



AN E-CIGARETTE MARKET UPDATE

FLAVORED PRODUCTS REMAIN WIDELY AVAILABLE THREE MONTHS AFTER COURT-ORDERED DEADLINE FOR FDA TO RULE ON MARKETING APPLICATIONS

December 2021

EXECUTIVE SUMMARY

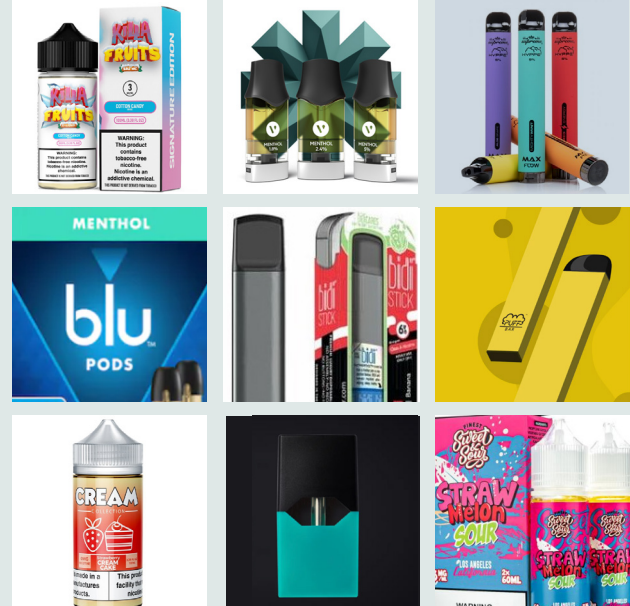
A federal court set a deadline of September 9, 2020 for e-cigarette manufacturers to submit applications, called premarket tobacco product applications (PMTAs), to the Food and Drug Administration (FDA) to keep their products on the market. The court order allowed products that were the subject of timely applications to stay on the market for up to one year while the FDA considered the applications, a period that expired on September 9, 2021. Now that this deadline has passed, unauthorized e-cigarette products on the market are subject to possible FDA enforcement action.

To date, the FDA has reported that it has acted on over 98% of the applications submitted by the September 9, 2020 deadline and has issued marketing denial orders (MDOs) for over one million flavored e-cigarette products. On October 12, 2021, the FDA issued its first, and to-date only, marketing authorization for an e-cigarette product to a Vuse Solo device and two accompanying tobacco-flavored e-liquid cartridges. Vuse Solo has been reported to have only a small share of the e-cigarette market.¹

However, despite issuing over one million MDOs, the FDA has yet to issue decisions on e-cigarette products that have the largest market shares or are most popular with kids, such as Juul, other Vuse products, NJOY, blu, Smok and Suorin. The FDA is also still considering whether to authorize the sale of any menthol-flavored e-cigarettes. In addition, the agency has indicated that it will not prioritize enforcement against the products that remain on the market pending decisions on their applications, meaning that these products can continue to be sold for an indefinite period.

To assess the impact of the FDA's actions to date on the availability of flavored e-cigarettes, and to understand the e-cigarette market landscape after the September 9, 2021 deadline, the Campaign for Tobacco-Free Kids conducted a scan of five top online e-cigarette retailers and 43 brick-and-mortar stores in eight cities across the United States. The results of this scan demonstrate that flavored e-cigarettes* remain widely available both online and in stores across the country.

* In this report, flavored e-cigarettes refer to non-tobacco-flavored products.



KEY FINDINGS FROM THIS ANALYSIS INCLUDE:

- Kid-friendly flavored e-cigarettes and e-liquids are still widely available online and in stores. Across the five websites assessed, over 100 flavored e-cigarette products remain available for sale. Many websites continue to sell products in egregious, kid-friendly flavors like Gummy Bear, Berry Crunch Cereal and Blueberry Lemonade. Retail assessments in the 43 stores surveyed demonstrate that flavored e-cigarettes also remain widely available in stores across the country.
- The best-selling e-cigarette brands are still available for sale online and in stores.
- The most popular e-cigarette brands among youth are still available online and in stores in flavors that appeal to youth.
- Disposable e-cigarettes in an extensive array of kid-friendly flavors remain widely available online and in stores. These include Puff Bar, which is now the most popular e-cigarette brand among youth and is sold in an assortment of appealing flavors. Puff Bar has sought to evade FDA regulation by using synthetic nicotine (nicotine that is not derived from tobacco) in its products.

INTRODUCTION

As a result of federal law (the 2009 Family Smoking Prevention and Tobacco Control Act) and a successful lawsuit[†] to enforce the premarket review requirements of the law filed by the Campaign for Tobacco-Free Kids and other public health groups, e-cigarette manufacturers were required to submit PMTAs to the FDA by September 9, 2020 to keep their products on the market. The federal court order allowed products that were the subject of timely applications to stay on the market for up to one year while the FDA considered the applications, a period that expired on September 9, 2021. Now that this deadline has passed, unauthorized e-cigarette products on the market are subject to possible FDA enforcement action.

Under the PMTA process, the FDA must determine whether the marketing of a product would be “appropriate for the protection of public health,” taking into account the impact of the product both on current tobacco users and on initiation of tobacco use by kids and other non-users.

To date, the FDA has reported that it has acted on over 98% of the applications submitted by the September 9, 2020 deadline and has issued marketing denial orders (MDOs) for over one million flavored e-cigarette products. According to the FDA, these applications “lacked sufficient evidence that the benefit to adult smokers who used the flavor products would overcome the public health concern posed by the well-documented and considerable appeal of the products to youth.”²

However, FDA action on e-cigarette marketing applications is far from complete, and e-cigarette manufacturers have taken legal and other steps to keep their products on the market:

- Despite issuing over one million MDOs, the FDA has yet to issue decisions about e-cigarette products that have the largest market shares or are most popular with kids, such as Juul, Vuse Alto, NJOY, blu, Smok and Suorin.
- The FDA is still considering whether to authorize the sale of any menthol-flavored e-cigarettes.
- The FDA has indicated that it will not prioritize enforcement against the products that remain on the market, pending decisions on their applications, meaning these products can continue to be sold.
- More than 40 companies have filed lawsuits challenging their marketing denial orders. As a result, the FDA has rescinded four MDOs and administratively stayed three other MDOs pending further agency review. Additionally, judges in two cases have issued stays to allow the companies to continue selling their products while their case is adjudicated.
- Several e-cigarette manufacturers, including Puff Bar, the most popular e-cigarette brand among kids, have switched to using synthetic nicotine in order to evade FDA regulation and continue marketing flavored products.

YOUTH E-CIGARETTE USE REMAINS A SERIOUS PUBLIC HEALTH CONCERN

Driven by Juul and other flavored, high-nicotine products, youth use of e-cigarettes skyrocketed from 2017 to 2019, with e-cigarette use among high school students more than doubling to 27.5%.³ These dramatic increases led the U.S. Surgeon General and other public health authorities to declare youth e-cigarette use to be a public health “epidemic.”⁴

While youth e-cigarette use has since declined, the CDC and the FDA have found that the problem remains a [serious public health concern](#). According to the 2021 National Youth Tobacco Survey (NYTS), over two million middle and high school students – including 11.3% of high school students – reported using e-cigarettes in the first half of 2021, even as many schools remained closed because of the COVID-19 pandemic. Other key findings of the 2021 NYTS include:⁵

- Flavored products continue to drive youth use: 85% of youth e-cigarette users report using flavored products, with fruit, candy/desserts/other sweets, mint and menthol reported as the most popular flavors. Among high school users of flavored e-cigarettes, 30% report using menthol products, including 46% of users of flavored cartridge-based products like Juul.
- In a clear sign of the addictiveness of the products now dominating the market, an alarming percentage of youth e-cigarette users report frequent or daily use: 43.6% of high school users report frequent use (at least 20 days a month) and 27.6% report daily use.
- Puff Bar has become the most popular e-cigarette brand among youth. Among high school students who currently use e-cigarettes, 26.1% report Puff Bar as their usual brand, followed by Vuse (10.8%), Smok (9.6%), Juul (5.7%) and Suorin (2.3%).

There is no question that, as long as flavored products are available, young people will get access to them, often directly from retail outlets. According to the 2020 NYTS, 22.2% of high school e-cigarette users reported obtaining e-cigarettes from a gas station or convenience store in the past month and 17.5% from a vape shop. In addition, 5.4% of high school and 8.4% of middle school e-cigarette users reported buying e-cigarettes from the internet.⁶ Studies have found that youth successfully purchased e-cigarettes over the internet in 94% to 97% of their online purchase attempts.⁷

85%

OF YOUTH E-CIGARETTE USERS REPORT USING FLAVORED PRODUCTS

[†] The lawsuit was filed by the American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Truth Initiative and five individual pediatricians.

MOST POPULAR BRANDS AMONG HIGH SCHOOL E-CIGARETTE USERS



Source: 2021 National Youth Tobacco Survey

REPORT METHODOLOGY

This report summarizes the results from a scan of five top online e-cigarette retailers[‡] (according to E-Cigarette Intelligence) and retail assessments conducted in 43 stores in eight cities across the country (Denver, CO; Detroit, MI; Los Angeles, CA; Portland, ME; Portland, OR; Seattle, WA; Tempe, AZ; and Washington, DC). These stores included 28 gas stations or convenience stores and 15 vape/tobacco shops. Store assessments documented the availability of top-selling e-cigarette brands, including Juul, Vuse, NJOY, blu, Puff Bar and Bidi, as well as other kid-friendly disposable e-cigarettes and e-liquids. This is not intended to be a representative sample of stores nationwide or online.

THE TOP-SELLING E-CIGARETTE BRANDS REMAIN WIDELY AVAILABLE

The FDA has yet to issue decisions about e-cigarette products with the largest market shares, including Juul, Vuse,[§] NJOY and blu, which make up over 80% of the market, according to Nielsen convenience store data.[§] The delay in ruling on these applications is inconsistent with previous statements by the FDA that it would identify and ensure “first review” of the applications for products “that account for most of the current market” to “achieve the greatest public health impact most quickly.”⁹

Juul was sold in brick-and-mortar stores across all cities in our assessment, while Vuse, NJOY and blu were available in most cities (it is likely these products are sold in all the cities involved in this scan, but not in the specific stores assessed).

While the FDA in February 2020 implemented a new policy guidance that prioritized enforcement against flavored cartridge-based e-cigarettes, it left menthol-flavored cartridge products on the market – including those made by Juul, Vuse, NJOY and blu. These menthol products have continued to drive youth e-cigarette use and e-cigarette sales:

- Among high school users of flavored e-cigarettes, 30% report using menthol products, including 46% of users of flavored cartridge-based products like Juul.¹⁰
- From February 2020 to August 2021, menthol-flavored e-cigarette sales** increased by 47.7% (from 6.4 million to 9.4 million units) and sales of menthol-flavored cartridge products increased by 54%, according to sales data from the CDC Foundation and Information Resources, Inc. As of August 2021, menthol-flavored e-cigarettes sales accounted for 38.4% of the e-cigarette market.¹¹
- While Juul's popularity among kids has declined in recent years as more kids have shifted to disposable products, Vuse's popularity has been increasing. In 2021, Vuse was the second most popular brand among youth e-cigarette users.¹² Nielsen convenience store data show that Vuse sales are catching up to Juul.¹³

MENTHOL-FLAVORED E-CIGARETTES REMAIN WIDELY AVAILABLE



JUUL
Menthol



Vuse
Menthol



NJOY
Menthol



blu
Menthol

[‡] Websites include: www.elementvape.com, www.vapordna.com, www.directvapor.com, www.electrictobacconist.com and www.myvaporstore.com.

[§] While the FDA issued a marketing authorization for a Vuse Solo device and two replacement cartridges in tobacco flavor, and a marketing denial for 10 non-tobacco flavored refill cartridges for Vuse Solo, the FDA has yet to rule on Vuse Alto, which is heavily advertised by R.J. Reynolds Vapor Company and comprises the large majority of Vuse product sales.

** Sales data does not reflect sales from vape shops or online retailers

E-LIQUIDS IN KID-FRIENDLY FLAVORS REMAIN WIDELY AVAILABLE

Despite the over one million MDOs issued by the FDA, many e-liquid manufacturers, flavored e-liquid products remain widely available online and in stores. The online scan yielded dozens of kid-friendly flavored e-liquids. Available flavors include fruit flavors in combinations like Melon Berry, Banana Dragonberry, Watermelon Wave, Mango Tango and many more. Our search also yielded a plethora of sweet and dessert flavors, such as Blue Cotton Candy and Funnel Cake, and drink flavors, including Fruit Punch and Orange Soda.

Flavored e-liquids were also available in brick-and-mortar stores in most cities assessed, in flavors including Green Apple, Cola, Peachy Rings, Tropical Fruit, Strawberry Macaroon and Island Orange. These flavored e-liquid products can be used with devices that are popular with youth, like Smok and Suorin.

FLAVORED DISPOSABLE E-CIGARETTES REMAIN WIDELY AVAILABLE

While many disposable e-cigarette manufacturers have received marketing denial orders, a large variety of flavored disposable products are still available for sale through online e-cigarette retailers and retail stores across the country. Disposable e-cigarettes are easily concealable like Juul, but are often cheaper (some for less than \$5), available in a wide variety of flavors and can have even higher nicotine concentrations than Juul.¹⁴

Our online search yielded an assortment of disposable e-cigarettes in fruit flavors like Peach Freeze and Pineapple Twist, sweet/dessert flavors like Gummy Bear and Vanilla Strawberry Custard, and drink flavors like Cola Ice and Cherry Lemonade. Disposable e-cigarettes were also found in a rainbow of flavors in every city in our assessment, including flavors such as Coconut Pineapple Smoothie, Strawberry Ice Cream, Gummy Bear, Mango Slushee and Blue Razz Lemonade.

Bidi Vapor, the market leader in disposable e-cigarette sales,¹⁵ is challenging its marketing denial orders in court, but remains available online in flavors like Zest, described as a combination of pineapple, banana and mint. Bidi products were also found in some brick-and-mortar stores in our assessment. Findings on Puff Bar, which is the most popular e-cigarette brand among youth and the second highest-selling disposable, are discussed in the following section on synthetic nicotine products.

After the FDA's February 2020 guidance exempted disposable e-cigarettes, many youth shifted to using these products.

- 55.8% of high school e-cigarette users report using disposable e-cigarettes, according to the 2021 NYTS. Among current youth users of disposable e-cigarettes, the most commonly used flavor type is fruit (78.7%), followed by candy/desserts/other sweets (32.3%).¹⁶
- E-cigarette sales data shows a similar shift to disposable e-cigarettes. From February 2020 to August 2021, sales of disposable e-cigarettes increased by 253% (from 2.8 million units to 9.8 million units), according to CDC Foundation and Information Resources, Inc. data. During this time, the market share of disposable devices more than doubled, from 18.8% to 40.2% of total e-cigarette sales. Flavors other than tobacco, mint and menthol comprise 81% of disposable e-cigarette sales.¹⁷

PRODUCTS AVAILABLE ONLINE

BLUEBERRY LEMONADE



CHOCOMINT



COTTON CLOUDS



STRAWBERRY MILK



FRUIT AND MINT FLAVORS



E-LIQUIDS

DISPOSABLE E-CIGARETTES

FLAVORED E-CIGARETTES WIDELY AVAILABLE IN STORES ACROSS THE COUNTRY

8 CITIES ASSESSED IN THIS REPORT

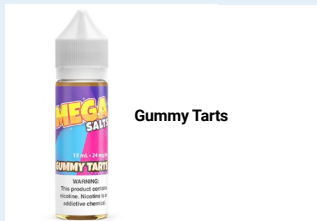


A WIDE VARIETY OF FLAVORED E-CIGARETTE PRODUCTS ARE AVAILABLE ONLINE

TOBACCO-DERIVED NICOTINE E-LIQUIDS



Orange Soda



Gummy Tarts

SYNTHETIC NICOTINE E-LIQUIDS

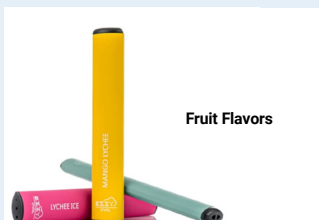


Watermelon Berry

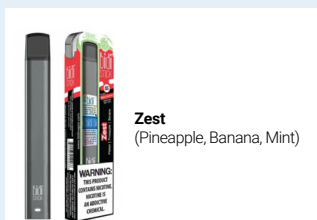


Kookie Krunch

TOBACCO-DERIVED DISPOSABLES



Fruit Flavors



Zest
(Pineapple, Banana, Mint)

SYNTHETIC DISPOSABLES



Blueberry Ice



Tropic Mango



VS



FLAVORED SYNTHETIC NICOTINE PRODUCTS LIKE PUFF BAR EVADE FDA REGULATION AND ARE WIDELY AVAILABLE

In recent months, a growing number of e-cigarette and e-liquid manufacturers have switched to using synthetic nicotine (sometimes marketed as “tobacco-free”) in order to evade FDA regulation and continue marketing their products. E-cigarettes made from synthetic nicotine are currently not regulated by the FDA as either tobacco products or drugs. The FDA’s Center for Tobacco Products (CTP) regulates products that contain tobacco or nicotine derived from tobacco and has not taken action to regulate products that contain synthetic nicotine. [The Campaign for Tobacco-Free Kids and other public health groups](#) have urged the FDA, through its Center for Drug Evaluation and Research (CDER), to assert jurisdiction over synthetic nicotine products as drugs and to take enforcement action against such products as illegal drugs being marketed without FDA authorization.



In February 2021, Puff Bar announced that it had switched to using synthetic nicotine in its products. As noted previously, Puff Bar was the most popular e-cigarette brand among youth in 2021.

Online, the Puff Bar website currently advertises three devices in nearly two dozen flavors, including Strawberry Banana, Cool Mint, Watermelon, Blue Razz,

Mango, Passionfruit and Lemon Ice. Puff Bar was found in stores in most cities in our assessment in the same array of flavors that are sold online. Other synthetic disposable e-cigarette brands found online offer additional fruity flavors like Pink Lemonade, Juicy Apples and Peach Passion.

Some e-liquid manufacturers have also made the switch to synthetic nicotine. Online e-cigarette retailers sell synthetic nicotine e-liquids in an array of kid-friendly flavors, including fruit flavors like Watermelon Berry and Mango Strawberry, desserts/sweets like Kookie Krunch and Banana Fried Cream Cakes, and drinks

like Cereal Milk. Some websites offered both tobacco-derived and synthetic varieties of the same brand and flavor combinations, clearly demonstrating that brands are ready to make the switch to synthetic if their tobacco-derived products are denied authorization by the FDA.

Synthetic nicotine uses different forms of nicotine than what is in tobacco-derived nicotine, and it is still unknown if synthetic nicotine may have unique health impacts for users.¹⁸

SUMMARY OF IN-STORE ASSESSMENTS

Retail assessments were conducted in 43 stores in eight cities across the country (Denver, CO; Detroit, MI; Los Angeles, CA; Portland, ME; Portland, OR; Seattle, WA; Tempe, AZ; and Washington, DC) between October 25, 2021, and November 1, 2021. These stores included 28 gas stations or convenience stores and 15 vape/tobacco shops. Store assessments documented the availability of top-selling e-cigarette brands, including Juul, Vuse, NJOY, blu, Puff Bar and Bidi, as well as other disposable e-cigarettes and e-liquids. Key findings:

- Juul was sold in all cities and Vuse, NJOY and blu were available in most cities (as noted previously, it is likely these products are sold in all the cities involved in this scan, but not in the specific stores assessed).
- Flavored e-liquids were found in most cities, in flavors like Green Apple, Cola, Peachy Rings, Tropical Fruit, Strawberry Macaroon and Island Orange.
- Disposable e-cigarettes were available in every city in a rainbow of flavors including Coconut Pineapple Smoothie, Strawberry Ice Cream, Gummy Bear, Mango Slushee and Blue Razz Lemonade.
- Puff Bar was found in most cities in the same array of flavors that are advertised online, including Banana Ice, Watermelon and Strawberry.



ACTION NEEDED TO CLEAR THE MARKET OF FLAVORED E-CIGARETTES

As this report demonstrates, despite the FDA's actions to date, flavored e-cigarettes remain widely available. The evidence is clear that flavored e-cigarettes have fueled the youth e-cigarette epidemic and that as long as any flavored e-cigarettes – including menthol-flavored products – are on the market, kids will shift to them and we will not end this public health crisis.

Both the FDA and state and local authorities must act to protect kids and public health:

- The FDA must act quickly on all remaining e-cigarette applications and deny authorization to all flavored e-cigarettes – including menthol-flavored products – and products with high nicotine levels that put kids at risk of addiction.
- The FDA must take enforcement action against products that remain on the market illegally. Robust surveillance and

enforcement efforts are needed to ensure that e-cigarette products that have received MDOs are no longer available in stores or online and no new products are introduced without prior FDA authorization.

- The FDA must take action against synthetic nicotine products. The FDA must no longer allow synthetic nicotine products like Puff Bar to evade regulation and be marketed in kid-friendly flavors.
- State and local efforts to end the sale of all flavored e-cigarettes, as well as other flavored tobacco products, continue to be critical. It is still unknown whether the FDA will deny applications for all flavored e-cigarettes, including menthol e-cigarettes. More than 40 companies have challenged the FDA's MDOs in court, and the outcomes of these cases are uncertain. States and cities cannot wait for the FDA and must act now to close the gaps left by the FDA in order to fully protect kids.

- 1 "Key Concerns About FDA's First E-Cigarette Authorization for Vuse Solo." Truth Initiative. October 18, 2021. <https://truthinitiative.org/research-resources/emerging-tobacco-products/key-concerns-about-fdas-first-e-cigarette>
- 2 "FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by the Agency." U.S. Food and Drug Administration. October 12, 2021. <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency>
- 3 Cullen, Karen A., et al., "E-Cigarette Use Among Youth in the United States, 2019." JAMA Network. November 5, 2019. <https://jamanetwork.com/journals/jama/fullarticle/2755265>
- 4 "Surgeon General's Advisory on E-Cigarette Use Among Youth." Office of the Surgeon General. December 18, 2018. <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>
- 5 Park-Lee, Eunice, et al., "E-Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, 2021." Morbidity and Mortality Weekly Report. October 1, 2021. <https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039a4-H.pdf>
- 6 Wang, Teresa W., et al., "Characteristics of E-Cigarette Use Behaviors Among US Youth, 2020." JAMA Network. June 7, 2021. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780705>
- 7 Williams, Rebecca S., Derrick Jason, & Ribisl, Kurt M., "Electronic Cigarette Sales to Minors Via the Internet." JAMA Network. March 2, 2015. <https://jamanetwork.com/journals/jamapediatrics/article-abstract/2174572>
- 8 Craver, Richard, "Reynolds' Vuse Closing Gap with Top-Selling E-Cigarette Juul." Winston Salem Journal. Nov. 5, 2021. https://journalnow.com/business/local/reynolds-vuse-closing-gap-with-top-selling-e-cigarette-juul/article_9e9de9b4-3bf6-11ec-bd91-cf6bd160ac28.html
- 9 Zeller, Mitch, "Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline." US Food & Drug Administration. Feb. 16, 2021. <https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline>
- 10 Park-Lee, Eunice, et al., "E-Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, 2021." Morbidity and Mortality Weekly Report. October 1, 2021. <https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039a4-H.pdf>
- 11 "Monitoring U.S. E-Cigarette Sales: National Trends." CDC Foundation & Information Resources, Inc., <https://www.cdcfoundation.org/programs/monitoring-e-cigarette-use-among-youth>
- 12 Wang, Teresa W., et al., "E-Cigarette Use Among Middle and High School Students – United States, 2020." Morbidity and Mortality Weekly Report. September 9, 2020. <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf>
- 13 Craver, Richard, "Reynolds' Vuse Closing Gap with Top-Selling E-Cigarette Juul." Winston Salem Journal. Nov. 5, 2021. https://journalnow.com/business/local/reynolds-vuse-closing-gap-with-top-selling-e-cigarette-juul/article_9e9de9b4-3bf6-11ec-bd91-cf6bd160ac28.html
- 14 Williams, Rebecca, "The Rise of Disposable JUUL-Type E-Cigarette Devices." Tobacco Control. December 5, 2019. <https://tobaccocontrol.bmj.com/content/29/e1/e134>
- 15 "Americas Tobacco: Nielsen Data Thru 9/11: Total Nicotine Volumes Remain Pressured." Goldman Sachs. September 21, 2021
- 16 Wang, Teresa W., et al., "E-Cigarette Use Among Middle and High School Students – United States, 2020." Morbidity and Mortality Weekly Report. September 9, 2020. <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf>
- 17 "Monitoring U.S. E-Cigarette Sales: National Trends." CDC Foundation & Information Resources, Inc., <https://www.cdcfoundation.org/programs/monitoring-e-cigarette-use-among-youth>
- 18 Jordt, Sven-Eric, "Synthetic Nicotine Has Arrived." Tobacco Control. September 7, 2021. <https://tobaccocontrol.bmj.com/content/early/2021/09/07/tobaccocontrol-2021-056626>