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April 4, 2025

Congressional Research Service
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R48483

CRS REPORT
Prepared for Members and
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SUMMARY

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April 4, 2025

Nora Wells
Analyst in Health Policy

U.S. Food and Drug Administration (FDA) Regulation of Electronic Nicotine Delivery Systems (ENDS): Background and Selected Policy Issues

Electronic nicotine delivery systems (ENDS) have become increasingly popular since their emergence in the United States. ENDS is an umbrella term for various electronic tobacco products, including electronic cigarettes (e-cigarettes). An e-cigarette is a battery-operated device containing an e-liquid, or a mixture of typically nicotine, flavorings, and other chemicals that, when heated, creates inhalable aerosol. ENDS products come in a variety of forms (e.g., e-hookahs, e-cigars, vape pens) and may be designed to be used only once (e.g., disposable ENDS) or multiple times (e.g., prefilled or refillable ENDS).

According to Centers for Disease Control and Prevention (CDC) analyses, 6.5% of American adults used e-cigarettes in 2023 and 5.9% of American middle and high school students used an e-cigarette within a 30-day period in 2024. Although youth usage of ENDS and other tobacco products decreased overall between 2023 and 2024, ENDS remain the most commonly used tobacco product for middle and high school students, and became increasingly popular with adults between 2019 and 2023.

The public health impact of ENDS products is a point of debate in the public health community. Some view ENDS products as a safer alternative for adults who smoke cigarettes, in part because the aerosol produced by e-cigarettes is generally less harmful in the short-term than the combusted smoke produced by cigarettes. Others are alarmed by youth ENDS use and are concerned that these products, particularly those sold in flavors appealing to children, may undermine years of tobacco control efforts.

The U.S. Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), is responsible for regulating the manufacture, marketing, distribution, and sale of tobacco products. FDA's Center for Tobacco Products (CTP)—established in 2009 pursuant to the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA; P.L. 111-31)—is primarily responsible for tobacco product regulation. The TCA established Chapter IX ("Tobacco Products") of the Federal Food, Drug, and Cosmetic Act (FFDCA), under which FDA is authorized to regulate tobacco products.

Upon enactment, the TCA explicitly covered the following tobacco products: cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The TCA also grants FDA authority to regulate any other product under FFDCA Chapter IX that it determines meets the established definition of "tobacco product." In 2016, FDA promulgated a regulation, known as the Deeming Rule, that extended the agency's authority to all other tobacco products not already subject to the FFDCA, including ENDS.

Both FDA and Congress have taken steps to address the regulation of ENDS in response to their increased use. Multiple policy considerations for Congress remain, including issues related to the flow of illicit ENDS into the United States, the use of ENDS as a harm reduction tool, flavored ENDS regulation, ENDS e-liquid composition and contamination, concentrations of nicotine in e-liquids, remote sales and advertising of ENDS, and whether ENDS should be subject to user fees.

On March 27, 2025, HHS issued a press release and fact sheet announcing that HHS was being restructured. The fact sheet indicated that this restructuring would include a reduction of approximately 3,500 full-time employees from FDA's workforce. At the time of this report's publication, the potential effect of this restructuring on CTP operations, and ENDS specifically, is unknown.

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Introduction

Nicotine is a naturally occurring chemical compound found in the tobacco plant.[1] While most tobacco products contain tobacco plant-derived nicotine, some tobacco products, including certain ENDS e-liquids, instead contain non-tobacco nicotine (NTN). NTN is nicotine not derived from the tobacco plant. NTN encompasses synthetic nicotine, or nicotine that was created in a lab but has a similar molecular structure to tobacco plant-derived nicotine.[2]

Repeated exposure to nicotine can cause addiction.[3] There is debate in the public health community regarding the inherent severity of harm from nicotine exposure alone.[4] A common misconception among the general public is that nicotine is the primary cause of various harms associated with tobacco use, particularly cigarette use. However, the U.S. Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), has identified, including nicotine, 93 harmful or potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke that, in combination, lead to the serious health effects of tobacco use.[5]

Some in the public health community have advocated for a harm reduction approach, emphasizing the use of noncombustible electronic nicotine delivery systems (ENDS) as an alternative to combustible tobacco products, the latter of which may contain more HPHCs. However, nicotine is not harmless. FDA has acknowledged that higher concentrations of nicotine can lead to harmful effects, particularly in youth.[6] For example, nicotine may damage the developing adolescent brain, affecting parts of the brain that control attention, learning, mood, and impulse control.[7]

Although youth usage of ENDS and other tobacco products decreased overall between 2023 and 2024, ENDS remain the most commonly used tobacco product for middle and high school

[1] FDA, "Nicotine is Why Tobacco Products are Addictive," January 15, 2025, https://www.fda.gov/tobacco-products/health-effects-tobacco-use/nicotine-why-tobacco-products-are-addictive."

[2] FDA, "Regulation and Enforcement of Non-Tobacco Nicotine (NTN) Products," November 6, 2023, https://www.fda.gov/tobacco-products/products-ingredients-components/regulation-and-enforcement-non-tobacco-nicotine-ntn-products. For more information on synthetic nicotine, see CRS Report R47043, *Synthetic Nicotine: Frequently Asked Questions* (particularly the section entitled "What is the difference between synthetic nicotine and nicotine derived from tobacco?"). FDA does have the authority to regulate tobacco products containing nicotine from any source, including synthetic nicotine; this authority was clarified by Congress via Section 111 of the Consolidated Appropriations Act, 2022 (CAA, 2022; P.L. 117-103), which went into effect on April 14, 2022. FDA, "Regulation and Enforcement of NTN Products.

[3] CDC, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*, 2014, pp. 30-31, ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf.

[4] Kate Kelland, "Is Nicotine All Bad?," Scientific American, May 19, 2015, https://www.scientificamerican.com/article/is-nicotine-all-bad/.

[5] FDA, "Harmful and Potentially Harmful Constituents (HPHCs)," October 7, 2019, https://www.fda.gov/tobacco-products/products-ingredients-components/harmful-and-potentially-harmful-constituents-hphcs; FDA, "Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List," October 7, 2019, https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list; FDA, "Nicotine is Why Tobacco Products are Addictive," January 15, 2025, https://www.fda.gov/tobacco-products/health-effects-tobacco-use/nicotine-why-tobacco-products-are-addictive.

[6] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry*, April 2020, p. 37, https://www.fda.gov/media/133880/download.

[7] CDC, "E-Cigarette Use Among Youth," October 17, 2024, https://www.cdc.gov/tobacco/e-cigarettes/youth.html.

students, and became increasingly popular with adults between 2019 and 2023.[8] ENDS is an umbrella term for various types of electronic tobacco products, including electronic cigarettes (e-cigarettes).[9] An e-cigarette is a battery-operated device containing an e-liquid, or a mixture of typically nicotine, flavorings, and other chemicals that, when heated, creates inhalable aerosol.[10] ENDS products come in a variety of forms (e.g., e-hookahs, e-cigars, vape pens) and may be designed to be used only once (e.g., disposable ENDS) or multiple times (e.g., prefilled or refillable ENDS). According to Centers for Disease Control and Prevention (CDC) analyses, 6.5% of American adults used e-cigarettes in 2023[11] and 5.9% of American middle and high school students used an e-cigarette within a 30-day period in 2024.[12]

The public health impact of ENDS products is a point of debate in the public health community. Some view ENDS products as a safer alternative for adults who smoke cigarettes, in part because the aerosol produced by e-cigarettes is generally less harmful in the short-term than the combusted smoke produced by cigarettes.[13] Others are alarmed by youth ENDS use and are concerned that these products, particularly those sold in flavors appealing to children, may undermine years of tobacco control efforts.[14]

FDA is responsible for regulating the manufacture, marketing, distribution, and sale of tobacco products.[15] FDA's Center for Tobacco Products (CTP)—established in 2009 pursuant to the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA; P.L. 111-31)—is primarily responsible for tobacco product regulation. The TCA established the Federal Food, Drug, and Cosmetic Act (FFDCA) Chapter IX ("Tobacco Products"), under which FDA is authorized to regulate tobacco products. Upon enactment, the TCA explicitly covered the following tobacco products: cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.[16] The TCA also grants FDA broad authority to regulate any other product under FFDCA Chapter IX that it

[8] Ahmed Jamal et al., "Tobacco Product Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2024," *Morbidity and Mortality Weekly Report (MMWR)*, vol. 73, no. 41 (October 17, 2024), p. 917, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7341a2-H.pdf; Anjel Vahratian et al., "Electronic Cigarette Use Among Adults in the United States, 2019-2023," *NCHS Data Brief*, no. 524 (January 2025), p. 1, https://www.cdc.gov/nchs/data/databriefs/db524.pdf.

[9] Other examples of ENDS products may include e-pipes, hookah pens, vape pens, vaporizers, vapes, and electronic cigars. FDA, "E-Cigarettes, Vapes, and Other Electronic Nicotine Delivery Systems (ENDS)," May 31, 2024, https://www.fda.gov/tobacco-products/products-ingredients-components/e-cigarettes-vapes-and-other-electronic-nicotine-delivery-systems-ends; CDC, *E-Cigarette, or Vaping, Products Visual Dictionary*, p.17, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/ecigarette-or-vaping-products-visual-dictionary-508.pdf.

[10] FDA, "E-Cigarettes, Vapes, and Other Electronic Nicotine Delivery Systems (ENDS)"; CDC, *E-Cigarette, or Vaping, Products Visual Dictionary*, p.17.

[11] Anjel Vahratian et al., "Electronic Cigarette Use Among Adults in the United States, 2019-2023," *NCHS Data Brief*, no. 524 (January 2025), p. 5, https://www.cdc.gov/nchs/data/databriefs/db524.pdf.

[12] Eunice Park-Lee et al., "*Notes from the Field*: E-Cigarette and Nicotine Pouch Use Among Middle and High School Students—United States, 2024,"*MMWR*, vol. 73, no. 35 (September 5, 2024), p. 774, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf; Ahmed Jamal et al., "Tobacco Product Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2024," *MMWR*, vol. 73, no. 41 (October 17, 2024), p. 917, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7341a2-H.pdf.

[13] Generally, e-cigarette aerosols contain fewer toxicants than combusted smoke from cigarettes. National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-Cigarettes*, 2018, pp. 598, 604, 612, 617, https://nap.nationalacademies.org/cart/download.cgi?record_id=24952.

[14] See, for example, Campaign for Tobacco-Free Kids, "E-Cigarettes: Flavored Products Fuel a Youth Addiction Crisis," January 28, 2025, https://www.tobaccofreekids.org/what-we-do/industry-watch/e-cigarettes.

[15] FDA, "Rules, Regulations, and Guidance Related to Tobacco Products," November 20, 2024, https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance-related-tobacco-products.

[16] FFDCA §901(b).

determines meets the established definition of "tobacco product."[17] In 2016, FDA promulgated a regulation, known as the Deeming Rule, that extended the agency's authority to all other tobacco products not already subject to the FFDCA, including ENDS.[18]

All tobacco products originally covered by the TCA are required to undergo premarket review, unless they are "pre-existing tobacco products."[19] Following the 2016 Deeming Rule, all newly deemed tobacco products became subject to premarket review requirements as well. After several deadline adjustments, premarket applications for ENDS products that were on the market on August 8, 2016, were ultimately due to FDA by September 9, 2020.[20] In addition to the enforcement priorities it expressed in April 2020 guidance, FDA stated that it may continue to exercise enforcement discretion for certain products for which applications were submitted by the aforementioned date.[21] In other words, barring a negative action on an application, FDA could effectively allow such products to be marketed for up to a year after the deadline (i.e., September 9, 2021) while applications were being reviewed.[22] As of early 2025, FDA has repeatedly noted that a legal safe harbor for the vast majority of ENDS products with pending applications no longer applies.[23]

In June 2021, Acting FDA Commissioner Janet Woodcock testified that the agency had completed initial processing of premarket tobacco product applications (PMTAs) for more than 6.5 million products submitted by over 550 companies.[24] The vast majority of these submissions

[17] FFDCA §901(b). A "tobacco product" is defined 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." FFDCA §201(rr).

[18] 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 Statement for Tobacco Products," 81 *Federal Register* 28974, May 10, 2016, https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10685.pdf. For more information about tobacco regulation generally, see CRS Report R45867, *FDA Regulation of Tobacco Products*.

[19] Products that do not meet the statutory definition of a new tobacco product are referred to as "pre-existing tobacco products" and do not require premarket review to be legally marketed. A pre-existing tobacco product is one that has been commercially marketed in the United States as of February 15, 2007. Note, "pre-existing tobacco products" were previously called "grandfathered tobacco products." FDA, "Pre-Existing Tobacco Products," January 21, 2025, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/pre-existing-tobacco-products.

[20] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*: Guidance for Industry*, April 2020, pp. 4-6, https://www.fda.gov/media/133880/download.

[21] FDA, *Enforcement Priorities for ENDS*, p. 27; FDA, "Coronavirus (COVID-19) Update: Court Grants FDA's Request for Extension of Premarket Review Submission Deadline for Certain Tobacco Products Because of Impacts from COVID-19," press release, April 23, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-court-grants-fdas-request-extension-premarket-review-submission-deadline. For more information on FDA enforcement discretion, see CRS Report R43609, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues*.

[22] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry*, April 2020, p. 27, https://www.fda.gov/media/133880/download; FDA, "Coronavirus (COVID-19) Update: Court Grants FDA's Request for Extension of Premarket Review Submission Deadline for Certain Tobacco Products Because of Impacts from COVID-19," press release, April 23, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-court-grants-fdas-request-extension-premarket-review-submission-deadline.

[23] See, for example, FDA, "Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products," January 15, 2025, https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products.

[24] FDA, "An Epidemic Continues: Youth Vaping America," June 23, 2021, https://www.fda.gov/news-events/congressional-testimony/epidemic-continues-youth-vaping-america-06232021; Testimony of Dr. Janet Woodcock, (continued...)

were for ENDS products.[25] On August 9, 2021, FDA issued a refuse to file (RTF)[26] letter to JD Nova Group LLC, stating that the e-liquid company had to remove approximately 4.5 million of its products from the market because the associated PMTAs failed to meet filing requirements.[27] On August 26, 2021, FDA issued marketing denial orders (MDOs)[28] for approximately 55,000 flavored ENDS products, citing a lack of evidence that they were "a benefit to adult smokers sufficient to overcome the public health threat posed by the well-documented, alarming levels of youth use of such products."[29]

On September 9, 2021, FDA stated that it had taken action on about 93% of all applications for deemed new tobacco products submitted by the September 9, 2020, deadline.[30] Many of the applications submitted to FDA by the PMTA pathway were issued RTF letters or MDOs. FDA further stated that it continued to work on the remaining applications, clarifying that in addition to the remaining ENDS PMTAs, FDA was also reviewing a number of other deemed new tobacco product applications submitted under the substantial equivalence (SE) and exemption from SE (EX REQ) pathways.[31]

Acting FDA Commissioner, in U.S. Congress, House Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, *An Epidemic Continues: Youth Vaping in America*, hearings, 117th Cong., 1st sess., June 23, 2021, p. 9, Ser.No. 117-31, https://docs.house.gov/meetings/GO/GO05/20210623/112808/HHRG-117-GO05-Transcript-20210623.pdf. Note, under the FFDCA, a tobacco product is defined 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 (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." FFDCA §201(rr)(1). A single PMTA may be submitted for multiple tobacco products; for example, a grouped submission could encompass e-liquids of varying sizes, nicotine concentrations, and flavors. FDA, "Preparing and Submitting a Premarket Tobacco Product Application," January 21, 2025, https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/preparing-and-submitting-premarket-tobacco-product-application. Of the applications for the over 6.5 million products received by FDA, approximately 4.5 million were associated with a single company, JD Nova Group LLC. FDA, "FDA Issues Refuse to File (RTF) Letter to JD Nova Group LLC," August 9, 2021, https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-refuse-file-rtf-letter-jd-nova-group-llc (see linked spreadsheets for product list).

[25] FDA, "An Epidemic Continues: Youth Vaping America," June 23, 2021, https://www.fda.gov/news-events/congressional-testimony/epidemic-continues-youth-vaping-america-06232021.

[26] A refuse-to-file letter is generally issued for applications containing insufficient information for review. See FDA, "Premarket Tobacco Product Applications and Recordkeeping Requirements," 86 *Federal Register* 55300, October 5, 2021, https://www.govinfo.gov/content/pkg/FR-2021-10-05/pdf/2021-21011.pdf.

[27] FDA, "FDA Issues Refuse to File (RTF) Letter to JD Nova Group LLC," August 9, 2021, https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-refuse-file-rtf-letter-jd-nova-group-llc.

[28] A marketing denial order is issued after a determination that a PMTA did not pass evaluation. "PMTAs are evaluated on several factors, including whether permitting the marketing of a new tobacco product would be appropriate for the protection of the public health, which is determined with respect to the risks and benefits of the product to the population as a whole, including users and non-users." FDA, "Tobacco Products Marketing Orders," August 26, 2021, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders.

[29] FDA, "FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health," press release, August 26, 2021, https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence.

[30] FDA, "FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 Million 'Deemed' New Tobacco Products Submitted," press release, September 9, 2021, https://www.fda.gov/news-events/press-announcements/fda-makes-significant-progress-science-based-public-health-application-review-taking-action-over-90.

[31] For a discussion on FDA premarket review pathways for tobacco products, see CRS Report R45867, *FDA Regulation of Tobacco Products*. See also FDA, "Perspective: FDA's Progress on Tobacco Product Application Review and Related Enforcement," September 9, 2021, https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-tobacco-product-application-review-and-related-enforcement.

On October 12, 2021, FDA announced that it had authorized the marketing of three R.J. Reynolds (RJR) Vapor Company tobacco-flavored ENDS products under the PMTA pathway—the first ENDS products to ever be granted such authorizations from the agency. FDA also noted it had taken action on over 98% of the applications submitted by the September 9, 2020, deadline.[32]

Thereafter, on March 24, 2022, FDA announced it had authorized the marketing of an additional eight tobacco-flavored ENDS products from Logic Technology Development LLC. At that time, FDA stated it had "taken action on approximately 99% of the nearly 6.7 million ENDS products submitted for premarket authorization, including issuing marketing denial orders for more than 1 million ENDS products."[33] From April 26, 2022, to June 10, 2022, FDA authorized marketing orders for another dozen ENDS products—six from NJOY LLC and six from RJR—resulting in a total of 23 tobacco-flavored e-cigarette products and devices authorized under the PMTA pathway.[34]

Following the September 9, 2020, deadline, FDA continued to receive applications for millions of deemed new tobacco products. On March 15, 2023, FDA stated it had "made determinations on more than 99% of the nearly 26 million deemed products for which applications were submitted, including … applications for nearly 6.7 million products received by the Sept[ember] 9, 2020, deadline, [and] more than 18 million products received after."[35]

In February 2024, FDA provided an update on its progress, stating that it had "made determinations on 99 percent of [the] applications" for over 26 million deemed products.[36] FDA further noted, "We remain committed to making determinations on all remaining applications as expeditiously as possible, while ensuring the decisions are scientifically accurate, legally defensible, and aligned with the authorities granted to us by Congress."[37]

On June 21, 2024, FDA announced it had, for the first time, authorized four menthol-flavored e-cigarette products from NJOY LLC under the PMTA pathway, bringing the total number of FDA-authorized ENDS products and devices on the market to 27.[38] Within the news release marking

[32] FDA, "FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by the Agency," press release, October 12, 2021, https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency.

[33] FDA, "FDA Issues Decisions on Additional E-Cigarette Products," press release, March 24, 2022, https://web.archive.org/web/20221121094452/https://www.fda.gov/news-events/press-announcements/fda-issues-decisions-additional-e-cigarette-products.

[34] FDA, "Premarket Tobacco Product Marketing Granted Orders," March 28, 2024, https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders; FDA, "Looking Back, Looking Ahead: FDA's Progress on Tobacco Product Regulation in 2022," January 31, 2023, https://web.archive.org/web/20250114160749/https://www.fda.gov/tobacco-products/ctp-newsroom/looking-back-looking-ahead-fdas-progress-tobacco-product-regulation-2022.

[35] FDA, "FDA Makes Determinations on More Than 99% of the 26 Million Tobacco Products for Which Applications Were Submitted," March 15, 2023, https://www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted. In a later posting, FDA noted that the majority of the 26 million applications received were for e-cigarette products. FDA, "FDA Issues Marketing Denial Orders for Approximately 6,500 Flavored E-Cigarette Products," May 12, 2023, https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-denial-orders-approximately-6500-flavored-e-cigarette-products. For more detailed metrics on the outcomes of ENDS PMTA applications between October 2019 and March 31, 2024, see FDA, *PMTA Acceptance Phase Metrics*, March 31, 2024, https://www.fda.gov/media/169533/download?attachment.

[36] FDA, "A Year in Review: FDA's Progress on Tobacco Product Regulation in 2023," February 22, 2024, https://web.archive.org/web/20250122192114/https://www.fda.gov/tobacco-products/ctp-newsroom/year-review-fdas-progress-tobacco-product-regulation-2023.

[37] FDA, "A Year in Review: 2023."

[38] FDA, "FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products After Extensive Scientific

(continued...)

the authorization of these four products, FDA further noted that it had "received applications for nearly 27 million deemed products and ha[d] made determinations on more than 26 million of these applications."[39] Most recently, on July 18, 2024, FDA authorized the marketing of seven additional tobacco-flavored e-cigarette products from RJR, bringing the total number of FDA-authorized ENDS products and devices on the market to 34.[40] According to FDA, all other ENDS products currently marketed in the United States are done so illegally and risk enforcement.[41]

Throughout this review process, some industry stakeholders have expressed frustration with FDA, claiming that the agency has failed to promptly review applications from companies who hold the largest market share of ENDS products.[42] Other advocacy groups have stated that FDA's decisions have not gone far enough to remove ENDS products from the market.[43] As a result of litigation, FDA has been required by a district court to submit quarterly reports on its review progress of certain final outstanding marketing applications that were submitted by the September 9, 2020, deadline.[44] The applications subject to the reports include those covering specified ENDS products selected by the court, as well as products meeting certain sales thresholds.[45] In the agency's final status report, submitted on July 22, 2024, FDA reported it had taken action on 99.5% of the pertinent applications, or 185 of 186 applications.[46]

Review," June 21, 2024, https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-four-menthol-flavored-e-cigarette-products-after-extensive-scientific.

[39] FDA, "FDA Authorizes Marketing of Menthol E-Cigarettes."

[40] FDA, "FDA Authorizes Marketing of Vuse Alto Tobacco-Flavored E-Cigarette Pods and Accompanying Power Unit," July 18, 2024, https://www.fda.gov/tobacco-products/ctp-newsroom/fda-authorizes-marketing-vuse-alto-tobacco-flavored-e-cigarette-pods-and-accompanying-power-unit. For a list of FDA-authorized e-cigarette products, see FDA, "E-Cigarettes Authorized by the FDA," January 2025, https://digitalmedia.hhs.gov/tobacco/hosted/E-Cigarettes-Authorized-FDA-JAN2025.pdf.

[41] FDA, "FDA Issues Marketing Denial Orders for Approximately 6,500 Flavored E-Cigarette Products," May 12, 2023, https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-denial-orders-approximately-6500-flavored-e-cigarette-products; FDA, "FDA Denies Marketing of 250+ Flavored and Tobacco-Flavored E-Liquids," May 18, 2023, https://www.fda.gov/tobacco-products/ctp-newsroom/fda-denies-marketing-250-flavored-and-tobacco-flavored-e-liquids.

[42] See, for example, Matt Richtel, "F.D.A. Delays Decision on Juul's E-Cigarettes but Orders Others Off the Market," *The New York Times*, October 12, 2021, https://www.nytimes.com/2021/09/09/health/fda-e-cigarettes-vaping.html; Campaign for Tobacco-Free Kids, "FDA Makes Progress Against Flavored E-Cigarettes, But Continued Delays Leave Kids at Risk," press release, January 23, 2024, https://www.tobaccofreekids.org/press-releases/2024_01_23_fda-makes-progress-against-flavored-e-cigarettes.

[43] See, for example, Matt Richtel, "F.D.A. Delays Decision on Juul's E-Cigarettes"; Campaign for Tobacco-Free Kids, "FDA Makes Progress Against Flavored E-Cigarettes."

[44] See Revised Remedial Order, ECF No. 229, Am. Acad. of Pediatrics v. FDA, No. 8:18-CV-883, (D. Md. Apr. 15, 2022). For background information related to this case, see CRS Report R45867, *FDA Regulation of Tobacco Products*, and CRS Legal Sidebar LSB11141, *Circuit Split over the Food and Drug Administration's Denial of Applications Seeking to Market Flavored E-Cigarettes, Part 1 of 2*.

[45] See Revised Remedial Order at 1-2, ECF No. 229, Am. Acad. of Pediatrics v. FDA, No. 8:18-CV-883, (D. Md. Apr. 15, 2022). For background information related to this case, see CRS Report R45867, *FDA Regulation of Tobacco Products*, and CRS Legal Sidebar LSB11141, *Circuit Split over the Food and Drug Administration's Denial of Applications Seeking to Market Flavored E-Cigarettes, Part 1 of 2*.

[46] FDA, Defendants' Status Report and Motion for Relief Under Rule 60(b) From Obligation to File Further Status Reports at 1, Am. Acad. of Pediatrics v. FDA, No. 8:18-CV-883, (D. Md. July 22, 2024). The district court, on October 18, 2024, granted FDA's motion to end the reporting requirement, given that only one application subject to the Revised Remedial Order remained. See ECF No. 234, Am. Acad. of Pediatrics v. FDA, No. 8:18-CV-883, (D. Md. Oct. 18, 2024).

On March 27, 2025, HHS issued a press release and fact sheet announcing that HHS was being restructured.[47] The fact sheet indicated that this restructuring would include a reduction of approximately 3,500 full-time employees from FDA's workforce.[48] At the time of this report's publication, the potential effect of this restructuring on CTP operations, and ENDS specifically, is unknown.

Selected Policy Issues

FDA continues to take steps to regulate ENDS products. However, stakeholders have raised ongoing issues regarding the regulation of ENDS that Congress may consider:

- **Flow of Illicit ENDS into the United States.** In recent years, there has been an influx of illicit ENDS devices into the United States and sold in stores. Potential regulatory gaps associated with the flow of illicit ENDS include the commonness of specifically disposable ENDS products, ineffective FDA import alerts, a lack of foreign facility registration, and CTP's lack of resources.
- **ENDS as a Harm Reduction Tool.** There has been ongoing debate regarding the public health impact of ENDS. Various stakeholders have concluded that additional information is needed to assess their harm reduction potential. Additionally, some stakeholders have expressed concern that educational information directed at adult smokers about harm reduction and ENDS is lacking due to a primary focus on preventing youth ENDS use.
- **Flavored ENDS Regulation.** The regulation of flavors in ENDS products is complicated by several factors, including mixed study results. Studies have documented that flavors may entice youth to use tobacco products; however, some studies indicate that adult cigarette smokers may be drawn to flavored ENDS as a way to quit cigarette smoking. FDA released a final guidance document in 2020 specifying its intended enforcement activities related to flavored ENDS, though some stakeholders expressed concern that the final guidance does not go far enough to reduce ENDS use among youth.
- **ENDS E-Liquid Composition and Contamination.** E-liquids may contain a number of substances, both intentionally and unintentionally present, that could contribute to respiratory irritation and other health complications. Electronic delivery systems that do not contain tobacco or nicotine from any source (e.g., marijuana concentrate e-liquid vaporizers) likely do not meet the definition of a tobacco product under the FFDCA. Consequently, such products may not be subject to FDA tobacco product regulation.
- **Concentrations of Nicotine in E-Liquids.** ENDS products use e-liquids containing various ingredients to deliver nicotine, the concentration of which may affect a user's health. Studies have demonstrated that the labeled concentration of nicotine in an e-liquid solution and the actual nicotine concentration may vary. Regulations do not currently specify a maximum allowable nicotine concentration in e-liquid solutions.

[47] HHS, "HHS Announces Transformation to Make America Healthy Again," press release, March 27, 2025, https://www.hhs.gov/about/news/hhs-restructuring-doge.html; HHS, "Fact Sheet: HHS' Transformation to Make America Healthy Again," March 27, 2025, https://www.hhs.gov/about/news/hhs-restructuring-doge-fact-sheet.html.

[48] HHS, "Fact Sheet: HHS' Transformation to Make America Healthy Again."

- **Remote Sales and Advertising.** With the advent of remote sales and advertising of tobacco products, various stakeholders have raised concerns that these practices may increase illegal sales of ENDS to minors due to enforcement challenges in virtual environments. FDA is statutorily authorized to promulgate regulations on the advertising and sale of tobacco products. However, regulatory gaps and barriers to enforcement remain, primarily centering on challenges with ENDS messaging to youth on social media, discreet shipping of ENDS products sold online to minors, and adequate remote age verification measures for ENDS purchases.
- **ENDS User Fees.** Though ENDS products represent an increasing proportion of CTP's received applications and regulatory activities, FDA is not authorized to collect user fees from ENDS manufacturers and importers. Consequently, CTP has dedicated a portion of its user fees paid by other tobacco product class manufacturers and importers to address ENDS-specific issues. Numerous parties have suggested that manufacturers and importers of ENDS products be subject to tobacco user fees to offset costs associated with FDA's current and future ENDS-specific activities.

These selected issues are discussed in greater detail below, along with potential considerations for policymakers.[49]

Flow of Illicit ENDS into the United States

In recent years, there has been an influx of illicit ENDS devices brought into the United States and illegally sold in stores. Reporting indicates that the majority of these illicit products are disposable ENDS, many of which are flavored, manufactured in the People's Republic of China (China).[50] In October 2022, China banned the domestic sale of all non-tobacco-flavored e-cigarettes, though manufacturers have still been able to export non-tobacco-flavored e-cigarettes to other countries.[51] The TCA amended the FFDCA to grant FDA the authority to prevent the trade of illicit tobacco products through a variety of means; however, the surge in illicit ENDS brought into the United States has overwhelmed CTP's enforcement efforts to date. At the time of this report's publication, 34 ENDS products and devices may legally be sold in the United States; however, thousands more may be illegally found in stores and available for purchase. Through a

[49] Policy issues with respect to other tobacco products are outside the scope of this report. For more information on tobacco products, see CRS Report R45867, *FDA Regulation of Tobacco Products*.

[50] Matthew Perrone, "Thousands of Unauthorized Vapes are Pouring into the US Despite the FDA Crackdown on Fruity Flavors," *The Associated Press (AP)*, June 26, 2023, https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f. Additional reporting states that more than 90% of the world's vapes, as of December 6, 2023, are manufactured in China. China banned the domestic sale of all flavored vaping products in 2022. Chris Kirkham and David Kirton, "China E-Cigarette Titan Behind 'Elf Bar' Floods the US with Illegal Vapes," *Reuters*, December 6, 2023, https://www.reuters.com/world/china/china-e-cigarette-titan-behind-elf-bar-floods-us-with-illegal-vapes-2023-12-06/.

[51] Chris Kirkham and David Kirton, "China E-Cigarette Titan Behind 'Elf Bar' Floods the US with Illegal Vapes," *Reuters*, December 6, 2023, https://www.reuters.com/world/china/china-e-cigarette-titan-behind-elf-bar-floods-us-with-illegal-vapes-2023-12-06/; Meng Lyu et al., "The Impact of New Regulations on Prevention and Control of E-Cigarettes on Adolescents in Middle Schools—A City in China, 2022-2023," *China CDC Weekly*, vol. 6, no. 14 (April 5, 2024), p. 289, https://pmc.ncbi.nlm.nih.gov/articles/PMC11018711/pdf/ccdcw-6-14-289.pdf.

number of congressional hearings[52] and other evaluative documents,[53] multiple related potential gaps in regulation have been raised and examined.

Potential regulatory gaps associated with the flow of illicit ENDS into the United States include the ubiquity of specifically disposable ENDS products, ineffective FDA import alerts, a lack of foreign facility registration, and CTP's lack of resources.

A variety of stakeholders have asserted that a loophole exists regarding enforcement efforts against specifically disposable ENDS products, which are also the most used ENDS products among youth.[54] This assertion stems from a guidance document, initially released in January 2020, and later revised in April 2020, by FDA entitled *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*: Guidance for Industry*.[55] Footnote 21 of the guidance document notes that "completely self-contained, disposable vapes" are not captured in the definition of "cartridge-based ENDS products," the latter being identified in the guidance as one of CTP's top enforcement priorities in the ENDS space.[56] When asked about whether this document created a loophole for disposable ENDS products, CTP's then-director, Dr. Brian King, said that "there's no loophole to close," and that FDA already has the authority to regulate disposable ENDS products and has recently shifted its focus to do so.[57] There has been at least one legislative effort to have FDA revise its guidance document to reflect prioritizing enforcement against specifically disposable ENDS products.[58]

Some stakeholders have identified potential regulatory gaps during the entry stage of illicit ENDS products being brought into the United States. Tobacco products imported or offered for import

[52] See, for example, U.S. Congress, House Committee on Oversight and Accountability, *Oversight of the U.S. Food and Drug Administration*, hearings, 118th Cong., 2nd sess., April 11, 2024, H.Hrg. 118-99; U.S. Congress, House Committee on Appropriations, *Fiscal Year 2025 Budget Request for the Food and Drug Administration*, hearings, 118th Cong., 2nd sess., April 18, 2024; U.S. Congress, Senate Committee on the Judiciary, *Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes*, hearings, 118th Cong., 2nd sess., June 12, 2024; U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health, *Evaluating FDA Human Foods and Tobacco Programs*, hearings, 118th Cong., 2nd sess., September 10, 2024.

[53] See, for example, FDA, *Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard*, March 15, 2018, https://www.fda.gov/files/tobacco%20products/published/Illicit-Trade-in-Tobacco-Products-After-Implementation-of-an-FDA-Product-Standard.pdf; George Jepsen et al., *Re: Docket No. FDA-2018-N-0529, Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard*, July 16, 2018, https://oag.ca.gov/sites/all/files/agweb/pdfs/tobacco/ag-illicit-trade-letter-fda-071618.pdf; Lauren Silvis et al., *Operational Evaluation of Certain Components of FDA's Tobacco Program*, Reagan-Udall Foundation, December 2022, https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf.

[54] Eunice Park-Lee et al., "*Notes from the Field*: E-Cigarette and Nicotine Pouch Use Among Middle and High School Students—United States, 2024," *Morbidity and Mortality Weekly Report (MMWR)*, vol. 73, no. 35 (September 5, 2024), p. 774, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf; Ahmed Jamal et al., "Tobacco Product Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2024," *MMWR*, vol. 73, no. 41 (October 17, 2024), p. 917, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7341a2-H.pdf.

[55] FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*: Guidance for Industry*, April 2020, p. 37, https://www.fda.gov/media/133880/download.

[56] FDA, *Enforcement Priorities for ENDS*, pp. 3, 9.

[57] Matthew Perrone, "Thousands of Unauthorized Vapes are Pouring into the US Despite the FDA Crackdown on Fruity Flavors," *AP*, June 26, 2023, https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f. Under FFDCA Section 902, any tobacco product sold without a marketing authorization is considered adulterated and thus illegal and at risk of enforcement. This includes unauthorized disposable ENDS. For more information on enforcement under the FFDCA, see CRS Report R43609, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues*.

[58] H.R. 901.

into the United States must comply with all relevant domestic requirements, including receipt of a marketing authorization from FDA. At the time of importation, FDA verifies that all necessary requirements have been met via label examinations and importer-submitted data entry screenings.[59] Labels and data entries must include certain specified information, such as the name and place of business of the relevant tobacco product manufacturer and a product description.[60] Under Section 801(a) of the FFDCA, FDA has the authority to issue import alerts regarding certain products. If a tobacco product or manufacturer has a known history of violations, an import alert may be issued, indicating that FDA may detain future shipments upon entry without first physically testing or examining its contents (this is known as "detention without physical exam" [DWPE]).[61]

While import alerts are theoretically a powerful tool at FDA's disposal, many industry experts agree that such alerts are easy to circumvent.[62] There have been numerous reports of illicit ENDS product manufacturers simply renaming their companies or misrepresenting the contents of shipments (e.g., as shoes, toys) to avoid detection and DWPE.[63] Under FFDCA Section 920(b), FDA is directed to, by regulation, "require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system."[64] Some stakeholders have asserted that the creation of such a system would "enable regulators to ascertain exactly where there is leakage in the system and to focus enforcement efforts in those areas," thus "reduc[ing] the quantity of non-compliant tobacco products in circulation."[65] Though FDA has issued proposed rules that contain provisions that may influence tracking and tracing certain tobacco products at particular stages in the commercial environment, they do not reference the FFDCA Section 920(b) authority in particular and have not been finalized.[66]

Stakeholders have identified an additional factor that may complicate detecting illicit ENDS products during entry into the United States: a lack of foreign facility registration.[67] Under

[59] FDA, "Transmitting Required Information," October 9, 2024, https://www.fda.gov/industry/entry-submission/transmitting-required-information.

[60] FDA, "Importing Tobacco Products," October 9, 2024, https://www.fda.gov/industry/importing-fda-regulated-products/importing-tobacco-products.

[61] FDA, "Import Alerts," October 9, 2024, https://www.fda.gov/industry/actions-enforcement/import-alerts; FDA, "FDA Updates Import Alerts to Reinforce that All Unauthorized E-Cigarettes May Be Detained Without Physical Examination," https://www.fda.gov/tobacco-products/ctp-newsroom/fda-updates-import-alerts-reinforce-all-unauthorized-e-cigarettes-may-be-detained-without-physical.

[62] Matthew Perrone, "Thousands of Unauthorized Vapes are Pouring into the US Despite the FDA Crackdown on Fruity Flavors," *AP*, June 26, 2023, https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f.

[63] Matthew Perrone, "Thousands of Unauthorized Vapes are Pouring into the US"; Matthew Perrone and AP, "The FDA is Losing a Whack-A-Mole Contest with Illegal Chinese E-Cigarettes as Health Experts Warn of More Teens Getting 'Addicted to Nicotine,'" *Fortune*, December 30, 2023, https://fortune.com/2023/12/30/fda-electronic-cigarettes-china-vaping-teens-health-warnings-nicotine-addiction/.

[64] FFDCA §920(b)(3).

[65] George Jepsen et al., *Re: Docket No. FDA-2018-N-0529, Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard*, July 16, 2018, p. 5, https://oag.ca.gov/sites/all/files/agweb/pdfs/tobacco/ag-illicit-trade-letter-fda-071618.pdf.

[66] See, for example, FDA, "Requirements for Tobacco Product Manufacturing Practice," 88 *Federal Register* 15174, March 10, 2023, https://www.govinfo.gov/content/pkg/FR-2023-03-10/pdf/2023-04591.pdf; FDA, "Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Certain Tobacco Products," 89 *Federal Register* 66647, August 16, 2024, https://www.govinfo.gov/content/pkg/FR-2024-08-16/pdf/2024-18343.pdf.

[67] Matthew Perrone, "Thousands of Unauthorized Vapes are Pouring into the US Despite the FDA Crackdown on (continued...)

FFDCA Section 905 subsections (b) through (d), any establishment that manufactures, prepares, compounds, or processes tobacco products within the United States must register with FDA. These domestic facilities are subsequently subject to biennial inspections, which facilitates the detection of illicit tobacco products.[68] Under FFDCA Section 905(h), FDA also has the authority to require that foreign facilities register with FDA if "adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable [FDA] to determine … whether tobacco products manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission." However, the exercise of this authority is dependent upon FDA rulemaking outlining such procedures.[69] To date,[70] FDA has not proposed or published such regulations. However, FDA has repeatedly published an entry in the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda) since the fall 2017 edition that appears would in part address foreign facility registration.[71] The most recent entry, published in the fall 2024 edition of the Unified Agenda, indicates that a notice of proposed rulemaking on the subject is now slated for May 2025.[72] However, President Trump's memorandum "Regulatory Freeze Pending Review" may affect this timeline.[73]

Certain stakeholders have also asserted that FDA's ability to efficiently regulate the flow of illicit ENDS products into the United States and enforce such requirements has been impeded by a lack of resources.[74] According to FDA, the agency "uses a comprehensive approach to tobacco product compliance and enforcement, taking action against those in the supply chain that violate the law, including manufacturers, importers, distributors[,] and retailers."[75] Consistent with many other administrative agencies, however, FDA cannot unilaterally bring enforcement actions to court.[76] Instead, FDA must work in tandem with the Department of Justice (DOJ), in addition to multiple other agencies, throughout the process of enforcing against the movement of illicit ENDS into the United States.[77] In the 2022 Reagan-Udall Foundation report, an independent report

Fruity Flavors," *AP*, June 26, 2023, https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f.

[68] FFDCA §905(g).

[69] FFDCA §905(h).

[70] See footnote 2 in FDA, *Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised*): Guidance for Industry*, March 2023, p. 1, https://www.fda.gov/media/78165/download.

[71] U.S. General Services Administration (GSA) and Office of Management and Budget (OMB), *Establishment Registration and Product Listing for Tobacco Products*, Fall 2017, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201710&RIN=0910-AH59.

[72] GSA and OMB, *Establishment Registration and Product Listing for Tobacco Products*, Fall 2024, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202410&RIN=0910-AH59.

[73] White House, "Regulatory Freeze Pending Review," presidential memorandum, January 28, 2025, https://www.govinfo.gov/content/pkg/FR-2025-01-28/pdf/2025-01906.pdf.

[74] See, for example, Lauren Silvis et al., *Operational Evaluation of Certain Components of FDA's Tobacco Program*, Reagan-Udall Foundation, December 2022, p. 24, https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf; Chris Kirkham and David Kirton, "China E-Cigarette Titan Behind 'Elf Bar' Floods the US with Illegal Vapes," *Reuters*, December 6, 2023, https://www.reuters.com/world/china/china-e-cigarette-titan-behind-elf-bar-floods-us-with-illegal-vapes-2023-12-06/.

[75] FDA, "Joint Federal Operation Results in Seizure of More Than $18 Million in Illegal E-Cigarettes," December 14, 2023, https://www.fda.gov/news-events/press-announcements/joint-federal-operation-results-seizure-more-18-million-illegal-e-cigarettes.

[76] Lauren Silvis et al., *Operational Evaluation of Certain Components of FDA's Tobacco Program*, Reagan-Udall Foundation, December 2022, p. 22, https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf.

[77] For example, FDA may also need to work with the Department of Homeland Security (Customs and Border (continued...)

commissioned by FDA to assess its tobacco regulation operations, evaluators recommended that FDA create an interagency task force to better coordinate enforcement activities and pool agency resources.[78] FDA announced the creation of such a task force in June 2024, noting that members included DOJ; the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF); the U.S. Marshals Service (USMS); the U.S. Postal Inspection Service (USPIS); and the Federal Trade Commission (FTC).[79] FDA's news release noted that other agencies may join the task force in the future.[80] Since its formation, the task force has publicized multiple enforcement actions.[81]

Congress has held multiple hearings and introduced legislation related to mitigating the flow of illicit ENDS into the United States.[82] Though FDA has taken certain steps, such as promulgating the proposed rules and forming the interagency task force mentioned above, some stakeholders have asserted FDA is not moving rapidly enough to clear the market of illicit ENDS.[83] Congress may consider proposals expediting FDA's rulemaking process regarding the tracking and tracing of tobacco products and the registration of foreign facilities. Congress may also consider directing the interagency task force to evaluate federal legislative options for further streamlining enforcement efforts and increasing the severity of penalties.[84] Alternatively, Congress may choose not to act and instead rely on FDA and the interagency task force to adjust their enforcement efforts.

ENDS as a Harm Reduction Tool

Since the mid-2000s emergence of ENDS products in the U.S. marketplace, there has been ongoing debate regarding their public health impact.[85] This debate has implications for how such products may be regulated. Some data suggest that ENDS products may serve as a harm reduction tool for certain tobacco smokers.[86] Harm reduction strategies "attempt … to diminish the

Protection) and the Department of the Treasury (Alcohol and Tobacco Tax and Trade Bureau) throughout this process. Lauren Silvis et al., *Operational Evaluation of FDA's Tobacco Program*, p. 24.

[78] Lauren Silvis et al., *Operational Evaluation of FDA's Tobacco Program*, p. 24.

[79] FDA, "Justice Department and FDA Announce Federal Multi-Agency Task Force to Curb the Distribution and Sale of Illegal E-Cigarettes," June 10, 2024, https://www.fda.gov/news-events/press-announcements/justice-department-and-fda-announce-federal-multi-agency-task-force-curb-distribution-and-sale.

[80] FDA, "Justice Department and FDA Announce Federal Multi-Agency Task Force."

[81] See, for example, FDA, "$76 Million in Illegal E-Cigarettes Seized in Joint Federal Operation," October 22, 2024, https://www.fda.gov/news-events/press-announcements/76-million-illegal-e-cigarettes-seized-joint-federal-operation; FDA, "More Than $7 Million Worth of Illegal E-Cigarettes Seized in Federal Operation," January 10, 2025, https://www.fda.gov/tobacco-products/ctp-newsroom/more-7-million-worth-illegal-e-cigarettes-seized-federal-operation.

[82] See, for example, U.S. Congress, Senate Committee on the Judiciary, *Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes*, hearings, 118th Cong., 2nd sess., June 12, 2024; U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health, *Evaluating FDA Human Foods and Tobacco Programs*, 118th Cong., 2nd sess., September 10, 2024; H.R. 7715.

[83] See, for example, Debbie Wasserman Schultz et al., letter to FDA calling for action on illegal e-cigarette products on shelves, October 16, 2024, p. 2, https://wassermanschultz.house.gov/uploadedfiles/fdaletter.pdf.

[84] Lauren Silvis et al., *Operational Evaluation of Certain Components of FDA's Tobacco Program*, Reagan-Udall Foundation, December 2022, p. 24, https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf.

[85] CDC, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, 2016, p. 10, https://www.ncbi.nlm.nih.gov/books/NBK538680/pdf/Bookshelf_NBK538680.pdf.

[86] See, for example, Caitlin Notley et al., "The Unique Contribution of E-Cigarettes for Tobacco Harm Reduction in Supporting Smoking Relapse Prevention," *Harm Reduction Journal*, vol. 15, no. 31 (June 20, 2018), https://harmreductionjournal.biomedcentral.com/counter/pdf/10.1186/s12954-018-0237-7.pdf; Katie Myers Smith et (continued...)

damaging effects of a particular behavior without aiming to eliminate the behavior itself" because elimination of the original activity is difficult or infeasible.[87] Some in the public health community view ENDS as a harm reduction tool for adults who smoke cigarettes.[88] Specifically, ENDS products may be able to reduce harm among adult cigarette smokers who have experienced difficulty quitting, as the aerosol from ENDS "contains fewer numbers and lower levels of most toxicants than does smoke from combustible tobacco cigarettes."[89]

Data regarding the effectiveness of ENDS as a harm reduction or cessation tool are complex. In 2018, the National Academies of Sciences, Engineering, and Medicine (NASEM) concluded that "there is general agreement that the number, size, and quality of studies for judging the effectiveness of e-cigarettes as cessation aids in comparison with cessation aids of proven efficacy are limited, and therefore there is insufficient evidence to permit a definitive conclusion at this time."[90] NASEM also reported that the long-term health effects associated with ENDS use are unclear.[91] To date, FDA has not approved any ENDS products as cessation devices.[92] However, FDA has stated that "e-cigarettes can generally be a lower-risk alternative for adults who smoke cigarettes," but that "further high-quality research on both short- and long-term health outcomes is needed."[93] Additionally, CDC has noted that "a number of studies suggest that e-cigarettes with nicotine may help adults quit smoking compared with e-cigarettes without nicotine or no treatment," though the agency also notes that long-term health effects of e-cigarettes are uncertain.[94] One of the studies referenced by CDC is a 2020 Surgeon General report which found that "evidence is suggestive but not sufficient to infer that the use of e-cigarettes containing nicotine is associated with increased smoking cessation compared with the use of e-cigarettes not containing nicotine, and the evidence is suggestive but not sufficient to infer that more frequent use of e-cigarettes is associated with increased smoking cessation compared with less frequent

al., "E-Cigarettes Versus Nicotine Replacement Treatment as Harm Reduction Interventions for Smokers Who Find Quitting Difficult: Randomized Controlled Trial," *Addiction*, vol. 117, no. 1 (January 2022), https://onlinelibrary.wiley.com/doi/epdf/10.1111/add.15628; Nicola Lindson et al., "Electronic Cigarettes for Smoking Cessation," *Cochrane Database of Systematic Reviews*, vol. 1, no. 1 (January 29, 2025), p. 41, https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub9/epdf/full.

[87] NASEM, *Public Health Consequences of E-Cigarettes*, 2018, pp. 589-590, https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf.

[88] See, for example, Thomas J. Glynn et al., "E-Cigarettes, Harm Reduction, and Tobacco Control: A Path Forward?," *Mayo Clinic Proceedings*, vol. 96, no. 4 (April 2021), https://www.mayoclinicproceedings.org/article/S0025-6196(20)31382-3/pdf; Ann McNeill et al., *Nicotine Vaping in England: An Evidence Update Including Health Risks and Perceptions, 2022: A Report Commissioned by the Office for Health Improvement and Disparities*, King's College London, September 29, 2022, pp. 76, 1264, https://assets.publishing.service.gov.uk/media/633469fc8fa8f5066d28e1a2/Nicotine-vaping-in-England-2022-report.pdf.

[89] NASEM, *Public Health Consequences of E-Cigarettes*, 2018, p. 1, https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf.

[90] NASEM, *Public Health Consequences of E-Cigarettes*, p. 579.

[91] NASEM, *Public Health Consequences of E-Cigarettes*, p. 221.

[92] FDA approval of ENDS devices as smoking cessation products would require regulatory approval not discussed at length in this report. While e-cigarettes not marketed for medical purposes are regulated by CTP as tobacco products, ENDS devices making smoking cessation claims would be required to demonstrate scientifically to FDA's Center for Drug Evaluation and Research that a specific ENDS product is safe and effective for users. See Benjamin A. Toll et al., "Nicotine E-Cigarettes: Considerations for Healthcare Providers," *Nature Medicine*, vol. 30, (2024), p. 1513, https://rdcu.be/d9vGF.

[93] FDA, "The Relative Risks of Tobacco Products," January 16, 2025, https://www.fda.gov/tobacco-products/health-effects-tobacco-use/relative-risks-tobacco-products.

[94] CDC, "Vaping and Quitting," May 15, 2024, https://www.cdc.gov/tobacco/e-cigarettes/quitting.html.

use of e-cigarettes."[95] Conversely, a report published in 2022 commissioned by the United Kingdom's Department of Health and Social Care asserted that "extant research evidence is sufficient to promote vaping products for smoking cessation and tobacco harm reduction."[96] This lack of consensus continues to cause debate among those in the public health field regarding ENDS as harm reduction tools.[97]

Various stakeholders have concluded that additional information is needed to assess the harm-reduction benefits, if any, of ENDS products. To help inform future regulatory standards for such products, Congress may consider directing federal agencies such as CDC and the National Institutes of Health (NIH) to expand studies researching the potential of ENDS products as cessation devices and harm reduction tools.

Additionally, some stakeholders have expressed concern that educational information directed at adult smokers about harm reduction and ENDS is lacking due to a primary focus on preventing youth ENDS use. In the 2022 Reagan-Udall Foundation report, evaluators noted that CTP's mission is to "not only … protect Americans by regulating the manufacturing, distribution, and marketing of tobacco products but also by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others."[98] While the authors of the report acknowledged CTP's published educational resources and efforts aimed at youth tobacco use prevention, they also mentioned that "many stakeholders stated that additional truthful and accurate information to help adult consumers make informed decisions about the role of nicotine and the risks of combustible and smoke-free products is needed," especially regarding e-cigarettes as a harm reduction tool and the relative risk of different tobacco products.[99] This concern builds upon long-standing similar stakeholder comments, including one from the former Surgeon General C. Everett Koop, who stated in a 1998 opinion piece that "we must not focus our efforts so narrowly on preventing tobacco use by youth that we send smokers the message that we have abandoned them."[100]

FDA's CTP responded to the Reagan-Udall Foundation's report by launching a funding opportunity in 2023 for research on messaging about the continuum of risk for tobacco products, publishing resources regarding the relative risk of tobacco products, and planning to further improve its public health educational materials for adults.[101] If Congress decides to bolster these

[95] CDC, *Smoking Cessation: A Report of the Surgeon General*, 2020, p. 547, https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf.

[96] Ann McNeill et al., *Nicotine Vaping in England: An Evidence Update Including Health Risks and Perceptions, 2022: A Report Commissioned by the Office for Health Improvement and Disparities*, King's College London, September 29, 2022, pp. 76, 1264, https://assets.publishing.service.gov.uk/media/633469fc8fa8f5066d28e1a2/Nicotine-vaping-in-England-2022-report.pdf.

[97] See, for example, Stopping Tobacco Organization and Products (STOP) and World Health Organization (WHO), *Hooking the Next Generation: How the Tobacco Industry Captures Young Customers*, 2024, p. 9, https://iris.who.int/bitstream/handle/10665/376853/9789240094642-eng.pdf?sequence=1; Physicians Research Institute (PRI), "Harm Reduction," March 15, 2023, https://www.physiciansresearchinstitute.org/harm-reduction/.

[98] Lauren Silvis et al., *Operational Evaluation of Certain Components of FDA's Tobacco Program*, Reagan-Udall Foundation, December 2022, p. 26, https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf.

[99] Lauren Silvis et al., *Operational Evaluation of FDA's Tobacco Program*, p. 26.

[100] C. Everett Koop, "Don't Forget the Smokers," *The Washington Post*, March 8, 1998, https://www.washingtonpost.com/archive/opinions/1998/03/08/dont-forget-the-smokers/3560fbed-880a-45ff-8669-110fd8b63509/.

[101] FDA, "An All-Center Approach: CTP's Response to the Reagan-Udall Foundation Evaluation Report," February 24, 2023, https://web.archive.org/web/20250119042609/https://www.fda.gov/tobacco-products/ctp-newsroom/all-center-approach-ctps-response-reagan-udall-foundation-evaluation-report; FDA, "CTP's Progress Addressing (continued...)

efforts, it may consider specifically tasking FDA with further expanding public education campaigns and informational materials that focus on the use of ENDS as a harm reduction tool for adult smokers and the relative risk of different tobacco products.

Flavored ENDS Regulation

The regulation of flavors in ENDS products is complicated by several factors.[102] Some in the public health community are alarmed by the number of youth using ENDS products, which remain the most popular tobacco product for this age group.[103] Research studies suggest that this usage occurs, in large part, due to access to flavored ENDS products.[104] Numerous studies have documented that flavors may entice youth to initiate and continue using tobacco products,[105] including ENDS.[106] However, some studies also indicate that adult cigarette smokers may be drawn to flavored ENDS as a way to quit cigarette smoking.[107] FDA alluded to this in its announcement regarding the authorization of four menthol-flavored ENDS products, noting that "evidence submitted by the applicant showed that the menthol-flavored products provided a benefit for adults who smoke cigarettes relative to that of the applicant's previously authorized

Recommendations form the Reagan-Udall Evaluation: Summer 2023 Update," June 29, 2023, https://web.archive.org/web/20241211211320/https://www.fda.gov/tobacco-products/ctp-newsroom/ctps-progress-addressing-recommendations-reagan-udall-evaluation; FDA, "CTP's Progress Addressing Recommendations from the Reagan-Udall Evaluation: Fall 2023 Update," October 27, 2023, https://web.archive.org/web/20241224113103/https://www.fda.gov/tobacco-products/ctp-newsroom/ctps-progress-addressing-recommendations-reagan-udall-evaluation-0; FDA, "Actions to Address Recommendations from the Reagan-Udall Evaluation of CTP," July 3, 2024, https://web.archive.org/web/20250122193528/https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/actions-address-recommendations-reagan-udall-evaluation-ctp; FDA, "A Year in Review: FDA's Progress on Tobacco Product Regulation in 2024," January 14, 2025, https://www.fda.gov/tobacco-products/ctp-newsroom/year-review-fdas-progress-tobacco-product-regulation-2024.

[102] Flavors may include tobacco and menthol, as well as more novel flavors like fruits and various sweets.

[103] Eunice Park-Lee et al., "*Notes from the Field*: E-Cigarette and Nicotine Pouch Use Among Middle and High School Students—United States, 2024," *MMWR*, vol. 73, no. 35 (September 5, 2024), p. 778, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf; Ahmed Jamal et al., "Tobacco Product Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2024," *MMWR*, vol. 73, no. 41 (October 17, 2024), p. 917, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7341a2-H.pdf.

[104] Eunice Park-Lee et al., "*Notes from the Field*: E-Cigarette and Nicotine Pouch Use Among Middle and High School Students—United States, 2024," *MMWR*, vol. 73, no. 35 (September 5, 2024), p. 774, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf; Ahmed Jamal et al., "Tobacco Product Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2024," *MMWR*, vol. 73, no. 41 (October 17, 2024), p. 924, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7341a2-H.pdf; FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*: Guidance for Industry*, April 2020, pp. 13-15, https://www.fda.gov/media/133880/download.

[105] CDC, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, 2012, pp. 205, 537-539, https://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf_NBK99237.pdf; Andrea C. Villanti, "Association of Flavored Tobacco Use With Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015," *JAMA Network Open*, vol. 2, no. 10 (October 2, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6820032/.

[106] CDC, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, 2016, pp. 58-59, https://www.ncbi.nlm.nih.gov/books/NBK538680/pdf/Bookshelf_NBK538680.pdf.

[107] See, for example, David L. Ashley et al., "E-Cigarettes: How Can They Help Smokers Quit Without Addicting a New Generation?," *Preventive Medicine*, vol. 140 (November 2020), p. 3, https://www.sciencedirect.com/science/article/pii/S0091743520301699/pdfft?md5=5ea2253de77167520f6002148b8f7b68&pid=1-s2.0-S0091743520301699-main.pdf; Abigail T. Evans et al., "What Motivates Smokers to Switch to ENDS? A Qualitative Study of Perceptions and Use," *International Journal of Environmental Research and Public Health*, vol. 17, no. 23 (2020), p. 13, https://pmc.ncbi.nlm.nih.gov/articles/PMC7729446/pdf/ijerph-17-08865.pdf.

tobacco-flavored products—in terms of complete switching—that is sufficient to outweigh the risks of the product, including youth appeal."[108]

Scientific findings remain mixed regarding whether adult use of non-tobacco flavored or tobacco-flavored ENDS products lead to higher successful smoking quit rates. Some studies indicate that the use of non-tobacco flavored ENDS products is more positively correlated with successful cigarette smoking cessation attempts compared with attempts made with tobacco-flavored ENDS products.[109] Two systematic reviews of the literature found a link was inconclusive between flavored ENDS and more successful cigarette smoking cessation attempts (compared with nonflavored ENDS and more successful cigarette smoking cessation attempts).[110] In turn, some industry-funded research has suggested that flavored ENDS products may help adult cigarette smokers quit cigarette smoking more successfully than tobacco-flavored ENDS products.[111]

In March 2019, FDA released a draft guidance document specifying its intended enforcement activities related to flavored ENDS.[112] This guidance in part specified that FDA would prioritize enforcement of premarket review, distribution, and sale requirements related to certain flavored ENDS products that may be most accessible to youth.[113] For example, FDA would prioritize enforcement of distribution and sale requirements in retail locations where certain flavored ENDS products may be most accessible to youth, such as convenience stores and gas stations that do not have adult-only sections.[114] In September 2019, FDA announced that it would finalize this guidance document "in the coming weeks," with the intention of clearing "the market of flavored e-cigarettes to reverse the deeply concerning epidemic of youth e-cigarette use."[115] Delays in guidance finalization led to a congressional hearing on December 4, 2019, to investigate the cause

[108] FDA, "FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products After Extensive Scientific Review," news release, June 21, 2024, https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-four-menthol-flavored-e-cigarette-products-after-extensive-scientific.

[109] See, for example, Yoonseo Mok et al., "Associations Between E-cigarette Use and E-cigarette Flavors With Cigarette Smoking Quit Attempts and Quit Success: Evidence From a U.S. Large, Nationally Representative 2018-2019 Survey," *Nicotine & Tobacco Research*, vol. 25, no. 3 (March 2023), pp. 449-550, https://pmc.ncbi.nlm.nih.gov/articles/PMC9910159/pdf/ntac241.pdf; Abigail S. Friedman and SiQing Xu, "Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation," *JAMA Network Open*, vol. 3, no. 6 (2020), pp. 8-9, https://jamanetwork.com/journals/jamanetworkopen/articlepdf/2766787/friedman_2020_oi_200180.pdf.

[110] Samane Zare et al., "A Systematic Review of Consumer Preference for e-Cigarette Attributes: Flavor, Nicotine Strength, and Type," *PLoS ONE*, vol. 13, no. 3 (2018), pp. 1, 9, https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0194145&type=printable; Alex C. Liber et al., "The Role of Flavored Electronic Nicotine Delivery Systems in Smoking Cessation: A Systematic Review," *Drug and Alcohol Dependence Reports*, vol. 7 (June 2023), pp. 1, 10, https://www.sciencedirect.com/science/article/pii/S2772724623000136/pdfft?md5=a67b2880cb2dafdcb7117c9ae9846ecd&pid=1-s2.0-S2772724623000136-main.pdf.

[111] See, for example, Christopher Russell, Farhana Haseen, Neil McKeganey, "Factors Associated With Past 30-Day Abstinence from Cigarette Smoking in a Non-Probabilistic Sample of 15,456 Adult Established Current Smokers in the United States Who Used JUUL Vapor Products for Three Months," *Harm Reduction Journal*, vol. 16, no. 22 (2019), pp. 1, 13-15, https://harmreductionjournal.biomedcentral.com/counter/pdf/10.1186/s12954-019-0293-7.pdf.

[112] FDA, *Modifications to Compliance Policy for Certain Deemed Tobacco Products: Guidance for Industry (Draft Guidance)*, March 2019, https://web.archive.org/web/20190317232854/https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM633281.pdf.

[113] FDA, *Modifications to Compliance Policy for Certain Deemed Tobacco Products*, p. 6.

[114] FDA, *Modifications to Compliance Policy for Certain Deemed Tobacco Products*, pp. 11, 13.

[115] FDA, "Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products," September 11, 2019, https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non.

for delay.[116] During this hearing, Mitch Zeller, the then-director for FDA's CTP, in part cited as cause for the delay "ongoing policy-related discussions between the agency, the department, and the White House about what the policy should be."[117]

In January 2020, with a subsequent update in April 2020, FDA released the final guidance document,[118] which included some changes to the draft guidance. Specifically, the March 2019 draft guidance focused enforcement of premarket authorization requirements on how and where ENDS products are sold, whereas the final guidance focuses such enforcement on

- "any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- all other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors."[119]

Some public health stakeholders expressed concern that the final guidance does not go far enough to reduce ENDS use among youth.[120]

In April 2021, FDA released a statement outlining its intent to issue two proposed product standards, one to ban menthol in cigarettes and another to ban all characterizing flavors[121] in cigars.[122] On May 4, 2022, both proposed rules were published in the *Federal Register*.[123] Neither of these proposed rules, however, contemplated banning characterizing flavors in ENDS products specifically.[124] On April 26, 2024, there were reports of the Biden Administration choosing to take more time to consider the proposed menthol ban rule, with then-HHS Secretary Xavier Becerra

[116] U.S. Congress, House Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, *The Federal Response to the Epidemic of E-Cigarette Use, Especially Among Children, and the Food and Drug Administration's Compliance Policy*, 116th Cong., 1st sess., December 4, 2019.

[117] Testimony of U.S. FDA CTP Director Mitch Zeller, in U.S. Congress, House Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, *The Federal Response to the Epidemic of E-Cigarette Use, Especially Among Children, and the Food and Drug Administration's Compliance Policy*, hearings, 116th Cong., 1st sess., December 4, 2019, H.Hrg. 116-74.

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

[119] FDA, *Enforcement Priorities for ENDS*, p. 3.

[120] See, for example, Abby Goodnough et al., "With Partial Flavor Ban, Trump Splits the Difference on Vaping," *The New York Times*, January 2, 2020, https://www.nytimes.com/2020/01/02/health/flavor-ban-e-cigarettes.html.

[121] Characterizing flavors are generally defined as those that smell or taste noticeably differently than tobacco, such as "vanilla," "candy," or "fruit." See Theresa Patten, Mariella De Biasi, "History Repeats Itself: Role of Characterizing Flavors on Nicotine Use and Abuse," *Neuropharmacology*, vol. 177 (October 15, 2020), https://www.sciencedirect.com/science/article/abs/pii/S0028390820302306.

[122] FDA, "FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers," press release, April 29, 2021, https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers.

[123] FDA, "Tobacco Product Standard for Menthol in Cigarettes," 87 *Federal Register* 26454, May 4, 2022, https://www.govinfo.gov/content/pkg/FR-2022-05-04/pdf/2022-08994.pdf; FDA, "Tobacco Product Standard for Characterizing Flavors in Cigars," 87 *Federal Register* 26396, May 4, 2022, https://www.govinfo.gov/content/pkg/FR-2022-05-04/pdf/2022-08993.pdf.

[124] FDA, "Tobacco Product Standard for Menthol in Cigarettes," 87 *Federal Register* 26454, 26473, May 4, 2022, https://www.govinfo.gov/content/pkg/FR-2022-05-04/pdf/2022-08994.pdf; FDA, "Tobacco Product Standard for Characterizing Flavors in Cigars," 87 *Federal Register* 26396, 26435, May 4, 2022, https://www.govinfo.gov/content/pkg/FR-2022-05-04/pdf/2022-08993.pdf.

stating that "this rule has garnered historic attention and the public comment period has yielded an immense amount of feedback…. It's clear that there are still more conversations to have, and that will take significantly more time."[125] On January 21, 2025, the Trump Administration formally withdrew both proposed product standards.[126]

In response to concerns regarding youth access to ENDS products, including flavored products, Congress may consider further limiting the use of flavors in ENDS. In addition, Congress may consider proposals aimed at reducing use of any tobacco product type, including ENDS, among youth, while leaving open the option of ENDS use for adult cigarette smokers, given the possible public health benefit. Congress may also consider how availability of flavored tobacco products would fit into those proposals. Alternatively, Congress may choose not to act and instead rely on FDA to determine whether recent measures have had their intended effects.

ENDS E-Liquid Composition and Contamination

E-liquids may contain a number of substances, both intentionally and unintentionally present, that could contribute to respiratory irritation and other health complications. Selected studies have found microbial toxin contaminants in certain e-liquid products,[127] while other research has identified unexpected or illicit substances in e-liquids that could harm consumers, especially when aerosolized.[128]

For example, some ENDS solutions contain tetrahydrocannabinol (THC), the primary psychoactive compound, or cannabinoid, found in marijuana.[129] Such THC-containing products, in particular those available in states that permit the sale of marijuana for recreational or medicinal purposes, may raise questions regarding federal oversight. Marijuana—including marijuana-derived compounds such as THC—is an illicit substance at the federal level subject to U.S. Drug Enforcement Administration (DEA) enforcement and regulatory control.[130] However, some states have implemented their own laws pertaining to recreational and medicinal marijuana use, and DEA has largely focused resources on criminal networks involved in the illicit marijuana trade.[131] In some cases, certain aerosol delivery systems (e.g., vaporizers) may comprise

[125] See, for example, Dan Diamond, "Biden Administration Delays Menthol Cigarette Ban Again Amid Political Concerns," *The Washington Post*, April 26, 2024, https://www.washingtonpost.com/health/2024/04/26/menthol-cigarette-ban-delayed-biden-administration/; HHS, "Secretary Becerra Statement on the Proposed Menthol Cigarette Rule," press release, April 26, 2024, https://web.archive.org/web/20240427003817/https://www.hhs.gov/about/news/2024/04/26/secretary-becerra-statement-proposed-menthol-cigarette-rule.html.

[126] GSA and OMB, *Tobacco Product Standard for Menthol in Cigarettes*, January 21, 2025, https://www.reginfo.gov/public/do/eoDetails?rrid=341411; GSA and OMB, *Tobacco Product Standard for Characterizing Flavors in Cigars*, January 21, 2025, https://www.reginfo.gov/public/do/eoDetails?rrid=341361.

[127] See, for example, Mi-Sun Lee et al., "Endotoxin and (1→3)-β-D-Glucan Contamination in Electronic Cigarette Products Sold in the United States," *Environmental Health Perspectives*, vol. 127, no. 4 (April 24, 2019), https://ehp.niehs.nih.gov/doi/epdf/10.1289/EHP3469.

[128] See, for example, Mina W. Tehrani et al., "Characterizing the Chemical Landscape in Commercial E-Cigarette Liquids and Aerosols by Liquid Chromatography–High-Resolution Mass Spectrometry," *Chemical Research in Toxicology*, vol. 34, no. 10 (October 5, 2021), https://pubs.acs.org/doi/epdf/10.1021/acs.chemrestox.1c00253?ref=article_openPDF.

[129] Marijuana is a variety or cultivar of the *Cannabis sativa* plant. See Figure 1 in CRS Report R46189, *FDA Regulation of Cannabidiol (CBD) Consumer Products: Overview and Considerations for Congress*.

[130] Marijuana is currently listed as a Schedule I controlled substance under the Controlled Substances Act (CSA). For more information, see CRS In Focus IF12270, *The Federal Status of Marijuana and the Policy Gap with States*.

[131] For more information on the evolution of federal enforcement prioritization regarding state marijuana laws, see CRS Report R44782, *The Evolution of Marijuana as a Controlled Substance and the Federal-State Policy Gap*, particularly the "Department of Justice Guidance Memos for U.S. Attorneys" section.

components, parts, or accessories that do not contain any ingredients derived from tobacco or nicotine from any source.[132] Such devices likely do not meet the definition of a tobacco product under the FFDCA and therefore may not be subject to FDA regulatory requirements pertaining to tobacco products.

The emergence of e-cigarette, or vaping, product use-associated lung injury ("EVALI") in 2019 highlighted the potential dangers of ENDS solutions that contain additives. EVALI is a medical condition characterized by gastrointestinal and respiratory symptoms.[133] Reported emergency department visits for EVALI began steeply increasing in August 2019 and peaked in September 2019.[134] Thereafter, reported emergency department visits steadily declined.[135] CDC collected data from states regarding EVALI between August 2019 and February 2020.[136] As of February 18, 2020, CDC reported that EVALI had led to the deaths of 68 individuals in 29 states and DC, and 2,807 hospitalizations in all 50 states, DC, Puerto Rico, and the U.S. Virgin Islands.[137] Research indicates a strong link between EVALI and the use of vaping products that contain THC and vitamin E acetate.[138] Vitamin E acetate is commonly used as a dietary supplement and in skin creams. Although the ingestion and dermal use of vitamin E acetate is not generally associated with adverse health effects, research suggests that vitamin E acetate may interfere with normal lung function when inhaled.[139]

FDA and CDC, along with state and local health departments, worked together to investigate the EVALI outbreak. FDA, DEA, and local and state authorities also investigated a possible connection between the ENDS supply chain and EVALI cases. FDA and DEA announced in 2019 that they had seized 44 websites advertising the sale of illicit THC-containing vape cartridges; however, none of the products advertised on the websites were linked to any cases of EVALI.[140] In October 2019, FDA urged individuals who used THC-containing ENDS products to stop.[141] The decline in EVALI cases over time may be due to various reasons, including increased law enforcement actions, removal of vitamin E acetate from some products, and increased public awareness of the issue. Although CDC stopped collecting data from states on EVALI cases in

[132] FFDCA §901(b); FDA, "FDA Updates Regulatory Documents to Include 'Non-Tobacco Nicotine' Products," March 17, 2023, https://www.fda.gov/tobacco-products/ctp-newsroom/fda-updates-regulatory-documents-include-non-tobacco-nicotine-products. For example, vaporizer e-liquids may contain only marijuana concentrate or other illicit substances such as fentanyl. DEA, *Vaping & Marijuana Concentrates*, April 2020, p. 2, https://www.dea.gov/sites/default/files/2020-06/Vaping%20and%20Marijuana%20Concentrates-2020.pdf; DEA, "Fentanyl Used in Vape Pens," bulletin, September 2020, https://www.dea.gov/sites/default/files/2020-09/Fentanyl%20Used%20in%20Vape%20Pens__PRB%20FINAL.pdf.

[133] Yale Medicine, "E-Cigarette, or Vaping Product, Use Associated Lung Injury (EVALI)," https://www.yalemedicine.org/conditions/evali.

[134] CDC, "Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products," February 25, 2020, https://archive.cdc.gov/#/details?url=https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

[135] CDC, "Outbreak of Lung Injury."

[136] CDC, "Outbreak of Lung Injury."

[137] CDC, "Outbreak of Lung Injury."

[138] CDC, "Outbreak of Lung Injury."

[139] CDC, "Outbreak of Lung Injury."

[140] FDA, "FDA, DEA Seize 44 Websites Advertising Sale of Illicit THC Vaping Cartridges to US Consumers as Part of Operation Vapor Lock," December 20, 2019, https://www.fda.gov/news-events/press-announcements/fda-dea-seize-44-websites-advertising-sale-illicit-thc-vaping-cartridges-us-consumers-part-operation.

[141] FDA, "Vaping Illness Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Vaping Products and Any Vaping Products Obtained Off the Street," October 4, 2019, https://web.archive.org/web/20191007123040/https://www.fda.gov/consumers/consumer-updates/vaping-illness-update-fda-warns-public-stop-using-tetrahydrocannabinol-thc-containing-vaping.

February 2020, it continues to monitor EVALI-related trends and has not reported a resurgence of EVALI at this time.[142] However, some physicians and researchers have flagged that the detection of new EVALI cases may have been complicated by the COVID-19 pandemic; COVID-19, in some cases, presents similarly to EVALI.[143]

FDA has the authority to establish via regulation good manufacturing practice (GMP) requirements for tobacco products under FFDCA Section 906(e). Such requirements would apply to the methods, facilities, and controls for the manufacture, design, packing, and storage of manufacturers' tobacco products to protect public health by minimizing contamination and ensuring product consistency.[144] On March 10, 2023, FDA published in the *Federal Register* a proposed rule pursuant to this authority entitled "Requirements for Tobacco Product Manufacturing Practice."[145] In the text of the proposed rule, FDA states that it would "establish requirements for the control of tobacco product manufacturing activities and the treatment of contaminated or otherwise nonconforming tobacco products, including the investigation, evaluation, and corrective and preventive actions (CAPA) necessary to protect the public health."[146] The proposed rule would apply to finished and bulk tobacco products, including ENDS and e-liquids.[147] In its regulatory impact analysis of the proposed rule, FDA notes that, if finalized, it could potentially prevent instances of ENDS and e-liquid recalls due to contamination and nonconformance.[148] At the time of this report's publication, a final rule has not been promulgated, and the last corresponding entry in the Unified Agenda dates to the spring 2022 edition; the entry does not indicate a timeline for a final rule.[149]

Additionally, beginning with the spring 2018 edition of the Unified Agenda, FDA has included another entry that may address toxicants and impurities through tobacco product standards for ENDS e-liquids; however, the full impact of the intended regulatory action is unclear due to limited publicly available information.[150] In the fall 2024 edition of the Unified Agenda, this

[142] CDC, "Surveillance Provides Clues on Vaping-Associated Lung Injury," March 31, 2024, https://www.cdc.gov/nssp/php/story/surveillance-provides-clues-vaping-lung-injury.html.

[143] See, for example, Lisa Gillespie, "Forgotten but Not Gone: EVALI Epidemic Continues," *Medscape*, April 17, 2023, https://www.medscape.com/viewarticle/990888?form=fpf; Michael Lanspa et al., "Clinical Presentation and Outcome Differences in E-Cigarette or Vaping Product Use Associated Lung Injury (EVALI) During the Initial Epidemic vs During the COVID-19 Pandemic," *CHEST*, vol. 164, no. 4 (October 2023), https://journal.chestnet.org/article/S0012-3692(23)05153-X/fulltext; Nick Klenske, "Differentiating EVALI from COVID-19 on Imaging Proves Challenging," *Radiological Society of North America*, March 10, 2022, https://www.rsna.org/news/2022/march/EVALI-Diagnosis.

[144] FFDCA §906(e)(1)(A).

[145] FDA, "Requirements for Tobacco Product Manufacturing Practice," 88 *Federal Register* 15174, March 10, 2023, https://www.govinfo.gov/content/pkg/FR-2023-03-10/pdf/2023-04591.pdf.

[146] FDA, "Requirements for Tobacco Product Manufacturing Practice," 88 *Federal Register* 15175.

[147] FDA, "Requirements for Tobacco Product Manufacturing Practice," 88 *Federal Register* 15183.

[148] FDA, "Requirements for Tobacco Product Manufacturing Practice, Docket No. FDA-2013-N-0227, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis," p. 36, https://www.fda.gov/media/166055/download?attachment.

[149] GSA and OMB, *Requirements for Tobacco Product Manufacturing Practice*, Spring 2022, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0910-AH91.

[150] GSA and OMB, *Safety Standards for Toxicants and Impurities in Nicotine, Propylene Glycol, and Vegetable Glycerin Used in E-Liquids; Tobacco Product Standard*, Spring 2018, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201804&RIN=0910-AI06.

regulatory action was listed as a long-term action, with a projected date for a notice of proposed rulemaking in February 2026.[151]

Congress may consider proposals expediting FDA's rulemaking process regarding required tobacco product manufacturing practices. Congress may also consider directing FDA to conduct more research on the prevalence of contaminants in e-liquids and their potential for harm, including when aerosolized, to support the regulatory process. Alternatively, Congress may choose not to act and instead rely on FDA to continue its regulatory actions.

Concentrations of Nicotine in E-Liquids

ENDS products use e-liquids containing various ingredients to deliver nicotine to the user. The e-liquid solution is heated to create an aerosol, which the user then inhales.[152] From the lungs, the nicotine is rapidly absorbed into the bloodstream. Research has demonstrated that higher concentrations of nicotine can lead to systemic adverse health effects, including addiction.[153] The concentration of nicotine in these e-liquids can vary, depending on the manufacturer.[154] As a result, the level of nicotine absorbed into a user's bloodstream can also vary. Studies have demonstrated that, in some instances, variability may exist between the labeled concentration of nicotine in an e-liquid solution and the actual nicotine concentration.[155] In addition, several e-cigarette manufacturers use nicotine salts[156] in their formulations of e-liquids, which may provide a more pleasing sensory experience for the user by masking the harshness of nicotine.[157] These

[151] GSA and OMB, *ENDS Safety Standards, Including Standards for Toxicants and Impurities in Nicotine, Propylene Glycol, and Vegetable Glycerin Used in E-Liquids; Tobacco Product Standards*, Fall 2024, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202410&RIN=0910-AI06.

[152] FDA, "E-Cigarettes, Vapes, and Other Electronic Nicotine Delivery Systems (ENDS)," May 31, 2024, https://www.fda.gov/tobacco-products/products-ingredients-components/e-cigarettes-vapes-and-other-electronic-nicotine-delivery-systems-ends.

[153] CDC, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*, 2014, pp. 109, 125-126, ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf.

[154] NASEM, *Public Health Consequences of E-Cigarettes*, 2018, pp. 89-90, https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf.

[155] See, for example, Kelly Buettner-Schmidt et al., "Electronic Cigarette Refill Liquids: Nicotine Content, Presence of Child-Resistant Packaging, and in-Shop Compounding," *Journal of Pediatric Nursing*, vol. 59 (2021), pp. 51-52, https://www.sciencedirect.com/science/article/pii/S0882596320306977/pdfft?md5=c33f6986678e148c742fa120610e446b&pid=1-s2.0-S0882596320306977-main.pdf; Scott Appleton et al., "Market Survey of Disposable E-Cigarette Nicotine Content and E-Liquid Volume," *BMC Public Health*, vol. 22, no. 1760 (2022), pp. 2, 3-4, 8, https://bmcpublichealth.biomedcentral.com/counter/pdf/10.1186/s12889-022-14152-2.pdf. The text of the proposed rule "Requirements for Tobacco Product Manufacturing Practice" indicates that it would address mismatched nicotine labeling concerns if finalized. FDA, "Requirements for Tobacco Product Manufacturing Practice," 88 *Federal Register* 15174, 15179-15180, 15196, 15201, 15215, 15220, 15224, 15230, 15235, March 10, 2023, https://www.govinfo.gov/content/pkg/FR-2023-03-10/pdf/2023-04591.pdf.

[156] Nicotine salts are formed via the combination of a nicotine base and a weak organic acid. NASEM, *Public Health Consequences of E-Cigarettes*, 2018, p. 95, https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf.

[157] Natalie Voos et al., "What is the Nicotine Delivery Profile of Electronic Cigarettes?," *Expert Opinion on Drug Delivery*, vol. 16, no. 11 (2019), p. 1195, https://www.tandfonline.com/doi/epdf/10.1080/17425247.2019.1665647?needAccess=true; Adam M. Leventhal et al., "Effect of Exposure to e-Cigarettes With Salt vs Free-Base Nicotine on the Appeal and Sensory Experience of Vaping: A Randomized Clinical Trial," *JAMA Network Open*, vol. 4, no. 1 (2021), p. 7, https://jamanetwork.com/journals/jamanetworkopen/articlepdf/2774851/leventhal_2021_oi_201008_1609777976.06387.pdf.

salts may increase the amount of nicotine the user receives and may allow manufacturers to include additional nicotine in the solution.[158]

The Deeming Rule that extended FDA's authority over ENDS products also extended to e-liquids.[159] While tobacco product manufacturers and importers are required to submit ingredient information for finished tobacco products[160] to FDA, regulations do not currently specify a maximum allowable nicotine concentration in e-liquid solutions.[161] FDA has previously discussed establishing a potential nicotine product standard, which would lower nicotine levels in combustible cigarettes to a minimal or nonaddictive level.[162] In March 2018, FDA issued an advance notice of proposed rulemaking (ANPRM) seeking comment on setting such a potential nicotine product standard, but this ANPRM was withdrawn by FDA in October 2019.[163] However, the spring 2022 edition of the Unified Agenda listed an entry for a new notice of proposed rulemaking (NPRM) with a discrete regulation identifier number for a tobacco product standard for nicotine levels in certain tobacco products.[164] On January 16, 2025, a proposed rule regarding a nicotine standard in cigarettes and certain other combusted tobacco products was published in the *Federal Register* for public comment.[165] The text of the proposed rule notes that "FDA is … not including noncombusted non-cigarette tobacco products, such as … ENDS …, in the scope of th[e] proposed product standard."[166] The proposed rule indicates that the public comment period

[158] Natalie Voos et al., "What is the Nicotine Delivery Profile of Electronic Cigarettes?," *Expert Opinion on Drug Delivery*, vol. 16, no. 11 (2019), p. 1195, https://www.tandfonline.com/doi/epdf/10.1080/17425247.2019.1665647?needAccess=true; Mays Shamout et al., "Notes From the Field: Characteristics of E-Cigarette, or Vaping, Products Confiscated in Public High Schools in California and North Carolina – March and May 2019," *MMWR*, vol. 69, no. 42 (October 23, 2020), p. 1552, https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6942a7-H.pdf.

[159] 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 *Federal Register* 28974, 28975, May 10, 2016, https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10685.pdf.

[160] A finished tobacco product is a tobacco product, including all components and parts, sealed in a final package and intended for consumer use. A component or part sold separately from other tobacco products is considered a finished product if it is sold in final packaging and meant for consumer use. FDA, "Deeming Tobacco Products to be Subject to the FFDCA," 81 *Federal Register* 28995.

[161] FFDCA §904; FDA, *Listing of Ingredients in Tobacco Products (Revised*): Guidance for Industry*, March 2023, https://www.fda.gov/media/101162/download; KFF Health News, "E-Cigs Are Still Flooding the US, Addicting Teens With Higher Nicotine Doses," June 26, 2023, https://kffhealthnews.org/news/article/e-cigs-are-still-flooding-the-us-addicting-teens-with-higher-nicotine-doses/.

[162] FDA, "Statement from FDA Commissioner Scott Gottlieb, M.D., on Pivotal Public Health Step to Dramatically Reduce Smoking Rates by Lowering Nicotine in Combustible Cigarettes to Minimally or Non-Addictive Levels," press release, March 14, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-pivotal-public-health-step-dramatically-reduce-smoking.

[163] FDA, "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes," 83 *Federal Register* 11818, March 16, 2018, https://www.govinfo.gov/content/pkg/FR-2018-03-16/pdf/2018-05345.pdf; GSA and OMB, *Tobacco Product Standard for Nicotine Level of Certain Tobacco Products*, Fall 2019, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=0910-AH86.

[164] GSA and OMB, *Tobacco Product Standard for Nicotine Level of Certain Tobacco Products*, Spring 2022, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0910-AI76.

[165] FDA, "Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products," 90 *Federal Register* 5032, January 16, 2025, https://www.govinfo.gov/content/pkg/FR-2025-01-16/pdf/2025-00397.pdf.

[166] FDA, "Tobacco Product Standard for Nicotine Yield of Certain Combusted Tobacco Products," 90 *Federal Register* 5034.

is to close on September 15, 2025; however, President Trump's memorandum "Regulatory Freeze Pending Review" may affect this timeline.[167]

Since the spring 2018 edition of the Unified Agenda, FDA has included another entry that may address nicotine levels through tobacco product standards for ENDS, though the full extent of the intended regulatory action is unclear due to limited publicly available information.[168] In the fall 2024 edition of the Unified Agenda, this regulatory action was listed as a long-term action, with a projected date for a notice of proposed rulemaking in February 2026.[169]

Citing some of the health issues mentioned above, Congress held various hearings in recent sessions.[170] Introduced in the 117th Congress, H.R. 3051, for example, would have required FDA to regulate nicotine levels in e-cigarettes to "(i) 20 milligrams per milliliter; or (ii) such lower nicotine concentration as is determined by the Secretary to be minimally addictive or non-addictive."[171] Some members of the ENDS industry have proposed similar standards. For example, the American E-Liquid Manufacturing Standards Association (AEMSA)—a volunteer-run trade association composed of American e-liquid manufacturers—publishes and updates recommended standards for manufacturers (though adherence to these standards are required for AEMSA members). AEMSA has recommended, among other things, that the nicotine content in a final flavored product have a set maximum level of 24 milligrams per milliliter.[172] Some studies, however, have suggested that low concentrations of nicotine in e-liquids may lead users to overcompensate by increasing their use of ENDS products, potentially negating any individual benefit from a nicotine concentration limit and possibly exposing users to additional harms from increased aerosols or HPHCs.[173]

FDA has funded various research projects to investigate whether differences in nicotine concentration may affect the abuse liability of ENDS products.[174] While this research is developing, Congress may consider directing FDA or other federal research agencies to further expand studies into the potential effects of reducing or standardizing nicotine concentrations in

[167] FDA, "Tobacco Product Standard for Nicotine Yield of Certain Combusted Tobacco Products," 90 *Federal Register* 5032. White House, "Regulatory Freeze Pending Review," presidential memorandum, January 28, 2025, https://www.govinfo.gov/content/pkg/FR-2025-01-28/pdf/2025-01906.pdf.

[168] GSA and OMB, *Safety Standards for Toxicants and Impurities in Nicotine, Propylene Glycol, and Vegetable Glycerin Used in E-Liquids; Tobacco Product Standard*, Spring 2018, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201804&RIN=0910-AI06.

[169] GSA and OMB, *ENDS Safety Standards, Including Standards for Toxicants and Impurities in Nicotine, Propylene Glycol, and Vegetable Glycerin Used in E-Liquids; Tobacco Product Standards*, Fall 2024, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202410&RIN=0910-AI06.

[170] See, for example, U.S. Congress, House Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, *An Epidemic Continues: Youth Vaping in America*, 117th Cong., 1st sess., June 23, 2021; U.S. Congress, Senate Committee on Commerce, Science, and Transportation, Subcommittee on Consumer Protection, Product Safety, and Data Security, *Toxic Marketing Claims and Their Dangers*, 117th Cong., 1st sess., August 3, 2021.

[171] This bill was introduced in the 116th Congress as H.R. 4624.

[172] AEMSA, *E-Liquid Manufacturing Standards*, March 8, 2017, p. 4, https://www.aemsa.org/wp-content/uploads/2017/03/AEMSA-Standards-v2.3.3.pdf.

[173] See, for example, Lynne Dawkins et al., "'Real-World' Compensatory Behaviour with Low Nicotine Concentration E-Liquid: Subjective Effects and Nicotine, Acrolein and Formaldehyde Exposure," *Addiction*, vol. 113, no. 10 (October 2018), https://pmc.ncbi.nlm.nih.gov/articles/PMC6150437/pdf/ADD-113-1874.pdf; Tarana Ferdous et al., "Partial Nicotine Reduction and E-Cigarette Users' Puffing Behaviors Among Adults Aged 21 to 35 Years: A Randomized Crossover Clinical Trial," *JAMA Network Open*, vol. 7, no. 7 (2024), https://jamanetwork.com/journals/jamanetworkopen/articlepdf/2821557/ferdous_2024_oi_240733_1721230300.16684.pdf.

[174] FDA, "Center for Tobacco Products Supported Tobacco Regulatory Research Projects," https://web.archive.org/web/20240721220950/https://www.fda.gov/tobacco-products/research/center-tobacco-products-supported-tobacco-regulatory-research-projects (may narrow results by ctrl+F searching the page and inputting "nicotine concentration").

ENDS products (e.g., compensatory usage, harm from increased aerosols exposure, population addiction statistics), as such research may help inform future regulatory standards.

Remote Sales and Advertising

With the advent of remote sales and advertising (including online) of tobacco products, various stakeholders have raised concerns that these practices may increase illegal sales of ENDS to minors due to enforcement challenges in virtual environments.[175] FDA is statutorily authorized to promulgate regulations on the advertising and sale of tobacco products.[176] Generally, FDA may restrict the advertising and promotion of tobacco products consistent with and to the full extent permitted under the Constitution's First Amendment if FDA finds that doing so would be appropriate for the protection of the public health.[177] Furthermore, for remote tobacco product advertising and sales in particular, FDA was tasked with promulgating regulations regarding age verification requirements and promotion and marketing practices.[178]

FDA first referenced these regulatory authorities in the spring 2010 edition of the Unified Agenda, projecting an expected NPRM around January 2011.[179] However, this projection was extended in the fall 2010 edition of the Unified Agenda to May 2011.[180] In the spring 2011 edition of the Unified Agenda, FDA announced its intent to publish an ANPRM regarding the remote sale and distribution of tobacco products around October 2011.[181] In September 2011, FDA issued an ANPRM requesting information from the public regarding the remote sales, distribution, advertising, promotion, and marketing of tobacco products.[182] While originally information was requested by December 8, 2011, this period was extended to January 19, 2012.[183] No further mention of this regulatory action appeared in the Unified Agenda until the spring 2017 edition, in

[175] See, for example, American Academy of Pediatrics et al., "FDA's Unlawful Withholding of Remote Sales Rule," letter to FDA, August 21, 2024, p. 4, https://www.lung.org/getmedia/90fd2a51-e0c5-4b2d-92f9-bc13c09068dd/Letter-to-FDA-on-Remote-Sales-8-21-24.pdf.

[176] FFDCA §906(d).

[177] FFDCA §906(d)(1).

[178] FFDCA §906(d)(4). Under the FFDCA, as amended by the TCA, FDA was directed to promulgate regulations regarding "the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer … including requirements for age verification," within 18 months of the TCA's enactment. FFDCA §906(d)(4)(A)(i). Likewise, FDA was directed to promulgate regulations that addressed the "promotion and marketing of tobacco products that are sold or distributed through means other than a direct, face-to-face exchange between a retailer and a consumer" to prevent underage sales within two years of the TCA's enactment. FFDCA §906(d)(4)(A)(ii).

[179] GSA and OMB, *Sale and Distribution and Promotion and Marketing of Tobacco Products That Occur or Are Conducted Through a Means Other Than a Direct, Face-to-Face Exchange Between a Retailer and Consumer*, Spring 2010, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201004&RIN=0910-AG43.

[180] GSA and OMB, *Sale and Distribution of Tobacco Products That Occur or Are Conducted Through a Means Other Than a Direct, Face-to-Face Exchange Between a Retailer and Consumer*, Fall 2010, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201010&RIN=0910-AG43.

[181] GSA and OMB, *Sale and Distribution of Tobacco Products That Occur or Are Conducted Through a Means Other Than a Direct, Face-to-Face Exchange Between a Retailer and Consumer*, Spring 2011, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201104&RIN=0910-AG43.

[182] FDA, "Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products," 76 *Federal Register* 55835, September 9, 2011, https://www.govinfo.gov/content/pkg/FR-2011-09-09/pdf/2011-23096.pdf.

[183] FDA, "Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products; Extension of Comment Period," 76 *Federal Register* 76096, December 6, 2011, https://www.govinfo.gov/content/pkg/FR-2011-12-06/pdf/2011-31225.pdf.

which FDA announced it was withdrawing the ANPRM; there has been no action related to this particular regulation publicly announced since.[184]

The Prevent All Cigarette Trafficking Act of 2009 (PACT Act; P.L. 111-154) amended the act of October 19, 1949 (Jenkins Act; P.L. 81-363) and placed certain restrictions on the remote sales of cigarettes and smokeless tobacco.[185] The PACT Act limited the ability of states and local governments to regulate common carriers involved in remote sales and did not originally place restrictions on tobacco products other than cigarettes and smokeless tobacco, such as ENDS.[186]

In December 2020, Congress enacted the Preventing Online Sales of E-Cigarettes to Children Act as part of the Consolidated Appropriations Act, 2021 (CAA; P.L. 116-260, Division FF, Title VI), which prohibited the remote sale of most ENDS by amending the Jenkins Act to include ENDS in the definition of cigarettes.[187] Congress further directed the United States Postal Service (USPS) to promulgate regulations to clarify the applicability to ENDS of the prohibition on mailing cigarettes.[188] The prohibition on mailing cigarettes was to be extended to ENDS immediately upon said regulations' promulgations.[189]

USPS released a guidance document on April 19, 2021, detailing how ENDS mailers could prepare applications for applicable exceptions for which cigarette mailers were eligible once the final rule was published.[190] On October 1, 2021, USPS published a final rule that generally extended the prohibition on mailing cigarettes and smokeless tobacco products[191] to ENDS, as defined in the Preventing Online Sales of E-Cigarettes to Children Act.[192]

Despite these and associated measures, stakeholders have identified ongoing regulatory gaps and barriers to enforcement, primarily centering on challenges with ENDS messaging to youth on social media, discreet shipping of ENDS products sold online to minors, and the adequacy of remote age verification measures for ENDS purchases. Regarding social media ENDS messaging, multiple studies have found that such messaging often portrays ENDS positively and in a promotional capacity.[193] Additionally, many of the accounts promoting ENDS belong to paid social media influencer accounts. Furthermore, at least one study examining ENDS messaging on the social media platform X found that pro-ENDS accounts tend to dominate discussions containing misinformation about ENDS intended to undermine factual information about ENDS

[184] GSA and OMB, *Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products*, Spring 2017, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0910-AG43.

[185] See Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), "Prevent All Cigarette Trafficking (PACT) Act," December 20, 2024, https://www.atf.gov/alcohol-tobacco/prevent-all-cigarette-trafficking-pact-act.

[186] Jenkins Act §2A(e)(5)(A); Public Health Law Center, *Online Sales of E-Cigarettes & Other Tobacco Products*, May 2022, pp. 12-14, https://www.publichealthlawcenter.org/sites/default/files/resources/Online-Sales-E-Cigarettes-Other-Tobacco-Products.pdf.

[187] 15 U.S.C. §375(2). "Electronic nicotine delivery system" is further separately defined in 15 U.S.C. §375(7).

[188] CAA §603(a).

[189] CAA §603(b).

[190] USPS, "Treatment of E-Cigarettes in the Mail," 86 *Federal Register* 20287, April 19, 2021, https://www.govinfo.gov/content/pkg/FR-2021-04-19/pdf/2021-07976.pdf.

[191] See generally 18 U.S.C. §1716E.

[192] USPS, "Treatment of E-Cigarettes in the Mail," 86 *Federal Register* 58398, October 21, 2021, https://www.govinfo.gov/content/pkg/FR-2021-10-21/pdf/2021-22787.pdf.

[193] See, for example, Juhan Lee et al., "E-Cigarette Marketing on Social Media: A Scoping Review," *Current Addiction Reports*, vol. 10 (2023), https://link.springer.com/content/pdf/10.1007/s40429-022-00463-2.pdf; American Psychiatric Association (APA), "New Research: E-Cigarette Content on Instagram Violates Policies, Is Marketed to Teens," May 4, 2024, https://www.psychiatry.org/news-room/news-releases/new-research-e-cig-content-on-instagram.

health risks.[194] Related concerns have also been raised in past congressional hearings and legislation.[195] Though FDA does require certain information on advertising messages,[196] and has taken enforcement and oversight actions in the past,[197] some stakeholders maintain that current regulatory and enforcement actions are insufficient.[198]

Relatedly, at least one study has also highlighted that some advertisements for ENDS on social media and other remote venues promote discreet shipping services (packaging and shipping practices that conceal the actual product being mailed) so that youth purchasers may circumvent detection.[199] In several documented cases, vendors advertised the discreet shipping of ENDS products hidden in cosmetics products.[200] Compounding barriers to the detection of youth ENDS purchasing, multiple studies and stakeholders have documented that many remote vendors of ENDS products do not have adequate age verification measures in place.[201] For example, one study found that the majority of remote ENDS vendors surveyed allowed purchasers to manually type in their birth date without any apparent independent verification.[202]

To address some of these barriers to regulation and enforcement regarding remote ENDS sales and advertising, Congress may consider several courses of action, including tasking FDA with the completion of promulgating regulations regarding age verification requirements and promotion and marketing practices for remote ENDS transactions. Such rules could address stricter age

[194] Ahmed Al-Rawi et al., "Twitter Misinformation Discourses About Vaping: Systematic Content Analysis," *Journal of Medical Internet Research*, vol. 25 (2023), https://www.jmir.org/2023/1/e49416/PDF.

[195] See, for example, U.S. Congress, House Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, *Examining JUUL's Role in the Youth Nicotine Epidemic: Part I*, hearings, 116th Cong., 1st sess., July 24, 2019, H.Hrg. 116-51, pp. 10, 17-18, 21; U.S. Congress, House Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, *Examining JUUL's Role in the Youth Nicotine Epidemic: Part II*, hearings, 116th Cong., 1st sess., July 25, 2019, H.Hrg. 116-54, pp. 2, 11-13, 25-26, 34-35; U.S. Congress, Senate Committee on Commerce, Science, and Transportation, Subcommittee on Consumer Protection, Product Safety, and Data Security, *Toxic Marketing Claims and Their Dangers*, 117 Cong., 1st sess., August 3, 2021, S.Hrg. 117-790, pp. 2, 6, 11, 24, 37-39, 46-48; S. 464.

[196] FDA, "Advertising and Promotion," January 30, 2020, https://www.fda.gov/tobacco-products/products-guidance-regulations/advertising-and-promotion; FDA, "Health Fraud," October 24, 2019, https://www.fda.gov/tobacco-products/health-effects-tobacco-use/health-fraud.

[197] See, for example, FDA, "FDA, FTC Take Action to Protect Kids by Citing Four Firms that Make, Sell Flavored E-Liquids for Violations Related to Online Posts by Social Media Influencers on their Behalf," press release, June 7, 2019, https://www.fda.gov/news-events/press-announcements/fda-ftc-take-action-protect-kids-citing-four-firms-make-sell-flavored-e-liquids-violations-related; FDA, "FDA in Brief: FDA Requires Four E-Cigarette Brands to Provide Critical Information on Social Media Practices," March 17, 2021, https://www.fda.gov/news-events/fda-brief/fda-brief-fda-requires-four-e-cigarette-brands-provide-critical-information-social-media-practices.

[198] See, for example, Truth Initiative, *Industry Influencer: How Tobacco Content is Infiltrating Social Media*, July 2023, pp. 2-3, 8-9, https://truthinitiative.org/sites/default/files/media/files/2023/08/Industry_Influencer_Report_FINAL.pdf; HHS, Office of Inspector General (OIG), *FDA's Approach to Overseeing Online Tobacco Retailers Needs Improvement*, December 2022, OEI-01-20-00241, https://oig.hhs.gov/documents/evaluation/2615/OEI-01-20-00241-Complete%20Report.pdf.

[199] See, for example, George Pearson et al., "'Discreet Shipping' on TikTok Enables Selling of E-Cigarettes to Youth," *Tobacco Control* (January 2024), https://tobaccocontrol.bmj.com/content/early/2024/01/08/tc-2023-058315.

[200] See, for example, George Pearson et al., "'Discreet Shipping' on TikTok."

[201] See, for example, Adrian Bertrand et al., "Easy Access: Identification Verification and Shipping Methods Used by Online Vape Shops," *Tobacco Control*, (January 2024), https://tobaccocontrol.bmj.com/content/early/2024/01/08/tc-2023-058303; Public Health Law Center, *Online Sales of E-Cigarettes & Other Tobacco Products*, May 2022, https://www.publichealthlawcenter.org/sites/default/files/resources/Online-Sales-E-Cigarettes-Other-Tobacco-Products.pdf.

[202] Adrian Bertrand et al., "Easy Access: Identification Verification and Shipping Methods Used by Online Vape Shops," *Tobacco Control* (January 2024), pp. 2-3, https://tobaccocontrol.bmj.com/content/early/2024/01/08/tc-2023-058303.

verification measures involving independent verification technologies and restricting advertising and promotion of ENDS on social media. Alternatively, some stakeholders have called for the complete banning of remote ENDS sales.[203]

ENDS User Fees

Though ENDS products represent an increasing proportion of CTP's received applications and regulatory activities, FDA is not authorized to collect user fees from ENDS manufacturers and importers. This is because FFDCA Section 919,[204] which authorizes CTP to collect user fees for selected tobacco product classes, does not specify an enumerated class for ENDS products and therefore does not provide a framework under which FDA could potentially assess user fees for ENDS products.[205] Consequently, CTP has dedicated a portion of its user fees paid by other tobacco product class manufacturers and importers to address ENDS-specific issues.[206] Numerous parties have suggested that manufacturers and importers of ENDS products should be subject to tobacco user fees to offset costs associated with FDA's current and future ENDS-specific activities.[207]

According to FDA, in order for ENDS manufacturers and importers to be subject to tobacco product user fees, Congress would need to provide FDA with the authority to assess and collect such fees. For example, Congress may consider amending both FFDCA Section 919 and specific provisions of the Fair and Equitable Tobacco Reform Act of 2004 (FETRA; P.L. 108-357, Title VI), which outlines the methodology for assessing tobacco product user fees currently collected on other tobacco product classes.[208] Although cigarettes and other tobacco products—including snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco—are subject to federal excise taxes,[209] ENDS products are not subject to such taxes.[210] These taxes are a critical component of the FETRA formula.[211] Therefore, if Congress were to amend FETRA and the

[203] See, for example, Stanton A. Glantz, "FDA Should Use Its Regulatory Authority and Take Immediate Steps to Tackle the Youth E-Cigarette Epidemic," February 3, 2019, https://tobacco.ucsf.edu/fda-should-use-its-regulatory-authority-and-take-immediate-steps-tackle-youth-e-cigarette-epidemic; Public Health Law Center, *Online Sales of E-Cigarettes & Other Tobacco Products*, May 2022, p. 16, https://www.publichealthlawcenter.org/sites/default/files/resources/Online-Sales-E-Cigarettes-Other-Tobacco-Products.pdf; American Academy of Pediatrics et al., "FDA's Unlawful Withholding of Remote Sales Rule," letter to FDA, August 21, 2024, pp. 12-13, https://www.lung.org/getmedia/90fd2a51-e0c5-4b2d-92f9-bc13c09068dd/Letter-to-FDA-on-Remote-Sales-8-21-24.pdf.

[204] 21 U.S.C. §387s.

[205] FDA, "Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco," 81 *Federal Register* 28707, 28709-28712, May 10, 2016, https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10688.pdf.

[206] HHS, *Fiscal Year 2025 Food and Drug Administration: Justification of Estimates for Appropriations for Congress*, March 2024, p. 187, https://web.archive.org/web/20241130125725/https://www.fda.gov/media/176925/download?attachment.

[207] See, for example, Lauren Silvis et al., *Operational Evaluation of Certain Components of FDA's Tobacco Program*, Reagan-Udall Foundation, December 2022, pp. 11, 15-16, https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf.

[208] 21 U.S.C. §387s.

[209] See generally FDA, Tobacco Product User Fees: Reponses to Frequently Asked Questions: Guidance for Industry, December 2021, https://www.fda.gov/media/154697/download.

[210] FDA, "Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco," 81 *Federal Register* 28707, 28710, May 10, 2016, https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10688.pdf.

[211] FETRA provisions specify a two-step formula. The first step determines the allocations for each of the six tobacco product classes, and the second step determines the individual domestic manufacturer and importer allocations within each respective tobacco product class. See CRS Report R45867, *FDA Regulation of Tobacco Products*.

FFDCA to explicitly provide FDA with the authority to assess user fees on ENDS manufacturers and importers, Congress would likely need to amend the Internal Revenue Code (IRC) as well to make ENDS products subject to federal excise taxes.[212] Alternatively, Congress may consider creating a new, separate ENDS user fee program outside of the existing FETRA framework.

FDA has requested authority from Congress to assess and collect user fees on ENDS products.[213] Some in Congress and the executive branch have expressed interest in requiring ENDS manufacturers and importers to pay user fees.[214] Legislation has been introduced in recent Congresses that, in whole or in part, would grant FDA the authority to collect user fees on ENDS products, though as of the date of this report, none have been enacted into law.[215] Congress may also choose not to act and maintain the status quo.

Conclusion

ENDS have become increasingly popular since their emergence in the United States. Although youth usage of ENDS and tobacco products decreased overall from 2023 to 2024, ENDS remain the most commonly used tobacco product for middle and high school students, and became increasingly popular with adults between 2019 and 2023.[216] The public health community continues to debate the impact of ENDS products. Some view ENDS products as a safer alternative for adults who smoke cigarettes;[217] others are alarmed by youth ENDS use.[218] FDA has received criticism from some industry stakeholders that its review process for ENDS marketing authorization applications moves too slowly,[219] while some advocacy groups have stated that FDA's decisions have not gone far enough to remove ENDS products from the market.[220]

[212] Relevant IRC provisions are found at 26 U.S.C. §§5701-5702.

[213] HHS, *Fiscal Year 2025 Food and Drug Administration: Justification of Estimates for Appropriations for Congress*, March 2024, p. 187, https://www.fda.gov/media/176925/download?attachment.

[214] The topic of ENDS user fees has also been discussed in multiple recent congressional hearings. See, for example, U.S. Congress, House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, FDA, *Fiscal Year 2025 Budget Request for the Food and Drug Administration*, 118th Cong., 2nd sess., April 18, 2024; U.S. Congress, Senate Committee on the Judiciary, *Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes*, 118th Cong., 2nd sess., June 12, 2024; U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health, *Evaluating FDA Human Foods and Tobacco Programs*, 118th Cong., 2nd sess., September 10, 2024.

[215] See, for example, S. 3653; H.R. 9425.

[216] Ahmed Jamal et al., "Tobacco Product Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2024," *Morbidity and Mortality Weekly Report (MMWR)*, vol. 73, no. 41 (October 17, 2024), p. 917, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7341a2-H.pdf; Anjel Vahratian et al., "Electronic Cigarette Use Among Adults in the United States, 2019-2023," *NCHS Data Brief*, no. 524 (January 2025), p. 1, https://www.cdc.gov/nchs/data/databriefs/db524.pdf.

[217] Generally, e-cigarette aerosols contain fewer toxicants than combusted smoke from cigarettes. National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-Cigarettes*, 2018, pp. 598, 604, 612, 617, https://nap.nationalacademies.org/cart/download.cgi?record_id=24952.

[218] See, for example, Campaign for Tobacco-Free Kids, "E-Cigarettes: Flavored Products Fuel a Youth Addiction Crisis," January 28, 2025, https://www.tobaccofreekids.org/what-we-do/industry-watch/e-cigarettes.

[219] See, for example, Matt Richtel, "F.D.A. Delays Decision on Juul's E-Cigarettes but Orders Others Off the Market," *The New York Times*, October 12, 2021, https://www.nytimes.com/2021/09/09/health/fda-e-cigarettes-vaping.html; Campaign for Tobacco-Free Kids, "FDA Makes Progress Against Flavored E-Cigarettes, But Continued Delays Leave Kids at Risk," press release, January 23, 2024, https://www.tobaccofreekids.org/press-releases/2024_01_23_fda-makes-progress-against-flavored-e-cigarettes.

[220] See, for example, Matt Richtel, "F.D.A. Delays Decision on Juul's E-Cigarettes; Campaign for Tobacco-Free Kids, "FDA Makes Progress Against Flavored E-Cigarettes."

FDA's regulation of ENDS products presents multiple policy issues and avenues that Congress may consider, including the following:

Flow of illicit ENDS into the United States. Congress may consider proposals expediting certain FDA rulemaking processes or directing the interagency task force to evaluate legislative options for streamlining enforcement.[221]

ENDS as a harm reduction tool. Congress may consider tasking FDA with further expanding certain public education campaigns and informational materials.

Flavored ENDS regulation. Congress may consider further limiting the use of flavors in ENDS.

ENDS e-liquid composition and contamination. Congress may consider proposals expediting certain FDA rulemaking processes or directing FDA to conduct more research on the prevalence of contaminants in e-liquids to support the regulatory process.

Concentrations of nicotine in e-liquids. Congress may consider introducing legislation to regulate nicotine levels in e-liquids, or direct federal research agencies to further expand studies into the potential effects of reducing or standardizing nicotine concentrations in ENDS products to inform future regulatory standards.

Remote sales and advertising. To address some of the barriers to regulation and enforcement regarding remote ENDS sales and advertising, Congress may consider tasking FDA with the completion of promulgating regulations regarding age verification requirements and promotion and marketing practices for remote ENDS transactions.

ENDS user fees. Congress may consider legislation authorizing FDA to collect user fees for ENDS products. Alternatively, Congress may choose not to act and instead rely on FDA to adjust its regulatory efforts.

Author Information

Nora Wells
Analyst in Health Policy

Acknowledgments

Hassan Z. Sheikh, Analyst in Health Policy, authored a prior report (CRS Report R46928, *Regulation of Electronic Nicotine Delivery Systems (ENDS): Background and Select Policy Issues in the 117th Congress*) that was partially adapted for this report.

[221] Lauren Silvis et al., *Operational Evaluation of Certain Components of FDA's Tobacco Program*, Reagan-Udall Foundation, December 2022, p. 24, https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf.

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