Considerations with regard to TPSAC’s review of dissolvable tobacco products

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Overview

The Family Smoking Prevention and Tobacco Control Act (the Act) charges the Tobacco Products Scientific Advisory Committee (TPSAC) with developing a report on dissolvable tobacco products. The specific charge is:

“(f) DISSOLVABLE TOBACCO PRODUCTS.—
“(1) REFERRAL; CONSIDERATIONS.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee for report and recommendation, under section 917(c)(4), the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsection (a)(3)(B)(i).
“(2) REPORT AND RECOMMENDATION.—Not later than 2 years after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).
“(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the Secretary’s authority to take action under this section or other sections of this Act at any time applicable to any dissolvable tobacco product.

This charge is parallel to that given TPSAC with regard to the use of menthol in cigarettes, although for dissolvable tobacco products TPSAC is requested to evaluate the “...nature and impact” of these products on the public health and not simply “impact” as specified for menthol in cigarettes. Additionally, TPSAC is asked to examine impact in children specifically, but not in other particular groups. Of course, there are substantial differences in the scope of evidence available to TPSAC for menthol in cigarettes, which had been on the market for decades and relatively extensively studied, compared with dissolvable products, only now entering the market.

In addressing the impact of menthol cigarettes on public health, TPSAC proposed that an adverse effect on public health from menthol in cigarettes could come as a result of an increased number of smokers, compared to the counterfactual of having only cigarettes without menthol as an additive, and as a result of increased risk for developing disease in smokers of menthol compared with nonmenthol cigarettes. A conceptual framework was proposed and used as the basis for a systematic review of the literature, evidence gathering, and development of a model. The planning document for the menthol report is attached for reference.
While the evidence base for dissolvable tobacco products is quite sparse, the general approach followed by TPSAC in the instance of menthol cigarettes remains useful. Its conceptualization of public health impact within a specified framework, the systematic approach to evidence synthesis, and the classification of strength of evidence are equally applicable to dissolvable tobacco products.

**Approach**

As a starting point, TPSAC proposes a conceptual framework that is parallel to that developed for menthol cigarettes (Figure 1). The framework offers hypothesized mechanisms by which dissolvable tobacco products could have impact on public health. The pathways include 1) increased experimentation and initiation of cigarette smoking as a consequence of access to an oral, nicotine-containing product; 2) experimental use leading to an established pattern of mixed use of tobacco products (e.g., dissolvable products, other smokeless products, and/or cigarettes); 3) decreased likelihood of smoking cessation, given a nicotine-delivering product that can be used where smoking is not permitted; and 4) differing profile of risk for tobacco-caused diseases and mortality. Through the first three mechanisms, the pool of nicotine addicted persons in the population would be increased. With use of dissolvable products, risks for tobacco-caused diseases and death might be altered from the risks associated with a profile of smoking cigarettes only.

As for menthol cigarettes, the model indicates the key items of evidence that the committee will need in meeting its charge. Direct epidemiological evidence is lacking and consequently the committee will need to address its charge through gaining understanding of the delivery of nicotine by the dissolvable products and their potential to facilitate initiation of smoking or to maintain addiction, thereby reducing cessation. A judgment will also be needed on the fourth mechanism, the impact of availability of dissolvables on risks for tobacco-caused diseases and death.

Figure 1. Model of Smoking and Health: From Experimentation to Disease