UNIVERSITY of MARYLAND
FRANCIS KING CAREY
SCHOOL OF LAW
LEGAL RESOURCE CENTER
FOR PUBLIC HEALTH POLICY

I. NEW AND EMERGING TOBACCO PRODUCTS

The landscape of tobacco products, including those that contain nicotine, is rapidly evolving with the introduction of new and emerging alternatives to traditional cigarettes. A tobacco product is defined as any product made or derived from tobacco, intended for human consumption, including components, parts, or accessories of a tobacco product.[1] Further, both the state and federal definitions note that a tobacco product includes nicotine from any source.[2] These products, including electronic smoking devices (ESDs),[3] nicotine pouches, and heat-not-burn tobacco products have gained significant popularity in part due to perceived reduced harm compared to smoking.[4] However, popularity, particularly among younger populations,[5] has prompted regulatory bodies to develop new frameworks and clarify the application of existing ones in order to protect public health and safety.

As these products continue to innovate, regulations are being adapted to address potential risks. This issue brief explores the latest trends in tobacco product development and the regulatory efforts in place to manage these products effectively. This section includes an introduction to these new and emerging tobacco products, with Part Two addressing federal regulatory schemes and Part Three focusing on state-level regulations that play a crucial role in shaping the landscape of tobacco product regulation. Part Four highlights gaps in these regulatory structures, while Part Five offers a detailed guide illustrating how these products are categorized under both federal and state regulations.

A. Identifying New and Emerging Tobacco Products

a. Electronic Smoking Devices

While electronic smoking devices (ESDs), referred to as Electronic Nicotine Delivery Systems (ENDS) by the FDA, are no longer "new" tobacco products, they are in many ways the products that began to transform the tobacco product market. ESDs, commonly known as e-cigarettes, are battery-operated devices that heat and aerosolize a liquid, typically containing nicotine, flavorings, and other chemicals. Examples of e-cigarettes include the brands JUUL, Vuse, Blu. Examples of ESDs include Puff Bar, SMOK Nord Series, and Vaporesso XROS.

Further, ESDs have evolved with products known as "smart" vapes. "Smart" vapes are a new generation of ESDs that incorporate advanced technology, displaying puff counts, battery levels, and even built-in games or animations. These technological enhancements enable users to track nicotine consumption and adjust temperature settings, increasing their appeal, especially to younger audiences.[6] Notable brands offering "smart" vape products include Geek Bar, RAZ, Spaceman, Lost Vape, and iJoy.

b. Synthetic Nicotine Products

Synthetic nicotine products, sometimes referred to as "non-tobacco" nicotine, are products that contain nicotine created in a lab, not derived from tobacco leaves. They are marketed as "tobacco-free" nicotine, also referred to as "non-tobacco" products. Both nicotine pouches and ESDs can contain synthetic nicotine rather than tobacco-derived nicotine. One example of a nicotine pouch made with synthetic nicotine is NIIN, while Puffbar is an example of an ESD that uses synthetic nicotine in its e-liquid.

c. Heat-not-Burn Products

"Heat-not-burn" or "heated tobacco products" are electronic devices that heat tobacco, rather than burn it, to produce an inhalable aerosol potentially containing nicotine and other chemicals. This technology differs from ESDs, which use a battery-powered coil to heat a liquid (e-liquid or vape juice), turning the liquid into vapor that is inhaled by the user. Product examples of heat-not-burn devices include IQOS, glo, Ploom, and PAX.

d. Nicotine Pouches

Nicotine pouches are small, smokeless products that contain nicotine and are designed to be placed between the gum and lip, similar to traditional chewing tobacco or snus. However, unlike those products, nicotine pouches don't contain tobacco. Rather, they can be made of synthetic nicotine or nicotine derived from tobacco. Brand names that produce nicotine pouches with tobacco-derived nicotine include ZYN, On!, and VELO, whereas brands that offer pouches with synthetic nicotine include NIIN and Rogue.

II. How New and Emerging Tobacco Products Fit into the Federal Regulatory Scheme

A. Family Smoking Prevention and Tobacco Control Act

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).[7] The law gave the U.S. Food and Drug Administration (FDA) comprehensive power to regulate the manufacturing, marketing, and sale of tobacco products, defined as any product made or derived from tobacco that was intended for human consumption, and to deem future products as subject to their authority. The Tobacco Control Act initially only applied to cigarettes, roll your own tobacco, cigarette tobacco, and smokeless tobacco. However, with continued innovation in the industry, the FDA issued the "Deeming Rule" on May 10, 2016, expanding its oversight to include all current and future tobacco-derived products. In response, some manufacturers began using synthetic nicotine, which is nicotine created in a lab, not derived from tobacco leaves, to sidestep regulation under the Deeming Rule. This led Congress to revise the definition of "tobacco product" in the Consolidated Appropriations Act of 2022 (the Appropriations Act), which was enacted on March 15, 2022. The Appropriations Act was amended so the definition of the term "tobacco product" now includes products containing nicotine from any source—including synthetic nicotine.[8]

a. What the Tobacco Control Act Does

The Act prohibits "characterizing flavors" in cigarettes—flavorings like candy, fruits, and desserts, but not menthol. Further, the Act mandates that the FDA develop specific graphic warning labels to replace the current text-only warnings. It also prohibits the sale of "modified risk" tobacco products—those claiming to be less harmful—without prior authorization from the FDA. Finally, the Act restricts tobacco product marketing at the point of sale and prohibits sale to underage individuals, which was raised from 18 to 21 in late 2019.

i. Premarket Review

The FDA is required to review new tobacco products before they can be sold. Manufacturers must submit evidence demonstrating that these products are appropriate for the protection of public health if they were introduced to the market after February 15, 2007.[9]

ii. Ingredient Disclosure

Tobacco manufacturers are required to disclose detailed information about the ingredients used in their products.[10] The FDA has the authority to collect data about the chemicals in tobacco products and monitor changes to ingredients. Manufacturers must submit reports to the FDA regarding the composition, additives, and tobacco-specific chemicals present in their products. This transparency helps the FDA assess the potential risks and effects on public health.

iii. Tobacco Product Standard Regulation

The FDA has the power to set standards for the manufacturing of tobacco products to protect public health.[11] This includes regulating the levels of harmful substances and nicotine. One notable measure under this provision is the ban on flavored cigarettes. The law specifically prohibits the sale of flavored cigarettes—such as those with candy or fruit flavors—to reduce their appeal to minors and young adults.

It is important to distinguish between a flavor ban as a sales restriction versus a marketing or manufacturing restriction. While states can regulate the sale and marketing of flavored tobacco products, they do not have the authority to impose manufacturing restrictions—that power lies exclusively with the federal government. Therefore, state and local governments are limited to restricting the sale and promotion of flavored products, not their production.

iv. Preserves State, Local, and Tribal Authority

While only the FDA may set standards for tobacco products, regulate and impose premarket review, establish manufacturing practices, or require product registration, the Act does include language allowing state and local governments to pass laws related to tobacco sales and distribution, youth access restrictions, smoke-

free laws, fire safety standards for tobacco products, and state and local taxation. In doing so, the Act maintains flexibility for jurisdictions to tailor tobacco control policies to local public health needs, without being preempted by federal regulations.

v. Restricts Tobacco Product Marketing and Sales to Youth

The Act restricts tobacco product marketing and sales to youths through several measures, including age restrictions, ID check, sample size restrictions, cigarette pack size, vending machine restrictions, and a prohibition on tobacco brand sponsorships of sports and entertainment events.[12] The sale of tobacco products to anyone under the age of 21 is prohibited, and retailers are required to check ID of those under age 30 to verify that customers purchasing tobacco products are of legal age.

The Act prohibits the distribution of free samples to the public, but for in adult-only facilities. It also bans the sale of single cigarettes—only full packs can be sold—in an effort to curb impulse purchases by minors. To further limit access, the Act prevents the sale of cigarettes and smokeless tobacco products through vending machines, except in adult-only facilities. Additionally, tobacco companies are prohibited from sponsoring sports or entertainment events, reducing the exposure of tobacco brands to young audiences and limiting their promotion in youth-oriented media.

vi. Requires FDA to Issue Regulations

The FDA is tasked with issuing detailed regulations on various aspects of the tobacco industry, including advertising, labeling, and the use of tobacco-related health claims.[13] These regulations must be aligned with the goal of protecting public health and reducing tobacco use. For example, the FDA must implement rules regarding health warnings on tobacco product packaging, how tobacco products can be marketed and advertised, the approval process for new or modified tobacco products, and the disclosure of ingredients and harmful chemicals in tobacco products. These regulations help ensure that the tobacco industry operates within established public health standards, while also allowing for flexibility to adapt to emerging trends—such as e-cigarettes and other new products.

b. What the Tobacco Control Act Does Not Do

The Act does not include menthol in the prohibition of flavored cigarettes, nor does it grant the FDA the authority to ban cigarettes, smokeless tobacco, and cigars entirely, or to reduce nicotine levels in tobacco products to zero. As previously mentioned, the Act does not preempt state and local governments from enacting their own sales restrictions, banning products entirely, or setting standards. Additionally, the Act does not prevent localities from imposing restrictions on the time, place, or manner of cigarette advertising or promotion.

B. The Deeming Rule: Tobacco Products Deemed to be Subject to the Federal Food, Drug, and Cosmetic Act

Prior to 2016, the FDA's pre-market review authority was limited to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. On May 10, 2016, the FDA issued its final "Deeming Rule," exercising their authority to regulate additional tobacco products. It brought e-cigarettes, hookah, cigars, pipe tobacco, and nicotine pouches, and any product containing tobacco or nicotine derived from tobacco under the Act's scope, effectively classifying all such products as tobacco products subject to FDA authority.

However, to avoid regulatory enforcement under the Deeming Rule, manufacturers began producing products containing synthetic nicotine because at that time the federal definition of a tobacco product was a product made or derived from tobacco that is intended for human consumption. Congress responded to this industry innovation with the Consolidated Appropriations Act of 2022 (the Appropriations Act), which was enacted on March 15, 2022, and amended the definition of the term "tobacco product" in Section 201(rr) of the Federal Food, Drug, and Cosmetic Act to include products containing nicotine from any source—including synthetic nicotine.[14] In short, any product containing tobacco—or now nicotine derived from any source—is subject to the FDA's regulatory authority. The Deeming Rule also applied many, but not all, of the Tobacco Control Act's provisions and accompanying regulations to these newly covered products.

Effectively, this means that all ESDs, including "smart" vape products, with tobacco-derived nicotine or synthetic nicotine, are now regulated by the FDA. Similarly, nicotine pouches, whether or not they contain synthetic nicotine or tobacco-derived nicotine, are covered under the Act. Heat-not-burn products are regulated

by the FDA as cigarettes and are not considered newly covered products under the Deeming Rule.

a. What the Deeming Rule Does

i. Age Restriction and Photo ID Check

No retailer may sell covered tobacco products to any person younger than 21 years of age.[15] Generally, each retailer must verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 21 years of age.[16] No such verification is required for any person over the age of 29.[17] The age restriction and photo ID check provisions in the Tobacco Control Act apply to all tobacco products, including ESDs, synthetic nicotine products, heat-not-burn products, "smart" vape products, and nicotine pouches.

ii. Advertising

Although the FDA has comprehensive authority over the advertising and marketing of all tobacco products, current regulations do not impose specific advertising restrictions on ESDs. The Deeming Rule primarily prohibits marketing that includes false, misleading, or unauthorized modified risk claims. Cigarette ads were banned from television and radio in 1971, and similar restrictions were placed on smokeless tobacco in 1986, but these provisions come from other sources of law and not the TCA. Since these rules were crafted specifically for those products, they do not automatically cover e-cigarettes. Nonetheless, the FDA retains the power to introduce additional advertising restrictions for ESDs and similar products in the future.

iii. Free Samples

The free sample ban makes it illegal for manufacturers, distributors, or retailers to give away free samples of cigarettes, smokeless tobacco, or other tobacco products, unless there is an exception in 21 CFR § 1140.16(d)(2). As prescribed in the Deeming Rule, "other tobacco products" encompasses all tobacco products, including ESDs, synthetic nicotine products, heat-not-burn products, "smart" vape products, and nicotine pouches.

C. FDA Premarket Review

A Premarket Tobacco Product Application (PMTA) is required for any new tobacco product seeking FDA marketing authorization under Section 910(b) of the Federal Food, Drug, and Cosmetic Act. This means that any product not commercially marketed in the United States as of February 15, 2007, must submit a PMTA and receive and FDA marketing order to sell the product. A tobacco product manufacturer gathers and submits scientific data to establish that the marketing of a new tobacco product meets the statutory standards of one of three marketing application pathways (PMTA, SE, or SE Exemption). If appropriate, the FDA issues a marketing order allowing the product to be introduced to the market and sold indefinitely. Alternatively, the FDA denies the marketing application and the product cannot be introduced to the market. If denied, manufacturers are free to resubmit the application with additional information.

The FDA has faced significant challenges in reviewing the PMTAs for newly covered products largely due to the overwhelming number of products subject to review. Because the Deeming Rule covers ESDs and no ESD was commercially marketed as of February 15, 2007, millions of products must be reviewed by the FDA via the PMTA process, contributing to a substantial backlog.

a. Enforcement Discretion

While tobacco products must receive FDA marketing authorization before they can be legally sold, many products remain on the market without a marketing order due to FDA's enforcement discretion. The FDA has allowed companies to continue selling products as long as they submitted applications on time if a decision is still pending. Unfortunately, the application due date has been delayed many times. However, for products with marketing denial orders, removal is required immediately. In January of 2020, as vaping became a youth epidemic, the FDA issued new enforcement discretion entitled the "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization" guidance for industry.[18] Under this guidance, the FDA established stricter enforcement priorities aimed at curbing youth access to tobacco products. These priorities specifically target flavored e-cigarettes—particularly those with youth appeal—marketing practices directed at minors, and failures to prevent youth access to tobacco products. In essence, the FDA conveyed a clear message to manufacturers and retailers: if you are selling flavored disposable e-cigarettes, failing to implement measures that restrict youth access, or

marketing products to minors, you will face regulatory action—even if a timely PMTA has been submitted and is pending with the FDA.

Any product the FDA classifies as "new" is required to go through the PMTA process. A tobacco product is considered "new" if it was not marketed in the United States before February 15, 2007, has been modified in any way since that date, or represents a new version of an existing product. Under this definition, products such as ESDs, synthetic nicotine products, heat-not-burn devices, "smart" vapes, and nicotine pouches are all considered "new" and must therefore undergo FDA review through the PMTA process.

III. How New and Emerging Tobacco Products Fit into Local and State Regulatory Schemes

As new and emerging tobacco products continue to gain market share, local and state governments are increasingly tasked with developing and adapting regulatory frameworks to address their unique characteristics and potential health risks. These products, such as e-cigarettes, heat-not-burn products, and nicotine pouches, often fall outside traditional tobacco regulation, requiring states to establish targeted policies that address both public health concerns and the enforcement of existing laws. However, preemption can play a significant role in shaping these regulatory efforts. Preemption occurs when a higher level of government (such as a state) limits the authority of a lower level of government (like a county or municipality) to act on a particular issue, such as tobacco control. This section explores how state and local regulatory schemes are evolving to integrate these new products, focusing on their role in controlling access, usage, advertising, and product safety at the regional level, and the impact of preemption on local regulatory authority.

A. Local Authority in Maryland

In 2013, the Maryland Court of Appeals found that state law comprehensively regulated the packaging, sale, and distribution of tobacco products.[19] As a result, the Maryland Court of Appeals ruled that state law preempts county ordinances regulating the packaging of cigars and effectively other tobacco-related sales and distribution controls. While this holding does not directly apply to ESDs, if there was a similar challenge to a local ordinance pertaining to ESDs, a local court would likely rely on this precedent. This has made it increasingly difficult for local governments to pass laws regulating these products and they have largely relied on the state to do so.

B. State Authority in Maryland

a. *Taxation and the Comptroller of Maryland*

The tobacco tax rate for cigarettes is $5.00 for each package of twenty cigarettes and $0.25 cents for each cigarette in a package of more than twenty cigarettes.[20] Generally, the tobacco tax rate for other tobacco products is 60% of the wholesale price of the tobacco products,[21] and the tobacco tax rate for cigars is 70% of the wholesale price of the cigars.[22] The tobacco tax rate for pipe tobacco is 30% of the wholesale price of the pipe tobacco or for pipe tobacco sold by an out-of-state seller.[23]

ESDs, including vapes and e-liquids, are subject to a tax rate of 20% based on the retail price for open-system devices (refillable),[24] and 60% of the wholesale price for closed-system devices (such as disposable vapes or prefilled cartridges).[25] "Smart" vape products, a type of ESD, should be taxed at a similar rate. Other Tobacco Products (OTPs), including some synthetic nicotine products and nicotine pouches, are taxed at 60% of the wholesale price.[26]

The tobacco sticks used in heat-not-burn products may fall under the definition of OTPs if it was determined that the stick is intended for human consumption, which would subject the stick, not the device, to the 60% wholesale price tax rate.[27] Alternatively, if the tobacco sticks used in heat-not-burn products are classified as "rolls for smoking"—defined as being made of tobacco or a tobacco mixture and wrapped in paper or any non-tobacco material[28] —then only the tobacco sticks, not the heating devices, may be taxed in the same manner as cigarettes: $5.00 per pack of twenty and $0.25 for each additional cigarette in packs exceeding twenty.[29]

b. *Licensure*

The Maryland Business Regulation Code includes three titles—§ 16, § 16.5, and § 16.7—that regulate tobacco products and state actors engaged in their commercial sale. If any provisions of the Maryland Business Regulation Code are violated, the Alcohol, Tobacco, and Cannabis Commission (ATCC) has the authority to suspend or revoke licenses.

i. Maryland Business Regulation Code § 16

Maryland Business Regulation Code § 16 applies to cigarette sales and distribution within the state. [30] It regulates licensing and other restrictions on the sale of cigarettes. It does not apply to ESDs, synthetic nicotine products, "smart" vape devices, or nicotine pouches. Maryland Business Regulation Code § 16 does not cover heat-not-burn products in their entirety. While the statute may apply to the tobacco sticks—if they are classified as "rolls for smoking" composed of tobacco or a tobacco mixture and wrapped in paper or other non-tobacco materials[31]—it does not extend to the devices used to heat or smoke these sticks.

ii. Maryland Business Regulation Code § 16.5

Next, Maryland Business Regulation Code § 16.5 applies to "other tobacco products," which is defined as any product, except cigarettes, that is intended for human consumption, whether smoked, heated, chewed, absorbed, dissolved, inhaled, or ingested in any other manner, and that is made of or derived from, or contains tobacco or nicotine.[32] Therefore, Section 16.5 applies to cigars, premium cigars, pipe tobacco, chewing tobacco, snuff, snus, filters, rolling papers, pipes, nicotine pouches—whether or not they are synthetic, and hookahs.[33] Within Section 16.5, Section 16.5-201 outlines licensing requirements for businesses dealing with other tobacco products (OTP) in the state. A person must have the appropriate license to operate as an OTP manufacturer, retailer, storage warehouse, wholesaler, or tobacconist.

Maryland Business Regulation Code § 16.5 applies exclusively to the sale of "other tobacco products," including non-ESD synthetic nicotine products and nicotine pouches. Heat-not-burn products do not expressly fall under Section 16.5; however, it possible that the tobacco stick itself—not the device used to heat the stick—could be regulated under Section 16.5 if it was determined that the stick is intended for smoking, falling within the statutory definition of "other tobacco products." Since Section 16.5 only applies to other tobacco products, it does not extend to ESDs or "smart" vape devices.

iii. Maryland Business Regulation Code § 16.7

Business Regulation § 16.7 pertains to ESDs and related products.[34] This includes e-cigarettes, vape pens and e-liquids (whether they contain nicotine or not), cartridges and refills for vaping devices, and any component or accessory related to electronic smoking.

Under Section 16.7, Section 16.7-201 provides that a person must have the proper license to operate as an electronic smoking device manufacturer, retailer, wholesaler distributor, wholesaler importer, or vape shop vendor.[35] Additionally, any business selling electronic smoking devices or operating as a vape shop must also be licensed.

Maryland Business Regulation Code § 16.7 governs ESDs, including electronic cigarettes, cigars, cigarillos, pipes, hookahs, "smart" vapes, vape pens, and vaping liquids. The section also applies to synthetic nicotine products (if the e-liquid is synthetic nicotine), as the law defines tobacco products to include those containing either tobacco or nicotine. However, because § 16.7 specifically regulates "electronic smoking devices"—defined as devices that deliver aerosolized or vaporized nicotine to a user through inhalation—it does not extend to heat-not-burn products or nicotine pouches, which do not function through aerosolization or vaporization.

c. *Age Restrictions and Product Placement*

Sections 16, 16.5, and 16.7 of the Maryland Business Regulation Code have age verification provisions. Sections 16-209.1, 16.5-214.2, and 16.7-204.1 each address age verification and access requirements, providing that a retailer is not required to verify the age of an individual at least 30 years old.[36] Additionally, Sections 16-209.1, 16.5-214.2, and 16.7-204.1 provide that an individual's age may only be verified by means of a government-issued photo identification containing the individual's date of birth, and in a direct face-to-face exchange without the assistance of any electronic or mechanical device.

In addition to age verification provisions, Sections 16, 16.5, and 16.7 all have product placement provisions. Section 16-209.1 addresses the display of cigarettes, prohibiting licensed retailers from displaying

cigarettes for sale unless they are kept behind a counter in an area accessible only to the retailer and its employees.[37] Similarly, Section 16.5-214.2 covers the display and sale of other tobacco products, detailing how a licensed other tobacco products retailer may not display other tobacco products for sale unless the other tobacco products are located behind a counter in an area accessible only to the licensed other tobacco products retailer and employees of the licensed other tobacco products retailer.[38] Lastly, Section 16.7-204.2 concerns the display of electronic smoking devices, outlining how a retailer or vape shop vendor may not display electronic smoking devices for sale unless the electronic smoking devices are located behind a counter in an area accessible only to the retailer or vape shop vendor and employees of the retailer or vape shop vendor.[39]

d. *Maryland Clean Indoor Air Act*

The updated Maryland Clean Indoor Air Act (the "Act") prohibits smoking and vaping in virtually all indoor public spaces and workplaces, to "preserve and improve the health, comfort, and environment of the people of Maryland by limiting exposure to environmental smoke."[40] Under the Maryland Clean Indoor Air Act, a retail tobacco establishment may qualify for an exemption from the general smoking prohibition if certain conditions are met. Specifically, the business's primary activity must be the retail sale of tobacco products and accessories. Additionally, it is interpreted that 70–80% of the establishment's revenue, based on average daily receipts, must come from the sale of tobacco-related items.

The Maryland Clean Indoor Air Act covers ESDs, synthetic nicotine products, and "smart" vape products. The Act may apply to heat-not-burn products if a heated cigarette is considered "light" and the use of a heated cigarette constitutes "burning." However, the Act does not extend to nicotine pouches, as these products do not emit smoke or vaporized nicotine.

e. *Enforcement*

Enforcement officials may issue criminal citations[41] or civil citations to a retailer and/or store clerk for selling tobacco products to underage individuals.[42] Maryland Code, Criminal Law Section 10-107 prohibits the distribution of tobacco products or paraphernalia to those under age 21. Violations of this section are misdemeanors, with fines ranging from $500 for a first offense to $3,000 for subsequent offenses within two years. Criminal Law Section 10-107 applies to *all* tobacco products—including ESDs, synthetic nicotine products, heat-not-burn products, "smart" vape products, and nicotine pouches.

Civil citations may be issued pursuant to Health-General Section 24-305 which prohibits the sale, distribution, or offer for sale of ESDs to individuals under 21.[43] A person that violates this section is guilty of a misdemeanor and subject to an escalating fine schedule. Section 24-305 applies to *only* ESDs, which includes "smart" vape products.

Lastly, Maryland Code, Health-General Section 24-307 prohibits the sale or distribution of tobacco products, tobacco paraphernalia, or a coupon redeemable for a tobacco products to individuals under 21.[44] Section 24-307 applies to *all* tobacco products—including ESDs, synthetic nicotine products, heat-not-burn products, "smart" vape products, and nicotine pouches.

IV. GAPS IN REGULATIONS

a. *Heat-not-Burn Products*

Heat-not-burn (HNB) tobacco products, also known as heated tobacco products, are not considered cigarettes under Maryland law but are considered cigarettes under federal law. HNBs are federally regulated primarily by the FDA under the Family Smoking Prevention and Tobacco Control Act. The FDA has reviewed and authorized some HNB products. For example, Philip Morris International's IQOS received PMTA approval in 2019.

These products meet the federal definition of a "cigarette" and are regulated as such, so there isn't a gap in federal regulation; however, given the nature of HNBs, Section 16, Section 16.5, and Section 16.7 of the Maryland Business Regulation Code do not cover HNB products in their entirety. HNBs are not classified as cigarettes under Maryland law. However, Sections 16 and 16.5 may apply to the tobacco stick but not the device that accompanies it—this ambiguity suggesting the need for an amendment to Maryland Business Regulation Code §16 or §16.5 to comprehensively regulate HNBs.

Some Maryland provisions directly apply to HNBs, including Maryland Code, Health-General Section 24-307[45] and Maryland Code, Criminal Law Section 10-107.[46] Because heated cigarettes contain tobacco,

qualifying them as tobacco products under Section 10-101(d), Maryland Code, Criminal Law Section 10-107 and Maryland Code, Health-General Section 24-307 apply.

Other Maryland provisions may apply to HNBs, depending on statutory interpretation. The Maryland Clean Indoor Air Act may apply to heat-not-burn products if enforcement authorities determined that a heated cigarette is "light" and that the use of a heated cigarette constitutes "burning" for the purposes of Section 24-501(g), making the use of HNBs prohibited where combustible cigarette use is prohibited. Additionally, if it is determined that the tobacco sticks used in heat-not-burn products are intended for smoking, they would be classified as Other Tobacco Products (OTPs), making the sticks, not the heating devices, subject to the 60% wholesale price tax rate.[47] Alternatively, if the tobacco sticks used in heat-not-burn products are classified as "rolls for smoking"—defined as being made of tobacco or a tobacco mixture and wrapped in paper or any non-tobacco material[48] —then only the tobacco sticks, not the heating devices, may be taxed in the same manner as cigarettes: $5.00 per pack of 20 and $0.25 for each additional cigarette in packs exceeding 20.[49]

V. How New and Emerging Products Fit within the State and Federal Scheme

Products	***Tobacco Control Act***	***Maryland Business Regulation Code § 16***	***Maryland Business Regulation Code § 16.5***	***Maryland Business Regulation Code § 16.7***	***Maryland Clean Indoor Air Act***	***Maryland Code, Criminal Law § 10-107***	***Marylan d Code, Health-General § 24-305***	***Maryland Code, Health-General § 24-307***
Electronic Smoking Devices	**applies**, the FDA may regulate any product containing nicotine from any source.	**does not apply**, Section 16 only applies to cigarettes.	**does not apply**, Section 16.5 only applies to other tobacco products.	**applies**, Section 16.7 applies to electronic smoking devices.	**applies**, the Maryland Clean Indoor Air Act prohibits smoking and vaping.	**applies** to all electronic smoking devices (ESDs).	**applies** to all ESDs.	**applies**, Section 24-307 applies to all tobacco products—including ESDs.
Synthetic Nicotine Products	**applies**, the FDA may regulate any product containing nicotine from any source.	**does not apply**, Section 16 only applies to cigarettes.	**applies** to non-ESD products, such as nicotine pouches containing synthetic nicotine. Nicotine pouches are considered "other tobacco products."	**applies** to ESDs and e-liquid containing synthetic nicotine.	**applies**, the Maryland Clean Indoor Air Act prohibits smoking and vaping.	**applies** to all products containing tobacco or nicotine.	**applies** to products containin g e-liquid made with synthetic nicotine.	**applies**, Section 24-307 applies to all products containing nicotine.

Heat-not-Burn Products	**applies**, the FDA may regulate any product that contains tobacco. The FDA regulates these as cigarettes because they meet the definition under federal law.	These products are not considered cigarettes under Maryland law but the title **may have some applicability** to the stick of tobacco, not the device itself.	**may** have some applicability to the stick of tobacco, not the device itself if not regulated under Business Regulation, Title 16.	**does not apply**, Section 16.7 applies to ESDs only.	**may apply** if a heated cigarette is considered "lighted" and the use of a heated cigarette constitutes "burning."	**applies** to all products containing tobacco.	**does not apply**, Section 24-305 applies to *only* ESDs.	**applies**, Section 24-307 applies to all products containing tobacco.
"Smart" Vape Products	**applies**, the FDA may regulate any product that contains nicotine from any source. Smart vape products are considered ESDs.	**does not apply**, Section 16 only applies to cigarettes.	**does not apply**, Section 16.5 only applies to other tobacco products.	**applies**, Section 16.7 applies to ESDs.	**applies**, the Maryland Clean Indoor Air Act prohibits smoking and vaping.	**applies** to all electronic smoking devices, including smart vape products.	**applies** to all ESDs.	**applies**, Section 24-307 applies to all tobacco products, including ESDs.
Nicotine Pouches	**applies**, the FDA may regulate any product that contains nicotine from any source.	**does not apply**, Section 16 only applies to cigarettes.	**applies**, Section 16.5 applies to other tobacco products.	**does not apply**, Section 16.7 applies to ESDs only.	**does not apply**, the updated Maryland Clean Indoor Air Act prohibits smoking and vaping.	**applies** to all products containing nicotine.	**does not apply**, Section 24-305 applies to *only* ESDs.	**applies**, Section 24-307 applies to all products containing nicotine or tobacco.

This document was developed by Jackie Ellis, J.D, Candidate '26 in the Pubic Health Law Clinic for the Legal Resource Center for Public Health Policy (LRC) at the University of Maryland Francis King Carey School of Law, with funding and support provided by the Maryland Department of Health. The LRC provides information and technical assistance on issues related to public health in Maryland. The legal information and assistance does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel. This information is current as of June 2025.

[1] 21 U.S.C. § 321(rr) (2018).
[2] Md. Code Ann., Bus. Reg. § 16.7 (2024); Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49 (2022).
[3] The FDA refers to ESDs as Electronic Nicotine Delivery Systems (ENDS). "Vapes" is a common term that usually refers to nicotine-based products whereas ESDs, or ENDS, is an umbrella term that covers all vapor-producing devices used to inhale substances, including vapes.
[4] *E.g.*, *Are Nicotine Pouches Safer Than Smoking?*, CLEVELAND CLINIC (Oct. 9, 2014), https://health.clevelandclinic.org/are-nicotine-pouches-safe ("Non-tobacco nicotine products like nicotine pouches are quickly flooding the market . . . . Many people see them as a healthier alternative to tobacco products") (internal quotations omitted).
[5] *Results from the Annual National Youth Tobacco Survey*, U.S. FOOD & DRUG ADMIN. (Jan. 22, 2025), https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey.

[6] Matthew C. Fadus et al., *The Rise of E-cigarettes, Pod Mod Devices, and JUUL Among Youth: Factors Influencing Use, Health Implications, and Downstream Effects*, 201 DRUG ALCOHOL DEPENDANCE 85, 85-86 (2019), https://pmc.ncbi.nlm.nih.gov/articles/PMC7183384/pdf/nihms-1578287.pdf.
[7] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).
[8] Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49 (2022).
[9] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 910, 123 Stat. 1776, 1790-91 (2009).
[10] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 904, 123 Stat. 1776, 1797-98 (2009).
[11] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 907, 123 Stat. 1776, 1794-95 (2009).
[12] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 102, 123 Stat. 1776, 1781-82 (2009).
[13] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 901, 123 Stat. 1776, 1790 (2009).
[14] Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49 (2022).
[15] 21 CFR § 1140.14(a)(1).
[16] 21 CFR § 1140.14(a)(2)(i).
[17] 21 CFR § 1140.14(a)(2)(ii).
[18] U.S. Food & Drug Admin., *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (Jan. 2020), https://www.fda.gov/media/133880/download.
[19] *Altadis U.S.A., Inc., et al. v. Prince George's County*, 431 Md. 307 (2013).
[20] Md. Code, Tax-Gen. § 12-105(a) (2024).
[21] Md. Code, Tax-Gen. § 12-105(b)(1) (2024).
[22] Md. Code, Tax-Gen. § 12-105(b)(2)(ii) (2024).
[23] Md. Code, Tax-Gen. § 12-105(b)(2)(iii) (2024).
[24] Md. Code, Tax-Gen. § 11-104 (j)(2) (2024).
[25] Md. Code, Tax-Gen. § 11-104 (j)(3) (2024).
[26] Md. Code, Tax-Gen. § 12-101(d) (2024); Md. Code, Tax-Gen. § 12-105(b)(1) (2024).
[27] Md. Code, Tax-Gen. § 12-101(d) (2024); Md. Code, Tax-Gen. § 12-105(b)(1) (2024).
[28] Md. Code Ann., Bus. Reg. § 16-101 (2024).
[29] Md. Code, Tax-Gen. § 12-105(a) (2024).
[30] Md. Code Ann., Bus. Reg. § 16 (2024).
[31] Md. Code Ann., Bus. Reg. § 16-101 (2024).
[32] Md. Code Ann., Bus. Reg. § 16.5-101 (2024).
[33] Md. Code Ann., Bus. Reg. § 16.5 (2024).
[34] Md. Code Ann., Bus. Reg. § 16.7 (2024).
[35] Md. Code Ann., Bus. Reg. § 16.7-201 (2024).
[36] Md. Code Ann., Bus. Reg. § 16.5-214.2 (2024); Md. Code Ann., Bus. Reg. § 16.7-204.1 (2024).
[37] Md. Code Ann., Bus. Reg. § 16-209.1 (2024).
[38] Md. Code Ann., Bus. Reg. § 16.5-214.2 (2024).
[39] Md. Code Ann., Bus. Reg. § 16.7-204.2 (2024).
[40] Md. Code Ann., Health-Gen. § 24-502(a) (2024).
[41] Md. Code Crim. Law §10-107 (2024).
[42] Md. Code Health-Gen. §24-305 and §24-307 (2024).
[43] Md. Code Ann., Health-Gen. § 24-305 (2024).
[44] Md. Code Ann., Health-Gen. § 24-307 (2024).
[45] Md. Code Ann., Health-Gen. § 24-501(g) (2024).
[46] Md. Code Ann., Crim. Law § 10-101(d) (2024).
[47] Md. Code, Tax-Gen. § 12-101(d) (2024); Md. Code, Tax-Gen. § 12-105(b)(1) (2024).
[48] Md. Code Ann., Bus. Reg. § 16-101 (2024).
[49] Md. Code, Tax-Gen. § 12-105(a) (2024).