

**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 18-20, 2012**

These summary minutes for the January 18-20, 2012 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on February 8, 2012.

I certify that I attended the January 18-20, 2012 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 18-20, 2012**

The Tobacco Products Scientific Advisory Committee (TPSAC) of the Food and Drug Administration, Center for Tobacco Products (CTP) met on January 18-20, 2012 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 background material from the FDA, background materials from invited industry representatives and 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 14 speakers for the Open Public Hearing session on January 19, 2012. The meeting was webcast; a link to the webcast was provided on the CTP website in the Advisory Committee section.

**Agenda:** As part of the TPSAC's required report to the Secretary of Health and Human Services, the committee continued discussing issues related to the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. Discussion included such topics as the composition and characteristics of dissolvable tobacco products, product use, potential health effects, and marketing.

The meeting was held on January 18, from 8:00 a.m. to 5:00 p.m., on January 19, 2012, from 8:00 a.m. to 5:00 p.m. and on January 20, 2012, from 8:00 a.m. to 2:30 p.m. On January 18, from 8:00 a.m. to 1:00 p.m., the meeting was closed to permit discussion and review of trade secret and confidential commercial information (5 U.S.C. 552b(c)(4)). The meeting was **open to the public** on January 18, from 2:00 p.m. to 5:00 p.m., on January 19, 2012, from 8:00 a.m. to 5:00 p.m. and on January 20, 2012, from 8:00 a.m. to 2:30 p.m.

### **Attendance:**

#### **Tobacco Products Scientific Advisory Committee (Voting):**

Jonathan Samet, M.D., M.S. (Committee Chair)  
Neal Benowitz, M.D. (January 19 & 20 only)  
Mark Clanton, M.D., M.P.H. (via Tele-conference)  
Dorothy Hatsukami, Ph.D.  
Patricia Nez Henderson, M.P.H., M.D. (Public Representative)  
Thomas Eissenberg, Ph.D.

#### **Industry Representative Members (Non-voting):**

Luby Arnold Hamm (Tobacco Growers Representative – via Tele-conference)  
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 (Non-Voting):**

Mirjana Djordjevic, Ph.D.  
Sandrine Pirard, M.D., Ph.D., M.P.H.  
Timothy McAfee, Ph.D., M.P.H.

#### **Temporary Voting Members:**

Robert L. Balster, Ph.D.  
Fred Pampel, Ph.D.

**Consultants (Non-Voting):**

Bruce Simons-Morton, Ed.D., M.P.H.  
Sherry Emery, M.B.A., Ph.D.  
Ellen Peters, Ph.D. (January 19 & 20 only)

**FDA Participants (Non-Voting):**

David Ashley, Ph.D.  
Lawrence Deyton, M.S.P.H., M.D.  
Sarah E. Evans, Ph.D.

**Designated Federal Official:**

Caryn Cohen, M.S.

*The agenda was as follows:*

**January 18-20 – open session**

Call to Order	Jonathan Samet, M.D., M.S. Chair, TPSAC
Conflict of Interest Statement	Caryn Cohen, M.S. Designated Federal Official, FDA/CTP
Introduction of Committee Members	Jonathan Samet, M.D., M.S. Chair, TPSAC
Opening Remarks	Sarah E. Evans, Ph.D. Social Scientist Office of Science, FDA/CTP

**Presentations:**

The Swedish Tobacco Harm Reduction Experience	Lars-Erik Rutqvist, M.D., Ph.D. Senior Vice President for Scientific Affairs Swedish Match, Smokefree Division
Smokeless Tobacco, Cigarettes, and Dual Product Use: Implications for Dissolvable Product Marketing	Scott L. Tomar, D.M.D., M.P.H., Dr.P.H. Professor, University of Florida College of Dentistry

**Committee discussion of Question 1**

**January 19, 2012**

Call to Order	Jonathan Samet, M.D., M.S. Chair, TPSAC
Conflict of Interest Statement	Caryn Cohen, M.S. Designated Federal Official, FDA/CTP

Introduction of Committee Members

Jonathan Samet, M.D., M.S.  
Chair, TPSAC

Opening Remarks

Sarah E. Evans, Ph.D.  
Social Scientist  
Office of Science, FDA/CTP

**Presentations:**

Health Effects of Dissolvable  
Tobacco Products

Ii-Lun Chen, M.D.  
Medical Officer  
Office of Science, FDA/CTP

Health Effect of Long-term Use  
of Therapeutic NRT

Priscilla Callahan-Lyon, M.D.  
Division of Nonprescription Clinical  
Evaluation, FDA/CDER

**Committee Discussion**

Toxic and Carcinogenic Constituents  
In Dissolvable Tobacco Products

Irina Stepanov, Ph.D.  
Chemist, University of Minnesota

Quantitative and Qualitative Analysis of  
Dissolvable Tobacco Products

Clifford Watson, Ph.D.  
Lead Research Chemist, CDC

Topography of Use;  
Nicotine Absorption

Sarah E. Evans, Ph.D.  
Social Scientist  
Office of Science, FDA/CTP

Indiana's Experience: Marketing of  
Dissolvable Tobacco Products

Miranda Spitznagle, M.P.H.  
Director of Program Evaluation  
Indiana Tobacco Prevention and  
Cessation Commission

**Committee Discussion**

Data on Accidental Ingestions:  
With Focus on Pediatric  
Ingestions

Ii-Lun Chen, M.D.  
Medical Officer  
Office of Science, FDA/CTP

CPSC and the Poison Prevention  
Packaging Act

John W. Boja, Ph.D.  
Consumer Product Safety  
Commission

**Committee Discussion**

Review of Peer-Reviewed Literature  
Regarding Dissolvable Tobacco Products

Linda Brown, M.P.H., Dr.P.H.  
RTI

**Committee Discussion**

**Open Public Hearing:**

Andrew Wolford  
Gregory Conley  
Christopher Proctor, British American Tobacco  
Bill Godshall, Smokefree Pennsylvania  
Gilbert Ross, MD, The American Council on Science and Health  
Scott Ramminger, American Wholesale Marketers Association  
Scott Ballin  
Jeff Stier, National Center for Public Policy Research  
Sandra Sulsky, MPH, PhD, Environ  
Dawn Yurkas  
Carl Phillips, MPP, PhD  
Elaine Keller, The Consumer Advocates for Smoke-free Alternatives Association  
Linc Williams  
Justin King

Review of Industry Documents Regarding  
Dissolvable Tobacco Products

**RTI International**

Overview

Jeanette Renaud, Ph.D.

Behavioral Effects

Jeanette Renaud, Ph.D.

Health Effects of Dissolvable Tobacco Products

Linda Brown, M.P.H., Dr.P.H.

Marketing Research and Marketing Practices

Brian Southwell, Ph.D.

Toxicological & Physiological Effects

Brian Thomas, Ph.D.

**January 20, 2012**

Call to Order

Jonathan Samet, M.D., M.S.  
Chair, TPSAC

Conflict of Interest Statement

Caryn Cohen, M.S.  
Designated Federal Official, FDA/CTP

Introduction of Committee Members

Jonathan Samet, M.D., M.S.  
Chair, TPSAC

Opening Remarks

Sarah E. Evans, Ph.D.  
Social Scientist, FDA/CTP

College Students' Awareness and  
Perceptions of Dissolvable  
Tobacco Products

Mark Wolfson, Ph.D.  
Professor, Social Sciences and Health Policy  
Wake Forest School of Medicine

**Committee Discussion:**

- Proposed Conceptual Framework
- Questions to the Committee

Adjourn

~~~~~

***Questions to the Committee***

1. Regarding the data from Sweden on smokeless tobacco products, discuss what, if any, extrapolations can be made:
  - a. To use of dissolvable tobacco products
  - b. From the impact of the use of traditional smokeless tobacco on oral health to the impact of the use of dissolvable tobacco products on oral health;
  - c. What factors may limit making these extrapolations?
2. With respect to the peer reviewed articles on dissolvable tobacco products, please discuss:
  - a. What scientific findings are more strongly supported by the literature?
  - b. What information gaps exist in the literature?
  - c. What additional research would inform an evaluation of the public health impact of dissolvable tobacco products?
3. What surveillance activities should be implemented to monitor poison events associated with dissolvable tobacco products?
4. Discuss whether dissolvable tobacco products increase overall initiation for the use of tobacco products and what further research would inform this question.
  - a. What evidence, if any, is there that dissolvable tobacco products encourage initiation of use of tobacco products generally?
  - b. What design features of dissolvable tobacco products encourage or discourage use by current non-users of tobacco products?
  - c. In what way, if any, does initiation of use of dissolvable tobacco products encourage eventual use of other forms of tobacco?
5. Discuss youth perceptions of dissolvable tobacco products and what further research would inform this question. What do children and adolescents think about dissolvable tobacco products and how might this affect use of the product?
  - a. What are the characteristics of dissolvable tobacco products that make them more or less appealing to children and adolescents, including users and non-users of tobacco products?
  - b. How do youth perceptions of dissolvable tobacco products compare to their perceptions of cigarettes and other smokeless tobacco products?
  - c. Which, if any, specific population groups are more likely to use dissolvable tobacco products?

6. Discuss adults' perception of dissolvable tobacco products and what further research would inform this question. What do adults think about dissolvable tobacco products and how might that affect use of the product?
  - a. What are the characteristics of dissolvable tobacco products that make them more or less appealing to adults, including users and non-users of tobacco products?
  - b. How do adults' perceptions of dissolvable tobacco products compare to their perceptions of cigarettes and other smokeless tobacco products?
  - c. Which, if any, specific populations are more likely to use dissolvable tobacco products?
7. Discuss dual use of dissolvable tobacco products with other tobacco products and what further research would inform understanding of this issue. To what extent are dissolvable tobacco products used in conjunction with other tobacco products by children, adolescents and adults?
  - a. How are dissolvable tobacco products used by children and adolescents in conjunction with other tobacco products (i.e., dual use)?
  - b. How are dissolvable tobacco products used by adults in conjunction with other tobacco products (i.e., dual use)?
  - c. What role, if any, does marketing play in promoting exclusive or dual use of dissolvable tobacco products?
8. Discuss potential abuse liability of dissolvable tobacco products and what further research would inform this question.
  - a. How do the nicotine levels and different rates of nicotine delivery impact the abuse liability of dissolvable tobacco products?
  - b. In what ways, if any, do the design characteristics of dissolvable tobacco products or their packaging encourage or discourage use by targeted users?
  - c. What aspects, if any, of the design characteristics of dissolvable tobacco products encourage or discourage use by non-targeted populations? What aspects, if any, of the design characteristics of dissolvable tobacco products encourage or discourage use in ways other than as stated by the manufacturer?
  - d. In what ways, if any, could the abuse liability of dissolvable tobacco products be reduced?
  - e. How does the abuse liability of dissolvable tobacco products compare to that of other tobacco products?
9. Discuss cessation rates as related to dissolvable tobacco products and what further research would inform this question. How are the tobacco cessation rates associated with use of dissolvable tobacco products related to the tobacco cessation rates for users of other tobacco products?
  - a. How does cessation differ among adolescents and adults with dissolvable tobacco products compared with other tobacco products?
  - b. What evidence, if any, suggests that children, adolescents and adults delay tobacco cessation by using dissolvable tobacco products?
  - c. What evidence, if any, suggests that dissolvable tobacco products alter tobacco cessation for users of other types of tobacco products (i.e., do users switch to dissolvable tobacco products rather than quit)?
10. Discuss the morbidity and mortality associated with the use of dissolvable tobacco products and what further research would inform this question.
  - a. How does the morbidity and mortality associated with use of dissolvable tobacco products differ compared to that associated with use of other tobacco products?

11. Discuss the toxicity related to dissolvable tobacco products.
  - a. What are the key toxicities of concern for dissolvable tobacco products that may require toxicity testing in *in vitro* and/or *in vivo* toxicology models?
  - b. What are the most applicable model(s) for toxicity testing of dissolvable tobacco products?
    - i. *In Vitro* toxicity testing
    - ii. *In Vivo* toxicity testing
  
12. Discuss the marketing strategies currently used to promote dissolvable tobacco products and what further research would inform this question.
  - a. Who is the target audience of dissolvable tobacco product marketing?
  - b. What are the primary messages used in dissolvable tobacco product marketing?
  - c. How does the marketing of dissolvable tobacco products affect consumer perceptions of the product?
  - d. How is the marketing of dissolvable tobacco products similar to and different from other tobacco products?
  
13. Discuss the public health impact, if any, and what further research would inform understanding of:
  - a. Risk of accidental ingestion of dissolvable tobacco products
  - b. Safety of package design of dissolvable tobacco products
  - c. Topography of use of dissolvable tobacco products
  - d. Youth perception of dissolvable tobacco products
  - e. Impact of the use of dissolvable tobacco on cardiovascular health
  - f. How knowledge of the impact of the use of chronic nicotine replacement therapy on health could inform the use of dissolvable tobacco products.

~~~~~

*On the morning of January 18, 2012 a closed session was held at which trade secret and commercial confidential information was presented to the TPSAC; only government employees and special government employees were in attendance at the closed session.*

*At approximately 2:00 on January 18, 2012 the open session commenced. The charge to the committee was reviewed, "...to review and provide recommendations to FDA regarding the nature and the impact of the use of dissolvable tobacco products (DTPs) on the public health, including such use among children." The TPSAC was asked to consider the following issues regarding DTPs: 1) risks and benefits, 2) likelihood that these products will influence use among existing users, and 3) likelihood that these products would influence use among those who do not currently use tobacco products.*

*Dr. Sarah Evans stressed that the meeting topic was specifically DTPs and not smokeless tobacco in general. Further, the committee was advised that their charge did not include: use of DTPs as cessation aids, whether existing DTPs are substantially equivalent to those on the market on February 15, 2007, the individual applications of these products, or DTPs as potential modified risk products.*

*At the July 20-21, 2011 meeting of the TPSAC, members asked for more information on the Swedish experience with snus usage. In response to this request, Dr. Lars-Erik Rutqvist, M.D., Ph.D., was invited to give a presentation. In his presentation entitled, "The Swedish Tobacco Harm Reduction Experience" Dr. Rutqvist described the Swedish "experience" as a dramatic change in tobacco use among the Swedish population – a switch from the cigarettes to snus. He explained that snus was considered a less harmful source of tobacco intake; additionally, snus had a history as a traditional product in the Swedish culture.*



*Continuing on the theme of smokeless tobacco in response to the TPSAC's July request, Scott Tomar, D.M.D., M.P.H., Dr.P.H. gave a presentation looking at smokeless tobacco use in the United States and related health implications. He proposed that there exists only weak and inconsistent evidence to support promoting smokeless tobacco as a public health strategy to reduce harm associated with cigarette smoking.*

*At the conclusion of these two presentations the TPSAC was asked to consider committee question #1 – regarding what, if any, extrapolations could be made relating the Swedish experience with smokeless tobacco to use in the United States. Because of the demographic, historical and cultural differences between the United States and Sweden, any direct extrapolation seemed imprudent.*

*Fourteen presentations on various topics related to DTPs were given on the January 19, 2012. Dr. Ii-Lun Chen discussed some of the available data on the health effects of DTPs. Because little information is available on DTPs per se, Dr. Chen presented data on reported negative health outcomes related to other types of smokeless tobacco products. She pointed out that health outcomes of any kind are related to multiple factors, both on the individual and public health levels, and that more clinical research was needed to better understand the health effects of DTPs.*

*Priscilla Callahan-Lyon, MD, from FDA's Center for Drug Evaluation and Research (CDER) gave a presentation on CDER's evaluation of the long-term use of nicotine replacement therapy (NRT). To date, insufficient data exist to label NRTs safe for long-term use. FDA has not approved NRTs for use by children or adolescents.*

*Irina Stepanov presented data on the toxic and carcinogenic constituents in DTPs. In summary, the data she presented show that there exist a wide range of nitrosamine levels among DTP brands, and variations within brands. There appear to be relatively low levels of polycyclic aromatic hydrocarbons and larger variations in protonated nicotine levels than in total nicotine levels among products.*

*Clifford Watson, Ph.D., of the Centers for Disease Control and Prevention (CDC) presented the results of an analysis requested by CTP. Dr. Watson did a quantitative analysis of constituents (including nicotine, pH, calculated free-based nicotine, tobacco-specific N-nitrosamines), and metals, as well as a qualitative survey of DTPs for additional chemical constituents of interest. Dr. Watson summarized, in part, that DTPs are chemically complex and that current measurement approaches may not be adequate to fully confirm and identify all potential constituents.*

*In her presentation on the topography of DTPs, Dr. Sarah Evans explained that "topography" assesses human tobacco consumption behavior. With smokeless tobacco (ST), topography measures include: self-reported measures of tobacco use such as ST tins used per week, total dips per day, total daily dip duration, and total daily dipping time (time from first dip in the morning until last dip of the day). Dissolvable tobacco product topography measures could include quantity, frequency, and duration of use. Dr. Evans presented data from three studies that were provided to the TPSAC as part of the background information for this meeting. Dr. Evans concluded that currently no standardized method of measuring the topography of DTPs exists and that further clinical research would be needed to fully evaluate the topography of DTPs.*

*Miranda Spitznagle, M.P.H. presented information about the state of Indiana's experience as a test market for Camel brand DTPs. She discussed awareness and perception among youth regarding the products – including indications that youth may find aspects of the product more appealing than cigarettes because for example., DTPs would not be recognized by adults as being a tobacco product, they would not smell like smoke, and DTPs could be used in smoke-free areas. In summary, she said the influx of the product raised concerns in the community and led to additional use of resources to educate and prevent use among youth.*

*In her second presentation, Ii-Lun Chen, M.D., presented data from the American Association of Poison Control Centers (AAPCC) on accidental ingestion of DTPs. A concern among public health advocates has been that DTPs may appeal to youth because of their size, color, and flavoring. With increased availability of DTPs reports of adverse events, while low, has increased. Dr. Chen suggests that work is needed to reverse this trend. John Boja,*

*Ph.D. from the U.S. Consumer Product Safety Commission (CPSC) gave a complementary presentation on the Poison Prevention Packaging Act.*

*Linda Brown, M.P.H., Dr.P.H. presented a summary of the peer reviewed literature that was provided to the TPSAC in preparation for this meeting. She presented study type, type of DTP, sample size and description, study objectives, and authors conclusions, for each paper.*

*The open public hearing portion of the meeting was followed by a brief review of releasable data, submitted by industry, and reviewed by RTI International, under contract with CTP. RTI reviewed the industry documents and presented information on behavioral and health effects, marketing research and practices, and toxicological and physiological effects of DTPs.*

*On January 20, 2012, the third and final day of the meeting, Dr. Sarah Evans described the expected next steps toward completion of the TPSAC's required report on DTPs. The next meeting on the topic is tentatively scheduled for March 1-2, 2012. The report will comprise the summary minutes, verbatim transcripts, and all other meeting materials (including slide presentations, public submissions, and background materials) from the TPSAC meetings on the topic. Additionally, Dr. Samet will prepare a summary of the topics discussed during the TPSAC meetings. This summary will be distributed to the TPSAC members and will be posted on the CTP website for comment prior to the March 1-2, 2012 meeting. The summary will be finalized during the March 1-2 meeting.*

*After Dr. Evans discussed plans for finalizing the report, two presentations related to youth and young adult perception of DTPs, were given . The first, by Mark Wolfson, Ph.D., looked at college students' awareness and perceptions. Using an observational cohort study design, Dr. Wolfson surveyed students from 11 colleges and universities;10,528 study participants completed the survey. He found that, among those surveyed, awareness of DTPs was higher than might be expected, DTPs were most appealing to co-users of other smokeless tobacco products, and DTPs were viewed as the least risky tobacco product. He found that almost half of the surveyed users of smokeless tobacco and cigarettes and over half of snus users surveyed, would try a free sample of DTPs. Dr. Wolfson plans to do further analysis on this topic.*

*The final presentation was given by a team from the Virginia Foundation for Healthy Youth. This presentation described a survey developed and administered by high school aged students to assess youth perception and knowledge about new DTPs. 8,150 individuals were surveyed in 210 communities across the state of Virginia. The overall conclusion drawn by the authors of this study was that the public, especially youth, associate the flavors and packaging of DTPs with candy, mints, or gum.*

*After the presentations, the committee members turned their attention to planning for the completion of the report. An outline describing the general approach for the TPSAC report, was presented:*

- Develop framework for report*
- Identify findings from evidence presented to TPSAC*
- List major points of uncertainty*
- Address charge in a brief summary*
- Provide recommendations for further information gathering, research and surveillance*

*Dr. Samet asked the committee members to consider findings from the materials presented to the TPSAC over the course of the two meetings on DTPs, including:*

- Peer-reviewed literature*
- Industry presentations*
- Industry documents (open and commercial confidential)*
- Open public hearing input*
- Review of Swedish experience*
- Indiana experience and youth presentations*

The committee took each of these points individually and expanded on some of the important issues to be considered within each area:

#### **Peer-reviewed literature (only products currently available)**

- *Constituent yields*
- *Abuse liability - tends to be less than that of cigarettes and conventional U.S. smokeless products*
- *Potential health effects based on information on TSNA, nicotine, cancer risk (with limited quantification of risk) – yields a profile, which looks like exclusive use of DTPs should be less hazardous than cigarettes; also less than smokeless tobacco products marketed in the U.S.*
- *Consumer perception – there some concern that DTPs may be perceived as being a non-tobacco products – this is a general concern, not just based on the literature (which is limited). There is also concern about confusing co-use and primary use*
- *Consumer response – in general people did not respond positively when tested (to these products)*
- *Constituent yields - variability across products, in nicotine, heavy metals & TSNA yields/less than cigarettes*
- *Product yield and delivery*
- *Literature on childhood poisoning - has been tracked, limited data, not many serious ingestions recorded so far*

#### **Industry presentations**

- *Presentations by industry - support denying access to children*
  - *Users smoke fewer cigarettes*
  - *There are a variety of products with different nicotine and TSNA yields*
- *Findings from 904(b) data reviews*
  - *Marketing as accessory items for established smokers (or other tobacco users), used to deal with craving, in circumstances where social perceptions weigh against smoking*
  - *Not positioning these as smoking cessation products, albeit they are not allowed to market as such*
  - *However, they can be marketed as complete substitutions for cigarettes (i.e., not just for when you can't smoke)*

#### **Open public hearing and public submissions**

- *Concern among some percentage of public that these products could be banned (maybe more so for e-cigarettes)*
- *Sense that various government agencies should take a more pro-active approach to providing education on individual risk (not lumping all tobacco products together) – because they believe it is useful for cessation*
- *They are concerned that people have an exaggerated perception of the health risk*
- *These products aren't particularly liked (except maybe e-cigarettes)*
- *These products are not used alone in stopping the use of cigarettes.*

#### **Review of Swedish experience**

- **Context** *makes generalizing the Swedish experience difficult due to the population differences, history of traditional snus use*
  - *Includes a voluntary product standard that is adhered to by manufacturers of snus in Sweden*
- *Distinction between males vs. females who became exclusive snus users (i.e., males tend to switch completely, females more likely to continue to smoke)*
- *Exploration of Swedish data may yield additional information about dual use*
- *For health benefit to accrue complete substitution is required (complete sub of cigarettes with snus)*
- *50% of snus users are naïve to tobacco when they begin using*
- *Labeling is different in Sweden*

#### **Indiana experience and youth presentations**

- *Relatively low penetration in youth market even of the products that have been around for a long time*
- *Packaging is very important to appeal among youth (as yet, no evidence that packaging has an impact)*

- *Virginia (Virginia Foundation for Healthy Youth) study shows packaging influences youth perception of product*
- *Possibly newer products are being packaged in such a way that is more appealing to youth based on lessons learned from the older products (see first bullet above) – evolution of packaging is something to monitor*
- *The way that DTPs are used among youth is co-use*
- *People seem confused (not just youth) as to what the product actually is*
- *There is an appeal related to the idea that other people cannot tell when/if one is using the products*

*Dr. Samet plans to prepare a summary for public and committee review prior to the next meeting. This summary is due to the CTP-TPSAC team by January 31, 2012. The summary will be given to the members of the TPSAC for their comments and will be posted on CTP's website (with any confidential information removed) in sufficient time for public comment. The summary will be discussed and edited as needed during the March 1-2, 2012 meeting, at which copies of the finalized version will be made available.*

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