



# Marketing and Advertising for Modified Risk Tobacco Products

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*Moderated by* **Bryan M. Haynes**, Partner, Troutman Sanders LLP



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# Risk Estimates for Tobacco Products

Aruni Bhatnagar, PhD, FAHA  
Director, American Heart Association Tobacco Regulation Center  
Department of Medicine  
University of Louisville, Louisville, KY

# Factors Affecting Risk Assessment

Exposure – Harmful and Potentially Harmful Constituents (HPHCs)

Patterns of Use - A 50% reduction in exposure could be offset by 50% greater use

Vulnerable populations – Some individuals may be more susceptible than others

Addiction potential

# Factors Affecting Risk Assessment

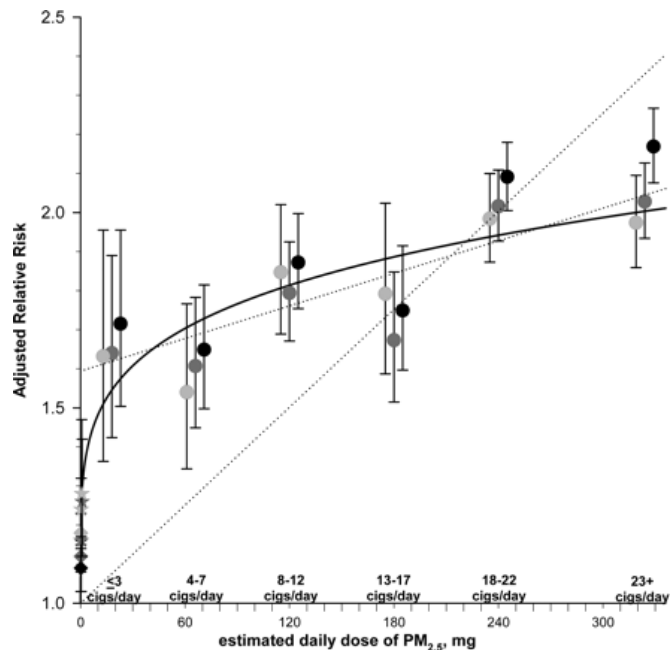
Individual versus population risk

Use liability or “off label” use

Number needed to treat

Unintended consequences

# Reduction in exposure is not proportional to reduction in harm



Most of the risk of smoking is at low doses: 80 % of the harm at <3 cigarettes/day



# **Marketing Modified Risk Tobacco Products**

*Cynthia Cabrera  
Cating Group*

@LungAssociation

Heard of **#NicSick**? This sickness is caused by nicotine overdosing. **@CDCgov** warns that 50 to 60 milligrams of nicotine is a deadly dose for an adult who weighs about 150 pounds. Find out why nicotine overdose can have serious consequences.



#### What It Means to Be Nic-Sick

The more nicotine present in a tobacco product, the more addictive it is, and when it comes to e-cigarettes and vaping, the risk is high. All nicotine is ...

[lung.org](https://lung.org)



## How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century

Bernd Maver<sup>✉</sup>

The mismatch between the generally accepted lethal dose and documented cases of nicotine intoxication raises the question for the genuine source of the 60-mg dose. Literature and Internet searches provided circular and often misleading references to databases or textbooks, which either simply state the dose

without reference or refer to another textbook and so on. To give an example, the following statement is found on the webpage of the Centers for Disease Control and Prevention

(<http://www.cdc.gov/niosh/idlh/54115.html>): “The fatal human dose has been estimated to be about 50–60 mg (Lazutka et al. 1969).” However, Lazutka et al. describe the determination of LD<sub>50</sub> values for mice and rats and do not even mention human toxicity (Lazutka et al. 1969). The second paper cited on this Web site (Lehman 1949) was actually published in 1949, and neither provides any supporting data (Lehmann 1949). Screening the German literature published before World War II eventually revealed references to a textbook published in 1906 by Rudolf Kobert (1854–1918), a renowned pharmacologist and pioneer of toxicology in Germany. In the chapter on nicotine of his *Lehrbuch der Intoxikationen*, Kobert makes the following statement (Kobert 1906):

Although an LD<sub>50</sub> of 0.8 mg/kg would implicate that the toxicity of nicotine is similar to or even higher than that of cyanide, fatal nicotine intoxications are relatively rare, and there are countless records of subjects who survived consumption of nicotine in amounts far higher than 60 mg (Larson et al. 1961). The most drastic example is probably survival of a suicide attempt with 4 g of pure nicotine (Schmidt 1931).

While this is certainly an exceptional case, in which the amount of bioavailable nicotine was markedly reduced by vomiting, ingestion of tobacco or nicotine gums at doses up to 6 mg/kg nicotine was reported to evoke symptoms of intoxication without causing death (Malizia et al. 1983; Smolinske et al. 1988). These and many other literature reports on nonfatal nicotine intoxications are hardly compatible with a lethal dose of 60 mg or less.

The discrepancy between the 60-mg dose and published cases of nicotine intoxication has been noted previously (Matsushima et al. 1995; Metzler et al. 2005), but nonetheless, this value is still accepted without scrutiny and taken as the basis for worldwide safety regulations of tobacco and other nicotine-containing products. Nicotine is a toxic compound that should be handled with care, but the frequent warnings of potential fatalities caused by ingestion of small amounts of tobacco products or diluted nicotine-containing solutions are unjustified and need to be revised in light of overwhelming data indicating that more than 0.5 g of oral nicotine is required to kill an adult.



**ParentsAgainstVaping** @ParentsvsVape · 22h

Vaping-related illnesses increase again, but at a slightly slower rate. At least 33 have died [usatoday.com/story/news/nat..](https://www.usatoday.com/story/news/nat..) via [@usatoday](#)

## Public Health Alert:

Severe Lung Illness  
Associated with  
E-Cigarette Use



Vaping-related illnesses increase again, but at a slower rate. At least ...

The number of vaping-related deaths climbed to 33 and injuries rose to 1,479, a decline in the previous pace, the CDC said.

[usatoday.com](https://www.usatoday.com)



**ROB** @wmpk32 · Sep 17

Replying to [@NYGovCuomo](#)

He just doesn't care. At all.

[#vapingsaveslives](#) [#ivapeivote](#) [#WeVapeWeVote](#) [#VapeBan](#) [#flavorban](#)

“Is vaping better than smoking?  
Technically yes. But, so what?”  
- Andrew Cuomo, New York State Governor, 2019






The executive order directs the Department of Public Health (CDPH) to launch a \$20 million statewide digital and social media public awareness campaign to educate youth, young adults and parents about the health risks of vaping nicotine and cannabis products.

“As a parent, I understand the anxiety caused by the deceptive marketing tactics and flavored options designed to target our kids. With mysterious lung illnesses and deaths on the rise, we have to educate our kids and do everything we can to tackle this crisis. <https://tobaccofreca.com/e-cigarettes/governor-gavin-newsom-signs-executive-order-to-confront-youth-vaping-epidemic/>”



**OUT OF FIVE "INFORMATIONAL" VIDEOS  
NONE  
MENTIONS THE LINK BETWEEN VAPING ILLNESS AND ILLICIT THC**





***If you are an adult using e-cigarettes, or vaping, products, to quit smoking, do not return to smoking cigarettes. Adults addicted to nicotine using e-cigarettes should weigh all risks and benefits, and consider utilizing FDA-approved nicotine replacement therapies.***

[https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html)

***No youth or pregnant women should be using any vaping product, regardless of the substance. Adults who do not currently use tobacco products should not start using these products. If you are an adult who uses e-cigarettes instead of cigarette smoking, do not return to smoking cigarettes.***

<https://www.fda.gov/consumers/consumer-updates/vaping-illness-update-fda-warns-public-stop-using-tetrahydrocannabinol-thc-containing-vaping>



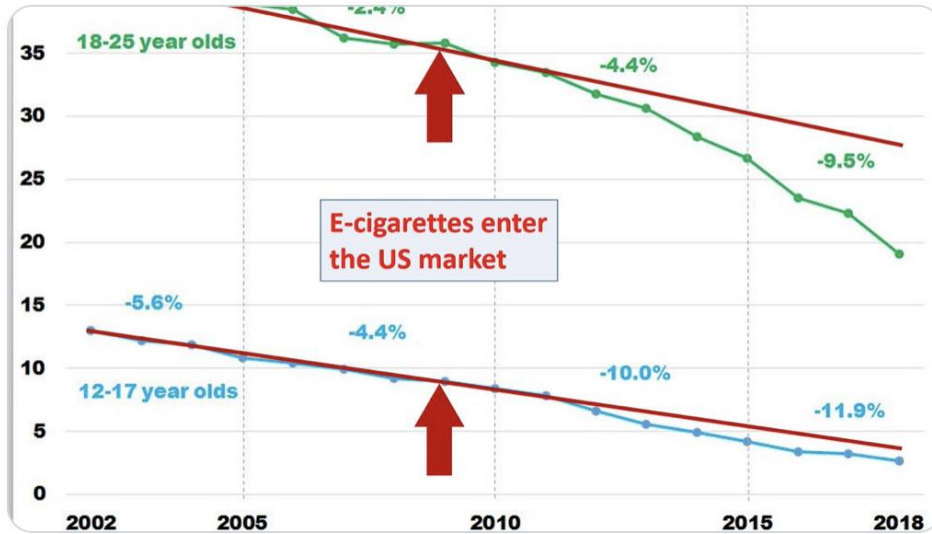
Charles A. Gardner, PhD @ChaunceyGardner · 12h

Replying to @ScottGottliebMD

Sorry. How can any sensible being NOT see this?

Data JUST shared by former FDA Commissioner Gottlieb (above). NO UNDER-AGE PERSON SHOULD VAPE. But no major media outlet is willing to carry this TRUTH.

@ABC @cbsnews @NBCNews @foxnews @nytimes @washingtonpost @chicagotribune



3

24

40

↑

The Results of the National Youth Tobacco Survey are in and more teens are vaping. Many are claiming that vaping is attracting youth due to flavor options. However, the details in the 2018 survey show that the chances are much higher for those who had already smoked cigarettes or used nicotine in some form to have used an e-cigarette in the past-month. The odds are 26.8 times higher for a teenager who has smoked 100 or more cigarettes in their lifetime to be a past-month vaper than they are for a never-smoker.

<https://medium.com/@rssvc/the-real-reason-why-some-teens-are-choosing-vapes-fc2d80188a77>



# Reduced Risk Messaging Is OK if it's Drugs & Sex



**The ObG Project** @TheObGProject · Jul 5, 2018

ALERT The FDA has approved PrEP for adolescents as well as adults. We summarize key @CDC\_HIVAIDS guideline recommendations on Truvada, including clinical actions, dosage regimen, & pregnancy-related issues [ht.ly/SM7K30kMWUJ](https://t.ly/SM7K30kMWUJ) #publichealth #safesex



CDC Guidelines on Daily Oral Antiretroviral Preexposure Prophylaxis t...

In May 2018, the FDA approved daily oral antiretroviral preexposure prophylaxis (PrEP) with Truvada (tenofovir plus emtricitabine) for ... [obgproject.com](https://t.ly/obgproject.com)



**TuSNHD** @TuSNHD · Feb 20, 2018

#NationalCondomWeek: @CDCgov reports that when male latex condoms fail, it is usually due to user error! There is a right and wrong way to use a condom: [j.mp/2okwUxG](https://t.me/j.mp/2okwUxG) #SafeSex




**NYHRE** @NYHarmReduction · Oct 29, 2018

@CDC director @RobertRedfield tells @statsnews's @HelenBranswell that he thinks #HIV transmission in the US "could be halted over the next 3 to 7 years"  
How? #HIVTreatment-- including in prisons, #PrEP, and #NeedleExchange programs




The end of HIV transmission in the U.S.: A once-unthinkable dream b...  
The struggle against HIV may be undergoing a sea change.  
[pbs.org](https://t.me/pbs.org)



 **laura** @frenchonionorgy · Oct 11  
before i started juuling, id smoke about a pack of marb lights a day. i quit that entirely when i started the juul. i typically would go through a pod a day. i switched back to marb lights and now i only smoke 3 a day

17 2 6

 **Erin Mills** @NYSMom4Kiddos Follow

Replying to @frenchonionorgy

Beautiful Laura ❤️ choose health. Your moment can help others 👍

12:43 AM - 13 Oct 2019



## weet

**From:** Fradkin, Nick (DOH)  
**Sent:** Tuesday, April 17, 2018 12:23 PM  
**To:** Wasmundt, Stacia N (DOH)  
**Subject:** RE: Nick's interview with the Spokesman Review

Thaaaaanks. Look at us, transforming *relatively* small issues (JUUL, cessation barriers) into bigger policy issues (T21, funding). 😊 😊

*Nick Fradkin*

Tobacco Cessation Consultant  
Washington State Department of Health  
Phone: (360) 236-3518

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**From:** Wasmundt, Stacia N (DOH)  
**Sent:** Tuesday, April 17, 2018 9:12 AM  
**To:** Limtiaco, Frances (DOH) <Frances.Limtiaco@DOH.WA.GOV>; Wischnesky, Shanae J (DOH) <Shanae.Wischnesky@doh.wa.gov>; Jakvani, Samroz (DOH) <Samroz.Jakvani@doh.wa.gov>; Fradkin, Nick (DOH) <nick.fradkin@doh.wa.gov>  
**Cc:** Migliore Santiago, Patti (DOH) <Patti.MiglioreSantiago@doh.wa.gov>  
**Subject:** RE: Nick's interview with the Spokesman Review

Awesome job, Nick!!!

*Stacia Wasmundt*

Youth Tobacco and Vapor Product Prevention Consultant  
Tobacco and Vapor Product Prevention and Control Program  
Office of Healthy and Safe Communities



**Wells Fargo** analyst Bonnie Herzog also saw a trend toward more traditional cigarette usage, seeing volumes fall 6.2% in the four-week period ending Oct. 5, better than the 6.9% decline the industry experienced over the previous 12 weeks.

As more investigations are conducted into the vaping crisis to determine its origins, health agencies may eventually clear the broader e-cig industry of complicity in the illness and deaths that occurred, but by then the damage may be done, as users may have already decided to revert to smoking cigarettes again.

[https://www.fool.com/pwa/investing/2019/10/19/is-e-cig-health-crisis-causing-users-to-start-smok.aspx?\\_\\_twitter\\_impression=true](https://www.fool.com/pwa/investing/2019/10/19/is-e-cig-health-crisis-causing-users-to-start-smok.aspx?__twitter_impression=true)

**Cowen & Co.'s** latest consumer survey for September showed the incidence of cigarette usage jumped 1 percentage point after several consecutive months of declines. While at 14.7% it is still near the all-time low it hit in August of 13.7%, and it remains 100 basis points below where it was a year ago, that the increase comes as the vaping crisis grabs headlines is significant.

[https://www.fool.com/pwa/investing/2019/10/19/is-e-cig-health-crisis-causing-users-to-start-smok.aspx?\\_\\_twitter\\_impression=true](https://www.fool.com/pwa/investing/2019/10/19/is-e-cig-health-crisis-causing-users-to-start-smok.aspx?__twitter_impression=true)



**Citi** upgrades Altria to Neutral on 'less bad' cigarette volume outlook Citi analyst Adam Spielman upgraded Altria Group to Neutral from Sell with a price target of \$46, up from \$45. The stock closed Thursday up 77c to \$44.28. The analyst now expects "less bad" cigarette volumes next year. Electronic vapor usage will fall due to the negative publicity around vaping and the imminent flavor ban, which will help cigarettes... <https://thefly.com/landingPageNews.php?id=2977295>



Thank you for listening!



# Modified Risk Tobacco Products: A Path Forward?

Brittani Cushman  
SVP, External Affairs  
Turning Point Brands, Inc.



FDA NEWS RELEASE

# **FDA grants first-ever modified risk orders to eight smokeless tobacco products**

*FDA concludes completely switching from cigarettes to these authorized products  
lowers certain health risks*

“Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

# M RTP Order

- Requires continued use of Smokeless Tobacco Warning Statements

**WARNING:** This product can cause mouth cancer.

**WARNING:** This product can cause gum disease and tooth loss.

**WARNING:** This product is not a safe alternative to cigarettes.

**WARNING:** Smokeless tobacco is addictive.

Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

**WARNING:** This product can cause mouth cancer.

**WARNING:** This product can cause gum disease and tooth loss.

**WARNING:** This product is not a safe alternative to cigarettes.

**WARNING:** Smokeless tobacco is addictive.

# A Path Forward?

- “Today’s action **demonstrates the viability of the pathway** for companies to market specific tobacco products as less harmful to consumers ...”
- “In addition to stringent restrictions to limit youth access and exposure to advertising, this **time-limited authorization** comes with a number of postmarket requirements that will allow us to keep a close watch on the marketplace.”
- “**Should any information lead us to determine that the marketing of these products as posing less risk no longer benefits the health of the population as a whole**, the agency would consider withdrawing this authorization.”

# The Process

- First submitted – June 2014
- TPSAC – April 2015
- Partial Decision – December 2016
- Amendment Submitted – September 2018
- TPSAC – February 2019
- Docket Closed – May 2019
- Decision – October 2019



# What's the point?

- Marketing?
- Tax Advantage?
- Flavor Bans?
- Public Health Campaign in reaction?

# FDA Must Not Allow IQOS to Become the Next Juul Among Kids

Statement of Matthew L. Myers, President, Campaign for Tobacco-Free Kids

April 30, 2019

Most public health groups criticized the F.D.A.'s decision. Erika Sward, an assistant vice president of the American Lung Association, said: "Inhaling chemicals and toxins into one's lungs always poses risks."

*FDA Permits the Sale of IQOS, a New Tobacco Device, New York Times (April 30, 2019)*

Health Groups' Comments Urging FDA to Deny Modified Risk Tobacco Product Applications for IQOS   
(Feb. 11, 2019)

## Heat-not-burn cigarettes may still harm the heart, as FDA mulls approval

By AMERICAN HEART ASSOCIATION NEWS



# Thank you

Brittani Cushman  
SVP, External Affairs  
Turning Point Brands, Inc.





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