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Flavored Tobacco Products Fact Sheet

Introduction

This resource introduces the federal and Maryland legal landscape surrounding flavored tobacco products, including menthol. It is intended to serve the Maryland local health department staff engaged in tobacco enforcement by providing background information on flavored tobacco products, an explanation of the tobacco industry's malicious history of targeting youth and minority populations, and an in-depth explanation of the Maryland and federal legal landscape.

I. Flavored Tobacco Products: A Background

The Food and Drug Administration (FDA) has authority to regulate tobacco product standards, including flavored tobacco products, also known as "characterizing flavors." The FDA defines "tobacco product" as any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product.[1] Tobacco products and Maryland law will be described in greater detail in section IV below. Although the FDA does not provide a specific definition for "characterizing flavor" it does use factors to determine when a tobacco product has a characterizing flavor:

- The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts;
- The multisensory experience (*i.e.,* taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts;
- Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packaging) or advertising of a tobacco product; and
- Any other means that impart flavor or represent that a tobacco product has a characterizing flavor.[2]

Flavored tobacco products, including menthol, entice youth use and increase the risk of nicotine addiction.[3] Although the FDA banned flavored cigarettes, excluding menthol, when Congress passed the Family Smoking Prevention and Tobacco Control Act (TCA)[4] in 2009, all other flavored tobacco products, including menthol cigarettes, are still permitted under federal law.

Flavored tobacco products mask the harshness of tobacco and drastically improve the flavor, making it more tolerable for consumers, namely youth, to consume.[5] Additionally, these products are often packaged in colorful wrappers and boxes and come in a variety of flavors with names that are likely to appeal to youth. For example, flavored products are described as cotton candy, gummy-bear, strawberry, bubble gum, and chocolate.[6]

Menthol-flavored tobacco products, though still permitted under federal law, also appeal to youth and young adults. Studies indicate that menthol use leads to a progression in regular use. Like other flavored tobacco products, menthol masks the tobacco flavor and makes it easier to consume.[7] These products are more addictive, making it even more difficult to quit.[8] The evidence base suggests that when other flavored tobacco products become unavailable, people are likely to transition to menthol-flavored products.[9]

II. The Tobacco Industry Targets Youth and Minority Populations with Flavored Tobacco Products

A. Youth Population

Big Tobacco has indisputably used flavored tobacco products to target, entice, and addict youth. In the 1950s and 1960s, big tobacco often used celebrity endorsements to promote cigarette use and in the 1990s and 2000s they used cartoon characters, sporting events, other event marketing, and other marketing at the point of sale.[10] In 1998, the state attorneys general of: 46 states, including Maryland; five U.S. territories; and the District of Columbia reached a settlement agreement with the four largest cigarette manufacturers in the U.S. This is known as the 1998 Master Settlement Agreement (MSA).[11] The MSA imposes restrictions on tobacco product advertising and marketing but does not include electronic smoking devices (ESDs) as these products were not yet commercially sold in the U.S.[12]

While these restrictions were a step in the right direction, flavored cigarettes were still permitted on the market. Prior to the 2009 flavored cigarette ban, cigarettes came in youth-appealing flavors such as Twista Lime, Kauai Kolada, Warm Winter Toffee, and Winter Mocha Mint. A 2017 study analyzed the impact of the 2009 flavored cigarette ban by using data from the 1999-2013 Youth Tobacco Surveys and found that overall cigarette use declined significantly after the ban, but that menthol cigarette use, cigar use, and pipe tobacco use significantly increased.[13] To date, menthol cigarettes are still permitted and comprise 36% of the U.S. market.[14]

Once the 2009 ban became effective, cigarette manufacturers altered their products to qualify as “little” or “filtered” cigars.[15] While cigarettes are wrapped in paper or another substance not containing tobacco, cigars, cigarillos, and little cigars are all wrapped in leaf tobacco or another substance containing tobacco.[16] The 2012 Surgeon General’s report, “Preventing Tobacco Use Among Youth and Young Adults” highlighted some of the specific product shifts made by cigarette manufacturers as an attempt to work around the FDA’s new product restriction.[17]

Some manufacturers began mislabeling their products as little cigars and others simply changed the product wrapper to meet the definition of little cigar, rather than cigarette.[18]

The 2016 Surgeon General Report on e-cigarettes concluded that, "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."[19] The 2021 National Youth Tobacco Survey found that 70.3% of middle and high school students had been exposed to ESD advertisements.[20] ESD manufacturers employ many of the same marketing strategies used by cigarette manufacturers. These include celebrity endorsements, social media influencers, TV and magazine advertisements, and sports and music sponsorships.[21] They also develop flavored products reminiscent of candy, fruit, and other similar flavors.[22]

B. Minority Populations

The tobacco industry has targeted Black Americans with shameless marketing and advertising campaigns. Beginning in the 1950s and 1960s, tobacco companies have targeted Black Americans with menthol cigarette advertisements.[23] The industry continues to target the community through advertising and price promotion.[24] Some tactics include placing advertisements in magazines and other print resources geared toward Black Americans.[25] The tobacco industry also markets their products with lower pricing in neighborhoods with higher proportions of Black Americans.[26] They have also been known to make contributions to Historically Black Colleges and Universities, along with sponsoring cultural events like festivals and concerts.[27] As a result, almost 9 in 10 Black youth ages 12 and older who smoke, use menthol cigarettes and 85% of all black smokers who smoke use menthol cigarettes, compared to 30% of white smokers.[28] The LGBTQ+ community is also facing the disproportionate burden of tobacco use, in large part due to menthol cigarette smoking.[29] Big tobacco has targeted the LGBTQ+ population with menthol tobacco products by advertising at community events, contributing financially toward HIV/AIDS organizations, and maintaining a presence at gay pride festivals.[30]

III. Federal Legal Landscape and Enforcement: A Substantive Timeline

A. 2009-2011: Family Smoking Prevention and Tobacco Control Act (TCA) and the Tobacco Product Scientific Advisory Committee (TPSAC)

In 2009, Congress passed the TCA which gave the FDA authority to regulate the manufacture, distribution, and marketing of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.[31] Among other things, the law banned cigarettes with characterizing flavors. The ban did not extend to menthol cigarettes, nor did it apply to other tobacco products.[32]

The TCA also mandated the establishment of the Tobacco Product Scientific Advisory Committee (TPSAC).[33] The TSPAC was charged with providing advice, information, and

recommendations to the Secretary of Health for Health and Human Services on the effects of altering nicotine yields and nicotine thresholds related to dependence and other safety, dependence, or health issues related to tobacco. Specifically, the TSPAC was asked to evaluate the impact of the use of menthol cigarettes on public health, including use among children, African Americans, and other racial minorities.

In 2011, the TSPAC finalized its report entitled, "Menthol Cigarettes and the Public Health: Review of the Scientific Evidence and Recommendations." The report concluded that "removal of menthol cigarettes from the marketplace would benefit public health in the United States."[34] Specifically, the report concluded that menthol is not merely a flavor additive but that its pharmacological actions reduce the harshness of smoke and irritation, increasing the likelihood of addiction.[35] Additionally, the availability of menthol cigarettes has had an adverse impact on public health by increasing premature death and avoidable morbidity.[36]

B. 2013: Public Health Groups File Citizen Petition with the FDA

By 2013, the FDA had taken no action on the TSPAC's menthol report. As a result, the Tobacco Control Legal Consortium (TCLC), now the Public Health Law Center (PHLC) led the charge and joined other leading organizations[37] in filing a citizen petition[38] with the FDA. A citizen petition is a process by which individuals and organizations may make formal requests to the FDA to change its policies. In its citizen petition, these organizations urged the FDA to remove menthol cigarettes from the market.

C. 2016-2020: FDA Publishes the Deeming Rule; FDA Modifies Enforcement Operations

In 2016, the FDA published the "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," also known as the "Deeming Rule."[39] The FDA asserted authority to begin regulating ENDS[40], cigars, pipe tobacco, and hookah, however the rule did not restrict the sale or manufacture of any flavored tobacco product. It did, however, require premarket tobacco product applications (PMTA).

Under the Deeming Rule, all manufacturers were required to submit PMTAs for existing tobacco products which were commercially marketed in the U.S. as of February 15, 2007. Without an FDA marketing order, manufacturers would not be permitted to continue selling these products commercially. Because no ENDS product was marketed commercially in the U.S. as of this date, every ENDS manufacturer would be required to submit a PMTA to the FDA, in addition to the other newly covered products that were not sold in the U.S. as of February 15th, 2007. This was and remains quite an undertaking for the FDA because it is required to review and grant or deny an order for each product. Rather than requiring all manufacturers to remove the products from the market immediately, the FDA opted to exercise enforcement discretion.

This means they have permitted these products to remain on the market while applications were pending with the FDA, so long as an application was submitted by the required due date. This is the reason we continue to see products on the market that have not yet been granted an FDA marketing order.

Finally, after seeing an uptick in youth use and addiction to ENDS products, the FDA announced a change in its enforcement priorities. On January 2, 2020, the FDA released new guidance, noting that even though PMTA applications were not yet due, it would prioritize enforcement against the following groups of unauthorized Electronic Nicotine Delivery Systems (ENDS)products:

1. Any flavored, cartridge-based ENDS[41] (other than tobacco or menthol flavored);
2. All other ENDS products for which the manufacturer has failed to take adequate measures to prevent underage access; and
3. Any ENDS product that is targeted to youth or likely to promote use by youth.[42]

This announcement came as the 2019 National Youth Tobacco Survey on ESD use showed that more than 5 million U.S. middle and high school students were current ESD users, and a majority reported using cartridge-based products.[43] In the FDA's press release, then Health and Human Services (HHS) Secretary Alex Azar noted, "The United States has never seen an epidemic of substance use arise as quickly as our current epidemic of youth use of e-cigarettes. HHS is taking a comprehensive, aggressive approach to enforcing the law passed by Congress, under which no e-cigarettes are currently on the market legally…"[44] Under the policy, companies that did not cease the manufacture, distribution, and sale of unauthorized flavored cartridge-based e-cigarettes (other than tobacco or menthol) risked FDA enforcement action. All suspected violations may be reported to the FDA.

D. 2022: The FDA's Proposed Rules

By June of 2020, the FDA had still failed to respond to the 2013 Citizen Petition. The African American Tobacco Control Leadership Council (AATCLC) along with other public health organizations sued the FDA asking that the agency prohibit menthol in cigarettes.[45] As a direct result of the lawsuit, the FDA announced on April 29, 2021, that it would issue a notice of proposed rulemaking banning menthol cigarettes within one year.

The FDA proposed two rules which were published in the Federal Register on May 4, 2022. The first rule proposed banning menthol as a characterizing flavor in cigarettes.[46] The second rule proposed banning characterizing flavors, including menthol, in cigars.[47] Neither proposed rule includes a ban on ENDS or any other specific tobacco product.[48] The public was invited to provide notice and comment on the proposed rules which were due August 2, 2022. In October 2023, the FDA's final rule was sent to the White House Office of Management and Budget for the Biden Administration's approval. This was the last step in finalizing the regulation. In

December 2023, the Office of Information and Regulatory Affairs Website was updated to reflect that any final ban on menthol would not take place until at least March 2024. In March 2024, no final rule was issued and its publication has been postponed indefinitely. On April 2, 2024, the AATCLC, the Action on Smoking and Health (ASH), and the National Medical Association (NMA) filed a second lawsuit against the FDA for its delay in issuing a rule to ban menthol cigarettes.[49] On January 16, 2025, the plaintiffs argued against the government's motion to dismiss in this matter. Then, on January 21, 2025 the Trump Administration withdrew the proposed rules banning menthol in cigarettes and flavored cigars. On February 4, 2025, the Court held a conference with the attorneys and all parties agreed that the withdrawal of the rules does not terminate or publish the regulation. This means that a future administration may decide to revive the proposed rule. Because the rule was withdrawn, this underscores the FDA's failure to take action on the 2013 Citizen's Petition.

E. 2024 PMTA Updates

Almost 7 million ENDS products were submitted for premarket review.[50] The FDA will take enforcement action against any products with marketing denial orders. Marketing orders and denial orders may be viewed here. The FDA has not yet completed its review of applications. allowing users to search and determine whether a tobacco product may be legally marketed. However, in March of 2024 the FDA launched a searchable database.

IV. Maryland Legal Landscape and Enforcement

In Maryland, a tobacco product is defined as a product "intended for human inhalation, absorption, ingestion, smoking, heating, chewing, dissolving, or any other manner of consumption that is made of, derived from, or contains tobacco or nicotine OR an accessory or a component used in any manner of consumption of a product."[51] Tobacco products include cigarettes, cigars, pipe tobacco, chewing tobacco, snuff, snus, electronic smoking devices, filters, rolling papers, pipes, and liquids used in ESDs regardless of nicotine content.[52] ESD is defined as a device used to deliver aerosolized or vaporized nicotine to an individual inhaling from the device. These include components, parts, and accessories, including any substance intended to be vaporized or aerosolized from the device.[53]

Maryland has no codified law limiting or banning the sale of flavored tobacco products. However, pursuant to Business Regulation, §16.7-207(a)(5), a license to sell tobacco and ESD products in Maryland is subject to disciplinary action if products are sold and marketed in violation of federal law.[54] These actions include denying a license to an applicant, reprimanding a license, or suspending or revoking a license. On February 10, 2020, the Comptroller of Maryland[55] announced that it would prioritize enforcement against unauthorized ESD products most widely used by children in violation of federal law. These include cartridge based and

disposable products with flavors other than tobacco or menthol.[56] Specifically, the Comptroller noted the FDA's newest enforcement priorities, announced on January 2, 2020:

1. Any flavored, cartridge-based ENDS[57] (other than tobacco or menthol flavored);
2. All other ENDS products for which the manufacturer has failed to take adequate measures to prevent underage access; and
3. Any ENDS product that is targeted to youth or likely to promote use by youth.[58]

The Comptroller's announcement highlights its authority to take action against licensees if in violation of federal law. Since the FDA had not yet granted any marketing order for any flavored ESD product, all of these products on the market are not technically legal under federal law.

Notably, beginning January 1, 2021, the Alcohol and Tobacco Commission, now the Alcohol, Tobacco, and Cannabis Commission (ATCC), has regulatory and enforcement authority over tobacco products instead of the Comptroller. It has opted to continue enforcing this bulletin. To date, the FDA has not issued marketing orders for any flavored ESD products. Thus, the ATCC may take disciplinary action over the licensees who sell these products, in violation of federal law. Notably, beginning January 1, 2021, the Alcohol and Tobacco Commission, now the Alcohol, Tobacco, and Cannabis Commission (ATCC), has regulatory and enforcement authority over tobacco products instead of the Comptroller. It has opted to continue enforcing this bulletin. To date, the FDA has not issued marketing orders for any flavored ESD products. Thus, the ATCC may take disciplinary action over the licensees who sell these products, in violation of federal law.

V. Flavored Electronic Smoking Devices: Federal and Maryland Product Restrictions

This chart provides a visual explanation of the current Federal and Maryland legal landscape governing the sale of flavored tobacco products. Note: Although there are slight differences in the language used to define ESDs (used when discussing Maryland law) and ENDS (used when discussing federal law), as used within this reference these terms refer to the same products.

	State Authority	**Federal Authority**
Legal Entity	Alcohol, Tobacco, and Cannabis Commission (ATC)	Food & Drug Administration (FDA)
Legal Authority	Office of the Comptroller, Field Enforcement Division Bulletin, TT-77 Business Regulation, §16.7-207(a)(5)[59]	Guidance for Industry 81 FR 28973-01
Are flavored ESDs ***prohibited?***	Yes, unless the FDA has authorized the sale of the product. Currently, no flavored ESD products (excluding tobacco flavor)	Yes, unless the FDA has authorized the sale of the product. Currently, no flavored ESD products (excluding tobacco flavor) have been authorized for sale.

	have been authorized for sale. Please see the box below re enforcement priorities.	Please see the box below defining enforcement priorities.
How is the agency ***prioritizing*** enforcement efforts?	• Flavored, disposable ESDs; • Flavored, cartridge-based ESDs; and • Products most widely used by children;	• Flavored, cartridge-based ENDS; • ENDS product for which youth access has not been adequately prevented; • ENDS product targeting youth/ marketing likely encourages youth use; • ENDS product offered for sale after 9/9/20, and for which the manufacturer has not submitted a premarket application; and • Products with marketing denial orders
Can products be confiscated?	No	Yes
Who can enforce?	ATCC Report a violation or file a complaint here.	FDA Report violation here.
Penalties	Disciplinary action on the **wholesaler** or **retailer** license	**Manufacturers** and/or **retailers** face warning letters, civil money penalties,[60] no-tobacco-sale orders
Products Defined	**"Electronic smoking device"** or **"ESD"** refers to a device that can be used to deliver aerosolized or vaporized nicotine to an individual inhaling from the device. This includes any component (such as e-liquid), parts, and accessories.	**Cartridge-based ENDS** are a type of ESD that includes a cartridge or pod that holds liquid to be aerosolized through product use. **Electronic nicotine delivery systems (or ENDS)** include devices, components, and/or parts that deliver aerosolized e-liquid when inhaled. **Accessory** means any product that is used with or for the human consumption of a tobacco product.

		Component or part means any materials which alter the tobacco product's performance ***or*** are used with consumption of a tobacco product.

VI. U.S. Flavored Tobacco Product Bans

Preemption occurs when a higher-level government passes a law that prevents a lower-level government from enacting laws that are stricter than or conflict with the higher-level authority. For example, federal law can preempt state and county laws. Similarly, state law can preempt county laws. The TCA preempts state and local governments from regulating tobacco product standards, premarket review, manufacturing practices, labeling, and product registration. However, it also expressly states that the Act does NOT preempt state and local governments from enacting more stringent tobacco sales and distribution restrictions. This includes prohibitions on the sale of flavored tobacco products.

Some bans in other states only include non-premium cigars and/or cigarettes, while others include ESDs only. In some instances, there are exemptions for menthol-flavored tobacco products while other jurisdictions have banned all flavors. Some jurisdictions permit only specialty retailers to sell flavored tobacco products.

A. *State and Local Flavored Tobacco Product Bans*

Maine, Rhode Island, New Jersey, New York, Massachusetts, Utah, and California all have statewide laws/policies banning flavored tobacco products.[61] In Maine, the law only covers flavored premium cigars and excludes menthol. Rhode Island, New Jersey, and New York only cover flavored ESDs, including menthol. Utah's ban covers all flavored tobacco products including menthol but does include an exemption for specialty tobacco stores. The ban in Massachusetts includes all tobacco products and all flavors but does permit an exemption for licensed smoking bars. Similarly, the ban in California covers flavored tobacco products including menthol, but exempts licensed smoking bars as well as hookah, premium cigars, and pipe tobacco.

More than 360 localities nationwide in California, Colorado, Illinois, Massachusetts, Minnesota, Montana, New Jersey, New York, Ohio, Pennsylvania, and Rhode Island[62] have also banned flavored tobacco products. The substance of these laws varies significantly from one jurisdiction to the next. Although many of these bans were challenged by the tobacco industry, the courts have consistently found that these bans are permissible sales restrictions.

1. Maryland and Local Flavored Tobacco Product Bans

a. Maryland

Flavored tobacco product ban bills were introduced during the 2020 (SB233/HB3), 2021 (SB177/HB134), and 2023 (SB259) Maryland legislative sessions; however, these have been unsuccessful.

b. Local Jurisdictions and Preemption in Maryland

Although the federal government leaves broad authority to state and local governments, the Maryland Court of Appeals has significantly limited this power in its decision on *Altadis U.S.A., Inc. v. Prince George's County*, *Maryland.*[63] In that case, the Prince George's County Council passed a law regulating the number of cigars required per package and the tobacco industry sued. The *Altadis* court determined that because the Maryland legislature has passed extensive laws regulating the sale and distribution of tobacco products, the legislature did not intend to leave any authority to local governments to regulate this subject matter. Thus, local legislative authorities are preempted from regulating the sale and distribution of tobacco products.[64]

The Court's decision can be read either narrowly or broadly. A narrow reading would mean that locals are only preempted from enacting laws relating to cigar packaging. A broad reading is that the Court preempts locals from enacting laws relating to the sale and distribution of non-vape products. Although neither reading has applicability to ESDs, there is concern that if the Court was faced with a similar question about these products, they would apply the precedent set in *Altadis* and if read broadly, could find that the state has also preempted locals from enacting laws relating to the sale and distribution of ESDs.

Montgomery County, Maryland passed a local law banning flavored ESDs, including menthol, within .5 miles of any elementary, middle, high school, library or recreational facility in the county.[65] No other jurisdiction in Maryland has passed any flavor restriction relating to traditional tobacco products or ESDs. The Montgomery County law has not been challenged in Court.

Conclusion

We hope you have found this resource helpful in understanding the history and impact of flavored tobacco products on youth use. Although both the state and federal legal landscape are currently in flux when it comes to flavored tobacco products, we do hope the chart and narrative provided assists in navigating the steps one may take if a potential violation is noted. As always, please do not hesitate to contact the Legal Resource Center for Public Health Policy with any questions or concerns.

Updated April 2025

[1] 21 CFR 1100.3.
[2] Tobacco Product Standard for Menthol in Cigarettes"; Docket No. FDA-2021-N-1349);
Tobacco Product Standard for Characterizing Flavors in Cigars; Docket No. FDA-2021-N-1309).
[3] Laura Bach, *Flavored Tobacco Products Attract Kids*, Campaign for Tobacco Free Kids (Dec. 5, 2024), https://assets.tobaccofreekids.org/factsheets/0383.pdf.
[4] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009), https://www.govinfo.gov/content/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf.
[5] Ganna Kostygina et al., *Tobacco Industry Use of Flavours to Recruit New Users of Little Cigars and Cigarillos*, 25 Tob. Control 1, 66-74 (Jan. 2016), https://pmc.ncbi.nlm.nih.gov/articles/PMC4414663/pdf/nihms-639512.pdf.
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[7] Press release, FDA, *FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers* (Apr. 29, 2021), https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers.
[8] *Id*.
[9] Louisa M. Holmes et al., *Flavored Tobacco Sales Restrictions Reduce Tobacco Product Availability and Retailer Advertising*, 19 Int'l J. Env't Res. & Pub. Health 6, 3455 (March 15, 2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC8953832/.
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[15] Christine D. Delnevo et al., *Close, but no cigar: certain cigars are pseudo-cigarettes designed to evade regulation*, 26 Tob. Control 3, 349-54 (May, 2017), https://pmc.ncbi.nlm.nih.gov/articles/PMC5482568/pdf/nihms865171.pdf.
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[36] *Id*.

[37] These organizations included: The African American Tobacco Control Leadership Council, ■ The American Academy of Pediatrics, ■ The American Association for Cancer Research, ■ The American Cancer Society — Cancer Action Network, ■ The American Heart Association, ■ The American Legacy Foundation, ■ The American Lung Association, ■ The American Public Health Association, ■ Americans for Nonsmokers' Rights, ■ Asian Pacific Partners for Empowerment, Advocacy and Leadership (APPEAL), ■ The Association for the Treatment of Tobacco Use and Dependence, ■ The Campaign for Tobacco-Free Kids, ■ Corporate Accountability International, ■ NAATPN, Inc. (parent organization of the National African American Tobacco Prevention Network), ■ The National Association of County and City Health Officials, ■ The National Latino Alliance for Health Equity, ■ The Society for Research on Nicotine and Tobacco, ■ Summit Health Institute for Research and Education, Inc., and ■ Valerie B. Yerger, N.D.

[38] Tobacco Control Legal Consortium et al., Citizen Petition to Food & Drug Admin., Prohibiting Menthol as a Characterizing Flavor in Cigarettes (Apr. 12, 2013), https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fdacitizenpetition-menthol-2013.pdf.

[39] FDA, 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, 81 Fed. Reg. 28974 (May 10, 2016), 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.

[40] The FDA uses the term Electronic Nicotine Delivery Systems (ENDS) to describe ESD products

[41] Cartridge-based ENDS products are a type of ENDS product that consists of, includes, or involves a cartridge or pod that holds liquid that is to be aerosolized through product use. For purposes of this definition, a cartridge or

pod is any small, enclosed unit (sealed or unsealed) designed to fit within or operate as part of an electronic nicotine delivery system. https://www.fda.gov/media/133880/download

[42] Press release, FDA, *FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint* (Jan. 2, 2020), https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children.

[43] Karen A. Cullen et al., *e-Cigarette Use Among Youth in the United States, 2019*, 322 JAMA 21, 2095-2103 (Nov. 2019), https://jamanetwork.com/journals/jama/fullarticle/2755265?guestAccessKey=54b2dc7d-3855-4728-a522-573083a5d2cd&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfl&utm_term=110519.

[44] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market without Premarket Authorization (Revised): Guidance for Industry* (Apr. 2020), https://www.fda.gov/media/133880/download.

[45] *African American Tobacco Control Leadership Council (AATCLC) et al. v. FDA*, Case No. 20-cv-04012-KAW, (N.D. Cal., 2021), https://caselaw.findlaw.com/court/us-dis-crt-n-d-cal/2153256.html.

[46] FDA, Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26454 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1162), https://www.govinfo.gov/content/pkg/FR-2022-05-04/pdf/2022-08994.pdf.

[47] FDA, Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26396 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1166), https://www.govinfo.gov/content/pkg/FR-2022-05-04/pdf/2022-08993.pdf.

[48] Note: The terms ”electronic smoking device” and ”electronic nicotine delivery system” or ”ESD” and ”ENDS” refer to the same products. However, we use ENDS when discussing federal law and ESD when describing Maryland law.

[49] *AATCLC et al. v. FDA*, Case No. 4:24-cv-01992 (N.D. Cal. Filed Apr. 2, 2024), https://ash.org/wp-content/uploads/2024/04/2024.04.02-1-Complaint.pdf.

[50] FDA, *Tobacco Product Applications: Metrics & Reporting*, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting.

[51] Md. Code, Bus. Reg. § 16-3A-01 (2019).

[52] *Id*.

[53] Md. Code, Bus. Reg. § 16.7-101.

[54]Md. Code, Bus. Reg. § 16.7-207.

[55] The Comptroller of Maryland was the agency with regulatory and enforcement authority over tobacco products in Maryland. Beginning January 1, 2021, the Comptroller was no longer authorized to enforce or regulate the state’s tobacco laws. The authority now rests with the Alcohol and Tobacco Commission (ATC).

[56]Md. Comptroller, Field Enf’t. Div., *Tobacco Bulletin No. 77* (Feb. 10, 2020), https://content.govdelivery.com/attachments/MDCOMP/2020/02/10/file_attachments/1376534/Tobacco%20Bulletin%2077%20-%2002.10.2020%20-%20Flavored%20ESDs%20Unlawful.pdf.

[57] Cartridge-based ENDS products are a type of ENDS product that consists of, includes, or involves a cartridge or pod that holds liquid that is to be aerosolized through product use. For purposes of this definition, a cartridge or pod is any small, enclosed unit (sealed or unsealed) designed to fit within or operate as part of an electronic nicotine delivery system. https://www.fda.gov/media/133880/download.

[58] *Supra* note 42.

[59] The Executive Director of the Alcohol, Tobacco, and Cannabis Commission may deny a license to an applicant, reprimand a licensee, or suspend or revoke a license if the applicant or licensee violates federal, State, or local law regarding the sale of electronic smoking devices.

[60] 1st violation: warning letter; 2nd violation within 12-month period: $320; 3rd violation within 24-month period: $638; 4th violation within 24-month period: $2,559; 5th violation within a 36-month period: $6,397; 6th violation within 48-month period: $12,794; FDA may pursue a no-tobacco-sale order if 5 or more violations occur within a 36-month period.

[61] Public Health Law Center, *U.S. Sales Restrictions on Flavored Tobacco Products* (July 2024), https://www.publichealthlawcenter.org/sites/default/files/resources/US-sales-restrictions-flavored-tobacco-products.pdf.

[62] *Id*.

[63] *Altadis U.S.A., Inc. v. Prince George's County, Maryland*, 41 Md. 307 (Ct. App. 2013).
[64] *Id*.
[65] *Supra* note 61.