

# ***FDLI Annual Conference***

## ***Panel***

### *Tobacco Harm Reduction: Opportunities & Regulatory Pathways to Achieve*

*May 5, 2017*

Joe Murillo

Vice President, Regulatory Affairs



**Altria**

Altria Client Services

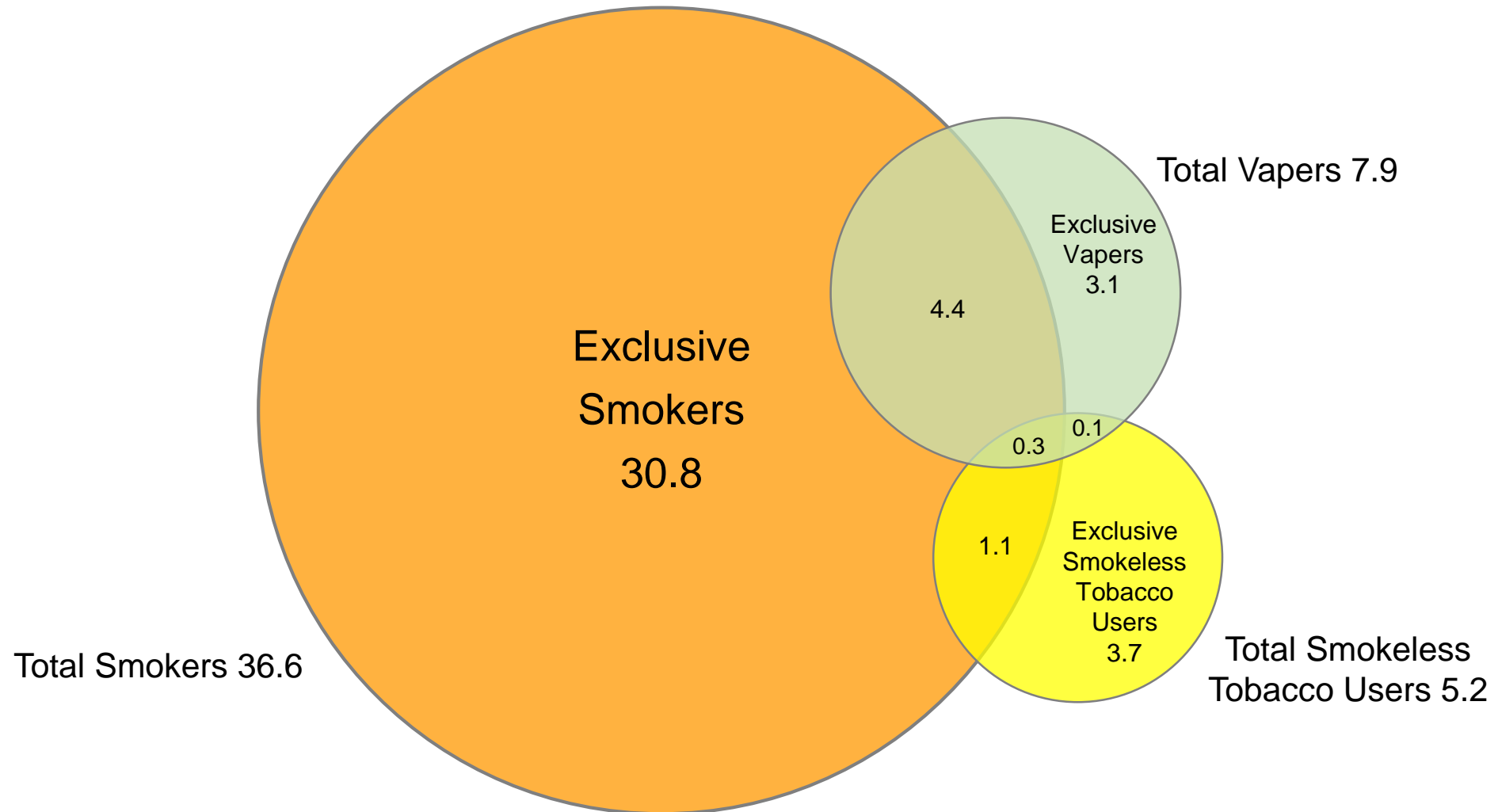


# Our Focus on Tobacco Harm Reduction

- Comprehensive approach
- Focus on products, science and pathways
- Building a portfolio of potentially reduced-harm products to appeal to adult tobacco consumers
- Supported by advocacy, communications and engagement

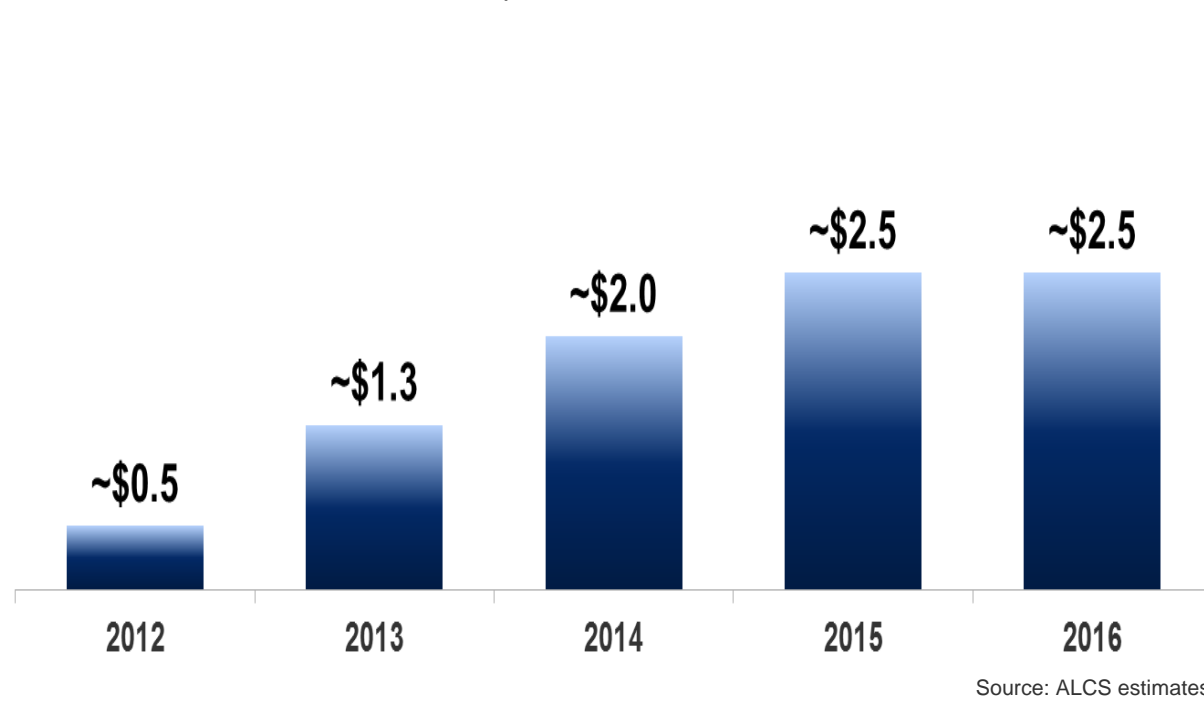


# Millions of U.S. Adult Smokers Currently Use or are Interested in E-Vapor & Smokeless Tobacco Products



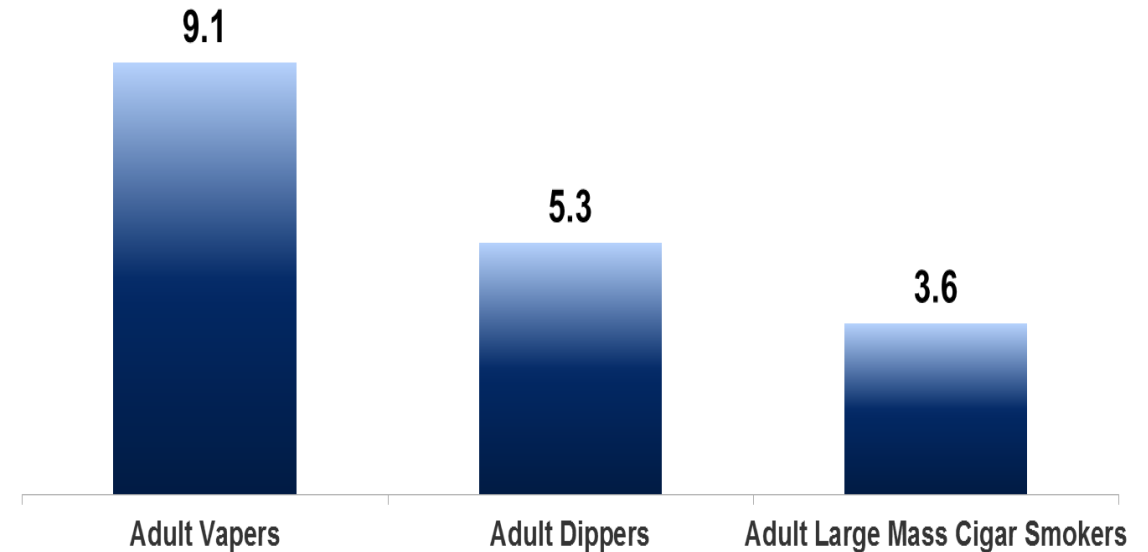
# E-Vapor Presents a Tobacco Harm Reduction Opportunity

Estimated U.S. Consumer Sales  
\$ in Billions



Long Term Opportunity  
in Millions

Past 30-Day Users



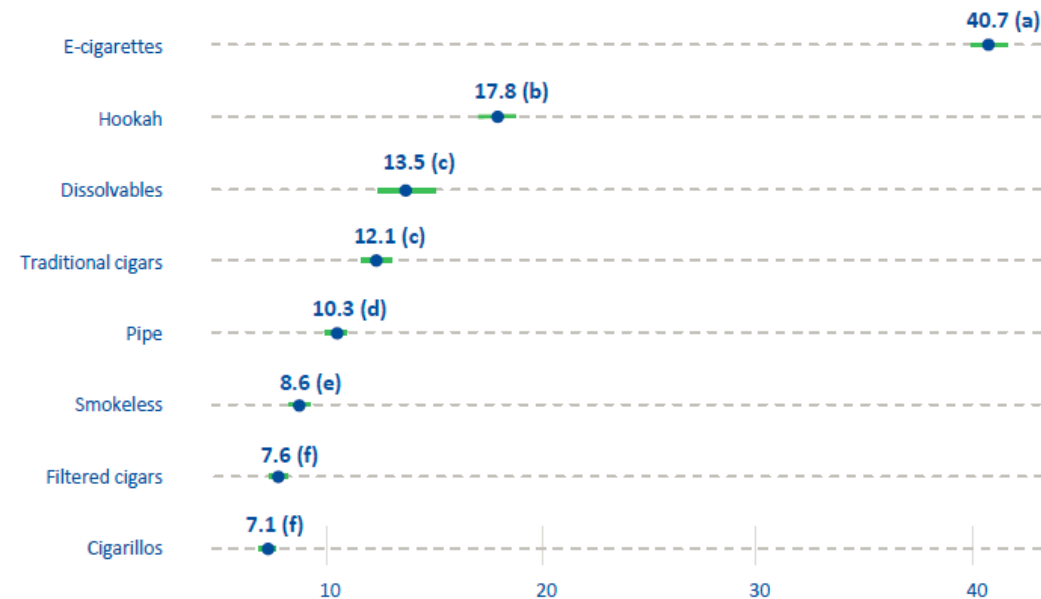
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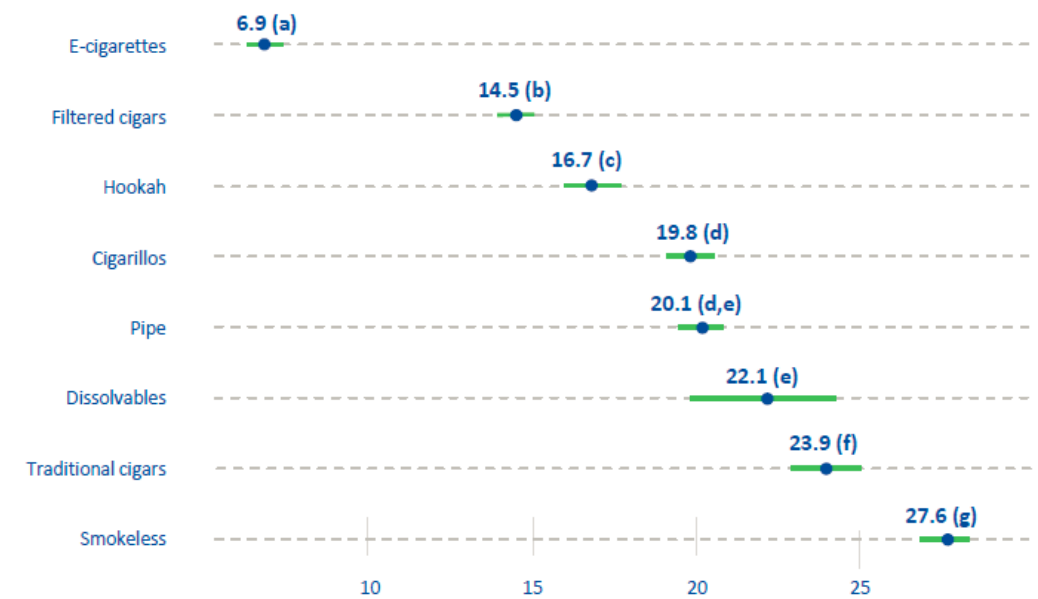


# People Don't Understand that E-Vapor & Smokeless Tobacco Products are Substantially Lower Risk than Cigarettes

% of population thinking each product is less harmful than cigarettes



% of population thinking each product is more harmful than cigarettes

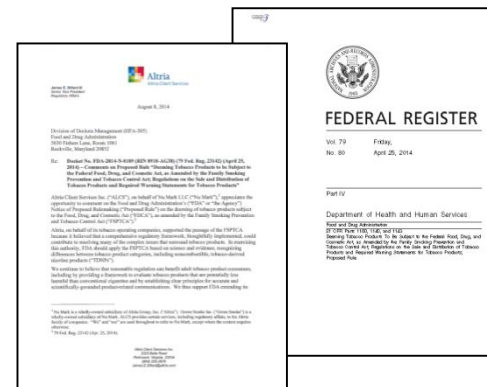


Over 90% of the population thinks smokeless tobacco is as harmful or more harmful than cigarettes

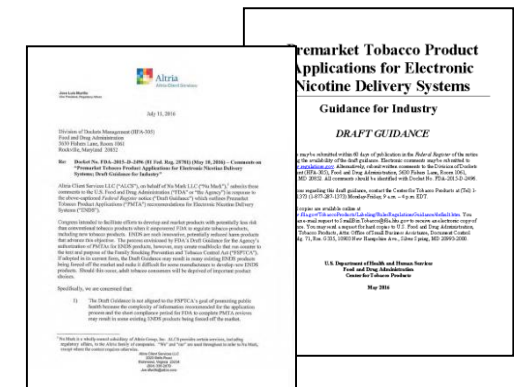
Over 59% of the population thinks e-vapor is as harmful or more harmful than cigarettes

# Premarket Tobacco Application Process Should Promote Public Health

- Pathways should facilitate tobacco product innovation that leads to reduced harm products
  - Implement an accelerated or modified premarket tobacco application pathway for electronic nicotine delivery systems
  - Establish product and performance standards



Comments on behalf of Nu Mark to FDA's proposed deeming rule



Comments on behalf of Nu Mark to FDA's draft guidance on PMTAs for ENDS

# Principles for Newly Deemed Products

- Opportunity for tobacco harm reduction
- Adult tobacco consumers are entitled to accurate, non-misleading information
- FDA regulation should encourage innovation
- Regulation should be science- and evidence-based
- Regulation should preserve and respect the choices of adult tobacco consumers
- Regulation should apply equally to all manufacturers
- FDA must adhere to constitutional principles



# Recent Publications

## PREVENTING CHRONIC DISEASE PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY Volume 14, E32 APRIL 2017

### RESEARCH BRIEF

#### Quit Methods Used by US Adult Cigarette Smokers, 2014–2016

Ralph S. Caraballo, PhD<sup>1</sup>; Paul R. Shafer, MA<sup>2</sup>; Deesha Patel<sup>1</sup>; Kevin C. Davis, MA<sup>2</sup>; Timothy A. McAfee, MD<sup>1</sup>

*Suggested citation for this article:* Caraballo RS, Shafer PR, Patel D, Davis KC, McAfee TA. Quit Methods Used by US Adult Cigarette Smokers, 2014–2016. Prev Chronic Dis 2017; 14:160600. DOI: <https://doi.org/10.5888/pcd14.160600>.

### PEER REVIEWED

### Abstract

To quantify the prevalence of 10 quit methods commonly used by adult cigarette smokers, we used data from a nationally representative longitudinal (2014–2016) online survey of US adult cigarette smokers (n = 15,943). Overall, 74.7% of adult current cigarette smokers use multiple quit methods during their most recent quit attempt. Giving up cigarettes all at once (65.3%) and reducing the number of cigarettes smoked (62.0%) were the most prevalent methods. Substituting some cigarettes with e-cigarettes was used by a greater percentage of smokers than the nicotine patch, nicotine gum, or other cessation aids approved by the US Food and Drug Administration. Further research into the effectiveness of e-cigarettes as a cessation aid is warranted.

### Objective

Quitting cigarette smoking greatly reduces the risk of developing smoking-related diseases; although the health benefits are greater for people who stop at earlier ages, there are benefits at any age (1). The use of electronic cigarettes (e-cigarettes) has increased in the United States (2). Little is known about how the rise in e-cigarette use, particularly among current and former adult cigarette smokers, may have affected quitting behaviors. This study assessed common methods used to try to quit cigarettes among a nationally representative online sample of US adult current smokers surveyed from April 2014 through June 2016.

### Methods

We used data from a nationally representative longitudinal online survey of adult cigarette smokers in the United States. Survey participants were recruited from a probability sample of residential mailing addresses derived from the US Postal Service's Delivery Sequence File, covering approximately 95% of all US households. Study invitation letters, which contained a website link and password to the selected household's survey, were mailed to all sampled households. Each sample household had a known probability of selection, and individual participants could not volunteer for study enrollment. All current smokers who participated at baseline were re-contacted for follow-up in the 5 waves that followed. Details on survey methods are available elsewhere (3). Free and informed consent of participants was obtained, and study methods were approved by the RTI International Institutional Review Board.

The survey was conducted in 6 waves, from April 7, 2014, through June 2, 2016. Our analysis was based on 15,943 current cigarette smokers who reported having made at least one quit attempt in the previous 3 months. The data were weighted to reflect national distributions of sex, age, race/ethnicity, and education among cigarette smokers. Current cigarette smokers were defined as adults aged 18 years or older who had smoked at least 100 cigarettes in their lifetime and currently smoked "every day" or "some days." A cigarette smoking quit attempt in the previous 3 months at follow-up was assessed by asking current smokers, "During the past 3 months, how many times have you stopped smoking for one day or longer because you were trying to quit smoking cigarettes for good?" Those who answered they tried to quit one or more times were categorized as having made a quit attempt and were subsequently asked, "When you last tried to quit smoking, did you do any of the following?" The survey provided a list of 10 quit methods, and respondents were asked to indicate which methods they used by responding yes or no to each method. Respondents were permitted to select multiple quit methods. We estimated the prevalence of using each quit method by calculating

## Centers for Disease Control and Prevention Research Brief: *Quit Methods Used by US Adult Cigarette Smokers, 2014–2016.* Caraballo, Shafer, Patel, Davis, McAfee. Preventing Chronic Disease. Volume 14, E32 April 2017

## College of Problems of Drug Dependence News and Views: *Adolescents and e-cigarettes: Objects of concern may appear larger than they are.*

Kozlowski, Warner. Drug and Alcohol Dependence 174. Page 209–214  
May 2017



## Adolescents and e-cigarettes: Objects of concern may appear larger than they are\*

Lynn T. Kozlowski<sup>1,2,\*</sup>, Kenneth E. Warner<sup>2</sup>

<sup>1</sup> University at Buffalo, State University of New York, School of Public Health and Health Professions, Department of Community Health and Health Behavior, 323 Kimbark Tower, 3405 Main St., Buffalo, NY 14214-2602, United States  
<sup>2</sup> University of Michigan, School of Public Health, Department of Health Management & Policy, Room 30517 SPH 2, 1415 Washington Heights, Ann Arbor, MI 48109-0029, United States

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### 1. Introduction

The debate about electronic cigarettes ranks as perhaps the most divisive in the history of tobacco control. Proponents believe that e-cigarettes could foster widespread abandonment of combusted tobacco products, by far the most dangerous form of tobacco use, and thereby dramatically reduce the disease and death caused by smoking (Abrams, 2014). Opponents fear these products may seduce new generations of youth into nicotine addiction, many of whom may even find a "gateway" to cigarette smoking. They see in e-cigarettes the potential of "renormalizing" smoking (U.S. Department of Health

and Human Services, 2016). In striking contrast to supporters' view, some opponents worry that dual use of cigarettes and e-cigarettes by adults will reduce smoking cessation. And in similarly striking contrast to opponents' worries about kids, supporters believe that e-cigarettes may be providing young people an alternative to far more dangerous cigarette smoking (Kozlowski, in press; Kozlowski and Sorensen, in press; Warner, 2016).

Uncertainty about the health hazards associated with novel products, how they are used and how their use affects smoking, has created a burgeoning research field. A systematic review of empirical research through May 2016 included 667 articles (Chen et al., 2016). The intensity of people's moral emotions (anger, disgust, or contempt) about the novel products can color their interpretation of the science, however (Kozlowski, 2013; Kozlowski, in press), consistent with the concept of signal detection (Anderson, 2015; Tanner and Swets, 1954). Detection of even simple signals, such as the presence or absence of a tone, is influenced by rewards for detecting or not

detecting the stimulus. When the signals, including evidence, support favored narratives on complex issues, especially in a morally and politically-charged context such as tobacco control (Kozlowski, 2015; Kozlowski, in press), there are biases for (a) seeking information that supports one's position (confirmation bias), (b) more critically assessing opposing work (disconfirmation bias), and (c) inclining to support one's prior beliefs (a prior belief effect) (Strack and et al., 2011). We believe that signal detection is playing a central role in the debate over e-cigarettes. People on both sides are finding evidence that supports what they want to believe.

In this essay we examine the relative merits of leading studies on whether e-cigarettes pose significant threats to youth's health and well-being. While we focus on youth, the context occasionally requires that we address adult-relevant considerations as well. Overall we conclude that the risks for youth posed by e-cigarettes likely fall far short of those feared by the products' opponents. Conversely, e-cigarettes may create a net benefit for some high-risk young people.

\* This material is not peer-reviewed by the journal, but is reviewed prior to publication by the members of the College Problems of Drug Dependence and members of the College News and Views is edited by the chair of the college Publications Committee: Dr. S. S. Muesel, M.D., Ph.D., Mailman School of Public Health, Department of Epidemiology, Columbia University, New York, NY 10032, USA.

\* Corresponding author.  
E-mail address: [LKozlowski@buffalo.edu](mailto:LKozlowski@buffalo.edu) (L.T. Kozlowski).

<https://doi.org/10.1016/j.drugalcdep.2017.01.001>  
0266-7267/



# **Establishing Regulatory Pathways Without Losing Sight of the Public Health Goal and Message**

Jim Solyst

Vice President, Federal Regulatory Affairs

Swedish Match North America

## Two Goals

- Establish PMTA and MRTPA pathways that are understood and provide needed evidence;
- Achieve an immediate public health benefit.

## Swedish Match PMTA and MRTPA Experience

- Company is proud to be the trailblazer.
- We understand that the Company has become Exhibit A in CTP's description of the PMTA and MRTP pathways.
- The regulated community and other stakeholders have a much better understanding of the process largely because of the Swedish Match experience.

# Concern

- More attention is paid to the regulatory pathways and not enough attention is given to the fundamental public health goal and risk communication message.

# PMTA Example

- On November 10, 2015 we received a PMTA order for the eight General snus products sold in the US.
- The decision document—the Technical Project Lead report, the TPL-- provides a very clear rationale for why the decision was made
  - The TPL is an outstanding report; one of the most important and significant regulatory documents in global tobacco control and harm reduction.
  - The TPL offers three “top-line reasons” why the PMTA order was issued: GOTHIA TEK, low TSNAs, and low other HPHCs.

# PMTA continued

- The brief and readable TPL Executive Summary includes a paragraph quantifying the risk reduction achieved by switching from another smokeless product to General snus, including the statement: “...an individual using these products with reduced NNN levels would reduce the excess cancer risk by 90% compared to use of moist snuff...”
- The TPL is a significant regulatory science document but does it impact adult tobacco consumers?
- The public health/risk communication message is there: switch from your current smokeless product (and certainly cigarettes) to General snus and will greatly reduce your risk. But you have to find the document and then decipher the message.

# PMTA continued

- CTP also issued a press release;
  - Page and a half long, nine paragraphs, and it is not until the second page, the 6th paragraph, that the product and the company are named.
  - The first 3 paragraphs are all about the pathway and it is not until the 4th paragraph that the term public health is used, and that is in the context of standard that must be met: “appropriate for the protection of the public health.”
- The press release contains several statements indicating that just because a product is a PMTA does not make it a safe. What the press release does not state is that if an adult tobacco consumer switches from cigarettes or other smokeless products to General snus they will greatly reduce their risk.

# MRTPA Claim

- The MRTPA claim is to remove two current warning labels that is on all smokeless products: this product causes mouth cancer and tooth loss and gum disease; and;
- Add a statement that the product is substantially less risky than smoking.
- On December 14, 2016 CTP issued a partial decision, denying the request to remove the tooth loss and gum disease warning label; stating that we would need to prove that the product **cannot** cause tooth loss and gum disease.



# MRTPA Status

- My interpretation of CTP correspondence, and public statements, most recently at the April TPSAC meeting, is that CTP believes General snus is a Modified Risk product; but at this time CTP is not willing to remove the existing warning labels.
- What needs to be resolved is how to characterize the product (what should be the claim) to satisfy CTP.

# MRTPA Status

- We don't agree with the CTP partial decision but we understand the rationale.
- But does the partial decision make sense from a public health and risk communication perspective?
- It is wise to determine a product is protective of the public health (PMTA decision) yet continue to have the mouth cancer, tooth loss/gum disease warning labels?