

## SUMMARY: TPSAC REPORT ON DISSOLVABLE TOBACCO PRODUCTS

### Explanatory Cover Page

The attached document reflects edits and comments from members and consultants of the TPSAC in response to the original “SUMMARY: TPSAC REPORT ON DISSOLVABLE TOBACCO PRODUCTS,” posted on the CTP website at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM290182.pdf>.

Edits are represented in red and blue (**red = additions**, **blue = deletions**), **comments are represented in green**.

Each participant in the January 18-20, 2012 meeting was given an opportunity to provide individual edits and comments. The TPSAC members and consultants who submitted the edits and comments reflected in this document are:

Robert T. Balster, Ph.D.  
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Other TPSAC Members and Consultants who have edits and comments will address them orally at the meeting on March 1-2, 2012.

1 DRAFT with Proposed Edits: January 31, 2012 [*Heck: I thought the*  
2 *Chairman did an excellent job of pulling together the main themes*  
3 *and points from the proceedings.*]  
4

5 SUMMARY: TPSAC REPORT ON DISSOLVABLE TOBACCO  
6 PRODUCTS  
7

8 **Introduction and Statement of Charge**

9 This document provides a summary of the report of the Tobacco  
10 Products Scientific Advisory Committee (TPSAC) on dissolvable  
11 tobacco products (DTP). Under Section 907(f) of the Family  
12 Smoking Prevention and Tobacco Control Act, the TPSAC was  
13 charged with developing a report on “...the nature and impact of

1 the use of dissolvable tobacco products on the public health,  
2 including such use among children.” (see Table 1) As detailed  
3 below, the TPSAC reviewed and discussed a wide array of  
4 materials, submissions, and presentations relevant to its charge.  
5 Those materials, along with the transcripts of the open portions of  
6 the TPSAC meetings, constitute the evidence evaluated by TPSAC  
7 in responding to its charge. This summary, together with the  
8 materials considered by TPSAC and the transcripts of its meetings,  
9 constitute its report.

10

**Table 1. Charges to the Tobacco Products Scientific Advisory  
Committee (TPSAC) under the Family Smoking Prevention and  
Tobacco Control Act**

## **Section 907(a)(3)(B) Tobacco Product Standards**

TPSAC is to consider:

“(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.”

## **Section 907(f) Dissolvable Tobacco Products**

TPSAC is required to review and provide recommendations to the FDA regarding the “the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children.”

## **Committee Approach**

The committee completed the task of developing this report over the course of three meetings, July 21-22, 2011, January 18-20, 2012, and March 1-2, 2012. The initial meeting was largely for the purpose of information-gathering, as were the initial two days of the second. The TPSAC spent most of January 20, 2012 in open discussion of the full set of materials that it had received. In this discussion, the committee members: 1) evaluated the relevant papers from the peer-reviewed literature for key findings; 2) considered the findings of the scan of the industry documents and the main points of the tobacco industry presentations; 3) reviewed themes from the open public hearing and submissions to FDA; and 4) considered the presentations on the experience

1 and perceptions of youth with regard to DTPs [Lauterbach: *This is*  
2 *misleading as not all relevant literature brought before TPSAC and*  
3 *presentations by those who oppose DTPs were considered*  
4 *authoritative when they were not peer-reviewed*]. Following this  
5 meeting a summary was prepared and reviewed by the TPSAC on  
6 March 1 and revised based on these discussions before approval  
7 on March 2, 2012.

8

### 9 **Committee Framework**

10 To guide its integration of the evidence, the TPSAC developed a  
11 conceptual framework describing the potential roles of DTPs in  
12 smoking experimentation and initiation, addiction and regular  
13 tobacco use, and risks to health (Figure 1) [Lauterbach: *Figure 1 is*

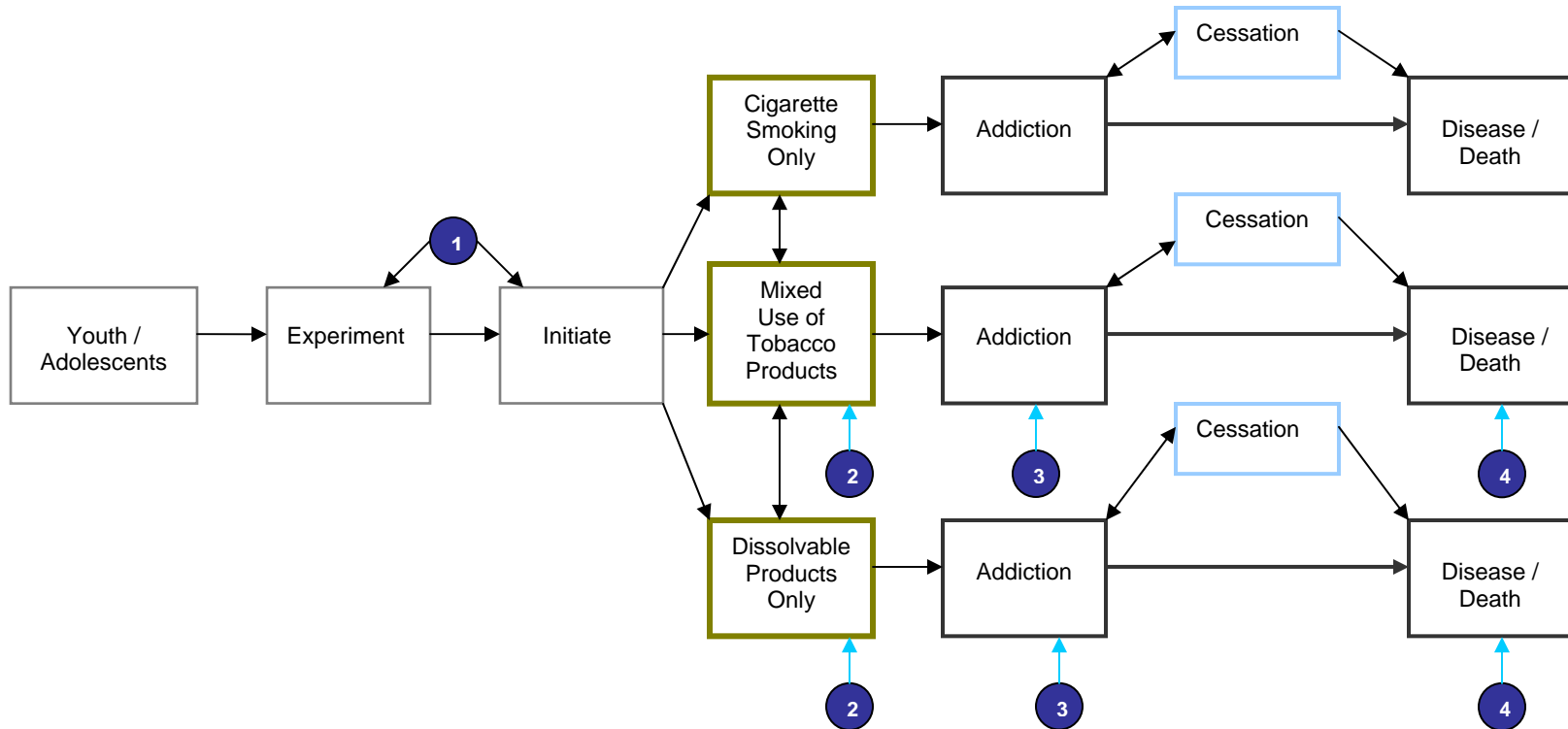
1 *incorrect and misleading. TPSAC did not receive any information*  
2 *that chronic use of DTPs would lead to disease/death. Figure 1*  
3 *would be a stretch even if ALL contemporary smokeless tobacco*  
4 *products manufactured in the USA and northern Europe were*  
5 *included]. The TPSAC acknowledges that the framework*  
6 *necessarily oversimplifies the potential complexities of tobacco*  
7 *use, particularly if the array of nicotine-containing products*  
8 *continues to expand. The framework represents three potential*  
9 *patterns of tobacco-product use: cigarettes alone, DTPs alone,*  
10 *and mixed patterns involving multiple products, including DTPs.*  
11 The numbers on the figure indicate those points at which the  
12 availability of DTPs could have impact. In this framework, the  
13 availability of DTPs might affect the likelihood of experimentation

1 and initiation of tobacco product use (#1 in the figure) and also  
2 affect progression to regular use and addiction (#2); the model  
3 also reflects the possibility that DTPs would influence the  
4 maintenance of tobacco use and nicotine addiction and the  
5 likelihood of cessation (#3). Further, the framework  
6 acknowledges that risk for morbidity and premature mortality  
7 caused by use of tobacco products could be affected by use of  
8 DTPs (#4). In addressing its charge, TPSAC searched for evidence  
9 relevant to determining if the availability of DTPs might have any  
10 consequences at these points in the framework and to estimating  
11 the potential magnitude of any effects [Balster: Because of  
12 changing patterns of tobacco use and differences in the definitions



- 1 *of addiction, I suggest changing the boxes on addiction to read*
- 2 *regular use/addiction].*

# Figure 1. Conceptual Framework: From Experimentation to Disease



1 *[Lauterbach: Figure 1 is misleading because it assumes all types of*  
2 *dual-use are equally harmful. Is it better for a smoker to smoke 5*  
3 *cigarettes per day and use 15 pieces of DTP than it is for the*  
4 *smoker to use cigarettes exclusively at 20 cigarettes per day? See*  
5 *Frost Pineda et al., 2011.]* Hypothesized mechanisms by which  
6 dissolvable tobacco products could have impact on public health.  
7 The pathways include 1) increased experimentation and initiation  
8 of cigarette smoking as a consequence of access to an oral,  
9 nicotine-containing product; 2) experimental use leading to an  
10 established pattern of mixed use of tobacco products (e.g.,  
11 dissolvable products, other smokeless products *[Lauterbach:*  
12 *Another error is the apparent classification of DTPs as new*  
13 *tobacco products when they are NOT new. Tableted smokeless*

1 *tobacco products have been on the market at least since 2002.*  
2 *Tobacco strips and bits have been around for much longer. Oliver*  
3 *Twist tobacco pellets date back to at least 1993 and probably*  
4 *earlier. Dissolvable reconstituted tobaccos have been used as*  
5 *wrappers for plug-style chewing tobaccos] , and/or cigarettes); 3)*  
6 decreased likelihood of smoking cessation, given a nicotine-  
7 delivering product that can be used where smoking is not  
8 permitted or possible likelihood of smoking but no evidence was  
9 presented that current dissolvables assist in smoking cessation;  
10 and 4) differing risk profile for tobacco-caused diseases and  
11 premature mortality from exclusive use, or partial to complete  
12 replacement of cigarette use by DTPs [*Heck: Although presently*  
13 *available published data are insufficient to document the utility of*

1 *DTPs as aids to smoking cessation, the accumulating literature on*  
2 *broadly similar snus products indicates that such potential is a*  
3 *worthy hypothesis here. [ref Rodu 2011 review]. This could be*  
4 *captured briefly with this or similar wording here, or present*  
5 *wording with a 94) tag on the chart's cigarette cessation arrow.]*

6  
7 **Key Findings from the Evidence Review** [*Lauterbach: When using*  
8 *the evidence, it should be specifically stated what brand-styles*  
9 *were considered. For example, did cited evidence apply to Camel*  
10 *DTP or to all contemporary brand-styles of DTP?]*

11 As described, the TPSAC reviewed a variety of sources of evidence  
12 on DTPs. The transcripts of the TPSAC discussions document the  
13 synthesis and summarization of the evidence by the TPSAC. A

1 brief, tabular summary of the main findings of TPSAC's review of  
2 the evidence follows, organized by the type of evidence:

3  
4 **Peer-Reviewed Literature** [Simons-Morton: Maybe a sentence  
5 about current prevalence of use.][Lauterbach: Need lead  
6 author's name and year for literature used to support each  
7 bullet point.]

8 • No tobacco product is safe and DTPs are not a safe  
9 alternative to conventional smoking products.

10 • Constituent yields: [Lauterbach: This paragraph is at best  
11 misleading and the statement on nicotine yields is wrong. All  
12 DTP TPSAC considered met the GothiaTek standard. This  
13 needs to be stated explicitly. Nicotine contents of the

1 *products were different by design, but there were no data to*  
2 *support the contention that there was more than normal*  
3 *manufacturing variation within a design. Nicotine yield of*  
4 *STONEWALL was more than mainstream yield for any*  
5 *cigarette, including Health Canada intensive smoking. TSNA*  
6 *yields of DTP lower \_\_\_ lower than mainstream smoke yields*  
7 *from cigarettes]* There is variation across products in yields  
8 of nicotine and tobacco-specific nitrosamines (TSNAs).  
9 Heavy metals are present, also in variable amounts. The  
10 yields of nicotine and TSNAs are lower than those of  
11 cigarettes [Lauterbach: *TPSAC needs to clarify which studies*  
12 *came from ISO 17025-accredited laboratories and which*  
13 *studies were conducted on samples obtained under validated*

1 *sampling plans such as CORESTA Recommended Method*  
2 *#71].*

- 3 • Abuse liability: Abuse liability in current smokers should be  
4 lower for current DTPs than for conventional cigarettes and  
5 for other smokeless tobacco products (SMTs) [*Peters: First*  
6 *mention;: write it out*][*Lauterbach: The term “SMTs” needs*  
7 *to be defined at first use in the report*] now available in the  
8 United States because of lower nicotine content.  
9 [*Lauterbach: Which literature citations were used to support*  
10 *this?*]
- 11 • Health risk: Based on information on TSNAs, nicotine, and  
12 studies of cancer risk of SMTs, exclusive use of DTPs should  
13 be less hazardous than either cigarettes or SMTs now



1 marketed in the United States [Lauterbach: *This statement is*  
2 *not accurate. There is no evidence to support any increase in*  
3 *health risks for current DTP that are not present from use of*  
4 *NRT such as nicotine lozenges.*].

- 5 ● Consumer perception: One study [Lauterbach: *if this study*  
6 *is not reported in the peer-reviewed literature, it should be*  
7 *deleted. I could find one article, Romito et al., 2011, which*  
8 *covers Camel DTP*] showed that Ariva was perceived as being  
9 a non-tobacco product. This perception may extend to  
10 other DTPs.
- 11 ● Consumer response: consumers have not responded  
12 positively to current products.

- 1       ● Childhood poisoning: Studies in the literature indicate that  
2       to date there have been few accidental ingestions with  
3       serious consequences ~~to date~~.

4  
5       ***Industry Presentations and Documents*** [Lauterbach: *Does this*  
6       *only apply to documents that were in public domain?*]

- 7       ● Product range: There are a variety of products with  
8       different nicotine and TSNA yields.
- 9       ● Available data for current DTPs in the United States indicate  
10       that they meet the voluntary Swedish standard for harmful  
11       or potentially harmful smokeless product constituents  
12       [Heck: *The HPHC data for current DTPs shows them to be*

1        *within the Gothiatek standards for snus – in some instances*  
2        *substantially lower [e.g. TSNAs].*

- 3        ● Cigarette use: Users of DTPs smoke fewer cigarettes than  
4        nonusers.
- 5        ● Marketing: DTPs are presently marketed as accessory  
6        products for smokers or other tobacco users to deal with  
7        craving in circumstances where social perceptions or bans  
8        make smoking difficult or impossible.
- 9        ● Cessation: Presently, DTPs are not being positioned by the  
10       industry as useful for cessation [Peters: *Wasn't there one*  
11       *advertising exception to this that the tobacco reps on the*  
12       *committee brought up?].*

- 1       ● Youth: Presentations by industry indicate that DTPs are not  
2       directed at youth.

3  
4       ***Open Public Hearing and Public Submissions***

- 5       ● Product perception: Based on the reports of individuals,  
6       TPSAC found evidence that DTPs were neither well liked nor  
7       being used by themselves for smoking cessation. Some  
8       commenters suggested that people may have a perception  
9       of the risks of DTPs that is exaggerated.
- 10      ● Government actions: Concern was expressed by some that  
11      DTPs might be banned [*Peters: Was the concern about DTPs*  
12      *or e-cigarettes being banned? I thought it was the latter but*  
13      *maybe it was both*]. Additionally, some recommended that

1 government agencies should more pro-actively educate the  
2 public on the risks associated with various products ~~without~~  
3 ~~combining~~ rather than all tobacco products associated with  
4 ~~various-specific products-product types~~ ~~without~~ rather than  
5 combining all tobacco products generally.

6  
7  
8 ***Review of Swedish Experience with Snus*** [Heck: True, Sweden's  
9 *unique society does impose constraints on extrapolation*  
10 *elsewhere without some qualifications. However, I feel that the*  
11 *“Swedish experience” is more worthy re DTPs than the draft’s*  
12 *“limited generalizability” statement conveys. May I suggest this*  
13 *additional bullet here. The recent Rodu 2011 review discusses*

1 *the Swedish and the emerging US experiences with cessation,*  
2 *youth, dual use, smoking gateway concerns, etc. for snus. Given*  
3 *the HPHC similarity, I think the snus literature can offer*  
4 *considerable value until the DTP literature matures. Ref: Rodu,*  
5 *Harm Reduction Journal 2011, 8:19*  
6 *<http://www.harmreductionjournal.com/content/8/1/19>*  
7 *[Lauterbach: This review is not fully accurate. US government*  
8 *required warnings on DTP tell consumers that DTP use is just as*  
9 *hazardous as cigarette use. We know that is not true. Please go*  
10 *to transcript of meeting that gives Dr. Rutqvist's answer to*  
11 *question asking him to compare US health warning and Swedish*  
12 *health warning for same product.]*

- 1       ● Context: The context of the Swedish experience with snus  
2       has unique characteristics (historic use of snus, marketing,  
3       government engagement, voluntary product standard and  
4       exclusive use pattern) that limits generalizability for DTPs in  
5       the United States.
- 6       ● The considerable scientific and epidemiological literature on  
7       Sweden's experience with snus may, with appropriate  
8       caveats, inform some aspects of the emerging DTP  
9       experience in the United States.
- 10      ● Health benefits: For health benefits to be ~~obtained~~fully  
11      realized, complete substitution of snus for cigarettes was  
12      needed.

- 1       ● New users: At present, 50% of snus users are new tobacco  
2       users.
- 3       ● Use by sex: More males tend to be exclusive snus users,  
4       reflecting historical Swedish tradition, while most female  
5       tobacco users continue to smoke cigarettes. ~~while females~~  
6       ~~are more likely to use snus and continue to smoke.~~ [Heck: To  
7       me, the main take-away was that so relatively few Swedish  
8       females use snus (under 5%) vs. males (20-25%), while they  
9       still smoke at levels similar to other developed countries &  
10      consequently have similarly high health risks (in contrast to  
11      men). I haven't been able to reconstruct the basis in the  
12      record for what seems to be expressed here – i.e., that dual  
13      use is markedly higher among the (relatively few) female



1 *snus users. Perhaps I overlooked it. Is that the intended*  
2 *meaning? If so, is this a key point? The heavily-referenced*  
3 *RJRT presentation by Dr. Curtin last July indicated that dual*  
4 *users seem more likely to quit smoking than exclusive*  
5 *smokers (about 10 studies). Although that was an industry*  
6 *presentation, the published papers are mainly on snus, so*  
7 *perhaps it should be mentioned here if dual use by women*  
8 *(or anyone) in Sweden is a key point to the Committee.]*

- 9 ● Labeling: Labeling in Sweden differs from that in the United  
10 States.

11  
12 ***Indiana Experience and Youth Presentations***

- 1 ● Youth use of DTPs: To date, there is little use of DTPs by  
2 youth, even though several products have been on the  
3 market for about 10 years. The Indiana experience during  
4 test marketing of DTPs suggested that some youth would try  
5 DTPs, particularly those already smoking cigarettes  
6 *[Lauterbach: It needs to be stated explicitly that Indiana*  
7 *experience refers to Camel DTP only. Furthermore, are*  
8 *Indiana officials credible? See their inaccurate statements*  
9 *on health risks of DTP at*  
10 *[http://www.in.gov/isdh/tpc/files/Dissolvable\\_tobacco\\_products\\_7\\_18\\_11.pdf](http://www.in.gov/isdh/tpc/files/Dissolvable_tobacco_products_7_18_11.pdf).*  
11  
12 ● Packaging: Appeal to youth is likely to depend on packaging.  
13 Newer packaging may have greater youth appeal

1 *[Lauterbach: Youth presentation was biased by semi-hidden*  
2 *image of TicTac package in the “ballot” they gave to other*  
3 *students.]*

4  
5 **Responses to Charge Issues** *[Lauterbach: A continuing critique of*  
6 *DTP is that the products taste like candy. Those who have tasted*  
7 *the products know that most products are far from candy-like and*  
8 *taste characteristics are inferior to those of oral NRT.]*

9 This element of the charge addresses the risks and benefits of  
10 DTPs. As noted, the TPSAC considerations of this question are  
11 based in counterfactual comparisons of a scenario of the United  
12 States, absent DTPs, to scenarios with current types of DTPs  
13 available. In constructing comparison scenarios, the TPSAC was

1 constrained [Lauterbach: “was constrained” should be replaced  
2 by “chose to be constrained” as TPSAC not given evidence that  
3 there was a longer history of dissolvables than just products new  
4 on market over past few years.]

5 by the limited “real world” experience to date—10 years with  
6 products from *Star Scientific Inc.* (Ariva and Stonewall) and test  
7 marketing of new products in several locations in the United  
8 States by several companies. Consequently, the TPSAC posed  
9 scenarios that would be most useful to addressing its charge. In  
10 particular, TPSAC gave weight to a scenario of widespread  
11 availability and marketing of DTPs, as representing a bounding  
12 case useful for addressing the charge. The current situation was

1 judged as one in which DTPs are having no impact on the  
2 elements of the framework.

3

4 *The risks and benefits to the population as a whole, including*  
5 *users and non-users of tobacco products;*

6

7 TPSAC considered the burden of tobacco-related morbidity and  
8 premature mortality to be the appropriate indicator in addressing  
9 this element of its charge. That burden reflects the number of  
10 users of tobacco products, their patterns of use, and the risks of  
11 the products that they use, as set out in Figure 1. The TPSAC  
12 framework indicates several ways that DTPs could reduce the  
13 disease burden caused by tobacco use: decreasing the number of

1 smokers, if availability of DTPs increases successful cessation or  
2 decreases the likelihood of initiation and use of smoked products,  
3 and decreasing the risk of tobacco caused disease, if availability of  
4 DTPs sufficiently reduces cigarette smoking or use of other types  
5 of SMT. The TPSAC members concurred that available evidence  
6 supports a conclusion that DTPs ~~are~~ {use is} –OR– {use of DTPs  
7 alone is} likely to be associated with far lower disease risks than  
8 smoking cigarettes although differences among DTPs may exist.  
9 The framework also shows how availability of DTPs could increase  
10 the disease burden, by either increasing the number of tobacco  
11 users or reducing cessation.

12

1 *[Lauterbach: This paragraph assumes that tobacco use of all kinds*  
2 *will result in premature mortality and serious morbidity. This is*  
3 *not supported by the facts. For example, what is*  
4 *morbidity/premature mortality for use of US-style chewing*  
5 *tobacco except for dental caries?]* The TPSAC noted the great  
6 uncertainty concerning how availability of DTPs would impact the  
7 burden of tobacco-caused morbidity and premature mortality in  
8 the population. To date, experience is limited and observational  
9 evidence on how DTPs might affect use of tobacco products is  
10 lacking. After 10 years of availability, the products made by Star  
11 *Scientific, Inc.* have had extremely limited market penetration and  
12 no apparent overall impact on disease burden. Furthermore,  
13 TPSAC concluded that the context set by industry marketing will

1 be critical in determining the impact of DTPs. [Lauterbach: *This*  
2 *statement is incorrect. I do not concur with it. Was there a vote*  
3 *taken in closed session?*] The committee was concerned that  
4 availability of DTPs with lower risks to health than cigarettes  
5 might affect the public perception of all tobacco products, leading  
6 to increased use because of reduced concern about health risks of  
7 tobacco products generally.

8

9 Given the substantial uncertainties and the potential for either  
10 risks or benefits, TPSAC could not reach a conclusion as to the  
11 potential point of balance between potential risks and benefits of  
12 DTPs.

13



1 *The increased or decreased likelihood that existing users of*  
2 *tobacco products will stop using such products;*

3

4 TPSAC concluded that DTPs are presently being positioned as a  
5 tobacco product that provides nicotine in circumstances where  
6 smoked products and specifically cigarettes cannot be used.

7 Smokefree regulations and changing social norms have narrowed  
8 the range of venues where smoking is allowed and acceptable.

9 Marketing strategies examined by TPSAC gave emphasis to use of  
10 DTPs in circumstances under which nicotine intake by smoking is  
11 not possible. Additionally, findings of several peer-reviewed  
12 papers, industry studies, and anecdotal reports from the public  
13 hearing speakers suggest that cigarette smokers do not find the

1 current DTPs to be sufficient by themselves, as an alternative to  
2 cigarette smoking. Beyond some anecdotal reports, TPSAC found  
3 no information on whether DTPs would increase the likelihood of  
4 cessation of cigarette use or of SMTs [Lauterbach: *This again goes*  
5 *against the evidence that use every type of tobacco product is*  
6 *bad. Why can't TPSAC and the FDA look at the epidemiology that*  
7 *shows little if any harm from contemporary SMT? ]*

8  
9 In considering scenarios for addressing this element of its charge,  
10 TPSAC offers the reminder that context will be critical in  
11 determining use patterns for DTPs. Will current marketing and  
12 product development approaches be continued, giving emphasis  
13 to use of DTPs when smoking is not possible or perceived

1 unfavorably? Will DTPs be marketed as facilitating cessation?  
2 Will adopters use the product as a cessation tool or to maintain  
3 their habit? Will the nicotine yield {in forthcoming products} – OR  
4 – {of future DTPs} be different from that of current products  
5 *[Lauterbach: Is a 2-mg or 4-mg DTP any more harmful than a 2-mg*  
6 *or 4-mg piece of nicotine-containing gum or nicotine-containing*  
7 *lozenge?]* ?

8  
9 TPSAC concluded that the availability of DTPs could either  
10 increase the likelihood of cessation of use of tobacco products, if  
11 they proved to facilitate cessation, or decrease the likelihood of  
12 stopping if they served to maintain use of tobacco products and  
13 nicotine addiction by offering a product that can be used in

1 circumstances where smoking is generally not possible. As noted,  
2 TPSAC could not reach any overall judgment as to whether the net  
3 consequence of DTPs would be an increase or decrease in the  
4 number of people who successfully quit smoking. This  
5 uncertainty provides a strong rationale for close surveillance of  
6 cessation and any impact of DTPs [Lauterbach: *Why is TPSAC*  
7 *avoiding the obvious? If all cigarette smokers switched to DTP, we*  
8 *would have far less lung cancer, COPD, and emphysema.*].

9

10 *The increased or decreased likelihood that those who do not use*  
11 *tobacco products will start using such products.*

12

1 For this component of the charge, the TPSAC concluded that the  
2 available evidence, while limited, leads to a qualitative judgment  
3 that availability of DTPs could increase the number of users of  
4 tobacco products. This judgment was based on experience with  
5 other SMTs, data presented from the State of Indiana showing  
6 that some adolescents were already using DTPs, the survey data  
7 on youth perceptions of the products from the State of Virginia,  
8 and the potential for youth to be drawn to a novel product  
9 *[Lauterbach: As noted in my earlier comments, there was*  
10 *substantial anti-DTP bias in both the IN and VA studies.]* . The  
11 TPSAC could find no basis for the contrary finding—that  
12 availability of DTPs would decrease ~~use~~ product initiation. With  
13 the very limited information available, however, the TPSAC could

1 not estimate the magnitude of any potential increment in  
2 numbers of tobacco-product users because of sales of DTPs.  
3 Based on its finding, the TPSAC offers strong recommendations as  
4 to the need for informative surveillance related to DTPs and  
5 youth.

6  
7 **Recommendations for Further Information Gathering,**

8 **Surveillance, and Research** *[Lauterbach: The recommendations*  
9 *on information gathering, surveillance, and research are excessive.*  
10 *If TPSAC is concerned about chemical composition of DTP, then the*  
11 *recommendation should be that DTP should meet the GothiaTek®*  
12 *standards for impurities in Swedish snus. There are no need for*  
13 *development of short-term bioassays as such studies have already*

1 *be done on several types of STP and the results show that*  
2 *contemporary STP have little if any activity in common bioassays*  
3 *used to assess cytotoxicity and genotoxicity. Also, it is likely that*  
4 *human studies using biomarkers of dose and biomarkers of harm*  
5 *will not yield significant new information.] [Lauterbach: How come*  
6 *there is not a recommendation on packaging in terms of*  
7 *resistance to opening/use of product by infants and young*  
8 *children?]*

9

10

11

## ***Additional Product Testing***

- 1 ● Further characterization of within-product variation in yields  
2 and delivery of nicotine, TSNAs, and other health-relevant  
3 components.
- 4 ● Characterization of variation in product composition at  
5 point-of-sale across the country.
- 6 ● Characterization of change in product composition with time  
7 since manufacture, and the influences of heat and moisture  
8 exposure on composition.
- 9 ● For each product, doses of key components delivered to  
10 users should be assessed with an appropriate suite of  
11 biomarkers.
- 12 ● For each product, detailed information is needed on  
13 topography in actual use.



1 • To facilitate accumulation of data on various DTPs, a  
2 standard product description is needed.

3 • Rapid collection of product composition, yields and delivery  
4 of nicotine, TSNAs and other health-relevant components  
5 and abuse potential information as new products are  
6 introduced.

### 7 ***Surveillance***

8 • Existing surveillance systems should be reviewed for their  
9 sensitivity to track patterns of DTP use and the various  
10 mixed use patterns, particularly among key sentinel  
11 populations, e.g., youth, and vulnerable population  
12 subgroups.

- 1 • Surveillance instruments will need to be developed for  
2 tracking DTP use.
- 3 • The impact of availability of DTPs on use of other tobacco  
4 products, particularly cigarettes, needs to be monitored  
5 closely.
- 6 • Research/surveillance will be needed to assess perceptions  
7 of DTPs and how availability and marketing (including  
8 packaging and product development) of DTPs affects  
9 perception of other tobacco products.
- 10 • Denominators reflecting individual product sales are needed  
11 for relative product risk assessment.
- 12 • Information is needed on how underage users obtain DTPs.

1 **Research**

- 2 ● Short-term bioassay systems are needed that may prove  
3 useful for assessing potential risks to health.
- 4 ● Studies with biomarkers of ~~response/~~exposure and injury in  
5 users of various products alone and in mixed users might  
6 prove useful for this purpose [Lauterbach: Why does TPSAC  
7 want to recommend research that has already been shown  
8 to be ineffective?].
- 9 ● Further refinement of models for abuse potential  
10 assessment of DTPs is needed.
- 11 ● Developing useful population models for assessing  
12 consequences of DTP availability.