FOOD AND DRUG ADMINISTRATION

Center for Tobacco Products (CTP)

Tobacco Products Scientific Advisory Committee (TPSAC)

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Tobacco Products Scientific Advisory Committee (TPSAC)
FDA White Oak Conference Center
Building 31, Room 1503, 10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 24-25, 2018

These summary minutes for the January 24-25, 2018 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on __2/26/18___.

I certify that I attended the January 24-25, 2018 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, MS
Designated Federal Official, TPSAC

_____/s/_____
Philip P. Huang, MD, MPH
Chair, TPSAC

Meeting of the Tobacco Products Scientific Advisory Committee
January 24-25, 2018

The Tobacco Products Scientific Advisory Committee (TPSAC) of the Food and Drug Administration, Center for Tobacco Products met on January 24-25, 2018 at the FDA White Oak Conference Center, Building 31, Room 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Prior to the meeting, committee members and invited participants were provided copies of the background material from the FDA and the submissions from the public. The meeting was called to order by Philip P. Huang, MD, MPH (Chair); the conflict of interest statement was read into the record by Caryn Cohen, MS (Designated Federal Official). There were approximately 225 persons in attendance. There were thirty speakers for the Open Public Hearing session.

Agenda: *On January 24-25, 2018, the Committee will discuss modified risk tobacco product applications (MRTPAs), submitted by Philip Morris Products S.A. for IQOS system with Marlboro Heatsticks, IQOS system with Marlboro Smooth Menthol Heatsticks, and IQOS system with Marlboro Fresh Menthol Heatsticks.*

Attendance:

TPSAC Members Present (Voting):
Philip P. Huang, MD, MPH (*Chair; Employee of a state or local government or of the Federal Government)*
Laura J. Bierut, MD
Pebbles Fagan, PhD, MPH (*Representative of the General Public)*
Gary A. Giovino, PhD
Robin J. Mermelstein, PhD
Richard J. O'Connor, PhD
Deborah J. Ossip, PhD
James F. Thrasher, PhD
Michael Weitzman, MD

Industry Representative Members Present (Non-voting):
William Andy Bailey, PhD *(Representative of the interests of tobacco growers)*
Willie McKinney, PhD, DABT *(Representative of the interests of the tobacco manufacturing industry)*
David M. Johnson, PhD *(Representative of the interests of small business tobacco manufacturing industry)*

Ex Officio Participants Present (Non-Voting):
Brian King, PhD, MPH (CDC)
Kris A. McLoughlin, DNP, APRN, PMH-CNS, BC, CADC-II, FAAN (SAMHSA)
Kay L. Wanke, PhD, MPH (NIH)

Consultants Present (Non-Voting):
Benjamin Blount, PhD
Stephen Hecht, PhD
Vaughan Rees, PhD

FDA Participants (Non-Voting):
Mitchell Zeller, JD
Matthew R. Holman, PhD
Benjamin Apelberg, PhD

Designated Federal Official:
Caryn Cohen, MS

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The agenda on January 24-25, 2018 was as follows:

January 24, 2018

Call to Order	Philip P. Huang, MD, MPH Chair, TPSAC
Conflict of Interest Statement	Caryn Cohen, MS Designated Federal Official Office of Science, FDA/CTP
Introduction of Committee Members	Philip P. Huang, MD, MPH Chair, TPSAC
Opening Remarks	Mitchell Zeller, JD Director FDA/CTP
Introduction to the Meeting Topics: PMP S.A. Modified Risk Tobacco Product Applications	Benjamin Apelberg, PhD Director, Population Health Science Office of Science, FDA/CTP
Philip Morris Products S.A., Presentations:	
IQOS System and Heating Technology	Moira Gilchrist, PhD VP Scientific & Public Communications Philip Morris International
Reduced Risk and Harm - Scientific Assessment of IQOS	Manuel Peitsch, PhD Chief Scientific Officer Philip Morris International
Population Health Benefit - Perception and Behavior	Antonio Ramazzotti VP Human Insights and Behavioral Research Philip Morris International
U.S. Commercialization and Controls	Sarah Knakmuhs VP Heated Tobacco Products Philip Morris USA
Population Modeling and Conclusion	Moira Gilchrist, PhD VP Scientific & Public Communications Philip Morris International
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FDA Presentations:

Evidence Related to the Health Risk of IQOS Use: Evaluation of Product Chemistry	Karina Zuck, PhD Chemist Office of Science, FDA/CTP
Evidence Related to the Health Risk of IQOS Use: Evaluation of Nonclinical Studies	Mayo J. Wright, PhD Toxicologist Office of Science, FDA/CTP
Evidence Related to the Health Risks of IQOS Use: Evaluation of Human Studies	Karen Konkel, MD Medical Officer Office of Science, FDA/CTP
Evidence Related to the Impact on Tobacco Users: Evaluation of Clinical and Behavioral Pharmacological Studies	Olga Rass, PhD & Elena Mishina, PhD Pharmacologists Office of Science, FDA/CTP
Evidence Related to the Impact on Tobacco Users: Evaluation of Epidemiological Studies	Gabriella Anic, PhD Epidemiologist Office of Science, FDA/CTP
Evidence Related to the Impact on Tobacco Users and Non-Users: Evaluation of Studies Related to Proposed Labels, Labeling, and Advertising (LLA)	Alexander Persoskie, PhD Social Scientist Office of Science, FDA/CTP
Committee Discussion	
Adjourn	

January 25, 2018

Call to Order	Philip P. Huang, MD, MPH Chair, TPSAC
Conflict of Interest Statement	Caryn Cohen, MS Designated Federal Official Office of Science, FDA/CTP
Introduction of Committee Members	Philip P. Huang, MD, MPH Chair, TPSAC

Open Public Hearing Session:

- Cheryl Lockhart – Hazy Hollow Vapors
- Craig Jones – Privis Health
- Gregory Angelo – Log Cabin Republicans
- Damon Jacobs
- Alex Clark – The Consumer Advocates for Smoke-Free Alternatives Association (CASAA)
- Gregory Conley – American Vaping Association
- Scott Ballin
- Julie Gunlock – Independent Women's Forum

- Naomi Lopez Bauman – Goldwater Institute
- Will Cohen – The Vape a Vet Project
- Jeff Stier – National Center for Public Policy Research
- Erika Bliss – Equinox Primary Care, LLC
- Robert McClure – The James Madison Institute
- Joseph Manupello – People for the Ethical Treatment of Animals
- David Williams – Taxpayers Protection Alliance
- Bill Godshall – Smokefree Pennsylvania
- Carrie Wade – R Street Institute
- Mario Lopez – Hispanic Leadership Fund
- Julian Morris – Reason Foundation
- Gregory Connolly – Northeastern University School of Law and Bouvé School of Health Sciences
- Paul Blair – Americans for Tax Reform
- Lauren Lempert – University of California, San Francisco
- Patrick Hedger – Freedom Works Foundation
- Jeff Fortenbacher – Access Health Inc.
- Daren Bakst – Institute for Economic Freedom, The Heritage Foundation
- Graham Boyd – Tobacco Growers Association of NC
- David Dobbins – Truth Initiative
- Hank Campbell – American Council on Science and Health
- Matthew Myers – Campaign for Tobacco-Free Kids
- Becki Gray – John Locke Foundation

Committee Discussion

Committee Discussion (continued)

Adjourn

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***Questions to the Committee*:**

1. Discuss evidence related to the health risks of the *IQOS* system and the appropriateness of the proposed modified risk information.
    a. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Scientific studies have shown that switching completely from cigarettes to the *IQOS* system can reduce the risks of tobacco-related diseases."? **(Vote)**

        Yes – 0 *No – 8* *Abstain – 1*

    b. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Switching completely to *IQOS* presents less risk of harm than continuing to smoke cigarettes."? **(Vote)**
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Yes – 4 *No – 5* *Abstain – 0*

Committee Discussion:

The committee discussed the strength of the scientific evidence. Members were concerned that the statement in question 1.a. was too broad considering the available data. There was less concern with the statement in 1.b., although the majority of members were not convinced by the evidence presented.

2. Discuss evidence related to human exposure to harmful or potentially harmful chemicals when combusted cigarette smokers completely switch to the *IQOS* system, including the implications of changes in exposure for long-term disease risk and the appropriateness of the proposed modified risk information.

    a. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Scientific studies have shown that switching completely from cigarettes to the *IQOS* system significantly reduces your body's exposure to harmful or potentially harmful chemicals."? **(Vote)**

    Yes – 8 *No – 1* *Abstain – 0*

    b. If the answer to question 2a is "yes", has the applicant demonstrated that the reductions in exposure are reasonably likely to translate to a measurable and substantial reduction in morbidity and/or mortality? **(Vote)** *[To be answered by Committee members who voted "yes" to 2a.]*

    Yes – 2 *No – 5* *Abstain – 1*

Committee Discussion:

Most of the committee members indicated that the data support the statement presented in 2.a. However, there was less support for the statement presented in 2.b.

3. Discuss evidence regarding the likelihood that existing combusted cigarette smokers will initiate use of the *IQOS* system, completely switch to *IQOS*, and/or become long-term dual users of *IQOS* and combusted cigarettes.

    a. What is the likelihood that that U.S. smokers would completely switch to use of the *IQOS* system? **(High/Medium/Low)**

    High – 0 *Medium – 2* *Low – 7* *Abstain – 0*

    b. What is the likelihood that U.S. smokers would become long-term dual users of *IQOS* and combusted cigarettes? **(High/Medium/Low)**

    High – 3 *Medium – 5* *Low – 1* *Abstain – 0*

Committee Discussion:

Members expressed concerns about the lack of data to support theories about prospective switching behavior in the U.S.

4. Discuss evidence regarding the likelihood that persons who do not use tobacco products will start using the *IQOS* system.

    a. What is the likelihood that U.S. never smokers, particularly youth, will become established users of the *IQOS* system? **(High/Medium/Low)**

    High – 2 *Medium – 1* *Low – 4* *Abstain – 2*

    b. What is the likelihood that former smokers will re-initiate tobacco use with the *IQOS* system? **(High/Medium/Low)**

    High – 0 *Medium – 0* *Low – 9* *Abstain – 0*

Committee Discussion:

Members expressed concerns about drawing conclusions about youth initiating tobacco use with IQOS, in light of the absence of data on youth usage. The committee indicated that the evidence did not seem to indicate a high appeal to former tobacco users.

5. Discuss evidence regarding consumer comprehension and perceptions of the proposed modified risk labeling and advertising.

    a. Has the applicant demonstrated that, after viewing the proposed modified risk labeling and advertising, consumers accurately understand the risks of *IQOS* use as conveyed in the modified risk information? **(Vote)**

    Yes – 0 *No – 9* *Abstain – 0*

What additional information, if any, needs to be communicated, other than what has been proposed by the applicant, for consumers to understand the health risks of the *IQOS* system?

Committee Discussion:

Committee members indicated the importance of clear statements that would not be misunderstood by consumers. Specifically, they suggested that the statements written by the seller are clearly attributed as such, so as not to be construed as written by FDA or another government agency. Similarly, they advised that the nuances in the difference between risk and relative risk must be considered. Members also pointed out the importance of being clear about the risks of becoming addicted to nicotine associated with a product pursuing an MRTP designation.

The meeting adjourned at 3:00 p.m. on January 25, 2018.

Please see the verbatim transcript for details of the discussion.