

**MEETING MINUTES  
OF THE  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
  
MEDICARE EVIDENCE DEVELOPMENT AND  
COVERAGE  
ADVISORY COMMITTEE**

February 25, 2009

Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Woodlawn, Maryland

# **Medicare Evidence Development and Coverage Advisory Committee**

**February 25, 2009**

## **Attendees**

### **Chair**

Barbara McNeil, M.D., Ph.D.

### **Vice-Chair**

Steven Pearson, M.D., M.S.C.

### **Panel Members**

Linda A. Bergthold, Ph.D.

Mina Chung, M.D.

Marion Danis, M.D.

Catherine Eng, M.D.

Mark D. Grant, M.D.

Clifford Goodman, Ph.D.

James Puklin, M.D.

Maren T. Scheuner, M.D., M.P.H.

Teresa M. Schroeder, B.S., M.B.A.

Deborah Shatin, Ph.D.

### **CMS Liaison**

Steve E. Phurrough, M.D., M.P.A.

### **Industry Representative**

Eleanor M. Perfetto, Ph.D., M.S.

### **Guest Speaker:**

Ralph Coates, Ph.D.

### **Guest Panelists:**

Steve Gutman, M.D.

Neil Holtzman, M.D.

### **Executive Secretary**

Maria A. Ellis

**Wednesday, February 25, 2009, 8:11 a.m.**

The Medicare Evidence Development and Coverage Advisory Committee met on February 25, 2009, to discuss the evidence, hear presentations and public comments, and make recommendations concerning the requirements for evidence to determine if diagnostic use of genomic testing and beneficiaries, with signs or symptoms of disease, improves health outcomes in Medicare beneficiaries.

The meeting began with a discussion of conflict of issue matters, opening remarks by the CMS liaison and chair, followed by an introduction of the panel members.

**CMS Presentation and Voting Questions**

Maria Ciccanti from CMS presented the panel with the goals and agenda for the meeting and read the questions that would be discussed and voted upon by the panel.

Jeffrey Roche from CMS provided context for the questions.

**Technology Assessment Presentation**

Results of the technology assessment were presented by Thomas A. Trikalinos, a representative from Tufts-New England Medical Center.

**Guest Speaker**

The panel heard from one invited guest speaker, Ralph J. Coates, Ph.D, who spoke about EGAPP in methods for assessing evidence for health improvements from the use of genomic tests.

**Scheduled Public Speakers**

The panel heard from several scheduled public speakers: a representative of the contractor medical director new technology work group; the Professor of Pathology at the Mount Sinai Hospital and School of Medicine in Manhattan; Bruce Quinn, M.D. from the law firm of Foley Hoag; the Vice President, Clinical Practices & Therapeutics, Medco

Health Solutions, Inc.; the Vice President, Programs, Center for Medical Technology Policy; the Vice President, Policy and Medical Affairs, American Clinical Laboratory Association; and the Medical Director, Molecular Oncology, Blood Center of Wisconsin.

### **Questions**

An extensive question and answer session was held between the panel, the presenters, and those who made comments.

### **Initial Panel Discussion**

The panel conducted an extensive discussion prior to casting their votes.


### **Formal Remarks and Voting**

The panel voted on the voting questions. Panelists displayed their numerical votes to be recorded by staff. Each panelist then explained the reasoning behind their vote.

### **Adjournment**

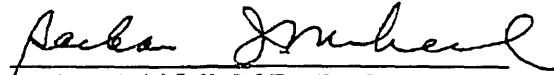
The meeting was adjourned at 3:15 p.m.

I certify that I attended the meeting of the  
MEDCAC Committee on February 25,  
2009, and that these minutes accurately  
reflect what transpired.

  
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Maria A. Ellis

Executive Secretary, MedCAC, CMS

I approve the minutes of this meeting  
as recorded in this summary.

  
Barbara McNeil, M.D., Ph.D.

Chair