

American Academy
of Pediatrics



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Statement of
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On behalf of the
American Academy of Pediatrics

Before the
Food and Drug Administration
Tobacco Products Scientific Advisory Committee

My name is Dr. Jonathan Winickoff. I am a practicing pediatrician and an associate professor at Harvard Medical School. My research focuses on tobacco control in child healthcare settings and child second-hand smoke exposure.

I am here today in an official capacity representing the American Academy of Pediatrics (AAP) as a member and past chair of the AAP Tobacco Consortium and as a principal with the AAP Julius B. Richmond Center of Excellence. The AAP is a non-profit professional organization of more than 62,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

The Academy's Richmond Center is dedicated to improving child health by eliminating children's exposure to tobacco and secondhand smoke. This mission is accomplished by changing the clinical practice of pediatrics through the development and dissemination of practice tools, research, health care systems change, and improvement of community health. The center works to create a healthy environment for children, adolescents and families through public education and the promotion of public health policies to eliminate tobacco.

The AAP welcomes this opportunity to address the Tobacco Products Scientific Advisory Committee (TPSAC) on the issue of dissolvable tobacco products. Pediatricians have two primary concerns related to dissolvable tobacco products: first, that children will accidentally ingest these products, resulting in serious harm or death from nicotine toxicity, and second, that these products will be attractive to youth, facilitating and maintaining nicotine addiction in adolescents. In a moment, I will address each of these concerns in detail.

We hope to soon share new data with the committee on the use of dissolvable and other emerging tobacco products. This data, currently under consideration for publication, comes from the Social Climate Survey of Tobacco Control (SCS-TC), a nationally representative survey of public attitudes and behaviors pertaining to tobacco. This survey is a project of the Richmond Center and is supported by the Flight Attendant Medical Research Institute and Legacy. The results of this survey will show that use of emerging tobacco products is troublingly high among never smokers and former smokers. While emerging tobacco products are often promoted as safer alternatives to cigarettes for current smokers, they may encourage those who have never smoked before and those who previously quit smoking to use these new products. When the paper is available, we will be sure that the committee has access to this important data.

While we are looking forward to sharing this new research, we recognize that on the whole, there is a relatively small evidence base on dissolvable tobacco. These products are a relatively new phenomenon and, as a result, do not benefit from decades of research. However, there are serious potential negative health consequences foreseeable with the expanded use and

availability of dissolvable products. Consequently, we do not have the luxury of waiting for years of data on child poisoning and adolescent addiction to accumulate before embarking on a regulatory path towards reducing these risks. We can and must do more than merely articulate a research agenda for dissolvable tobacco. This committee, therefore, has the challenging task of assessing the danger of these products and making recommendations to decrease these harms based on the best scientific information currently available. It was clearly the intent of Congress when it passed the *Family Smoking Prevention and Tobacco Control Act* to give the Food and Drug Administration (FDA) the authority to regulate both long-standing and emerging tobacco-related threats to the public health.

Accidental Ingestion and Nicotine Toxicity

The Academy is concerned about the potential for dissolvable tobacco to cause serious harm to young children through accidental ingestion. Ingestion of tobacco products remains a major cause of unintentional poisoning in the U.S. From 2006 to 2008, a total of 13,705 cases of ingestions were reported to poison control centers for all types of tobacco products, 70 percent of which involved infants less than one year of age.¹ The vast majority of these ingestions involved cigarettes. If small children ingest unpalatable cigarettes in large numbers, we can have no doubt that they will ingest dissolvable tobacco, products specifically designed to taste good.

The toxicity of tobacco and nicotine is well known. Nicotine poisoning manifests itself through a number of different symptoms. Milder symptoms of nicotine poisoning include vomiting, nausea, diarrhea, and headaches. In severe toxicity, one may experience involuntary twitching and skeletal muscle paralysis, which can lead to difficulty breathing, sweating, palpitations, abdominal pain or cramps, seizures, or death.² Very small amounts of tobacco can be toxic to children. Ingestion of one cigarette, three to five cigarette butts, a pinch of chewing tobacco, or several pieces of gum or a transdermal nicotine patch may be toxic to a child.³ The estimated minimal lethal pediatric dose is 1 milligram (mg) of nicotine per kilogram (kg) of body weight.⁴

Given the recognized toxicity of nicotine, there is reason for great concern about potential child poisonings from dissolvable tobacco products. The serious and potentially life-threatening health effects of nicotine ingestion, combined with the easily accessible and attractive taste of dissolvable tobacco products, may result in an increase in nicotine poisoning among children.

¹ Unintentional child poisonings through ingestion of conventional and novel tobacco products. Connolly GN, Richter P, Aleguas A Jr, Pechacek TF, Stanfill SB, Alpert HR. *Pediatrics*. 2010 May;125(5):896-9

² 5-Minute Toxicology Consult - 1st (2000) ed, Nicotine. Benjamin Camp Richard C. Dart

³ 5-Minute Toxicology Consult - 1st (2000) ed, Nicotine. Benjamin Camp Richard C. Dart

⁴ McGuigan MA. Nicotine. In: Dart RC, ed. *Medical Toxicology*. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2003:601– 604

As an example, one brand of dissolvable tobacco products, RJ Reynolds' Camel Orbs, contains approximately 1.2 mg of nicotine per pellet. At 12 pellets per pack, the total of 14 mg of nicotine in one package could be fatal if ingested by a 2-year-old child of average weight. Camel Sticks can contain 2.4 mg of nicotine per piece. One pack of 12 sticks contains 29 mg nicotine, a potentially lethal dose of nicotine for an average 9-year-old child. This is particularly distressing because as RJ Reynolds said yesterday, its recently redesigned products were deliberately made easier to open and contain no child-proofing after the outer package has been opened.

Merely requiring dissolvable tobacco products to be sold in child-resistant packaging would be insufficient to prevent infants and children from suffering nicotine poisoning. A study evaluating child poisoning incidents treated in U.S. hospital emergency departments demonstrated that approximately 55 percent of more than 86,000 poisoning incidents in 2004 involved products that were stored in child-resistant packaging.⁵ In addition, infants and young children are particularly susceptible to toxic exposures from these products due to their natural curiosity and developmental stage of oral exploration. Studies have shown that infants as young as one year of age have developed an affinity for sweet tastes.⁶ Unlike the bitter, unattractive taste of cigarette tobacco, mint or cinnamon-flavored dissolvable tobacco will be much more palatable to children, and they are therefore more likely to ingest multiple pellets.

The practice and routine of adult consumption of dissolvable tobacco products will also impact the likelihood of nicotine poisoning among infants and children. Unlike cleaning products or other toxic household items, children are likely to view dissolvable tobacco as a food product to be consumed at will, especially due to the resemblance of dissolvable tobacco products to other food products, including breath mints and candy. Young children, in particular, do not possess the developmental and mental capacity to understand the difference between food products and dissolvable tobacco products, and in an attempt to imitate adult behavior, these children may ingest dissolvable tobacco as a food object.

Adolescent Use and Nicotine Addiction

Pediatricians are also concerned that dissolvable tobacco products will be attractive to adolescents, making them susceptible to developing a strong nicotine addiction without ever having to smoke a single cigarette. Nicotine is a highly addictive drug. An adolescent who begins to use dissolvable tobacco may quickly develop an addiction to nicotine. Once this addiction is established, there is a risk that a dissolvable tobacco user would begin using even

⁵ Unintentional child poisonings treated in United States hospital emergency departments: national estimates of incident cases, population-based poisoning rates, and product involvement. Franklin RL, Rodgers GB. *Pediatrics*. 2008 Dec;122(6):1244-51.

⁶ Developmental changes in the acceptance of the five basic tastes in the first year of life. Schwartz C, Issanchou S, Nicklaus S. *Br J Nutr*. 2009 Nov;102(9):1375-85.

more dangerous tobacco products, such as cigarettes. Not only is oral tobacco dangerous in its own right, but it can add to and sustain an adolescent's addiction to smoking by permitting tobacco use when smoking is not allowed, such as at school.

Packages of dissolvable tobacco are the approximate size and shape of a cell phone, allowing children to carry them without raising suspicions of parents and teachers. They can be consumed without the tell-tale signs of smoke or spitting. While parents can smell cigarette smoke on their children, they cannot similarly detect the use of dissolvable tobacco products, which are flavored like breath mints. In essence, dissolvable tobacco products are a nearly perfect product for a child who wants to conceal tobacco use. If you wanted to design a product that would appeal to youth and addict adolescents and young adults to nicotine, this would be it.

We know that adolescent's perceptions of harm differ substantially from reality. Adolescents may believe that dissolvable tobacco products are not dangerous, especially since they resemble food products that are routinely consumed by this age group. We have also known for years that flavored tobacco products appeal to children. With this understanding, Congress banned candy-flavored cigarettes and this committee's previous recommendations support doing the same for menthol cigarettes. Dissolvable tobacco products are similarly flavored, which will undoubtedly increase their appeal to youth.

Recommended Areas of Consideration for TPSAC

The AAP supports the use of smoking cessation therapies that are approved by the FDA as safe and effective. All other nicotine-containing products, including dissolvable tobacco and electronic cigarettes, may be harmful and must be carefully regulated if they continue to be permitted on the market. If this committee does not come to the conclusion that dissolvable tobacco products should be prohibited, we recommend that the committee consider controls necessary to lessen their potential harm to children, adolescents, and all current non-smokers. The American Academy of Pediatrics strongly recommends that the committee address the following topics:

Nicotine Content

The committee should consider the public health benefits of capping the amount of nicotine in each dissolvable piece or serving, as well as in one entire package. For instance, nicotine content could be restricted to levels that would eliminate or drastically reduce the potential to cause nicotine addiction or harm through accidental ingestion.

Child-Resistant Packaging

The committee should consider principles for reducing the likelihood that a child could ingest these products. It may be necessary to employ child proofing technology not only on the outer

package but also for each individual piece, such as blister packs. The committee may also recommend a testing regimen to measure youth accessibility of packaging. It is important to note here that current law bars the Consumer Product Safety Commission (CPSC)—which typically has jurisdiction over child product safety—from regulating any tobacco products. This leaves it solely up to the FDA to ensure that children remain safe from these tobacco products. It will be important for the committee take this responsibility seriously and craft helpful recommendations to assist the agency in protecting children.

Flavoring

The *Tobacco Control Act* banned the use of candy flavors in cigarettes because of their appeal to children, and in March, this committee came to a determination that the public would benefit by expanding this policy to menthol cigarettes as well. The logic behind these actions clearly extends to dissolvable tobacco products as well, and therefore, this committee must seriously consider whether flavorings in these products are appropriate.

Marketing

The committee should also consider characteristics of dissolvable product packaging and advertising that could increase their appeal to children. Packaging that uses bright colors or resembles safe products such as breath mints, for instance, may increase the risk that a young child will mistake tobacco for food. Advertisements meant to convince consumers that dissolvable tobacco products can be consumed safely may also increase usage by children.

Warnings

This committee should consider what warnings—both on packing and advertisements—are necessary to adequately convey the potential dangers of these products to children, including the likelihood of addiction. Camel's dissolvable products currently instruct users in small print to keep "out of reach of children," but do not describe how they might be harmful. Warnings could advise against use by anyone other than current tobacco users or smokers. Public education efforts beyond warnings may also be advisable.

Thank you for the opportunity to speak to you today. We look forward to continuing to work with the FDA and this committee to protect children from the harms of tobacco.