February 10, 2011

These summary minutes for February 10, 2011 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on June 20, 2011.

I certify that I attended the February 10, 2011 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/ Caryn Cohen, M.S.
Designated Federal Official, TPSAC

/s/ Jonathan Samet, M.D., M.S.
Committee Chair, TPSAC
The Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on February 10, 2011 at the Center for Tobacco Products, 9200 Corporate Blvd., Rockville, Maryland, 20850. Prior to the meeting, committee members and invited guests were provided copies of the background material from the FDA and the submissions from the public. The meeting was called to order by Jonathan Samet, M.D., M.S. (Committee Chair); the conflict of interest statement was read into the record by Caryn Cohen, M.S. (Designated Federal Official). There were approximately 100 persons in attendance. There were 7 speakers for the Open Public Hearing session.

**Agenda:** On February 10, 2011, the Committee 1) received an update on the Menthol Report Subcommittee; and 2) received and discussed presentations regarding the data requested by the Committee at the March 30–31, 2010 meeting of the Tobacco Products Scientific Advisory Committee.

**Attendance:**

**Tobacco Products Scientific Advisory Committee (Voting):**
Jonathan Samet, M.D., M.S. (Committee Chair)
Neal Benowitz, M.D.
Mark Clanton, M.D., M.P.H.
Karen DeLeeuw, M.S.W. (State/Local Government)
Dorothy Hatsukami, Ph.D.
Patricia Nez Henderson, M.P.H., M.D. (Public Representative)
Jack Henningfield, Ph.D.

**Industry Representative Members Present (Non-voting):**
Luby Arnold Hamm (Tobacco Growers Representative)
Daniel Heck, Ph.D, D.A.B.T. (Tobacco Manufacturing Industry Representative)
John Lauterbach, Ph.D., D.A.B.T. (Small Business Tobacco Manufacturing Industry Representative)

**Ex Officio Members Present (Non-Voting):**
Timothy McAfee, M.D., M.P.H. (CDC)
Cathy Backinger, Ph.D., M.P.H. (NIH)
H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM (SAMHSA)
Susan V. Karol, M.D. (HIS)

**Guest Speakers** (Non-Voting):
Kenneth H. Davis
David Mendez, Ph.D.
Hernán Navarro, Ph.D. (via Tele-conference)
James Hersey, Ph.D.
Brian D. Thomas, Ph.D.

**FDA Participants** (Non-Voting):
David Ashley, Ph.D.
Lawrence Deyton, M.S.P.H., M.D.
Corinne Husten, M.D., M.P.H.

**Designated Federal Official:**
Caryn Cohen, M.S.
The agenda on February 10, 2011 was as follows:

Call to Order and Introductions
Jonathan Samet, M.D., M.S.
Committee Chair
Tobacco Products Scientific
Advisory Committee

Conflict of Interest Statement
Caryn Cohen, M.S.
Designated Federal Official
Tobacco Products Scientific
Advisory Committee

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FDA presentation: Menthol Report
Corinne Husten, M.D., M.P.H.
FDA/CTP

Building a Population Dynamics Model of the
Consequences of Menthol Cigarettes for Smoking
Prevalence and Disease Risks
Policy
David Mendez, Ph.D.
Associate Professor
Department of Health Management &
Policy
University of Michigan
School of Public Health

Presentations on Industry Documents Related to Menthol:

Dose Response Relationships for the Physiologic
Effects of Mentholated Tobacco Smoke: Topic 1
Brian F. Thomas, Ph.D.
RTI International

Chemosensory Effects of Menthol Compounds
in Tobacco Smoke: Topic 2
Hernán Navarro, Ph.D.
RTI International

Understanding Menthol in Tobacco Products:
Summary of Industry Responses to Topics 11 & 12
Kenneth H. Davis, Jr.
RTI International

Comparative Rates of Initiation for Menthol and
Non-menthol Cigarettes: Topic 9
James Hersey, Ph.D.
RTI International

Open Public Hearing
Greg Connolly – Harvard School of Public health
William True – Lorillard
Jim Tozzi – Center for Regulatory Effectiveness
Mohamadi Sarkar – Altria
Joe Murillo – Altria
Glynis C. Lough, Ph.D. - Battelle
At this meeting the Committee received information about the continued development of a model to assess the public health impact of menthol in cigarettes. Dr. David Mendez described the scenarios used to frame the outcomes.

Researchers from RTI International continued to present their analyses of Industry data received in response to requests made by the TPSAC at the March 30-31 meeting. Issues discussed included physiological effects related to dose response interactions, chemosensory effects of menthol in cigarettes, and switching and initiation in relationship to menthol in cigarette.

Dr. Jonathan Samet discussed chapters 1 and 2 of the Menthol Report. He talked about the extensive input the Menthol Writing Group has received from Industry and the public during open public hearing sessions, which has informed the content of these chapters.

The session adjourned @ approximately 5:30 p.m.

Please see the verbatim transcript for details of the discussion.