



THE FLAVOR TRAP

How Tobacco Companies Are
Luring Kids with Candy-Flavored
E-Cigarettes and Cigars

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™



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Executive Summary

A 2009 federal law, the Family Smoking Prevention and Tobacco Control Act, prohibited the sale of cigarettes with characterizing flavors other than menthol or tobacco, including candy and fruit flavors. However, this prohibition did not apply to other tobacco products. In recent years, tobacco companies have significantly stepped up the introduction and marketing of flavored non-cigarette tobacco products, especially electronic cigarettes (e-cigarettes) and cigars.

This report documents the widespread availability of these flavored other tobacco products and the scientific evidence demonstrating that flavors play a critical role in the popularity of these products among youth. These flavored products are undermining the nation's overall efforts to reduce youth tobacco use and putting a new generation of kids at risk of nicotine addiction and the serious health harms that result from tobacco use. This report's key findings include:

- In recent years, there has been an explosion of sweet-flavored tobacco products, especially e-cigarettes and cigars.** These products are available in a wide assortment of flavors that seem like they belong in a candy store or ice cream parlor – like gummy bear, cotton candy, peanut butter cup, cookies 'n cream and pop rocks for e-cigarettes and chocolate, wild berry, watermelon, lemonade and cherry dynamite for cigars. A 2014 study identified more than 7,700 unique e-cigarette flavors, with an average of more than 240 new flavors being added per month. Sales of flavored cigars have increased by nearly 50 percent since 2008, and flavored cigars made up more than half (52.1 percent) of the U.S. cigar market in 2015, according to Nielsen convenience store market scanner data. Further, the number of unique cigar flavor names more than doubled from 2008 to 2015, from 108 to 250.
- These sweet products have fueled the popularity of e-cigarettes and cigars among youth.** While there has been a steep drop in youth use of traditional cigarettes, overall youth use of any tobacco product has remained steady in recent years due to the popularity of tobacco products like cigars and e-cigarettes – products that are predominantly flavored. From 2011 to 2015, current use of e-cigarettes among high school students increased more than ten-fold – from 1.5 percent to 16 percent – according to the National Youth Tobacco Survey (while the 2016 Monitoring the Future survey shows the first evidence of a decline in youth use of e-cigarettes, it also shows that e-cigarettes continue to be the most popular tobacco products among kids). In addition, more high school boys now smoke cigars than cigarettes – 14 percent vs. 11.8 percent.
- Studies show that flavors play a major role in youth use of tobacco products such as e-cigarettes and cigars.** A government study found that 81 percent of kids who have ever used tobacco products started with a flavored product, including 81 percent who have ever tried e-cigarettes and 65 percent who have ever tried cigars. Youth also cite flavors as a major reason for their current use of non-cigarette tobacco products, with 81.5 percent of youth e-cigarette users and 73.8 percent of youth cigar users saying they used the product “because they come in flavors I like.”

- **Tobacco companies have a long history of developing and marketing flavored tobacco products as “starter” products that attract kids.** Flavors improve the taste and reduce the harshness of tobacco products, making them more appealing and easier for beginners – often kids – to try the product and ultimately become addicted. Since most tobacco users start before age 18, flavored tobacco products play a critical role in the industry’s marketing playbook. Flavors can also create the impression that a product is less harmful than it really is.
- **Strong FDA regulation is needed to protect kids from flavored tobacco products.** After years of delay, the U.S. Food and Drug Administration (FDA) in 2016 issued new rules for previously unregulated tobacco products, including e-cigarettes and cigars. Despite the strong evidence that flavored tobacco products are attracting and addicting a new generation of kids, legislation has been introduced in Congress that would greatly weaken FDA oversight of e-cigarettes and cigars, including the many candy-flavored products on the market. Congress should reject these proposals. In fact, the FDA should strengthen its rules by prohibiting all flavored tobacco products.



Introduction

Cigarettes with characterizing flavors other than menthol and tobacco were prohibited in the United States on September 22, 2009, as part of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which gave the FDA authority over tobacco products.¹ Prior to 2009, tobacco companies marketed cigarettes with candy and fruit flavors, images and names that appealed to a young audience.

However, the prohibition on characterizing flavors did not apply to other tobacco products. In recent years, tobacco companies have significantly stepped up the introduction and marketing of flavored non-cigarette tobacco products, especially e-cigarettes and cigars (i.e., large cigars, small cigars and cigarillos). These products are widely available through convenience stores, other retail outlets and online retailers.

As this report documents, these flavored tobacco products are popular with kids, and the scientific evidence demonstrates that flavors play a major role in youth initiation and continued use of these products. The recent proliferation of flavored tobacco products also continues tobacco companies' long history of developing and marketing flavored products as "starter" products that attract kids.



These flavored products are undermining the nation's overall efforts to reduce youth tobacco use and putting a new generation of kids at risk of nicotine addiction and the serious health harms that result from tobacco use.

Flavored tobacco products contain nicotine, the highly addictive chemical that makes it so easy to get hooked on tobacco products and so hard to quit. The 2016 U.S. Surgeon General's Report, *E-Cigarette Use Among Youth and Young Adults*, warned that youth use of products containing nicotine in any form is unsafe, can cause addiction and can harm the developing adolescent brain, disrupting attention and learning. The U.S. Surgeon General's Report also concluded, "E-cigarette use is strongly associated with the use of other tobacco products among youth and young adults, including combustible tobacco products." The report further found that e-cigarette aerosol is not harmless and can contain harmful and potentially harmful constituents, including nicotine.²

Cigar smoking also poses serious health risks. According to the National Cancer Institute, cigar smoking causes cancer of the oral cavity, larynx, esophagus and lung, and cigar smokers are also at increased risk for aortic aneurysms. Daily cigar smokers, particularly those who inhale, have an increased risk of heart disease and chronic obstructive pulmonary disease (COPD).³

Given the health risks of these products and the role of flavors in promoting their use among youth, addressing the impact of flavored tobacco products must be a public health priority.



Trends in Youth Tobacco Use

Since 1997, current (past-month) cigarette use among high school students has declined by 70 percent, from 36.4 percent to a record-low 10.8 percent in 2015, according to the Youth Risk Behavior Survey (YRBS) conducted by the Centers for Disease Control and Prevention (CDC).⁴ However, the popularity of other tobacco products threatens to undermine progress in reducing overall youth tobacco use. The 2015 YRBS found that 31.4 percent of high school students reported using some form of tobacco in the past month, including cigarettes, smokeless tobacco, cigars or e-cigarettes. Another government survey, the National Youth Tobacco Survey (NYTS), found there was no significant decline in overall tobacco use from 2011-2015, with an estimated 4.7 million middle and high school students who were current tobacco users in 2015.⁵

E-cigarettes, first introduced to the U.S. marketplace in 2006-2007, have skyrocketed in popularity among kids, contributing to this stall in reducing overall tobacco use. From 2011-2015, past-month e-cigarette use increased more than ten-fold among high school students, from 1.5 percent to 16 percent, according to the NYTS, which has tracked youth e-cigarette use the longest of any survey.⁶ Recent data from another national survey, the 2016 Monitoring the Future survey, show the first evidence of a decline in youth use of e-cigarettes, but prevalence of e-cigarette use continues to exceed that of all other tobacco products.⁷ In at least 43 states, e-cigarette use among high school students exceeds cigarette smoking.⁸ Data from the 2015 NYT show that 13.1 percent of high school students who have never used another tobacco product have tried e-cigarettes.⁹ Earlier data from the NYTS show that the number of youth who had used e-cigarettes, but had never smoked a regular cigarette, increased from 79,000 in 2011 to more than 263,000 in 2013.¹⁰

MORE HIGH SCHOOL BOYS SMOKE CIGARS THAN CIGARETTES (2015)

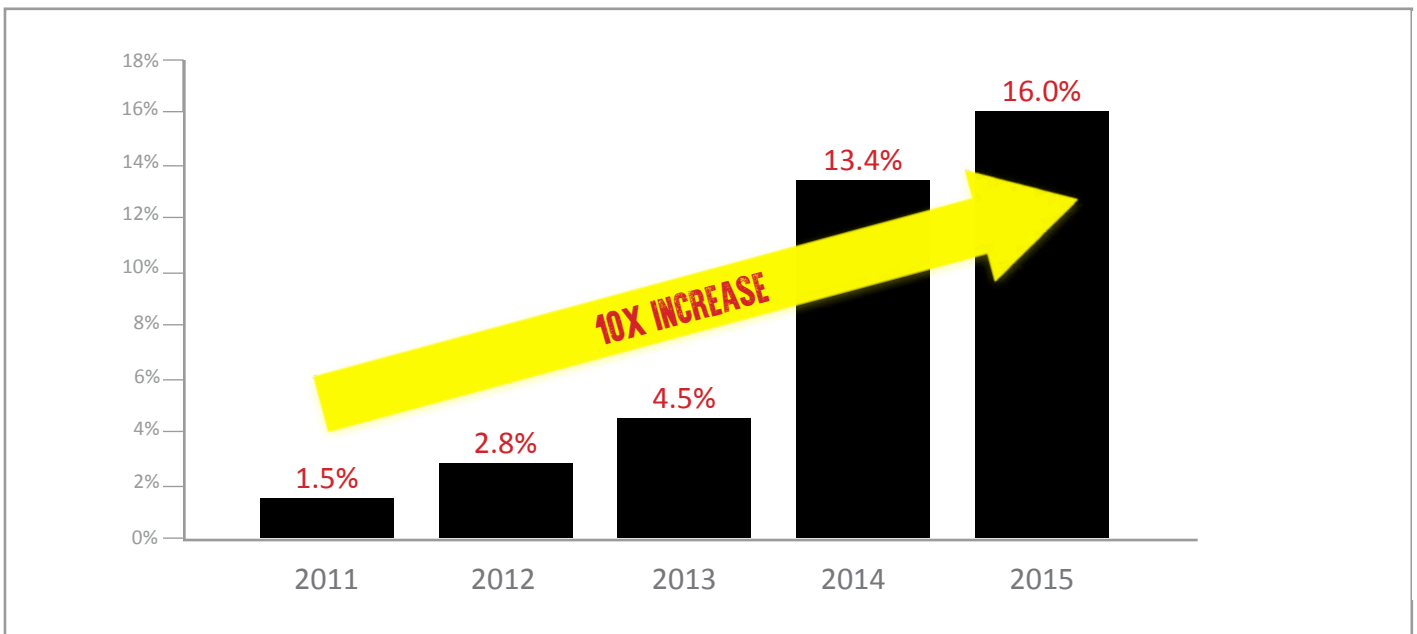


Source: CDC 2015 Youth Risk Behavior Survey

While overall cigar use has been declining in recent years, cigars remain popular among youth, particularly high school boys. While 11.8 percent of high school boys smoke cigarettes, 14 percent are current cigar smokers.¹¹ In at least 33 states, prevalence of cigar use equals or surpasses use of cigarettes among high school boys.¹²

The scientific evidence indicates these trends are linked to the growing market of flavored tobacco products.

HIGH SCHOOL E-CIGARETTE USE 2011-2015



Source: CDC National Youth Tobacco Survey



Flavored Tobacco Products Are on the Rise

Despite the FDA’s ban on flavored cigarettes, the overall market for flavored tobacco products is growing. Continuing a long tradition of designing products that appeal explicitly to new users, tobacco companies in recent years have significantly stepped up the introduction and marketing of flavored other tobacco products (OTPs), particularly e-cigarettes and cigars, as well as smokeless tobacco and hookah (water pipes). Although tobacco companies claim to be responding to adult tobacco users’ demand for variety, flavored tobacco products play a key role in enticing new users, particularly kids, to a lifetime of addiction. This growing market for flavored tobacco products is undermining the nation’s overall progress in reducing youth tobacco use.

Tobacco companies market products in many kid-friendly flavors such as gummy bear, berry blend, chocolate, peach, cotton candy, strawberry and grape. A 2013 survey of internet tobacco retailers found that more than 40 percent of cigarette-sized cigars, machine-made cigars, moist snuff smokeless tobacco and dry snuff smokeless tobacco were flavored, including fruit, sweet and mint/menthol.¹³ An article in *Convenience Store News* stated that “flavored tobacco is offering a bright spot in the category,” referring to the increased tobacco sales – and number of consumers – in stores that sell such products.¹⁴

Here’s a look at the growing marketplace of flavored tobacco products:



CIGARS

Historically, cigar manufacturers designed flavored cigars to serve as “starter” smokes for youth and young adults because the flavorings helped mask the harshness, making the products easier to smoke.¹⁵ Recently, there has been an explosion of cheap, flavored cigars. Despite a 10 percent decline between 2014 and 2015, sales of all cigars (i.e., large cigars, cigarillos and small cigars) doubled between 2000 and 2015, from 6.1 billion cigars to 12.3 billion cigars, and sales have been generally increasing at a time when cigarette sales have been slowly declining.¹⁶

Much of the growth in cigar sales can be attributed to smaller types of cigars, many of them flavored. An industry publication stated, “While different cigars target a variety of markets, all flavored tobacco products tend to appeal primarily to younger consumers.”¹⁷ These products are often colorfully packaged and much cheaper than cigarettes; for instance, cigarillos can be priced as low as 3 or 4 for 99 cents, making them even more appealing to price-sensitive youth.

- There has been explosive growth in flavor options for cigars, such as candy, fruit, chocolate and various other kid-attracting tastes. The vice president of one distributor commented, “For a while it felt as if we were operating a Baskin-Robbins ice cream store” in reference to the huge variety of cigar flavors available – and, no doubt, an allusion to flavors that appeal to kids.¹⁸
- Flavored cigars have made a substantial contribution to the overall growth of the cigar market. 2015 Nielsen convenience store market scanner data show that sales of flavored cigars increased by nearly 50 percent since 2008. As a proportion of all cigar sales, the share of flavored cigars rose from 43.6 percent to 52.1 percent in 2015. Among flavored cigars sold in 2015, the most popular flavors were fruit (38.8 percent), sweet or candy (21.2 percent), and wine (17.0 percent). Further, the number of unique cigar flavor names more than doubled from 2008 to 2015, from 108 to 250.¹⁹

- The top five most popular cigar brands among 12- to 17-year olds who have used cigars – Black & Mild, Swisher Sweets, Al Capone, White Owl and Dutch Masters – all come in flavor varieties.²⁰ For example, Black & Mild cigars come in flavors such as apple, cherry vanilla and cherry; Swisher Sweets comes in a huge variety of flavors such as grape, chocolate, strawberry, peach and “sticky sweets”; and White Owl has flavors such as mango, peach and “very berry.” Altria, the nation’s largest tobacco manufacturer and parent company of Philip Morris USA, expanded its business to the cigar category in 2007 by acquiring John Middleton, Inc., which sells Black & Mild.
- The cigar industry acknowledges that flavors attract new users. The vice president of marketing for the international division of Swedish Match, which sells White Owl cigars and Game cigars in the U.S., stated, “It is mainly new recruits to cigar smoking who take to the new flavors, while long-time consumers still prefer the more traditional cigars.”²¹ Industry insiders also recognize the use of flavors for the uninitiated. The luxury lifestyle magazine, *Cigar Aficionado*, stated in an article, “More likely, flavored cigars serve as a bridge to premium cigars for the uninitiated, something to be smoked as an entryway into the world of cigar smoking. For the novice, a simple, sweet and easily identifiable flavor (honey or cherry, for example) is an easier step than moving into a box marked Cuban-seed Corojo.”²²
- Nielsen convenience store market scanner data also show an increasing number of “other” options have emerged in the past few years, using names that do not explicitly identify a flavor, such as Swisher’s “Wild Rush” and Altria’s “Jazz,” even though they are flavored. This could be an attempt by cigar manufacturers to circumvent local sales restrictions on characterizing flavors, which rely on definitions that describe flavors.²³



Since the Tobacco Control Act prohibited flavored cigarettes in 2009, cigarette makers have manipulated their products to qualify as “little” or “filtered” cigars.²⁴ For instance, the 2012 Surgeon General’s report, *Preventing Tobacco Use Among Youth and Young Adults*, noted that flavored cigarettes such as Sweet Dreams re-emerged as Sweet Dreams flavored cigars after the federal restriction on flavored cigarettes went into effect.²⁵ In October 2009, U.S. Representatives Henry Waxman and Bart Stupak sent letters to two flavored cigarette companies, Cheyenne International and Kretek International, that began making little cigars shortly after the federal flavored cigarette ban went into effect.²⁶ Rep. Waxman discovered that Kretek International intentionally changed its cigarettes to cigars to exploit a loophole in the Tobacco Control Act.²⁷ In December 2016, the FDA issued warning letters to four tobacco manufacturers – Swisher International, Inc., Cheyenne International LLC, Prime Time International Co. and Southern Cross Tobacco Company Inc. – for marketing and selling fruit-flavored cigarettes labeled as cigars, in violation of the Tobacco Control Act.²⁸



ELECTRONIC CIGARETTES

Although these products are relatively new to the market, the variety of flavors available for use in e-cigarettes has grown exponentially. E-cigarette marketing employs many of the same strategies used for years by cigarette manufacturers that proved so effective in reaching kids, such as celebrity endorsements, slick TV and magazine advertisements, and sports and music sponsorships. Another strategy has been the widespread marketing of e-cigarettes and nicotine “e-juice” with a wild assortment of candy, fruit and other flavors.

- As of January 2014, researchers had identified more than 7,700 unique e-cigarette flavors available online, with an average of more than 240 new flavors being added per month.²⁹ Among more than 400 available brands, 84 percent offered fruit flavors and 80 percent offered candy and dessert flavors.³⁰
- In addition to the more traditional candy and fruit flavors like cherry and chocolate, the liquid nicotine solutions are also being sold in such kid-friendly options as cotton candy, gummy bear, root beer float and banana split. One study even uncovered over twenty different types of unicorn-flavored e-liquid, often paired with cartoon imagery, undoubtedly appealing to kids.³¹

- The top three cigarette manufacturers now sell e-cigarettes in a variety of flavors other than tobacco. Altria’s MarkTen brand e-cigarettes come in Fusion, Menthol and Winter Mint varieties.³² Reynolds American’s Vuse product comes in flavors such as Melon, Nectar, Berry, Mint and Chai, while ITG Brand’s blu e-cigarette features such flavors as Berry Cobbler, Blueberry, Cherry Crush, Strawberry Mint, Vivid Vanilla and Pina Colada.³³
- “Vape shops,” which are specialty e-cigarette retail stores, offer an even wider assortment of flavors. In addition to the pre-made options, these stores allow patrons to mix their own preferred flavor combinations.³⁴



The use of flavors in e-cigarette products is of even greater concern because e-cigarettes are the subject of extensive advertising campaigns, and there is evidence that young people are exposed to significant amounts of e-cigarette advertising. In 2012, e-cigarette companies began airing media campaigns on television. One study found that exposure of youth aged 12-17 to television e-cigarette advertising increased 256 percent from 2011 to 2013 and that e-cigarette companies advertise their products to a broad audience that includes 24 million youth.³⁵ Ads for the blu brand (then owned by Lorillard) accounted for 81 percent of the youth exposure.³⁶ The 2014 Youth Tobacco Survey found that nearly seven in ten middle and high school students were exposed to e-cigarette advertising in 2014.³⁷

SMOKELESS TOBACCO

The variety of flavored smokeless tobacco products has grown over time and continues to grow.

- U.S. Smokeless Tobacco Company (UST, owned by Altria) increased the number of its sub-brands – including flavored products – by 140 percent from 2000 to 2006 in order to “cast a wide net” and appeal to as many potential users as possible.³⁸ In 2011, more than 80 percent of Skoal smokeless tobacco sold in convenience stores was flavored and more than one out of five (21.1 percent) were fruit-flavored, including vanilla, apple and berry blend.³⁹ Skoal is the third most popular brand among smokeless tobacco users ages 12-17.⁴⁰
- Between 2005 and 2011, sales of moist snuff increased by more than two-thirds; increases in the sale of *flavored* moist snuff accounted for about 60 percent of this growth.⁴¹ In 2012, flavored products made up more than half (58 percent) of all smokeless tobacco sales. Menthol and mint flavors are most popular, followed by fruit flavors.⁴²



- A trade publication for convenience stores quoted one retailer stating, “In the case of smokeless tobacco, you get a new flavor once every quarter.”⁴³

HOOKAH

Hookahs originate from Middle Eastern countries, but their use has rapidly increased in the U.S. The tobacco used in hookah often has flavorings or sweeteners added to enhance the taste and aroma. In the U.S., even more kid-friendly flavors are available, such as watermelon, tropical fruit, orange cream, caramel, chocolate, tutti frutti, vanilla and strawberry.⁴⁴



CIGARETTES

Menthol cigarettes, the only remaining flavored cigarette, maintain a significant market share. While overall cigarette sales have been declining, the proportion of smokers using menthol cigarettes has been increasing.⁴⁵

- Data from the Federal Trade Commission show that in 2014 (the most recent year for which data are available), menthol cigarettes comprised 30 percent of the market.⁴⁶
- Before cigarettes with specific characterizing flavors were prohibited by the Tobacco Control Act, R.J. Reynolds’ “Camel Exotic Blends” came in flavors such as Twista Lime, Kauai Kolada, Warm Winter Toffee and Winter Mocha Mint, among others. Bright, colorful and alluring ads for these cigarettes appeared in magazines popular with kids, including *Rolling Stone*, *Cosmopolitan* and *Sports Illustrated*.
- Using data from the 1999-2013 Youth Tobacco Surveys, a 2017 study analyzed the impact of the 2009 ban on characterizing flavors in cigarettes on youth tobacco use. The researchers found that cigarette use declined significantly after the ban, whereas cigar and pipe tobacco use significantly increased. Further, use of menthol cigarettes, the only remaining flavored cigarettes, increased significantly after the ban.⁴⁷





Source: Journal of the American Medical Association (2015)

Flavored Products Are Popular Among Kids and Young Adults

Research shows that no matter what the tobacco product, flavors appeal to youth and young adults. Data from the government’s 2013-2014 Population Assessment of Tobacco and Health (PATH) study found that 80.8 percent of 12-17 year olds who had ever used a tobacco product initiated tobacco use with a flavored product and 79.8 percent of current tobacco users had used a flavored tobacco product in the past month.⁴⁸ Moreover, for each tobacco product, at least two-thirds of youth report using these products “because they come in flavors I like.”⁴⁹

Additional national data from the 2014 NYTS found that 70 percent of current middle and high school tobacco users – a total of over 3.2 million youth (12 percent of all youth) – had used a flavored tobacco product in the past month.⁵⁰ Another national study found that 18.5 percent of young adult tobacco users (18-34 years old) currently use a flavored tobacco product, with younger age being a predictor of flavored tobacco product use. In fact, the study found that those aged 18-24 years old had an 89 percent increased chance of using a flavored tobacco product compared to those aged 25-34 years old.⁵¹

According to the 2012 Surgeon General Report, “Much of the growing popularity of small cigars and smokeless tobacco is among younger adult consumers (aged <30 years) and appears to be linked to the marketing of flavored tobacco products that, like cigarettes, might be expected to be attractive to youth.”⁵² The 2016 Surgeon General Report on e-cigarettes concluded that flavors are among the most commonly cited reasons for using e-cigarettes among youth and young adults.⁵³

CIGARS

More than 2,100 children under age 18 try cigar smoking for the first time every day.⁵⁴ Teens and young adults are much more likely than adults 25 years and older to report smoking cigars.⁵⁵ Research demonstrates that flavored cigars are driving much of this usage and not surprisingly, flavored cigars are the most popular among youth. Cheap, sweet cigars can serve as an entry product for kids to a lifetime of smoking.

- The 2013-2014 PATH study found that 65.4 percent of 12-17 year olds who had ever smoked cigars smoked a flavored cigar the first time they tried the product, and 71.7 percent of current cigar smokers had used a flavored product in the last month.⁵⁶ Additionally, 73.8 percent of current youth cigar smokers said they smoked cigars “because they come in flavors I like.”⁵⁷
- The 2014 NYTS found that 63.5 percent of middle and high school cigar smokers – a total of 910,000 youth – had smoked a flavored cigar in the past month.⁵⁸
- Data from the 2013-2014 National Adult Tobacco Survey indicate that use of flavored cigars decreases with age. Flavored cigar use among cigar smokers was 48.3 percent among 18-24 year olds, 41.0 percent among 25-29 year olds, 37.1 percent among 30-44 year olds, 28.8 percent among 45-64 year olds and 17.8 percent among those ages 65 and older.⁵⁹
- Youth and young adults prefer brands that come in a variety of flavors, and that preference declines significantly with age. In one national study, 95 percent of 12-17-year-old cigar smokers reported a usual brand that makes flavored cigars compared with 63 percent of cigar smokers aged 35 and older.⁶⁰

ELECTRONIC CIGARETTES

Given the dramatic growth in the availability and marketing of flavored e-cigarettes, it’s no surprise that e-cigarette use among high school students increased more than ten-fold from 2011 to 2015.⁶¹ E-cigarettes are now the most commonly used tobacco products among youth, surpassing conventional cigarettes; more than 3 million middle and high school students were current e-cigarette users in 2015.⁶²

One tobacco company has acknowledged that youth are attracted to sweet-flavored e-cigarettes. Lorillard Inc.’s Youth Smoking Prevention Program posted a page on e-cigarettes on its “Real Parents Real Questions” website that stated: “Kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, piña-colada and berry.”⁶³



- The 2013-2014 PATH study found that 81 percent of 12-17 year olds who had ever smoked an e-cigarette used a flavored e-cigarette the first time they tried the product, and 85.3 percent of current users used a flavored product in the last month. Additionally, 81.5 percent of current youth e-cigarette users said they used e-cigarettes “because they come in flavors I like.”⁶⁴
- The 2015 NYTS found that 44.6 percent of middle and high school e-cigarette users – totaling 1.26 million youth – had used a flavored e-cigarette in the past month.⁶⁵
- The 2013-2014 National Adult Tobacco Survey found that use of flavored e-cigarettes was highest among young adults (ages 18-24), compared to those over age 25, and that flavored e-cigarettes were most popular among adults who were never cigarette smokers.⁶⁶
- A national phone survey found that youth (ages 13-17) were more likely to report interest in trying an e-cigarette offered by a friend if it were flavored like fruit, candy or menthol, compared to tobacco. This study also found that youth believed that fruit-flavored e-cigarettes were less harmful than tobacco-flavored e-cigarettes.⁶⁷
- Another study found that compared to college students, high school students were more likely to report experimenting with e-cigarettes because of appealing flavors (47 percent vs. 33 percent).⁶⁸



“Kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, piña-colada and berry.”
 – Lorillard Inc.’s Youth Smoking Prevention Program, 2014

SMOKELESS TOBACCO

As with cigarettes, characterizing flavors in other tobacco products (OTPs) mask the tobacco flavor and can make the products appealing to youth. Smokeless (or spit) tobacco companies, particularly UST, have a long history of creating new products that appeal to kids and marketing them aggressively to children to “graduate” them to more potent smokeless tobacco varieties.⁶⁹

- The 2013-2014 PATH study found that 68.9 percent of 12-17 year olds who had ever used smokeless tobacco used flavored smokeless tobacco the first time they tried the product, and 81 percent of current smokeless tobacco users had used a flavored product in the last month.⁷⁰
- The 2014 NYTS found that 58.8 percent of middle and high school smokeless tobacco users – a total of nearly 700,000 youth – had used flavored smokeless tobacco in the past month.⁷¹

HOOKAH

Research shows that many youth and young adults perceive hookah to be safer than other combustible tobacco products.⁷² However, according to the CDC, using a hookah to smoke tobacco poses serious health risks to smokers and others exposed to the smoke from the hookah.⁷³ Because the flavors and the smoking technique create a more soothing (“smooth”) experience, hookah smokers can inhale more deeply and spend more time in a “hookah session,” which typically lasts for 40 to 45 minutes (three to four times longer than it typically takes to smoke a cigarette). While a typical cigarette requires about 20 puffs,⁷⁴ an hour-long hookah session may involve 100 to 200 puffs, potentially exposing the user to more smoke over a greater period of time than what occurs when smoking a regular cigarette.⁷⁵ The appeal of flavored hookah undoubtedly contributes to its popularity among youth and young adults.

- The 2013-2014 PATH study found that 88.7 percent of 12-17 year olds who had ever smoked hookah used flavored hookah the first time they tried the product, and 89 percent of current hookah users had used a flavored product in the last month.⁷⁶
- According to the PATH study, use of flavored tobacco is highest for users of hookah than for any other tobacco product, and more than three-quarters (78.9 percent) of youth hookah users reported that they use hookah “because they come in flavors I like.”⁷⁷
- The 2014 NYTS found that 60.6 percent of middle and high school hookah users – a total of over 1 million youth – had used flavored hookah in the past month.⁷⁸

CIGARETTES

As the only flavored cigarette left on the market, it is no surprise that menthol cigarettes are popular among youth. Menthol cools and numbs the throat, reducing the harshness of cigarette smoke, thereby making menthol cigarettes more appealing to youth who are initiating tobacco use.⁷⁹

- Over half (54 percent) of youth smokers ages 12-17 use menthol cigarettes compared to nearly one-third (32 percent) of older adult smokers.⁸⁰ Prevalence of menthol use is even higher among African Americans: 85 percent of all African-American smokers smoke menthol cigarettes and seven out of ten African-American youth smokers smoke menthol cigarettes.⁸¹
- The popularity of menthol flavored cigarettes is also evidenced by brand preference among youth. According to data from the 2014 National Survey on Drug Use and Health, one in five smokers ages 12-17 prefers Newport cigarettes, a heavily marketed menthol cigarette brand. Preference for Newport is even higher among



African-American youth smokers (64.3 percent) because of targeted marketing by the tobacco industry.

- Daily menthol cigarette smokers have higher odds of also using flavored little cigars/cigarillos compared to occasional non-menthol smokers.⁸³

According to FDA’s Tobacco Products Scientific Advisory Committee:⁸⁴

- Menthol cigarettes increase the number of children who experiment with cigarettes and the number of children who become regular smokers, increasing overall youth smoking.
- Young people who initiate using menthol cigarettes are more likely to become addicted and become long-term daily smokers.
- The availability of menthol cigarettes reduces smoking cessation, especially among African Americans, and increases the overall prevalence of smoking among African Americans.

FDA’s own scientific analysis concluded that menthol cigarettes lead to increased smoking initiation among youth and young adults, greater addiction and decreased success in quitting smoking.⁸⁵

Although they are no longer on the market, older studies on flavored cigarettes other than menthol are still relevant to reinforce the general appeal of flavors to youth and young adults. When they were available, flavored cigarettes were being tried and used primarily by the young.⁸⁶ Candy-flavored cigarettes clearly had their greatest appeal to new smokers, 90 percent of whom were teens or younger. Research indicated that youth and young adults were more likely to notice flavored tobacco products and their ads, and this awareness translated into higher use rates among young smokers.

- Older adolescents and young adults aged 17 to 19 were more than twice as likely to report using flavored cigarettes (specifically Camel Exotic blends, Kool Smooth Fusion or Salem Silver Label brands) in the past 30 days compared to those 22 years or older.⁸⁷
- A significant gradient in flavored cigarette use was seen across age, with the highest rates of use among 17-year-old smokers (22.8 percent) and 18-19-year-old smokers (21.7 percent). Just nine percent of 24-26 year olds reported flavored cigarette use.⁸⁸



Flavored Products Have Long Been Used to Attract Kids

The tobacco companies know that almost all new tobacco users begin their addiction as kids, but they also know that to novice smokers, tobacco can be harsh and unappealing. Internal tobacco industry documents show that tobacco companies have a long history of using flavors to reduce the harshness of their products to make them more appealing to new users, almost all of whom are under age 18.⁸⁹ By masking the harshness and soothing the irritation caused by tobacco smoke, flavors make it easier for beginners – primarily kids – to try the product and ultimately become addicted. As early as the 1970s, the tobacco companies were discussing the “benefits” of sweet flavors. Their internal documents and public statements show that the tobacco industry’s use of sweet flavors goes beyond just encouraging current smokers to switch brands, but rather to attract new users, mostly kids.

- As early as 1972, advisors to Brown & Williamson reviewed new concepts for a “youth cigarette,” including cola and apple flavors, and a “sweet flavor cigarette,” stating, “It’s a well-known fact that teenagers like sweet products. Honey might be considered.”⁹⁰
- A 1974 summary of an RJR meeting discussed cigarettes designed for beginning smokers, noting that such a cigarette should be “low in irritation and possibly contain added flavors to make it easier for those who never smoked before to acquire the taste of it more quickly.”⁹¹

- An RJR interoffice memo revealed ideas for new products: *“Make a cigarette which is obviously youth oriented. This could involve cigarette name, blend, flavor and marketing technique ... for example, a flavor which would be candy-like but give the satisfaction of a cigarette.”*⁹²
- A Lorillard report summarizing the test results from new cigarette flavors included smokers’ description of “Tutti Frutti” flavored cigarettes as *“for younger people, beginner cigarette smokers, teenagers... when you feel like a light smoke, want to be reminded of bubblegum.”*⁹³
- U.S. Tobacco, noticing declines in smokeless tobacco use in the 1980s, instituted a “graduation strategy,” developing mint- and cherry-flavored smokeless products with lower nicotine content as a way to attract new users.⁹⁴
- A former UST sales representative revealed that *“Cherry Skoal is for somebody who likes the taste of candy, if you know what I’m saying.”*⁹⁵



“Cherry Skoal is for somebody who likes the taste of candy, if you know what I’m saying.”

– Former UST sales representative, 1994

With their colorful packaging and sweet flavors, today’s flavored tobacco products are often hard to distinguish from the candy displays near which they are frequently placed in retail outlets. In fact, the same flavor chemicals used in sweet-flavored cigars and smokeless tobacco products are also used in popular candy and drink products such as LifeSavers, Jolly Ranchers and Kool-Aid.⁹⁶ Flavors are not just a critical part of the product design, but are a key marketing ploy for the industry. The 2016 Surgeon General Report on e-cigarettes concluded, **“E-cigarettes are marketed by promoting flavors and using a wide variety of media channels and approaches that have been used in the past for marketing conventional tobacco products to youth and young adults.”**⁹⁷



Flavored Tobacco Products Pose Serious Health Risks, Including Addiction, and Flavors May Pose Unique Risks

Flavored tobacco products contain nicotine, the highly addictive chemical that makes it so easy to get hooked on tobacco products and so hard to quit. The 2016 Surgeon General’s report on e-cigarettes warned that youth use of products containing nicotine in any form is unsafe, can cause addiction and can harm the developing adolescent brain, disrupting attention and learning.⁹⁸ Here is a summary of other health risks posed by cigars and e-cigarettes, including the flavored versions of these products.

HEALTH HARMS FROM CIGAR SMOKE

Cigar smoke is composed of the same toxic and carcinogenic constituents found in cigarette smoke.⁹⁹ According to the National Cancer Institute, smoking cigars causes serious health consequences, including cancer of the oral cavity, larynx, esophagus and lung, and cigar smokers are also at increased risk for aortic aneurysms.¹⁰⁰ Daily cigar smokers, particularly those who inhale, have an increased risk of heart disease and chronic obstructive pulmonary disease (COPD). Each year, about 9,000 Americans die prematurely from regular cigar use.¹⁰¹

HEALTH HARMS FROM NICOTINE AND OTHER E-CIGARETTE CONSTITUENTS

E-cigarettes and refill liquids contain widely varying levels of nicotine. Nicotine is a highly addictive drug that can have lasting damaging effects on adolescent brain development and has been linked to a variety of adverse health outcomes for the developing fetus.¹⁰² The 2016 Surgeon General’s report also concluded, “E-cigarette use is strongly associated with the use of other tobacco products among youth and young adults, including combustible tobacco products.”¹⁰³

Exposure to liquid nicotine also carries a poisoning risk. Delivered in high doses, nicotine can be lethal. The Surgeon General found, “Ingestion of e-cigarette liquids containing nicotine can cause acute toxicity and possibly death if the contents of refill cartridges or bottles containing nicotine are consumed.”¹⁰⁴ Exposure to liquid nicotine found in e-cigarettes has resulted in thousands of calls to poison control centers in recent years, peaking in 2014, according to the American Association of Poison Control Centers.¹⁰⁵ In 2014, more than half of these calls to poison hotlines were to report exposures among children under the age of six.¹⁰⁶ To address this poisoning risk, Congress in 2016 enacted the Child Nicotine Poisoning Prevention Act, which gave the Consumer Product Safety Commission authority to enforce child resistant packaging standards for e-cigarette products.

There is currently insufficient research on the long-term effects of using e-cigarettes, which involves regular inhalation of nicotine, glycerin or some other solvent, and other additives.¹⁰⁷ According to the Surgeon General, “E-cigarette aerosol is not harmless. It can contain harmful and potentially harmful constituents, including nicotine.”¹⁰⁸ Studies have found other chemicals and toxins present in some e-cigarettes, including formaldehyde, acrolein, volatile organic compounds like toluene, tobacco-specific nitrosamines, and metals like nickel and lead.¹⁰⁹ These compounds are generally present at levels much lower than in cigarette smoke, although the compounds themselves are found on the FDA’s list of harmful or potentially harmful substances.¹¹⁰ Because the FDA has just begun to regulate e-cigarettes, which are available in hundreds of different brands,¹¹¹ consumers cannot know for sure yet what is in the products or the aerosol.¹¹²



HEALTH HARMS FROM FLAVORINGS IN TOBACCO PRODUCTS

In addition to playing a detrimental role in addicting youth and other users, some flavored tobacco products pose their own unique health risks. The 2016 Surgeon General’s report stated that “while some of the flavorings used in e-cigarettes are generally recognized as safe for ingestion as food, the health effects of their inhalation are generally unknown” and noted that some of the flavorings found in e-cigarettes have been shown to cause serious lung disease when inhaled.¹¹³ An article in the *Journal of the American Medical Association* raised concerns that the chemical flavorings found in some e-cigarettes and e-liquids could cause respiratory damage when the e-cigarette aerosol is inhaled deeply into the lungs.¹¹⁴



FDA and Congress Must Protect Kids from Flavored Tobacco Products

The 2009 Tobacco Control Act gave the FDA immediate regulatory authority over cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco, and it authorized the FDA to extend its jurisdiction to all other tobacco products. Among other things, the law prohibited the sale of cigarettes with characterizing flavors other than menthol or tobacco, including candy and fruit flavors.

More than five years after first stating its intention to do so, the FDA in May 2016 issued a final rule (called the deeming rule) extending its jurisdiction to all previously unregulated tobacco products, including e-cigarettes, cigars and hookahs.* The rule extended key provisions of the 2009 law to these products, including provisions that prohibit sales to children under age 18 nationwide; prohibit free samples; restrict vending machine sales to adult-only facilities; require addiction and health warnings; require disclosure of ingredients; prohibit the introduction of

* Despite the assertion by some manufacturers that e-cigarettes are not “tobacco products,” there is no question that e-cigarettes meet the definition of “tobacco product” in the 2009 Tobacco Control Act to the extent that they contain nicotine “derived from tobacco that is intended for human consumption.” 21 U.S.C. §321(rr)(1). Indeed, when an e-cigarette company challenged FDA’s authority to regulate e-cigarettes as drugs or devices, it did so on the ground that “electronic cigarettes qualify as a tobacco product and are therefore exempt from regulation as a drug-device combination.” *Smoking Everywhere, Inc. v. FDA*, 680 F.Supp.2d 62, 67, aff’d, 627 F.3d 891 (D.C. Cir 2010). See also, *Joint Opposition of Appellees Smoking Everywhere, Inc. and Sottera, Inc to Appellants’ Emergency Motion for Stay Pending Appeal, Smoking Everywhere, Inc. v. FDA*, Appeal No. 10-5032 (Feb. 4, 2010) (“As the District Court correctly observed, e-cigarettes marketed to provide the same structure/function

new products without prior FDA review and scientific evidence demonstrating a benefit to public health; set standards manufacturers must meet before they are allowed to make health-related claims; and authorize the FDA to regulate the content of tobacco products.¹¹⁵

However, the deeming rule did not extend the prohibition on characterizing flavors to these newly regulated products despite the substantial evidence that flavors play a critical role in youth use of these products. The FDA itself proposed removing these flavored products from the marketplace in the version of the rule that it sent to the White House Office of Management and Budget (OMB) for review, but OMB deleted this provision from the final rule. This key change was revealed in a [“redline” version of the rule](#) published on May 27, 2016, which showed changes made by OMB.

The deleted provision would have removed flavored e-cigarettes, cigars, hookah and other newly regulated products from the market by November 2016 and required those products to receive pre-market authorization from the FDA before re-entering the marketplace. This provision would also have affected menthol-flavored products. The deleted portion of the rule provided 17 pages of scientific evidence to support removing flavored products from the market, concluding that these products should be removed “given the attractiveness of flavors, especially to youth and young adults, and the impact flavored tobacco products may have on youth initiation.”¹¹⁵

Despite this change in the final rule, the FDA retains another pathway for reviewing and removing flavored tobacco products from the market. The rule requires all new tobacco products introduced after February 15, 2007, to undergo FDA scientific review



effects as traditional tobacco products fall squarely within the Tobacco Act’s definition of ‘tobacco products’ and thus are expressly excluded from regulation as drugs or devices.”) Both the District Court and the Court of Appeals agreed with this argument and held that e-cigarettes could not be regulated as drugs or devices because they can only be regulated as tobacco products under the TCA. In direct contradiction to the position taken by the e-cigarette plaintiffs in the Smoking Everywhere case, the e-cigarette industry now seeks to avoid regulation under the TCA because its products are not “tobacco products.” The only consistency in the industry’s position is its desire to avoid FDA regulation of any kind.

to determine their impact on public health, including their appeal to kids (products can remain on the market for up to three years from the rule's effective date – until August 2019 – while undergoing this review). The FDA has the authority to remove from the market products that it determines are harmful to public health, including the many sweet-flavored e-cigarettes and cigars that have been introduced during this time period.

However, two bills introduced in Congress would significantly weaken the FDA's authority over these newly regulated products and make it much more difficult, if not impossible, for the FDA to remove sweet-flavored products from the market. One bill (H.R.1136) would "grandfather" e-cigarettes, cigars and other newly deemed tobacco products already on the market (those introduced between February 15, 2007, and August 8, 2016, when the FDA's rule took effect) and exempt these products from the critical FDA review needed to determine their impact on public health. Tobacco companies would also be able to introduce similarly flavored products in the future. In short, this bill would allow existing flavored tobacco products to stay on the market and make it easier for tobacco companies to introduce new ones.

In September 2016, The New York Times reported that Altria drafted the legislation to change the "grandfather" date for e-cigarettes, cigars and other newly-regulated products and that it was endorsed by R.J. Reynolds. The Times reported that the legislation as introduced "pulled verbatim from the industry's draft."¹¹⁷ Reynolds and Altria make two of the best-selling e-cigarette brands in the U.S. (Vuse and MarkTen).

A second bill (S.294/H.R.564) would exempt what the tobacco industry calls "traditional large and premium cigars," but defines such cigars so broadly that it could also exempt some cheap, machine-made, flavored cigars that are widely used by kids. This legislation invites manufacturers to manipulate their products to qualify for the exemption and continue targeting kids, as they have done before.

In addition to being introduced as stand-alone legislation, such measures have also been added in recent years to the U.S. House appropriations bill that funds the FDA. They could be considered again this year as Congress finalizes appropriations for the rest of Fiscal Year 2017 and considers appropriations bills for Fiscal Year 2018. A large coalition of public health and medical groups has repeatedly urged Congress to reject these measures.

Given the strong evidence summarized in this report that flavored tobacco products such as e-cigarettes and cigars are attracting and addicting a new generation of kids, Congress must reject any proposals to weaken FDA oversight of these products. In fact, the FDA should strengthen its new rule by prohibiting all flavored tobacco products, including menthol products. As the FDA itself has demonstrated and as this report documents, there is more than sufficient scientific evidence to support such a prohibition. Eliminating all flavored tobacco products is a critical step in preventing tobacco companies from addicting another generation of kids and reversing our nation's progress in the fight against tobacco.

Sources

- 1 See U.S. Food and Drug Administration's (FDA) Flavored Tobacco webpage at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/FlavoredTobacco/default.htm>.
- 2 U.S. Department of Health and Human Services (HHS), E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
- 3 National Cancer Institute (NCI), Cigars: Health Effects and Trends. Smoking and Tobacco Control Monograph No. 9, 1998, http://cancercontrol.cancer.gov/Brp/tcrb/monographs/9/m9_complete.pdf.
- 4 Centers for Disease Control and Prevention (CDC), "Youth Risk Behavior Surveillance—United States, 2015," *MMWR*, 65(6), June 10, 2016. http://www.cdc.gov/healthyyouth/data/yrbs/pdf/2015/ss6506_updated.pdf.
- 5 CDC, "Tobacco Use Among Middle and High School Students — United States, 2011-2015," *Morbidity and Mortality Weekly Report (MMWR)* 65(14):361-367, April 14, 2016, <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6514a1.pdf>.
- 6 CDC, "Tobacco Use Among Middle and High School Students — United States, 2011-2015," *Morbidity and Mortality Weekly Report (MMWR)* 65(14):361-367, April 14, 2016, <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6514a1.pdf>.
- 7 University of Michigan, Monitoring the Future Study, 2016, <http://www.monitoringthefuture.org/data/16data/16cigtbl7.pdf>.
- 8 Data from YRBS, YTS and other state-specific surveys. 43 states include AL, AK, AZ, AR, CA, CO, DE, FL, HI, ID, IL, IN, KY, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OK, OR, PA, RI, SC, SD, TN, TX, VT, VA, WA, WV, WI and WY.
- 9 HHS, E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
- 10 Bunnell, R., et al., "Intentions to smoke cigarettes among never-smoking U.S. middle and high school electronic cigarette users, National Youth Tobacco Survey, 2011-2013," *Nicotine & Tobacco Research*, Epub ahead of print, pii: ntu166, August 2014.
- 11 CDC, "Youth Risk Behavior Surveillance—United States, 2015," *MMWR*, 65(6), June 10, 2016. http://www.cdc.gov/healthyyouth/data/yrbs/pdf/2015/ss6506_updated.pdf.
- 12 Data from YRBS, YTS and other state-specific surveys. 33 states include AL, AZ, CA, CO, DE, FL, GA, ID, IL, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NV, NH, NM, NY, ND, PA, RI, SC, SD, TN, VT, VA and WY.
- 13 Morris, DS, Fiala, SC, "Flavoured, non-cigarette tobacco for sale in the USA: an inventory analysis of Internet retailers," *Tobacco Control* [Epub ahead of print] doi: 10.1136/tobaccocontrol-2013-051059, August 8, 2013.
- 14 "Flavors Add New Dimension to Tobacco," *Convenience Store News*, October 1, 2007.
- 15 Kostygina, G, Glantz, S, & Ling, PM, "Tobacco industry use of flavours to recruit new users of little cigars and cigarillos," *Tobacco Control* 25(1):66-74, January 2016.
- 16 U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), Tobacco Statistics. December 2000, 2014, 2015, <https://www.ttb.gov/tobacco/tobacco-stats.shtml>.
- 17 Niksic, M, "Flavored Smokes: Mmmmm...More Profits?" *Tobacco Retailer*, April 2007.
- 18 Niksic, M, "Flavored Smokes: Mmmmm...More Profits?" *Tobacco Retailer*, April 2007.
- 19 Delnevo, CD, et al., "Changes in the mass-merchandise cigar market since the Tobacco Control Act," *Tobacco Regulatory Science*, 3(2 Suppl 1): S8-S16, 2017. [In press]
- 20 HHS, Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Behavioral Health Statistics and Quality. National Survey on Drug Use and Health, 2014. ICPSR36361-v1. Ann Arbor, MI: Inter-university Consortium for Political and Social Research [distributor], 2016-03-22. <http://doi.org/10.3886/ICPSR36361.v1>
- 21 Swedish Match, "No. 2 worldwide in cigars," March 7, 2007, <http://www.swedishmatch.com/Media/Pressreleases-and-news/News/No-2-worldwide-in-cigars/>.
- 22 Savona, D, "Cigars of a Different Flavor," *Cigar Aficionado*, July/August 2005.
- 23 Viola, AS, et al., "A cigar by any other name would taste as sweet," *Tobacco Control*, published online October 1, 2015. See also Delnevo, CD, et al., "Changes in the mass-merchandise cigar market since the Tobacco Control Act," *Tobacco Regulatory Science*, 3(2 Suppl 1): S8-S16, 2017. [In Press]
- 24 Delnevo, CD, et al., "Close, but no cigar: certain cigars are pseudo-cigarettes designed to evade regulation," *Tobacco Control*, Online first, doi:10.1136/tobaccocontrol-2016-052935, May 24, 2016.
- 25 HHS, Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 2012, <http://www.cdc.gov/Features/YouthTobaccoUse/>.

- ²⁶ House Committee on Energy & Commerce, “Energy and Commerce Committee Requests Information on Sales and Marketing of Flavored Tobacco Products,” October 2, 2009, accessed April 18, 2012 at <http://democrats.energycommerce.house.gov/index.php?q=news/energy-and-commerce-committee-requests-information-on-sales-and-marketing-of-flavored-tobacco-p>.
- ²⁷ Representative Henry A. Waxman, “Rep. Waxman Urges FDA to Ban Clove-Flavored Cigars,” Letter to FDA Commissioner Margaret Hamburg, March 28, 2011, accessed April 18, 2012 at <http://democrats.energycommerce.house.gov/index.php?q=news/rep-waxman-urges-fda-to-ban-clove-flavored-cigars>.
- ²⁸ FDA, Center for Tobacco Products, “FDA takes action against four tobacco manufacturers for illegal sales of flavored cigarettes labeled as little cigars or cigars,” December 9, 2016, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm532563.htm>.
- ²⁹ Zhu, S-H, et al., “Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation,” *Tobacco Control*, 23(Suppl 3):iii3-iii9, 2014.
- ³⁰ Zhu, S-H, et al., “Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation,” *Tobacco Control*, 23(Suppl 3):iii3-iii9, 2014.
- ³¹ Jackler, RK, and Ramamurthi, D. “Unicorn cartoons: marketing sweet and creamy e-juice to youth,” *Tobacco Control*, published online August 19, 2016.
- ³² “Altria’s MarkTen Getting Supersized,” *Convenience Store News*, February 19, 2015, <http://www.csnews.com/product-categories/tobacco/altrias-mark-ten-getting-supersized>. See also: <http://www.trinketsandtrash.org/detail.php?articleid=10081>.
- ³³ blu cigs, Flavor Cartridges, accessed December 21, 2016 from <https://www.blu.com/en/US/flavors?view=list>. Kress, M, “Innovation Defines RAI’s Investor Day,” *Convenience Store News*, November 17, 2014, [uct-categories/tobacco/innovation-defines-rai-investor-day](http://www.csnews.com/prod-uct-categories/tobacco/innovation-defines-rai-investor-day). On June 12, 2014, Reynolds American, Inc. and Lorillard completed a merger, by which ownership of the blu brand was transferred to Imperial Tobacco Group PLC.
- ³⁴ Johnson, A, “Up in smoke? Alamance e-cigarette store operators concerned about proposed regulations,” *Times-News*, April 30, 2014, <http://www.thetimesnews.com/news/top-news/up-in-smoke-alamance-e-cigarette-store-operators-concerned-about-proposed-regulations-1.313005>. The website for VapeRite ATL also boasts that customers can “mix well over 100,000 possible flavor and mix type combinations” [<https://atlanta.vaperite.com/#vape-bar>, accessed May 30, 2014].
- ³⁵ Duke, JC, et al., “Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults,” *Pediatrics*, June 2, 2014.
- ³⁶ Duke, JC, et al., “Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults,” *Pediatrics*, June 2, 2014.
- ³⁷ CDC, “Vital Signs: Exposure to Electronic Cigarette Advertising Among Middle and High School Students—United States, 2014,” *MMWR*, 64(52): 1403-1408, January 8, 2016, <https://www.cdc.gov/mmwr/pdf/wk/mm6452.pdf>.
- ³⁸ Alpert, HR, et al., “Free nicotine content and strategic marketing of moist snuff tobacco products in the United States: 2000-2006,” *Tobacco Control* 17:332-338, 2008.
- ³⁹ Delnevo, C, et al., “Examining market trends in the United States smokeless tobacco use: 2005 – 2011,” *Tobacco Control*, October 31, 2012, doi:10.1136/tobacco-control-2012-050739.
- ⁴⁰ HHS SAMHSA Center for Behavioral Health Statistics and Quality. National Survey on Drug Use and Health, 2014. ICPSR36361-v1. Ann Arbor, MI: Inter-university Consortium for Political and Social Research [distributor], 2016-03-22. <http://doi.org/10.3886/ICPSR36361.v1>
- ⁴¹ Delnevo, CD, et al., “Examining market trends in the United States smokeless tobacco use: 2005-2011,” *Tobacco Control*, 23: 107-112, 2014.
- ⁴² Chaloupka, F, et al., Analysis of 2012 Nielsen Store Data, results forthcoming.
- ⁴³ “Flavors Add New Dimension to Tobacco,” *Convenience Store News*, October 1, 2007.
- ⁴⁴ American Lung Association, An Emerging Deadly Trend: Waterpipe Tobacco Use, February 2007, http://www.lungusa2.org/embargo/slati/Trendalert_Waterpipes.pdf.
- ⁴⁵ Villanti, A., et al., “Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014,” *Tobacco Control*, published online October 20, 2016
- ⁴⁶ U.S. Federal Trade Commission (FTC). Cigarette Report for 2014, 2016, https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2014-federal-trade-commission-smokeless-tobacco-report/ftc-cigarette_report_2014.pdf[Data for top 5 manufacturers only].
- ⁴⁷ Courtemanche, CJ, et al., “Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use,” *American Journal of Preventive Medicine*, published online January 9, 2017.
- ⁴⁸ Ambrose, BK, et al., “Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,” *Journal of the American Medical Association*, published online October 26, 2015.
- ⁴⁹ Ambrose, BK, et al., “Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,” *Journal of the American Medical Association*, published online October 26, 2015.
- ⁵⁰ Corey, CG, et al., “Flavored Tobacco Product Use Among Middle and High School Students—United States, 2014,” *Morbidity and Mortality Weekly Report* 64(38):1066-1070, 2015.
- ⁵¹ Villanti, AC, et al., “Flavored Tobacco Product Use Among U.S. Young Adults,” *American Journal of Preventive Medicine* 44(4):388-391, 2013.

- ⁵² HHS, Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 2012, <http://www.cdc.gov/Features/YouthTobaccoUse/>.
- ⁵³ HHS, E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
- ⁵⁴ Substance Abuse and Mental Health Services Administration (SAMHSA), HHS, Results from the 2015 National Survey on Drug Use and Health, NSDUH: Detailed Tables, 2016. <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.pdf>. Cigars are defined as cigars, cigarillos or little cigars.
- ⁵⁵ 2013 YRBS. King, BA, Dube, SR, & Tynan, MA, "Flavored Cigar Smoking Among U.S. Adults: Findings From the 2009–2010 National Adult Tobacco Survey," *Nicotine & Tobacco Research* 15(2):608-14, 2013.
- ⁵⁶ Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.
- ⁵⁷ Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.
- ⁵⁸ Corey, CG, et al., "Flavored Tobacco Product Use Among Middle and High School Students—United States, 2014," *Morbidity and Mortality Weekly Report* 64(38):1066-1070, 2015.
- ⁵⁹ Bonhomme, MG, et al., "Flavoured non-cigarette tobacco product use among US adults: 2013-2014," *Tobacco Control*, 25: ii4-ii13, 2016.
- ⁶⁰ Delnevo, C, et al., "Preference for flavoured cigar brands among youth, young adults and adults in the USA," *Tobacco Control* 24(4):389-94, 2015.
- ⁶¹ CDC, "Tobacco Use Among Middle and High School Students — United States, 2011-2015," *Morbidity and Mortality Weekly Report (MMWR)* 65(14):361-367, April 14, 2016, <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6514a1.pdf>.
- ⁶² CDC, "Tobacco Use Among Middle and High School Students — United States, 2011-2015," *Morbidity and Mortality Weekly Report (MMWR)* 65(14):361-367, April 14, 2016, <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6514a1.pdf>.
- ⁶³ Real Parents Real Answers, "What you need to know about e-cigarettes – Infographic," April 23, 2014, accessed November 7, 2014, <http://www.realparentsrealanswers.com/what-you-need-to-know-about-e-cigarettes-infographic/>. See also https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/What%20you%20need%20to%20know%20about%20e-cigarettes%20E2%80%93%20Infographic%20_%20Real%20Parents%20Real%20Answers_may31-2014.pdf.
- ⁶⁴ Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.
- ⁶⁵ HHS, E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
- ⁶⁶ Bonhomme, MG, et al., "Flavoured non-cigarette tobacco product use among US adults: 2013-2014," *Tobacco Control*, 25: ii4-ii13, 2016.
- ⁶⁷ Pepper, JK, et al., "Adolescents' interest in trying flavoured e-cigarettes," *Tobacco Control*, 25: ii62-ii66, published online September 15, 2016.
- ⁶⁸ Kong, G, et al., "Reasons for Electronic Cigarette Experimentation and Discontinuation Among Adolescents and Young Adults," *Nicotine & Tobacco Research* 17(7):847-54, July 2015.
- ⁶⁹ Connolly, GN, "The Marketing of Nicotine Addiction by One Oral Snuff Manufacturer," *Tobacco Control* 4(1):73-79, Spring 1995.
- ⁷⁰ Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.
- ⁷¹ Corey, CG, et al., "Flavored Tobacco Product Use Among Middle and High School Students—United States, 2014," *Morbidity and Mortality Weekly Report* 64(38):1066-1070, 2015.
- ⁷² See e.g., Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015. Wackowski, OA and Delnevo, CD. "Young Adults' Risk Perceptions of Various Tobacco Products Relative to Cigarettes: Results from the National Young Adult Health Survey," *Health Education & Behavior*, published online August 24, 2015. Villanti, AC, et al., "Correlates of Hookah Use and Predictors of Hookah Trial in U.S. Young Adults," *American Journal of Preventive Medicine*, 48(6): 742-746, 2015.
- ⁷³ CDC. "Hookahs." Available at http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/hookahs/. Accessed March 4, 2016
- ⁷⁴ CDC. "Dangers of Hookah Smoking." Available at <http://www.cdc.gov/features/hookahsmoking/>. Accessed March 4, 2016
- ⁷⁵ World Health Organization. WHO Advisory Note: "Waterpipe Tobacco Smoking: Health Effects, Research Needs and Recommended Actions by Regulators," WHO 2005; HHS, Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 2012, <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html>; American Lung Association, An Emerging Deadly Trend: Waterpipe Tobacco Use, February 2007, http://www.lungusa2.org/embargo/slati/Trendalert_Waterpipes.pdf.

- American Lung Association, Hookah Smoking: A Growing Threat to Public Health, 2011, <http://www.lung.org/assets/documents/tobacco/hookah-policy-brief-updated.pdf>.
- 76 Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015. The 2014 NYTS found that 60.6 percent of middle and high school hookah smokers—totaling over 1 million youth—had used flavored hookah in the past month.
- 77 Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.
- 78 Corey, CG, et al., "Flavored Tobacco Product Use Among Middle and High School Students—United States, 2014," *Morbidity and Mortality Weekly Report* 64(38):1066-1070, 2015.
- 79 FDA. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes (2013).
- 80 Villanti, A., et al., "Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014," *Tobacco Control*, published online October 20, 2016.
- 81 Villanti, A., et al., "Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014," *Tobacco Control*, published online October 20, 2016.
- 82 HHS, SAMHSA, Center for Behavioral Health Statistics and Quality. National Survey on Drug Use and Health, 2014. ICPSR36361-v1. Ann Arbor, MI: Inter-university Consortium for Political and Social Research [distributor], 2016-03-22. <http://doi.org/10.3886/ICPSR36361.v1>.
- 83 Sterling, K, et al., "Association between menthol-flavoured cigarette smoking and flavoured little cigar and cigarillo use among African-American, Hispanic, and white young and middle-aged adult smokers," *Tobacco Control* 25(Suppl 2):ii21-ii31, November 2016.
- 84 Tobacco Products Scientific Advisory Committee, Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, July 21, 2011 <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>
- 85 FDA. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes (2013).
- 86 Carpenter, CM, et al, "New Cigarette Brands with Flavors that Appeal to Youth: Tobacco Marketing Strategies," *Health Affairs* 24(6):1601-1610, Nov/Dec 2005. Lewis, M. et al., "Dealing with an Innovative Industry: A Look at Flavored Cigarettes Promoted by Mainstream Brands," *American Journal of Public Health* 96(2), February 2006.
- 87 Klein, S, et al., Use of flavored cigarettes among older adolescent and adult smokers: United States, 2004 – 2005," *Nicotine and Tobacco Research*, Volume 10, Number 7, July 2008.
- 88 Klein, S et al., Use of flavored cigarettes among older adolescent and adult smokers: United States, 2004 – 2005," *Nicotine and Tobacco Research*, Volume 10, Number 7, July 2008.
- 89 HHS, Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 2012, <http://www.cdc.gov/Features/YouthTobaccoUse/>.
- 90 Marketing Innovations, "Youth Cigarette - New Concepts," Memo to Brown & Williamson, September 1972, Bates No. 170042014.
- 91 R.J. Reynolds Tobacco Company, "Conference report #23," June 5, 1974, Bates No. 500254578-4580.
- 92 R.J. Reynolds Inter-office Memorandum, May 9, 1974, Bates No. 511244297-4298.
- 93 R.M. Manko Associates report for Lorillard, Summary Report: New Flavors Focus Group Sessions, August, 1978, Bates No. 85093450-3480.
- 94 HHS, Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 2012, <http://www.cdc.gov/Features/YouthTobaccoUse/>. See also U.S. Smokeless Tobacco. Graduation process: Copenhagen. 1984. US Smokeless Tobacco Collection. Bates No. 4604754. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=qhff0044>.
- 95 "Juiced Up: How a Tobacco Giant Doctors Snuff Brands to Boost Their 'Kick,'" *The Wall Street Journal*, October 26, 1994.
- 96 Brown, JE, et al., "Candy Flavorings in Tobacco," *New England Journal of Medicine*, 370: 2250-2252, 2014.
- 97 HHS, E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
- 98 HHS, E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
- 99 NCI, Cigars: Health Effects and Trends. Smoking and Tobacco Control Monograph No. 9, 1998, http://cancercontrol.cancer.gov/Brp/tcrb/monographs/9/m9_complete.pdf. Chang, CM, et al., "Systematic review of cigar smoking and all cause and smoking related mortality," *BMC Public Health*, 15(1): 390, 2015.
- 100 NCI, Cigars: Health Effects and Trends. Smoking and Tobacco Control Monograph No. 9, 1998, http://cancercontrol.cancer.gov/Brp/tcrb/monographs/9/m9_complete.pdf. See also, Baker, F, et al., "Health Risks Associated with Cigar Smoking," *Journal of the American Medical Association* 284(6):735-740, 2000. See also, Shapiro, JA, Jacobs, EJ, Thun, MJ, "Cigar Smoking in Men and Risk of Death From Tobacco-Related Cancers," *Journal of the National Cancer Institute*, 92(4):333-7, February 16, 2000.

101 Nonnemaker, J, et al., "Mortality and Economic Costs from Regular Cigar use in the United States, 2010," *American Journal of Public Health* 104(9):e-86-91, September 2014.

102 HHS, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General, CDC, Office of Smoking and Health (OSH), 2014*, <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>. See also: CDC Office on Smoking and Health, "Electronic Nicotine Delivery Systems: Key Facts," July 2015. Accessed November 19, 2015. <https://www.cdc.gov/tobacco/stateandcommunity/pdfs/ends-key-facts-oct-2016.pdf>.

103 HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.*

104 HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.*

105 American Association of Poison Control Centers (AAPCC), "Electronic Cigarette and Liquid Nicotine," <http://www.aapcc.org/alerts/e-cigarettes/>.

106 CDC, "Notes from the Field: Calls to Poison Centers for Exposures to Electronic Cigarettes — United States, September 2010–February 2014," *MMWR* 63(13):292-293, April 4, 2014, <http://www.cdc.gov/mmwr/pdf/wk/mm6313.pdf>.

107 CDC, "Dual Use of Tobacco Products." <http://www.cdc.gov/tobacco/campaign/tips/diseases/dual-tobacco-use.html#ten>. Accessed November 19, 2015.

108 HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of*

Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

109 Cheng, T, "Chemical Evaluation of Electronic Cigarettes," *Tobacco Control* 23:ii11-ii17, May 2014. Goniewicz, ML, et al., "Levels of selected carcinogens and toxicants in vapour from electronic cigarettes," *Tobacco Control* 23(2):133-9, March 6, 2013. Williams, M, et al., "Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol," *PlosOne*, 8(3), March 2013. See also Williams, M, "Electronic Cigarette Liquids and Vapors: Is It Harmless Water Vapor," presented October 3, 2013 at TRDRP Electronic Cigarette Webinar. <http://www.trdrp.org/files/e-cigarettes/williams-slides.pdf>.

110 Goniewicz, ML, et al., "Levels of selected carcinogens and toxicants in vapour from electronic cigarettes," *Tobacco Control* 23(2):133-9, March 6, 2013. Williams, M, et al., "Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol," *PlosOne*, 8(3), March 2013. See also FDA, "Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List," March 2012, <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297786.htm>.

111 Zhu, S-H, et al., "Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation," *Tobacco Control*, 23(Suppl 3):iii3-iii9, 2014.

112 CDC, "Dual Use of Tobacco Products." <http://www.cdc.gov/tobacco/campaign/tips/diseases/dual-tobacco-use.html#ten>. Accessed November 19, 2015.

113 HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.*

114 Barrington-Trimis, JL, Samet, JM, &

McConnell, R, "Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?" *The Journal of the American Medical Association*, doi:10.1001/jama.2014.14830, published online November 10, 2014.

115 Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products (May 10, 2016), 81 FR 28973, <https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>.

116 Deeming Final Rule Redline Changes in Docket No. FDA-2014-N-0189-83193, Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products (May 27, 2016), <https://www.regulations.gov/document?D=FDA-2014-N-0189-83193>.

117 Lipton, E, "A Lobbyist Wrote the Bill. Will the Tobacco Industry Win Its E-Cigarette Fight?" *New York Times*, September 2, 2016, <http://www.nytimes.com/2016/09/03/us/politics/e-cigarettes-vaping-cigars-fda-altria.html>.