

FOOD AND DRUG ADMINISTRATION
Center for Tobacco Products (CTP)

Tobacco Products Scientific Advisory Committee (TPSAC)

Center for Tobacco Products
9200 Corporate Blvd.
Rockville, MD 20850

January 10-11, 2011

These summary minutes for January 10-11, 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 January 10-11, 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

**Meeting of the Tobacco Products Scientific Advisory Committee
January 10-11, 2011**

The Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on January 10 and 11, 2011 at the FDA White Oak Conference Center, Building 31, Room 1503, 10903 New Hampshire Ave., Building 31, Silver Spring, MD 20993-0002. 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 9 speakers for the Open Public Hearing session.

Agenda: On January 10-11, 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.
Jack Henningfield, Ph.D.
Melanie Wakefield, 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)

Guest Speakers (Non-Voting) :

Richard O'Connor, Ph.D. (via Tele-conference)
David Mendez, Ph.D.
Hernan Navarro, Ph.D. (via Tele-conference)
James Hersey, Ph.D.
Eric Johnson, Ph.D.
Andrew Hyland, Ph.D.
Michael G. Hering, J.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 January 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

FDA Presentation

Menthol Report

Corinne Husten, M.D., M.P.H.
Senior Medical Advisor, CTP, FDA

Questions to the Presenter

Guest Speaker Presentations:

Menthol Modeling Schema

David Mendez, Ph.D.
Associate Professor
Department of Health Management & Policy
University of Michigan School of Public Health

Questions to the Presenter

Dose-related Interactions between
Menthol and Nicotine

Richard O'Connor, Ph.D.
Roswell Park Cancer Institute

Questions to the Presenter

Impact of Menthol on the Neurobiology of
Tobacco Dependence

Hernan Navarro, Ph.D.
RTI International

Questions to the Presenter

Comparative Rates of Initiation

James Hersey, Ph.D.
RTI International

Questions to the Presenter

Rates of Switching

Eric Johnson, Ph.D.
RTI International

Questions to the Presenter

Rates of Cessation

Andrew Hyland, Ph.D.

Roswell Park Cancer Institute

Contraband and Menthol

Michael G. Hering, J.D.
Deputy Chief Counsel –
MSA Payments
Tobacco Project
National Association of
Attorneys General

Questions to the Presenter

Open Public Hearing

Dennis W. Carlton and Frederick Flyer - Compass Lexecon

Jim Tozzi - Center for Regulatory Effectiveness

Geoffrey M. Curtin - RJ Reynolds

Dr. William R. True - Lorillard Tobacco Company

Dave Bryans - Ontario Convenience Stores Association

Michael Weisman Esq.

Jitender Sidh

Anne M. Hartman, M.S., M.A., NCI

TPSAC Discussion

Questions to the TPSAC Members

Closing Remarks

Adjourn

The session adjourned @ approximately 5:15 p.m.

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*The agenda on January 11, 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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Menthol Report, Chapter Presentations:

|                                                   |                               |
|---------------------------------------------------|-------------------------------|
| Chapters 1 & 2 – Introduction & Evidence          | Jonathan M. Samet, M.D., M.S. |
| Chapter 3 – Physiological Effects                 | Neal L. Benowitz, M.D.        |
| Chapter 4 – Patterns of Smoking                   | Karen DeLeeuw, M.S.W.         |
| Chapter 5 – Initiation, Cessation,<br>& Marketing | Dorothy K. Hatsukami, Ph.D.   |
| Chapter 6 – Risk Factors                          | Jonathan M. Samet, M.D., M.S. |
| Chapter 7 – Public Health Impact                  | Mark S. Clanton, M.D., M.P.H  |
| Committee Discussion                              |                               |
| Wrap-up                                           |                               |

The session adjourned @ approximately 11:00 a.m.

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At this meeting the Committee heard information about the development of a Menthol Modeling Schema, presentations based on the Industry data, and one presentation on contraband and menthol :

Dr. David Mendez presented a proposed modeling schema for a predictive projection of smoking menthol initiation and prevalence with and without menthol. He concluded his presentation by showing a detailed diagram of his proposed model from birth through initiation and finally death rate for former smokers.

Researchers from RTI International presented data on their review of the Industry data requested at the March 30-31, 2010 meeting:

- Dr. Richard O’Conner gave a presentation on dose-related interactions between menthol and nicotine.*
- Dr. Hernan Navarro presented: “The Impact of Menthol on the Neurobiology of Tobacco Dependence”*
- Dr. James Hersey presented: “Comparative Rates of Initiation for Menthol and Non-Menthol Cigarettes”*
- Dr. Eric Johnson presented: “Rates of Users Switching to and from Menthol and Non-menthol Cigarettes”*
- Dr. Andrew Hyland presented: “Comparative Rates of Cessation for Users of Menthol and Non-Menthol Cigarettes”*

Michael G. Hering gave a presentation on the “Potential Market Reaction to a Ban on Menthol Cigarettes”

The Menthol Writing Group members presented slides describing the progress and contents of the Menthol Report Chapters, which they were in the midst of writing at the time of the meeting.

Questions to the committee:

1. What suggestions does the TPSAC have regarding the proposed model?
2. What suggestions does the TPSAC have regarding the general approach to the review of the evidence?
3. What suggestions does the TPSAC have regarding the strength of evidence criteria?

4. What suggestions does the TPSAC have regarding the approach outlined by each of the chapter writing groups?

Please see the *verbatim* transcript for details of the discussion.