

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

**September 22, 2010**

**Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland**

**Medicare Evidence Development & Coverage Advisory Committee**

**September 22, 2010**

**Attendees**

Clifford Goodman, Ph.D.  
Chairperson

Saty Satya-Murti, M.D., F.A.A.N.  
Vice-Chairperson

Maria A. Ellis  
Executive Secretary

Voting Members

Ray Baker, M.D.  
Kevin J. Bozic, M.D., M.B.A.  
Helen Darling, M.A.  
Charles Davis, III, M.D., Ph.D.  
Jeffrey G. Jarvik, M.D., M.P.H.  
Susan Kendig, J.D., M.S.N.  
Edward Kim, M.D., M.B.A.  
Courtland G. Lewis, M.D.  
Robert McDonough, M.D., J.D.  
J. Sanford Schwartz, M.D.  
Andrew Sloan, M.D., F.A.C.S.  
Robert L. Steinbrook, M.D.

CMS Liaison

Tamara Syrek Jensen, J.D.

Industry Representative

Peter Juhn, M.D., M.P.H.

Guest Panel Members

John S. Kirkpatrick, M.D., F.A.C.S.  
Raj Rao, M.D.

Invited Guest Speaker

Julie Glowacki, Ph.D.

**Wednesday, September 22, 2010, 8:30 a.m.**

The Medicare Evidence Development & Coverage Advisory Committee met on September 22, 2010, to discuss the evidence, hear presentations and public comment, and make recommendations concerning currently available evidence regarding the clinical benefits and harms of on-label and off-label use of bone morphogenetic protein, BMP.

The meeting began with a reading of a conflict of interest statement, welcoming remarks, and an introduction of the Committee.

**CMS Presentation and Voting Questions.** A CMS representative presented the panel and audience with a summary of the development as well as current FDA approval status regarding BMPs, the specific types of BMP and clinical indications that would be considered by the panel, an explanation of the voting scale to be used, and the voting and discussion questions that would be considered by the panel.

**Presentation by Invited Guest Speaker.** The panel heard a presentation from Dr. Julie Glowacki, from Harvard Medical School, describing the basic and technical vocabulary used in the study and application of BMPs; a summary of the research and development regarding molecular, cellular and tissue issues through the preclinical stage; and the translational research questions remaining to be addressed.

**Presentation of Technology Assessment.** The panel heard a presentation from the associate director of the Blue Cross Blue Shield Association Technology Evaluation Center concerning their technology assessment performed under contract to AHRQ. Following the presentation, there was limited time for the panelists to question the presenter before moving on to public comments.

**Scheduled Public Comments.** The panel heard from a total of five scheduled speakers, including a clinician, three professional society representatives, and one manufacturer representative.

**Open Public Comments.** The panel heard from one member of the public, a consultant to medical technology companies and investors.

**Questions to Presenters.** The panel posed questions to the presenters.

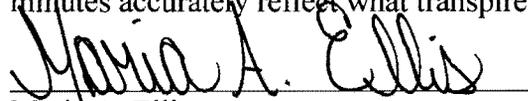
**Initial Open Panel Discussion.** The panel conducted discussion on each of the voting questions posed by CMS. During the discussion, it was decided to divide question 1.A(1) into two parts, with separate votes for the PMA indication and HDE indication.

**Formal Remarks and Voting Questions.** The panel turned its attention to the voting questions, with focused additional discussion before votes on each question. The results of the voting were announced by individual panelists, are included in the transcript, and were recorded by staff.

**Final Open Panel Discussion.** After resolution of the voting questions, the panel discussed question seven, the non-voting question.

**Adjournment.** The meeting adjourned at 2:50 p.m.

I certify that I attended the meeting  
of the Medicare Evidence Development &  
Coverage Advisory Committee on  
September 22, 2010, 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.



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Clifford Goodman, Ph.D.  
Chairperson