Ms. Michele Mital  
Acting Director, Center for Tobacco Products  
U.S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993-0002  

June 9, 2022  

RE: Latest evidence that menthol e-cigarettes and flavored disposable products, two products widely used by youth, remain popular

Dear Director Mital:

I write to bring your attention to two recent publications. The first (Attachment 1) consists of the latest CDC Foundation e-cigarette sales data – through February 2022 – showing that sales of menthol flavored e-cigarettes remain high.1 The second (Attachment 2) discusses why this sales data is useful and should be considered when assessing youth usage of e-cigarettes.2

As the data has shown, when flavored pre-filled cartridges, including mint, were prohibited, sales of menthol flavored e-cigarettes rose rapidly and became very popular among youth.

For example, following the January 2020 national restriction on the sale of certain flavored cartridge-based e-cigarettes (excluding menthol and tobacco), increases occurred in US sales of menthol-flavored e-cigarettes and disposable e-cigarettes, the latter of which were still available for sale with fruit, candy, mint, and other flavors. Disposable e-cigarette use increased among US youths during 2019 to 2020, and in 2020, among youths who used flavored e-cigarettes, menthol use was 34.3% among those who used disposable e-cigarettes and 48.4% among those who used prefilled cartridges or pods.3

The 2021 NYTS also found high menthol flavored e-cigarette use among youth users of flavored e-cigarettes (28.8%), particularly among current flavored prefilled cartridge users (46.3%).4 In short, the evidence is strong that menthol e-cigarettes pose a high risk to youth and, after February 2020, have become a major source of the youth e-cigarette epidemic.

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1 CDC Foundation, Monitoring U.S. E-Cigarette Sales: National Trends (Feb. 2022) (Attachment 1).
The evidence also demonstrates that the use of menthol e-cigarettes, especially among youth, remains at consistently high levels. The CDC Foundation tracks sales of E-cigarettes and posts the most recent data on a monthly basis. The latest data published on the CDC Foundation website runs through February 2022. It shows that from February 23, 2020, to February 20, 2022, overall menthol flavored e-cigarette sales increased by 39.4% (from 6.4 million to 8.9 million units), including a 45.2% increase in menthol-flavored cartridge sales (from 5.9 million units to 8.5 million units). As of February 20, 2022, menthol flavored e-cigarettes sales accounted for 39.3% of the overall e-cigarette market and 62.0% of the prefilled cartridge market. In fact, in February 2022 there was an increase in the sales of both menthol e-cigarettes and flavored disposable products. (See Attachment 1). The underlying data is available at the CDC Foundation website.

Because the CDC Foundation sales data does not include demographic data it cannot by itself be used in isolation to demonstrate what percentage of sales of a specific product is to youth. Nonetheless, it does provide useful and reliable information that has consistently and accurately reflected youth use trends in the past, as the recently-published article notes (see Attachment 2) and, therefore, provides a meaningful data source that reaffirms the evidence that the use of menthol e-cigarettes among youth has been and remains at exceptionally high levels.

For E-cigarettes, retail sales trends have been historically consistent with those from self-reported surveys of youth; for example, in the U.S., E-cigarette use increased by 78% (from 11.7% to 20.8%) between 2017 and 2018, with a similar increase occurring in national E-cigarettes sales during the same period (115% increase from 87.7 million standardized units sold in 2017 to 188.6 million standardized units sold in 2018).

In a separate letter, medical and public health groups have cited the evidence found by FDA that the combination of nicotine and menthol contributes to youth initiation, increased levels of addiction and greater difficulty in quitting. The data attached to this letter demonstrates that menthol e-cigarettes contribute significantly to the youth e-cigarette epidemic and provides further evidence that no menthol e-cigarette should be authorized as a consumer product by the FDA Center for Tobacco Products.

Respectfully submitted,

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

CC: The Honorable Robert M. Califf, Commissioner, U.S. Food and Drug Administration

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5 Attachment 2, at 2.
Attachment 1
Federal Regulatory Actions and Other Emergent Events

- The U.S. Food and Drug Administration (FDA) issued an enforcement policy, effective February 2020, prohibiting the sale of flavored prefilled cartridges e-cigarettes, which does not apply to tobacco-and menthol-flavored prefilled cartridges, e-liquids, or single use disposable products.
- FDA began issuing marketing denial orders for flavored e-cigarette products leading up to the court-ordered deadline of September 9, 2021 to rule on product applications. However, the FDA has yet to rule on products with over 75% of the e-cigarette market.
- Emergent events at the national level may have affected e-cigarette sales, including the e-cigarette or vaping product use-associated lung injury (EVALI) outbreak during August 2019 - January 2020 and COVID-19 pandemic.

Key Findings

- Total e-cigarettes:
  - Annual total e-cigarette unit sales increased by 31.1% from 2020 to 2021, and by 231.2% from 2017 to 2021.
  - From February 23, 2020, to February 20, 2022, total e-cigarette unit sales increased by 52.3% (from 14.8 million units to 22.5 million units). During this period, sales of non-tobacco flavored e-cigarettes (mint, menthol and other flavors) increased by 73.2% (from 9.7 million to 16.8 million).
  - The 2021 National Youth Tobacco Survey (NYTS) found that 11.3% (1.72 million) of high school and 2.8% (320,000) of middle school students were current e-cigarette users. Overall, 84.7% used flavored e-cigarettes.¹

- Flavored disposable e-cigarettes:
  - From February 23, 2020, to February 20, 2022, sales of disposable e-cigarettes increased by 215.4% (from 2.8 million units to 8.8 million units). During this period, the market share of disposable devices increased from 18.8% to 38.9% of total e-cigarette sales. As of February 20, 2022, 80.2% of disposable sales were of flavors other than tobacco, mint and menthol.
  - Consistent with sales trends, the 2021 NYTS found that more than half (53.7%) used disposable e-cigarettes. Among current youth users of flavored disposable e-cigarettes, the most commonly used flavor types were fruit (78.7%) and candy/desserts/other sweets (32.3%).

- Menthol flavored prefilled cartridge e-cigarettes:
  - From February 23, 2020, to February 20, 2022, overall menthol flavored e-cigarette sales increased by 39.4% (from 6.4 million to 8.9 million units), including a 45.2% increase in menthol-flavored cartridge sales (from 5.9 million units to 8.5 million units). As of February 20, 2022, menthol flavored e-cigarettes sales accounted for 39.3% of the overall e-cigarette market and 62.0% of the prefilled cartridge market.
  - The 2021 NYTS also found high menthol flavored e-cigarette use among youth users of flavored e-cigarettes (28.8%), particularly among current flavored prefilled cartridge users (46.3%).

Conclusion

Restrictions that exempt certain flavors and product types are likely to shift sales to the products and flavors that remain on the market, deterring progress in reducing overall use. Comprehensive policies that prohibit all non-tobacco flavored e-cigarettes, including flavored disposable e-cigarettes and menthol-flavored prefilled cartridges, may reduce e-cigarette sales, reduce youth access to flavored e-cigarettes, and ultimately reduce youth e-cigarette use.

Figure 1. National E-Cigarette Unit Sales by Flavor, 4 Week Estimates 01/28/2018 – 02/20/2022*

**Trends of Unit Sales by Flavor Following FDA’s Flavor Enforcement Policy**

- From February 23, 2020, to February 20, 2022, total monthly e-cigarette unit sales increased by 52.3% to 22.5 million units.
- From February 23, 2020, to February 20, 2022, sales of non-tobacco flavored e-cigarettes (mint, menthol and other flavors) increased by 73.2% (from 9.7 million to 16.8 million).
- From February 23, 2020, to February 20, 2022:
  - Menthol-flavored e-cigarette sales increased by 39.4% (from 6.4 million to 8.9 million); market share decreased from 43.0% to 39.3%.
  - Tobacco-flavored e-cigarette sales increased by 11.9% (from 5.1 million to 5.7 million); market share decreased from 34.3% to 25.2%.
  - Mint-flavored e-cigarette sales increased by 41.3% (from 0.7 million to 0.9 million); market share decreased from 4.4% to 4.1%.
  - All other-flavored e-cigarette sales increased by 160.3% (from 2.7 million to 7.0 million); market share increased from 18.3% to 31.2%.
- From September 5, 2021, to February 20, 2022, e-cigarette sales declined by 6.3% (from 24.1 million units to 22.5 million units).

*Sales data does not reflect sales from vape shops or online retailers; dates represent end of 4-week periods; All Other Flavors category includes fruit, clove/spice, chocolate, alcoholic drink (such as wine, cognac, or other cocktails), candy/desserts/other sweets, some other flavor; e-cigarette accessories and devices sold without e-liquids were excluded (11.5% of total sales).
Figure 2. National E-Cigarette Unit Sales by Product Type, 4 Week Estimates 01/28/2018 – 02/20/2022*

Trends of Unit Sales by Product Following FDA’s Flavor Enforcement Policy

- Following FDA’s flavor enforcement policy, which prohibited the sale of flavored prefilled cartridges but exempted disposable devices and menthol and tobacco prefilled cartridges, between February 23, 2020, and February 20, 2022:
  - Sales of disposable devices increased by 215.4% (from 2.8 million to 8.8 million); market share increased from 18.8% to 38.9%.
  - Sales of prefilled cartridges increased by 14.8% (from 12.0 million to 13.8 million); market share decreased from 81.1% to 61.1%.

*Sales data does not reflect sales from vape shops or online retailers; dates represent end of 4-week periods; prefilled cartridges include tanks, cartridges, and pods used in rechargeable and reusable e-cigarette device; disposable devices include nonrechargeable and nonreusable e-cigarette devices that are not intended to be refilled with e-liquid after being depleted; e-liquids are containers of the liquid used in e-cigarette devices, which typically contains a humectant (e.g., propylene glycol), nicotine, and flavoring.
Figure 3. National E-Cigarette Unit Sales by Product Type and Flavor, 4 Week Estimates 01/28/2018 – 02/20/2022

Prefilled Cartridges

Disposable Devices
Figure 4. National E-Cigarette Unit Sales by Product Type and Flavor, 4 Week Estimates
01/28/2018 – 02/20/2022
Figure 5. Market Share of National E-Cigarette Unit Sales by Flavor, Annual Estimates 2017 – 2021*

Unit Sales Annual Trends by Flavor (2020 - 2021)

- From 2020 to 2022:
  - Market share of menthol-flavored e-cigarette sales decreased from 46.0% to 40.4%;
  - Market share of tobacco-flavored e-cigarette sales decreased from 31.6% to 25.8%;
  - Market share of mint-flavored e-cigarette sales increased from 3.0% to 3.9%; and
  - Market share of other-flavored e-cigarette sales increased from 19.3% to 29.9%.

*Sales data does not reflect sales from vape shops or online retailers; All Other Flavors category includes fruit, clove/spice, chocolate, alcoholic drink (such as wine, cognac, or other cocktails), candy/desserts/other sweets, some other flavor; e-cigarette accessories and devices sold without e-liquids were excluded (11.5% of total sales).
Figure 6. Market Share of National E-Cigarette Unit Sales by Flavor, Annual Estimates 2017-2021*

Unit Sales Annual Trends by Flavor (2020 - 2021)

- From 2020 to 2021:
  - Annual total e-cigarette unit sales increased by 31.1% (from 221.5 million to 290.4 million units);
  - Market share of menthol-flavored e-cigarettes decreased from 46.0% to 40.4%;
  - Market share of tobacco-flavored e-cigarettes decreased from 31.6% to 25.8%;
  - Market share of mint-flavored e-cigarette sales increased from 3.0% to 3.9%; and
  - Market share of other-flavored e-cigarette sales increased from 19.3% to 29.9%.

*Sales data does not reflect sales from vape shops or online retailers; All Other Flavors category includes fruit, clove/spice, chocolate, alcoholic drink (such as wine, cognac, or other cocktails), candy/desserts/other sweets, some other flavor; e-cigarette accessories and devices sold without e-liquids were excluded (11.5% of total sales).
Attachment 2
Different Times Call for Different Measures: Using Retail Sales to Monitor the Tobacco Product Landscape

Elizabeth L. Seaman, PhD, MHS,1 Fatma Romeh M. Ali, PhD, MA,1 Barbara A. Schillo, PhD,2 Donna M. Vallone, PhD, MPH,2 Brian A. King, PhD, MPH3

In the past 15 years, the tobacco product landscape has evolved rapidly. After the introduction of E-cigarettes in the 2000s and the growth and promotion of several brands, including JUUL, the use of these products rapidly increased among U.S. youth during 2011–2019.1−3 These increases were driven by multiple factors, including advertising themes that are similar to those previously found to promote youth cigarette smoking,4 flavors that appeal to youth,5 and the introduction of newer products with characteristics that appeal to young people (e.g., smaller and easily concealable or similar in size and shape to a USB flash drive). Newer E-cigarette types also deliver nicotine in the form of nicotine salts, which allows a particularly high level of nicotine to be inhaled more easily and with less irritation than the free-base nicotine that has traditionally been used in conventional tobacco products and older E-cigarette types.6 However, the diversification of the tobacco product landscape has not been limited to E-cigarettes, and other products also continue to reemerge or newly emerge. More recently, updated versions of heated tobacco products, which were originally introduced in the 1990s with limited consumer interest, have returned to the marketplace in several countries.7,8 Novel smokeless tobacco products,9 including nicotine pouches, have also recently emerged; these prefilled, microfiber pouches contain nicotine powder that dissolves in the mouth without requiring spitting. Given the quickly evolving tobacco product marketplace, it is critical that researchers rapidly collect data on these emerging products, particularly to document seminal increases in sales and use to inform timely public health interventions that can expeditiously mitigate the use among populations at increased risk, including young people.

Most longstanding or gold-standard surveillance systems that assess tobacco product use in the U.S. are fielded annually (e.g., National Youth Tobacco Survey, Monitoring the Future Survey), biennially (e.g., Youth Risk Behavior Survey), or even less frequently (e.g., Tobacco Use Supplement to the Current Population Study). These surveys typically use established sampling (e.g., probability-based) and survey administration (e.g., household-based, school-based) approaches. Although these established surveillance systems have strengths, including robust validity and reliability, they are not able to capture rapid, subannual changes in awareness and use, which is critical to assess emergent trends in novel products. It also takes time for items related to new and emerging tobacco products to be added to these surveillance systems. Rapid surveys can quickly collect this information, albeit not with the same rigor as with established surveillance systems. Rapid surveys can serve as an important complement to but not a replacement for these established surveillance systems mentioned earlier. These types of rapid surveys can also be useful for collecting timely data to inform efforts related to concurrent public health issues. For example, at the onset of the coronavirus disease 2019 (COVID-19) pandemic, rapidly collected data on tobacco product use were important to understanding the relationship between cigarette smoking and the risk of severe illness from COVID-19. Rapid surveillance systems that have gained momentum in recent years include web-panel surveys; however, these surveys can be time and resource intensive, including securing probability-based samples, particularly among young people.
Retail sales data are one rapidly available source to assess tobacco product consumption that does not require the resources associated with securing representative, self-reported population-level data, which is the case for gold-standard surveillance systems. Through vendors that compile universal product code (UPC)-level scanner data from a cohort of retailers, researchers can purchase retail sales data for cigarettes, E-cigarettes, cigar products, smokeless tobacco, nicotine replacement therapy, and other emerging products. These data are projected to account for nonparticipating retailers using propriety vendor calculations, yielding estimates that illustrate the total marketplace in a given geography. Data are generally available monthly or quarterly, allowing for subannual assessment. Retail sales data can be purchased from vendors (e.g., NielsenIQ, IRI) at national and subnational levels in the U.S.; for example, data are available for individual U.S. states and for scantrack market areas. Aside from measuring various aspects of overall population-level sales (e.g., dollar and unit sales), retail sales data also provide critical information on new products on the market, the price of these products, the venue in which the product was purchased (e.g., convenience stores, grocery stores, drug stores, mass merchandizer stores, club stores, dollar stores, and Military sales) and any accompanying promotions (e.g., buy one get one). In addition, to providing a cross-sectional snapshot of the product market at a given time (i.e., most sold product type and flavor), retail sales data can also provide information on weekly, monthly, quarterly, or annual trends in key measures over time. Studies analyzing retail sales data have contributed to the literature and advanced understanding of E-cigarette product availability and trends in purchasing. Retail sales data can be used to assess the introduction of new products to the marketplace, measure shifts in market share by flavor type, and assess the relationship between regulatory action and changes in product sales.

In the context of a rapidly emerging landscape, retail sales data have several inherent strengths. The data are timely—most vendors offer monthly data delivery, allowing for the rapid detection of trends. In addition, data are generally collated and analyzable at the weekly level, allowing for the assessment of temporally precise changes from week to week, which can be easily cross-linked with specific policies or interventions (Figure 1). Certain vendors have restrictions around publishing sales at the weekly level and require aggregation into 2- or 4-week periods. Retail sales data provide considerable detail about specific product information that is tied to the UPC, including products names, brands, and characteristics such as flavors. The UPC is constant across different retailers, which is not the case for other bar codes such as stock-keeping units (SKU); therefore, products are captured in the database as long as they are sold and scanned by participating retailers, which were estimated to cover 77% of retail stores in the U.S. (excluding online and vape shops). Finally, the availability of national, state, and some city or scantrack market-level data allows for comparisons between geographies, including those that have implemented relevant policies and those used as control jurisdictions.

However, despite these strengths, there are also several notable limitations. Retail sales data are reported in aggregate at the UPC level; therefore, there is no demographic information about those who purchased the products or actually used the products. For example, retail sales data can document changes in dollar or unit sales of a specific product in a given area, which are presumably being used; however, it is not possible to ascertain whether those purchases have been made by adults or youth. Nonetheless, the sales reflect products purchased and available in society, which could be obtained directly or indirectly by youth. For E-cigarettes, retail sales trends have been historically consistent with those from self-reported surveys of youth; for example, in the U.S., E-cigarette use increased by 78% (from 11.7% to 20.8%) between 2017 and 2018, with a similar increase occurring in national E-cigarettes sales during the same period (115% increase from 87.7 million standardized units sold in 2017 to 188.6 million standardized units sold in 2018). Another limitation of retail sales data is that they reflect sales for brick-and-mortar retailers (e.g., convenience stores, gas stations); data are not obtained for some retailers for which a sizable portion of certain products might be sold, including tobacco specialty/vape stores and online. Although this is not problematic for products largely sold through brick-and-mortar retailers (e.g., cigarettes), it can introduce bias for some products that might be available in excluded store types. For example, in the U.S., the exclusion of Internet purchases is of particular importance for E-cigarettes, which are available for online purchase; in contrast, conventional tobacco products such as cigarettes and smokeless tobacco are illegal to sell through the Internet. Finally, retail sales data can be relatively costly to purchase, and the data require technical expertise to analyze.

When considering the potential for the bias associated with retail sales data, it is important to understand the proportion of tobacco products sold through channels excluded from the data source, particularly related to Internet sales of emerging products such as E-cigarettes. Estimates of the proportions of sales in noncovered brick-and-mortar stores such as tobacco specialty stores and vape shops are unknown. To date, some general estimates of the potential proportion of overall sales.
attributed to the Internet have been proposed. For example, Wells Fargo analysts estimated that in 2019, 28.3% of U.S. E-cigarette sales were online. In the same year, ECigIntelligence estimated that 15% of U.S. E-cigarette sales were online, which increased to 20% by 2020. Euromonitor International estimated that 25.6% of U.S. E-cigarette sales were online in 2019, which increased to 32.6% in 2020. In the most detailed assessment to date, CDC Foundation recently commissioned an analysis from DigitalCommerce360, a leading research and media organization specializing in electronic commerce reporting and analysis, to assess the size of the online E-cigarette market in the U.S. Through analysis of available market data (e.g., U.S. Department of Commerce, Gales reports) assessing information from annual 10-K and investor day filings from publicly held tobacco product manufacturers and interviews with web merchants and industry analysts, DigitalCommerce360 estimated that 18.3% of U.S. E-cigarette sales were online in 2020 (increasing from 17.7% in 2019) and projected that this proportion would grow to approximately 19% in 2021. Taken together, although there is some variation in estimates across sources, they suggest that online sales comprise approximately one third or less of the marketplace. Retail sales likely include the majority of the U.S. E-cigarette market and provide a reasonable gauge of the patterns of a majority of the E-cigarette sales occurring in the U.S. In summary, the tobacco product landscape is constantly changing; tobacco control practitioners and researchers can benefit from access to rapidly available data to be able to understand emerging products and trends as they are occurring. This is particularly important in the context of rapid onset public health threats that might impact product access and use, such as EVALI (E-cigarette or vaping product use associated lung injury) or COVID-19, as well as the proliferation of tobacco control policies being implemented at varying geographies, such as flavor prohibitions, and the need to evaluate the impact of these policies in a timely manner. Importantly, rapid response surveillance, including retail sales data, is an important complement to but not a replacement for gold-standard surveillance systems such as annual and biennial nationally representative surveys. Although retail sales data have certain limitations, preliminary evidence suggests that retail sales data cover a sizable portion of tobacco product sales. Moreover, in the absence of an alternative approach for obtaining similarly timely data, retail sales data afford the most scientifically robust option for quickly collecting emerging tobacco product sales at subannual levels of periodicity. These data also have utility for both public health and clinical practice; retail sales data can identify emerging products, which can help clinicians to screen for use of these products among their patients. Retail sales data can also be used to assess

Figure 1. National E-cigarette unit sales by flavor and 4-week estimates, January 2017–January 2022.

Sales data do not reflect sales from vape shops or online retailers; dates represent the end of 4-week periods; All Other Flavors category includes fruit, clove/spice, chocolate, alcoholic drink (such as wine, cognac, or other cocktails), candy/desserts/other sweets, and some other flavor; E-cigarette accessories and devices sold without electronic liquids were excluded (4.0% of total sales). Unknown flavors were excluded from this figure (<0.1%).
the trends in purchasing of products across a variety of health behaviors and risk factors (e.g., sugar-sweetened beverages, alcohol) in a similar way to how they are used to assess the tobacco product landscape. The benefits of retail sales data are further reinforced by its broad domestic availability, the diversity of scientific opportunities to which it can be applied (e.g., surveillance, evaluation, and research), and its utility for quickly informing public health policy, planning, and practice.

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CREDIT AUTHOR STATEMENT

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REFERENCES