Grand Foyer**

9:00 a.m. **Day 2 Welcome**

Courtney Harper, Ph.D., Director, Division of Chemistry and Toxicology Devices, Center for Devices and Radiological Health, Silver Spring, Maryland

9:10 a.m. **Keynote Address: Liability Issues In The Use of Blood Glucose Meters**

Jack R. Bierig, Sidley Austin LLP, Chicago, Illinois

**Session 3: Tight Glycemic Control**

9:40 a.m. **Moderator's Introduction of Session 3**

Irl B. Hirsch, M.D., University of Washington Medical Center, Seattle, Washington

9:50 a.m. **FDA Perspective: Regulatory Challenges for Safe use of Blood Glucose Meters in Hospital Settings**

Carol Benson, M.S., M.T.(ASCP), Division of Clinical Chemistry and Toxicology Devices

10:15 a.m. **Payer Perspective: Reimbursement Issues Associated with Glycemic Control**

Jim Rollins, M.D., Ph.D., MSHA, Centers for Medicare and Medicaid Services, Baltimore, Maryland

10:40 a.m. Break in Grand Foyer

11:00 a.m. **Advantages of Tight Glycemic Control in Hospital Settings**

Richard Bergenstal, M.D., International Diabetes Center at Park Nicollet, Minneapolis, Minnesota

11:25 a.m. **Why Tight Glycemic Control May Not be Appropriate in Hospital Settings**

Dieter Mesotten, M.D., Ph.D., University Hospitals Leuven, Belgium

11:45 a.m. **Current Practice and Experiences with Tight Glycemic Control in Hospital Settings**

Irl B. Hirsch, M.D.



- 12:10 p.m. Lunch on your own
- 1:30 p.m. **Session 3 Panel Discussion**  
Additional panel member: Patricia Beaston, M.D., Ph.D., Office of Device Evaluation
- 2:30 p.m. **How Meters are Used at Home and How Consumers Choose Meters**  
Ellen H. Ullman, MSW, Close Concerns, Boca Raton, Florida
- 2:55 p.m. **Risk Mitigation in Hospitals**  
Dawn Hanson, MS MLS(ASCP), DLM, St. Agnes Hospital, Baltimore, Maryland
- 3:20 p.m. **Wrap-up; Where do we go from here?**  
David C. Klonoff, M.D., F.A.C.P.
- 3:30 p.m. **Closing Comments**  
Alberto Gutierrez, Ph.D.
- 3:40 p.m. **Meeting Adjourns**