

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

November 18, 2010

These summary minutes for November 18, 2010 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 November 18, 2010 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
November 18, 2010**

The Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on November 18, 2010 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 7 speakers for the Open Public Hearing session.

Agenda: On November 18, 2010, 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: (* - participation by webcast/telecom)

Tobacco Products Scientific Advisory Committee Members Present via Tele-Conference (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) *

Gregory Connolly, D.M.D., M.P.H. *

Jack Henningfield, Ph.D. *

Melanie Wakefield, Ph.D. *

Industry Representative Members Present via Tele-Conference (Non-voting):

Luby Arnold Hamm (Tobacco Growers Representative) *

J. 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 via Tele-Conference (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. (SAMHSA) *

Guest Speakers (Non-Voting) :

Brett Loomis (via Tele-Conference)

James Hersey, Ph.D. (Present)

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 was as follows:
November 18, 2010***

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

Status of TPSAC Information Corinne Husten, M.D., M.P.H.
Requests Senior Medical Advisor, CTP, FDA

Questions to the Presenter

Chair Presentation

Update on Menthol Report Jonathan Samet, M.D., M.S.
Subcommittee Committee Chair
Tobacco Products Scientific Advisory Committee

Questions to the Presenter

Guest Speaker Presentation

Secondary Analysis of the Effects James C. Hersey, Ph.D.
of Smoking Menthol Cigarettes RTI International

Questions to the Presenter

Guest Speaker Presentation

Trends in Menthol Cigarette Sales, Brett JR. Loomis
Price, and Promotion in the RTI International
United States

Questions to the Presenter

Open Public Hearing

Jonathan Winickoff, M.D., M.P.H. - American Academy of Pediatrics

Frederick Flyer - Compass Lexecon

Gilbert Ross, M.D. - American Council on Science and Health

Bruce Levinson - Center for Regulatory Effectiveness

Lyle Beckwith - National Association of Convenience Stores

Gary Giovino, Ph.D., M.S. - Department of Community Health and Health Behavior, School of Public Health and Health Professions, University at Buffalo; State University of New York
Mike Little - National Black Chamber of Commerce

TPSAC Discussion

Questions to the TPSAC Members

Closing Remarks

Adjourn

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*At this meeting the Committee continued to discuss the plans for writing the Menthol Report. The specific questions to be addressed by the Writing Groups were presented by the TPSAC Chair along with the general process for the Report; i.e., evidence-based decision making:*

- Systematic reviews*
- Evidence synthesis approaches*
- Causal inference and classification of strength of evidence*

*The Committee discussed basing possible future recommendations gleaned from the evidence review around the concept of equipoise:*

- The evidence is sufficient to conclude that a relationship is more likely than not.*
- The evidence is sufficient to conclude that a relationship is at least as likely as not.*
- The evidence is insufficient to conclude that a relationship is more likely than not*
- There is insufficient evidence to make a determination of strength of evidence.*

*Dr. James Hersey presented interim analysis based on his ongoing secondary analysis of the effects of smoking menthol cigarettes. Brett Loomis gave a presentation on trends in menthol cigarette sales, price, and promotion in the United States.*

The session adjourned @ approximately 5:19 p.m.

***Questions to the committee:***

1. Are the questions proposed by the Chapters 1 and 2 writing workgroups the scientific questions that should be addressed in the report?
2. Does the Committee agree with the proposed approach for evaluating the scientific evidence?

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