Meeting of the Tobacco Products Scientific Advisory Committee

June 26, 2024

TPSAC Committee Members (Voting)
Cristine Delnevo, Ph.D., M.P.H. Chair
Mignonne C. Guy, Ph.D. +
Sven-Eric Jordt, Ph.D.
Adam Leventhal, Ph.D.
Lucy Popova, Ph.D.
Nancy A. Rigotti, M.D.
Risa Robinson, Ph.D.
Scout, Ph.D., M.A.*
Dona Upson, M.D., M.A.**

Industry Representatives (Non-Voting)
William Andy Bailey, Ph.D. (Growers)
Maria Gogova, Ph.D., M.D. (Manufacturers)
Amy Madl, Ph.D., DABT (Small Business)

Ex-Officio Participants (Non-Voting)
Deirdre Lawrence Kittner, Ph.D., M.P.H. (CDC)
Lisa Postow, Ph.D. (NIH)
Taryn Watson, M.Ed. (IHS – Alt.)

Consultants (Non-Voting)
Annette Kaufman, Ph.D., M.P.H.
Olivia Wackowski, Ph.D., M.P.H.

FDA Administrative Staff
CAPT Serina A. Hunter-Thomas, M.S.A., R.N.
Janice O'Connor

FDA Participants
Benjamin Apelberg, Ph.D.
Jennifer Bernat, Ph.D.
Carol H. Christensen, Ph.D., M.P.H.
Karen Cullen, Ph.D., M.P.H.
Erin M. Ellis, Ph.D., M.P.H.
Monique Gaines-Harris, M.P.H.
Tamirra Glover, M.S.
Nicholas Hasbrouck, M.S.
Ouida Holmes, M.P.H.
Lisa Lagasse, Ph.D., M.H.S.
Robert Lee, M.D., M.S.
CAPT Kimberly Lindsey, M.D., M.A.
Alex Lowe, Ph.D., M.S.
Vy Nguyen, D.D.S., M.P.H
Jessica Pepper, Ph.D.
Alexander Persoskie, Ph.D.
Mark Rinella, Ph.D.
Mary L. Searing, M.S., PE
Samantha Stanley-Venrick, Ph.D.
Emily Storch, M.D., M.P.H.
LaTasha Swanson, Ph.D.
Nicole Tashakkori, M.P.H.
Dilip Venugopal, Ph.D., M.S.

Legend
+ Remote Attendance
* General Public Representative
**State, Local or Federal Gov't. Representative

Tobacco Products Scientific Advisory Committee (TPSAC)

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Tobacco Products (CTP)
FDA White Oak Conference Center
Building 31, Room 1503
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 26, 2024

These summary minutes for the June 26, 2024 Meeting of the Tobacco Products Scientific Advisory Committee were approved on September 19, 2024.

I certify that I participated in the June 26, 2024, Meeting of the Tobacco Products Scientific Advisory Committee and that these minutes accurately reflect what transpired.

/s/ Serina Hunter Thomas -S Digitally signed by Serina Hunter Thomas -S Date: 2024.09.19 19:14:20 -04'00'
Serina A. Hunter-Thomas
Designated Federal Officer

/s/
Cristine Delnevo, PhD, MPH
Chair

The Tobacco Products Scientific Advisory Committee (TPSAC) of the Food and Drug Administration, Center for Tobacco Products (CTP) met on June 26, 2024, at the FDA White Oak Conference Center, Building 31, Room 1503, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002. Prior to the meeting, committee members and invited participants were provided copies of the background materials from the FDA. The meeting was called to order by Cristine Delnevo, Ph.D., M.P.H. (Chair); housekeeping items and the conflict-of-interest statement was read into the record by CAPT Serina Hunter-Thomas, M.S.A, R.N. (Designated Federal Officer). There were approximately 25 persons in attendance in person, and over 200 persons in attendance virtually. There was a total of nine speakers for the Open Public Hearing session.

Agenda: *On June 26,2024 the committee met in open session to discuss the renewal modified risk tobacco product applications (MRTPAs) submitted by Swedish Match USA, Inc. for eight General Snus tobacco products: MR0000256*

After the housekeeping and COI statement was read by the DFO, presentations began with Dr. Jennifer Bernat providing the first FDA presentation. At the completion of Dr. Bernat's presentation, the meeting proceeded with the presentation from Swedish Match USA, Inc. After the presentation from Swedish Match, some members of the TPSAC Committee asked a few clarifying questions prior to the brief morning break. After the break, the meeting resumed with the 2nd FDA presentation by Ms. Nicole Tashakkori. The 2nd FDA presentation was followed by a 3rd FDA presentation by Dr. Samantha Venrick. After Dr. Venrick's presentation, there was time for the TPSAC committee to ask a few clarifying questions. After this, the meeting proceeded to the Open Public Hearing (OPH) session. Two OPH speakers presented in-person, while the nine other OPH speakers provided their comment virtually.

Following the open public hearing the meeting proceeded to a lunch break. At the end of the lunch break the meeting reconvened and the committee members addressed discussion questions 1 and 2. After discussing questions 1 and 2, the committee took a brief afternoon break. After the afternoon break, Dr. Alexander Persoskie provided the 4th FDA presentation, which was related to consumer understanding of MRTPAs, generally, and not the Swedish Match renewal MRTPA. Following the last presentation, the meeting proceeded to committee discussion.

The discussion questions and committee comments/responses were as follows:

Discussion Questions on General Snus Use and Impacts to the Population

1. FDA reviewed the literature and the applicant's data and conducted internal analyses of the applicant's data to describe characteristics of people who use snus, patterns of tobacco use among people who use General Snus, and transitions from combusted cigarette (CC) smoking to exclusive use of General Snus.

Discuss the use behaviors of these modified risk tobacco products and any implications.

Committee Discussion: The Committee noted difficulties in assessing the patterns of use based on Swedish Match's post market surveillance study which was focused on General Snus consumers.

The Committee voiced concerns over high rates of attrition and lack of information related to dual use. The committee acknowledged the difficulties in developing strong post market surveillance studies to assess the use behaviors for specific products and that FDA reviewed Swedish Match's study proposal before the study began. The Committee expressed interest in providing input on proposed post market studies for new and reauthorized MRTPs. Committee members found the analyses provided by FDA from NYTS and PATH useful and noted that the youth specific data were reassuring such that at the population level, there does not appear to be an increase in youth use of snus corresponding with the time period associated with the General Snus risk modification order.

2. FDA reviewed the applicant's data on consumer understanding and perception of the modified risk information.
   Discuss the evidence related to consumer understanding and perceptions of the modified risk claim and any implications.
   Committee Discussion: The Committee felt the post market surveillance data point to some indication of accurate risk perceptions – specifically that one should use snus exclusively for reduced risks. However, there were overarching concerns with the study design, which challenged the Committee's deliberation on how to interpret the data and observations on consumer perception and understanding of the modified risk claims. First, the wording of the survey question was inadequate to assess the understanding of complete switching. Second, while the post market study pointed to some accurate perceptions, the Committee felt it was not possible to attribute this solely to the MRTP messaging since they did not assess MRTP message exposure. Additional concerns were noted related to halo effects. .

Discussion Questions on Consumer Understanding of MRTPAs

1. We presented a potential framework for conceptualizing what aspects of consumer understanding should be demonstrated in MRTPAs. The potential framework had three components:
   - Understanding what risk or exposure reduction is described
   - Understanding that the proposed MRTP is more harmful than non-use and cessation
   - Understanding how to use the proposed MRTP to reduce one's risk or exposure.

   What does the Committee think of this potential framework? Does the Committee suggest any modifications?

   Committee Discussion: The Committee responded positively to the framework. Some

members suggested additions, such as comparing the proposed MRTP to nicotine replacement therapies and considering how perceptions vary by whether people consider the claim to be personally relevant.

2. In most studies of consumer understanding of modified risk LLA, participants view the LLA as part of a controlled laboratory experiment, whereas in the real world, consumers could be exposed to LLA repeatedly and in various advertising formats.
    A. Does the Committee expect consumer understanding to differ between real-world and experimental settings? If so, how should we account for this in study designs or evaluation of experimental studies?
    B. What does understanding in the real world look like and how could CTP and applicants monitor consumer understanding as part of postmarket surveillance following an authorization?

    Committee Discussion: The Committee agreed that understanding and reactions would differ for real-world settings versus controlled laboratory experiments and felt there would be value in testing claims in real-world settings. In particular, Committee members noted that levels of attention to the message and levels of exposure to the message vary in the real world, and these factors should be measured. Additionally, the Committee noted that it may be important to also consider and evaluate real-world factors such as exposure to marketing, conflicting messages, social media, and interpersonal conversations.

3. As covered in the presentation, there may be unique consumer understanding considerations for the intended and unintended users of an MRTP.
    A. Should consumer understanding be assessed differently for various populations?
    B. What are possible red flags that indicate consumers are misled or not understanding and how could those red flags be measured?

    Committee Discussion: Committee members mentioned multiple populations of interest, including youth, Latino, Queer, and Black populations. They noted that some members of these populations might interpret messages differently and that they might have different levels of trust in government communications. Committee members suggested using social media monitoring, sales data monitoring, and qualitative research to better understand differences in consumer understanding of claim language by population.

4. Consumers (study participants) bring with them pre-existing beliefs that affect how they interpret claim information and answer survey questions. For example, the majority of the public believes smokeless tobacco products are equally as harmful or more harmful than cigarettes.

    How, if at all, should FDA take pre-existing beliefs into account when assessing and evaluating consumer understanding of proposed MRTP claims?

    Committee Discussion: Committee members reiterated the importance of assessing and accounting for pre-existing beliefs because those beliefs will impact the

interpretation of the claim. Committee members discussed how best to incorporate that measurement in study design, such as whether assessing preexisting beliefs prior to claim exposure could influence their understanding of the claim.

After the committee provided closing summary statements, the Chair invited FDA to provide final comments. After final comments from Dr. Benjamin Apelberg, the TPSAC meeting was adjourned.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed via the following YouTube links:

https://youtu.be/DL046wonDB8

https://youtu.be/V4SmC9f9kx8