

*March 8 & 9, 2011*  
**DTC Advisory Panel Meeting: Day 1**  
**Gaithersburg Holiday Inn**

**Panel Chairperson**  
John Waterson, M.D.

**Designated Federal Officer**  
James Swink

- 8:00 AM** Call to Order  
Conflict of Interest and Deputization to Voting Member Status Statements  
Panel Introductions
- 8:15 AM** Why are we here? History and landscape of DTC genetic tests  
Elizabeth Mansfield, PhD, Director, Personalized Medicine Staff, OIVD, FDA
- 8:45 AM** Research background: Genome-wide association studies and clinical applications  
Teri Manolio, MD, PhD, Director, Office of Population Genomics, Senior Advisor to the Director, NHGRI, for Population Genomics
- 9:15 AM** Regulating consumer genetics – an overview of global trends  
Stuart Hogarth, PhD, Global Biopolitics Research Group, Department of Political Economy, King's College London
- 10:00 AM** Benefits, harms and value of knowing genetic information  
Nancy S. Wexler, PhD, Higgins Professor of Neuropsychology, Columbia University
- 10:30 AM** Break
- 10:45 AM** Considerations, pros and cons of offering genetic tests DTC  
Daniel B. Vorhaus, JD, Robinson, Bradshaw & Hinson, P.A., Editor, Genomics Law Report
- 11:15 AM** The Multiplex Initiative - Effects Of Genetic Susceptibility Testing In Healthy Populations; Potential Risks And Mitigations  
Colleen McBride, PhD, Chief & Senior Investigator, Social and Behavioral Research Branch, Head, Public Health Genomics Section, NHGRI
- 11:45 AM** Impact of Consumer Genome-wide Disease Risk Profiling: The Scripps Genomic Health Initiative.  
Cinnamon S. Bloss, PhD, Assistant Professor, Scripps Translational Science Institute, Scripps Health & The Scripps Research Institute
- 12:15 PM** Lunch
- 1:15 PM** Open Public Hearing\*
- 2:15 PM** FDA Questions & Panel Deliberations (first/second set of questions)
- 3:15 PM** Break
- 3:30 PM** FDA Questions & Panel Deliberations Continued
- 6:00 PM** Adjourn



*March 8 & 9, 2011*  
**DTC Advisory Panel Meeting: Day 2**  
**Gaithersburg Holiday Inn**

**Panel Chairperson**

John Waterson, M.D.

**Designated Federal Officer**

James Swink

- 8:00 AM** Call to Order  
Conflict of Interest and Deputization to Voting Member Status Statements  
Panel Introductions
- 8:15 AM** Current evidence requirements of safety and effectiveness:
- FDA evaluation of prescription genetic tests  
Reena Philip, PhD, Deputy Director, Division of Immunology and Hematology, OIVD
  - FDA regulation of at-home testing  
Carol Benson, Deputy Director, Division of Chemistry and Toxicology, OIVD
- 9:00 AM** Risk assessment tests  
Marina Kondratovich, PhD, Associate Director for Clinical Studies, Personalized Medicine Staff, OIVD
- 9:30 AM** Break
- 10:00 AM** FDA Questions and Panel Deliberations (second set of questions)
- 12:00 PM** Lunch
- 1:00 PM** Open Public Hearing\*
- 2:30 PM** FDA Questions & Panel Deliberations (third set of questions)
- 3:30 PM** Break
- 3:45 PM** FDA Questions & Panel Deliberations Continued
- 5:30 PM** Closing Remarks
- 6:00 PM** Adjourn

**\*Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.

