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Regulation of Electronic Nicotine Delivery Systems (ENDS): Background and Select Policy Issues in the 117th Congress

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In recent years, electronic nicotine delivery systems (ENDS) have become increasingly popular. ENDS is an umbrella term for various types of electronic tobacco products, including electronic cigarettes (e-cigarettes). An e-cigarette is a battery-operated device typically containing nicotine, flavorings, and other chemicals that, when heated, creates inhalable vapor. According to Centers for Disease Control and Prevention (CDC) analyses, 10.9 million American adults used e-cigarettes every day or some days in 2019, and about 3.6 million American middle and high school students used an e-cigarette in the past 30 days in 2020. Members of the public health community have debated the impact of ENDS on public health. Some view ENDS as a safer alternative for adult cigarette smokers, while others are alarmed by its increased use among youth.

Regulation of ENDS Products

The 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. The Family Smoking Prevention and Tobacco Control Act of 2009 (TCA; P.L. 111-31) amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to establish a new Chapter IX (“tobacco products”), which, as enacted, applied to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. FDA has the broad authority to regulate any other tobacco products that it determines meet the established definition and are thus subject to Chapter IX of the FFDCA. In 2016, pursuant to this authority, FDA promulgated regulations (known as “the deeming rule”) that extended the agency’s authority over all tobacco products not already subject to the FFDCA, including ENDS. Some ENDS solutions contain tetrahydrocannabinol (THC), an illicit substance at the federal level subject to various Drug Enforcement Agency (DEA) regulations. In addition, Congress has directed the United States Postal Service to promulgate regulations clarifying how the prohibition on mailing cigarettes applies to ENDS.

Policy Considerations

Both FDA and Congress have taken steps to address the regulation of ENDS in response to increased ENDS use among youth. FDA has prioritized enforcement of ENDS products that are more likely to be used by minors, and the agency is reviewing premarket applications for newly deemed products, including ENDS. Legislation introduced in the 116th and 117th Congresses thus far includes various provisions addressing youth ENDS use, such as banning all flavors in tobacco products (including ENDS) and setting a maximum nicotine concentration limit in e-liquids. In FY2020 appropriations, Congress enacted provisions raising the federal minimum age of sale of tobacco products from 18 to 21. The application of certain FFDCA requirements to tobacco product manufacturers and retailers, such as requiring ENDS manufacturers and importers to pay user fees, would require congressional action.

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Introduction

Nicotine is a naturally occurring chemical found in the tobacco plant. Repeated exposure to nicotine can cause addiction.¹ There is debate in the public health community regarding the severity of harms of nicotine.² 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, FDA has identified, including nicotine, 93 harmful or potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke.³ Some in the public health community have advocated for a harm-reduction approach, emphasizing the use of noncombustible electronic nicotine devices (ENDS) as an alternative to combustible tobacco products that may contain more HPHCs. On the other hand, nicotine is not harmless. FDA has acknowledged that higher concentrations of nicotine can lead to harmful effects, particularly in youth.⁴ For example, nicotine may damage the developing adolescent brain, affecting parts of the brain that control attention, learning, mood, and impulse control.⁵

ENDS use has proliferated in recent years, particularly among youth (anyone under the age of 18). ENDS is an umbrella term for various types of electronic tobacco products, including electronic cigarettes (e-cigarettes).⁶ An e-cigarette is a battery-operated device typically containing nicotine, flavorings, and other chemicals that, when heated, creates inhalable aerosol (i.e., vapor). ENDS products come in a variety of formats (such as e-hookahs, e-cigars, vape pens). Whereas earlier generations of ENDS products were designed to be used only once, current devices come with a prefilled or refillable cartridge (“pod”) containing e-liquid, which is converted to an aerosol by the ENDS product. This e-liquid can contain a number of ingredients in addition to nicotine.⁷ According to Centers for Disease Control and Prevention (CDC) analyses, 10.9 million American adults used e-cigarettes every day or some days in 2019.⁸ About 3.6 million American middle and high school students used an e-cigarette within a 30-day period in 2020.⁹

¹ National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, Centers for Disease Control and Prevention, *The Health Consequences of Smoking—50 Years of Progress*, U.S. Department of Health and Human Services, Atlanta, GA, 2014, <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf>.

² Scientific American, “Is Nicotine All Bad?” May 19, 2015, <https://www.scientificamerican.com/article/is-nicotine-all-bad/>.

³ FDA, “Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List,” updated October 19, 2019, <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list>.

⁴ FDA, *Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization*, January 2020, pp. 41-42, <https://www.fda.gov/media/133880/download>.

⁵ CDC, “Why Is Nicotine Unsafe for Kids, Teens, and Young Adults?” updated July 7, 2021, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html?s_cid=OSH_emg_GL0004#why-is-nicotine-unsafe.

⁶ Other examples of ENDS products may include e-pipes, hookah pens, vape pens, vaporizers, or vapes, or electronic cigars. See CDC, “E-Cigarette, or Vaping, Products Visual Dictionary,” https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/ecigarette-or-vaping-products-visual-dictionary-508.pdf.

⁷ CDC, “E-Cigarette, or Vaping, Products Visual Dictionary,” https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/ecigarette-or-vaping-products-visual-dictionary-508.pdf.

⁸ See Monica E. Cornelius, Teresa W. Wang, and Ahmad Jamal, et al., “Tobacco Product Use Among Adults—United States, 2019,” *Morbidity and Mortality Weekly Report (MMWR)*, vol. 69, no. 46 (November 20, 2020), pp. 1736-1742.

⁹ Andrea S. Gentzke, Teresa W. Wang, Ahmed Jamal, et al., “Tobacco Product Use Among Middle and High School

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 because the aerosol produced from e-cigarettes is considered less harmful in the short-term than the combusted smoke produced from cigarettes.¹⁰ Others are alarmed by the marked increase in ENDS use among youth, and are concerned that these products, particularly those sold in flavors appealing to children, may undo the years of tobacco control efforts that have successfully reduced cigarette smoking among both youth and adults.¹¹

The 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 FFDC Chapter IX, under which FDA is authorized to regulate tobacco products. Upon enactment, the TCA explicitly covered the following tobacco products: cigarettes and cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The TCA gave FDA broad authority to regulate any other tobacco products that the agency determines meet the established definition and are thus subject to Chapter IX of the FFDC. In 2016, FDA promulgated regulations (known as “the deeming rule”) that extended the agency’s authority over all tobacco products not already subject to the FFDC, including ENDS.¹²

All tobacco products originally covered by the TCA are required to undergo premarket review, unless they are “grandfathered products.”¹³ Following the 2016 deeming rule, all newly deemed tobacco products became subject to premarket review requirements. Premarket applications for ENDS products were due to the agency by September 9, 2020. In addition to the enforcement priorities it expressed in April 2020 guidance, FDA stated that it may continue to exercise enforcement discretion for manufacturers that submitted applications by the aforementioned date.¹⁴ In other words, barring a negative action on an application, FDA may effectively allow such products to be marketed for up to a year after the deadline (i.e., September 9, 2021) while applications are being reviewed.¹⁵ As of June 2021, Acting Commissioner of Food and Drugs Janet Woodcock testified that the agency has completed initial processing of Premarket Tobacco Product Applications (PMTA) for 6.5 million products submitted by over 550 companies. The vast majority of these submissions are for ENDS products.¹⁶ On August 9, 2021, FDA issued a

Students—United States, 2020,” *Morbidity and Mortality Weekly Report (MMWR)*, vol. 69, no. 50 (December 18, 2020), pp. 1881-88.

¹⁰ National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes*, The National Academies Press, p. 18, Washington, DC, 2018, <https://www.nap.edu/read/24952/chapter/3>.

¹¹ See, for example, Laura Bach, *JUUL and Youth: Rising E-Cigarette Popularity*, Campaign for Tobacco Free Kids, June 8, 2021, pp. 3-5, <https://www.tobaccofreekids.org/assets/factsheets/0394.pdf>.

¹² For more information about tobacco regulation, see CRS Report R45867, *FDA Regulation of Tobacco Products*.

¹³ Products that do not meet the statutory definition of a new tobacco product are referred to as “grandfathered products” and do not require premarket review to be legally marketed. Grandfathered products have been commercially marketed in the United States as of February 15, 2007.

¹⁴ FDA, *Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization*, January 2020, <https://www.fda.gov/media/133880/download>.

¹⁵ 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>.

¹⁶ FDA, Testimony of Dr. Janet Woodcock, Acting Commissioner, *An Epidemic Continues: Youth Vaping in America*,

Refuse to File (RTF)¹⁷ letter stating that an e-liquid company must remove approximately 4.5 million products from the market because its PMTAs failed to meet the filing requirements.¹⁸ On August 26, FDA issued market denial orders (MDOs)¹⁹ for more than 50,000 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.”²⁰

As of September 9, 2021, FDA stated that it had taken action on 93% of all applications to date.²¹ Many of the applications submitted to the FDA by the PMTA pathway were issued a RTF for failure to include required information such as ingredient listings, or labels for marketed products. FDA has further stated that it continues to work on the remaining applications, clarifying that in addition to the remaining applications FDA is also reviewing a number of products submitted under a substantial equivalence (SE) pathway.²² Some industry stakeholders have expressed frustration at the FDA, claiming that FDA had failed to promptly review the applications of companies who hold the largest market share of vape products.²³ Other advocacy groups have stated that the FDA’s decisions had not gone far enough to remove vape products from the market.²⁴ Ultimately, as FDA continues to process applications there may be significant upcoming implications for the ENDS industry. While various stakeholders are demanding prompt FDA action, Congress may consider whether or not to act before FDA has finished reviewing all product applications.

Over the past few years, FDA and Congress have taken steps to regulate ENDS products. Stakeholders have recently identified several issues regarding the regulation of ENDS that may be of interest to Congress:

before the U.S. Congress, House Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, 117th Cong., 1st sess., June 23, 2021, <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Woodcock%20Testimony.pdf>, (hereinafter, FDA, Testimony of Dr. Janet Woodcock, “An Epidemic Continues: Youth Vaping in America”).

¹⁷ A “refuse-to-file” letter is generally issued for applications for which there is insufficient information available for review.

¹⁸ FDA, “FDA Issues Refuse to File (RTF) Letter to JD Nova Group LLC,” August 09, 2021 at https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-refuse-file-rtf-letter-jd-nova-group-llc?utm_source=CTPTwitter&utm_medium=social&utm_campaign=ctp-pmta.

¹⁹ A market-denial-order is issued after a determination that an application’s 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.” See FDA, “Tobacco Products Marketing Orders,” August 26, 2021, <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#Marketing%20Denial>.

²⁰ 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>.

²¹ 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>.

²² For a discussion on FDA premarket review pathways for tobacco products, see CRS Report R45867, *FDA Regulation of Tobacco Products*.

²³ Matt Richel, “F.D.A. Delays Decision on Juul’s E-Cigarettes but Orders Others Off the Market,” *The New York Times*, September 9, 2021.

²⁴ *Ibid.*

- **“ENDS as a Harm-Reduction Tool.”** The data regarding the effectiveness of ENDS as a harm-reduction or cessation tool for adults who smoke cigarettes are complex. FDA has not approved any ENDS products for smoking cessation, although some stakeholders have stated that adults who switch from cigarettes to ENDS may have better health outcomes.
- **“Flavored ENDS Regulation.”** FDA and public health stakeholders remain concerned about increased ENDS use among youth. Although data suggest that both adults and youth enjoy flavored ENDS products, some in the public health community argue that the increase in ENDS use among youth is largely driven by the availability of youth-friendly flavors. FDA has issued policies prioritizing enforcement against unauthorized flavored e-cigarette products; some public health stakeholders have expressed concern that the policies do not go far enough to reduce ENDS use among youth.
- **“ENDS Solutions Containing ”** Along with the rise in ENDS use among youth, the emergence of e-cigarette or vaping use-associated lung injury (“EVALI”) has further heightened concern among public health stakeholders, Congress, and the general public. Laboratory data suggest that in addition to tetrahydrocannabinol (THC) containing ENDS products, vitamin E acetate—an additive sometimes found in such products—is closely associated with EVALI. These THC-containing products may raise a larger question of how they might be federally regulated in states that permit the sale of marijuana for recreational or medicinal purposes.
- **“Variable Concentration of Nicotine in E-Liquids.”** The nicotine concentration in commercially available solutions used in ENDS devices (“e-liquids”) is variable and unregulated. As a result, users may have variable concentrations of blood nicotine levels, which may contribute to increased side-effect profiles such as nicotine dependence and addiction, particularly among youth. However, variable nicotine levels may contribute to the utility of ENDS products as possible harm-reduction tools. To address this concern, Congress has previously introduced bills setting a maximum concentration of nicotine in e-liquids.
- **“Remote Sales.”** The remote sales (i.e., non-face-to-face sales) of ENDS products may enable youth to purchase tobacco products illegally, due to difficulties in enforcing purchasing restrictions.
- **“ENDS User Fees.”** FDA has determined that it currently does not have the authority to assess user fees from manufacturers and importers of ENDS, despite these products being deemed subject to FDA regulation.²⁵
- **“Increasing Minimum Age for Purchasing ENDS Products.”** Many public health stakeholders have been concerned about youth access to tobacco products more broadly and expressed support for raising the minimum age of purchasing tobacco products from 18 to 21. Although, FDA was required to publish the final

²⁵ Currently, ENDS products are not subject to federal excise taxes; however, a discussion of this policy issue is outside the scope of this report. For more information, see U.S. Government Accountability Office, *Electronic Cigarettes: Effect on Federal Excise Taxes Collected on Traditional Cigarettes is Not Currently Evident*, GAO-15-771, September 2015, <https://www.gao.gov/assets/680/672467.pdf>.

rule to reflect this change by May 2021, these rules have not been published as of the date of this report.

These select issues are discussed in greater detail below, along with potential considerations for policymakers.²⁶

ENDS as a Harm-Reduction Tool

Since the emergence of ENDS products in the tobacco marketplace, there has been ongoing debate regarding their public health impact. This debate has implications for how such products should be regulated. Some data suggest that ENDS products may provide a harm-reduction tool for some tobacco smokers.²⁷ *Harm reduction* refers to the replacement of a more harmful activity with a less harmful one when elimination of the original activity is difficult or infeasible. Some in the public health community view ENDS as a harm-reduction tool for adults who smoke cigarettes.²⁸ 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.”²⁹

Data regarding the effectiveness of ENDS as a harm-reduction or cessation tool are complex. As of early 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.”³⁰ Further, the long-term health effects associated with use of ENDS are still largely unknown,³¹ and FDA has not yet approved any ENDS products as cessation devices.³² A 2018 CDC study, however, found that “15% of smokers who were current exclusive users of e-cigarettes reported recent successful smoking cessation.”³³ Despite these questions, some argue

²⁶ 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*.

²⁷ Caitlin Notley, Emma Ward, Lynne Dawkins, 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).

²⁸ Thomas J. Glynn, J. Taylor Hays, and Katherine Kemper, “E-Cigarettes, Harm Reduction, and Tobacco Control,” *Mayo Clinic Proceedings*, vol. 96, no. 4 (January 22, 2021), [https://www.mayoclinicproceedings.org/article/S0025-6196\(20\)31382-3/fulltext](https://www.mayoclinicproceedings.org/article/S0025-6196(20)31382-3/fulltext).

²⁹ National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes*, National Academies Press, Washington, DC, 2018, p. 1, <https://www.nap.edu/read/24952>.

³⁰ National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes*, National Academies Press, p. 579.

³¹ National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes*, National Academies Press, p. 483.

³² FDA approval of ENDS devices as smoking cessation products would require regulatory approval not discussed at length in this report. While e-cigarettes are regulated by the FDA’s Center for Tobacco Products, ENDS devices purporting a smoking cessation claim would likely be regulated similarly to other smoking cessation products and would likely require that the FDA’s Center for Drug Evaluation and Research evaluate whether a specific ENDS product is safe and effective for an end user. See Elizabeth Richardson, Meredith Freed, and Mark B. McClellan, “Regulating Nicotine Replacement Therapies: Next Steps In A Comprehensive Strategy For Tobacco Harm Reduction,” *Health Affairs*, February 14, 2018, <https://www.healthaffairs.org/doi/10.1377/hblog20180212.333148/full/>.

³³ Kimp Walton, Teresa W. Wang, Yvonne Prutzman, et al., “Characteristics and Correlates of Recent Successful Cessation Among Adult Cigarette Smokers, United States, 2018,” *Preventing Chronic Disease*, vol. 17 (December 10, 2020).

that adults who completely switch from cigarettes to ENDS may have a positive effect on public health, given the morbidity and mortality associated with cigarette smoking.³⁴

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 the CDC and the National Institutes of Health (NIH) to expand studies researching the potential of ENDS products as cessation devices.

Flavored ENDS Regulation

The regulation of flavors in ENDS products is complicated by several factors. Some in the public health community are alarmed by the marked increase among youth in the use of ENDS products, which are now the most popular tobacco product for this age group.³⁵ Research studies suggest that this increase has occurred, in large part, as a result of access to flavored ENDS products.³⁶ Numerous studies have documented that flavors entice youth to initiate and continue using tobacco products,³⁷ including ENDS.³⁸ On the other hand, many adult cigarette smokers have expressed an interest in ENDS as a way to quit cigarette smoking.³⁹

The availability of flavored ENDS products has created tension between industry and some members of the public health community. One systematic review of the literature found that both youth and adults enjoy flavors in e-cigarettes. However, the authors of this review stated that “in terms of whether flavored e-cigarettes assisted [adults] quitting smoking, we found inconclusive evidence.”⁴⁰ Industry-funded research suggested that flavored ENDS products may be more appealing to adult cigarette smokers (compared with nonsmoking teens) and could help them quit smoking.⁴¹

³⁴ U.S. Department of Health and Human Services, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, Atlanta, GA, January 2014, <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/50-years-of-progress-by-section.html>.

³⁵ Andrea S. Gentzke, Teresa W. Wang, Ahmed Jamal, et al., “Tobacco Product Use Among Middle and High School Students—United States, 2020,” *Morbidity and Mortality Weekly Report (MMWR)*, vol. 69, no. 50 (December 18, 2020), pp. 1881-88.

³⁶ FDA, *Draft Guidance for Industry: Modifications to Compliance Policy for Certain Deemed Tobacco Products*, March 2019, <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM633281.pdf>.

³⁷ National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, Centers for Disease Control and Prevention, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, U.S. Department of Health and Human Services, Atlanta, GA, 2012, <https://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf>.

³⁸ National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, Centers for Disease Control and Prevention, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, U.S. Department of Health and Human Services, Atlanta, GA, 2016, https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf.

³⁹ Matthew J. Carpenter, Bryan W. Heckman, Amy E. Wahlquist, et al., “A Naturalistic, Randomized Pilot Trial of E-Cigarettes: Uptake, Exposure, and Behavioral Effects,” *Cancer Epidemiology, Biomarkers & Prevention*, vol. 26, no. 12 (December 2017).

⁴⁰ Samane Zare, Mehdi Nemati, and Yuqing Zheng, “A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type,” *PLoS ONE*, vol. 13, no. 3 (2018).

⁴¹ Saul Shiffman, Mark A. Sembower, Janine L. Pillitteri, et al., “The Impact of Flavor Descriptors on Nonsmoking Teens’ and Adult Smokers’ Interest in Electronic Cigarettes,” *Nicotine & Tobacco Research*, January 7, 2015, pp.

In March 2019, FDA released a draft guidance document specifying its intended enforcement activities related to flavored ENDS.⁴² This guidance 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. 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 in convenience stores and gas stations that do not have adult-only sections. 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.”⁴³ Delays in guidance finalization led to a congressional hearing on December 4, 2019, to investigate the cause for delay.⁴⁴

In January 2020, with a subsequent update in April 2020, FDA released the final guidance document,⁴⁵ 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 a manufacturer has failed to take (or is failing to take) adequate measures to prevent minors’ access; and
- any ENDS product targeted to minors or whose marketing is likely to promote the use of ENDS by minors.

Some public health stakeholders expressed concern that the final guidance does not go far enough to reduce ENDS use among youth.⁴⁶

In April 2021, FDA released a statement outlining its intent to issue proposed product standards to ban menthol in cigarettes and all characterizing flavors⁴⁷ in cigars.⁴⁸ The spring 2021 White

1255-1262.

⁴² FDA, *Draft Guidance for Industry: Modifications to Compliance Policy for Certain Deemed Tobacco Products*, March 2019, <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM633281.pdf>.

⁴³ 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>.

⁴⁴ 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.

⁴⁵ FDA, *Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization*, January 2020, <https://www.fda.gov/media/133880/download>.

⁴⁶ Abby Goodnough, Maggie Haberman, and Sheila Kaplan, “With Partial Flavor Ban, Trump Splits the Difference on Vaping,” *The New York Times*, January 2, 2020.

⁴⁷ *Characterizing flavors* are those that noticeably smell or taste 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, no. 15 (October 2020), <https://www.sciencedirect.com/science/article/abs/pii/S0028390820302306>.

⁴⁸ 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>.

House OMB Unified Agenda of Federal Regulatory and Deregulatory Actions indicates that FDA aims to release a proposed rule regarding cigars in August 2021 and a proposed rule regarding cigarettes in April 2022.⁴⁹ However, these rules will likely not address flavors in ENDS products.

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 the 116th session, Congress saw proposal of an outright ban on all flavors (including menthol) in ENDS, as well as in other tobacco products.⁵⁰ Congress may consider proposals that reduce any tobacco product use, 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. Congress may choose to not act and rely on the FDA to determine if the recent measures have had their intended effects.

ENDS Solutions Containing Additives

Some ENDS solutions contain tetrahydrocannabinol (THC), the primary psychoactive compound, or cannabinoid, found in marijuana.⁵¹ Such THC-containing products, in particular those available in states that permit the sale of the sale of marijuana for recreational or medicinal purposes, may raise a question regarding federal oversight. Marijuana—including marijuana-derived compounds such as THC—is an illicit substance at the federal level subject to Drug Enforcement Administration (DEA) enforcement and regulatory control.⁵² However, some states have implemented their own laws pertaining to recreational and medicinal marijuana use, and the DEA has largely focused resources on criminal networks involved in the illicit marijuana trade.⁵³ It is unclear how the DEA intends to prioritize enforcement efforts in states that allow recreational and medicinal marijuana versus those that do not.⁵⁴ Further, ENDS products that do not contain any components, parts, or accessories derived from tobacco (e.g., do not contain nicotine) and are not expected to be consumed like a tobacco product may not meet the definition of a tobacco product under the FFDCA. Therefore, such products may not be subject to FDA regulatory requirements pertaining to tobacco products. FDA has indicated that the agency would regulate such products on a “case-by-case basis, based on the totality of the circumstances.”⁵⁵

⁴⁹ OMB, “Agency Rule List – Spring 2021: Department of Health and Human Services, Tobacco Product Standard for Characterizing Flavors in Cigars,” <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202104&RIN=0910-AI28>, and OMB, “Agency Rule List – Spring 2021: Department of Health and Human Services, Tobacco Product Standard for Menthol in Cigarettes,” <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202104&RIN=0910-AI60>.

⁵⁰ H.R. 1498, 116th Congress; H.R. 2339, 116th Congress.

⁵¹ Marijuana is a variety or cultivar of the *Cannabis sativa* plant. See Figure 1 of CRS Report R46189, *FDA Regulation of Cannabidiol (CBD) Consumer Products: Overview and Considerations for Congress*.

⁵² Marijuana is currently listed as a Schedule I controlled substance under the Controlled Substances Act (CSA). For more information, see CRS Report R44782, *The Marijuana Policy Gap and the Path Forward*.

⁵³ Deputy Attorney General David W. Ogden, *Memorandum for Selected United States Attorneys*, U.S. Department of Justice, Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana, Washington, DC, October 19, 2009, pp. 1-3.

⁵⁴ In some reported instances, DEA has seized vape pens containing THC in jurisdictions that allow purchasing of medicinal marijuana. See for example, Tracy Carlross, “More than 15,000 THC vaping cartridges seized by DEA agents in Cleveland,” *News 5: Cleveland*, April 23, 2019, <https://www.news5cleveland.com/news/local-news/cleveland-metro/more-than-15-000-thc-vaping-cartridges-seized-by-dea-agents-in-cleveland>.

⁵⁵ See question 14 in FDA, “Commonly Asked Questions: About the Center for Tobacco Products,” June 11, 2019, <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/commonly-asked-questions-about-center-tobacco-products#14>.

The emergence of e-cigarette or vaping use-associated lung injury (“EVALI”) has highlighted the potential dangers of ENDS solutions that contain additives. EVALI, which is characterized in individuals by gastrointestinal and respiratory symptoms, has led to the deaths of 68 individuals in 29 states and DC, and 2,807 hospitalized in all 50 states, DC, Puerto Rico, and the U.S. Virgin Islands as of February 18, 2020.⁵⁶ Among a subset of hospitalized EVALI patients,⁵⁷ 82% reported using THC-containing products. Laboratory data suggest that in addition to THC-containing ENDS products, vitamin E acetate is also closely associated with EVALI.⁵⁸ 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 functioning when inhaled.⁵⁹

FDA and CDC, along with state and local health departments, have worked together closely to investigate the EVALI outbreak. FDA, DEA, and local and state authorities have 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 have been linked to any cases of EVALI.⁶⁰ In late 2019, FDA urged individuals who used THC-containing ENDS products to stop.⁶¹ The CDC has reported that cases of EVALI spiked in September 2019 and have gradually declined 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 February 2020, it continues to monitor EVALI-related trends and has not reported a resurgence of EVALI at this time.⁶²

Variable Concentration of Nicotine in E-Liquids

ENDS products use nicotine solutions (“e-liquids”) containing various ingredients to deliver nicotine to the user. The solution is heated to create an aerosol, which the user then inhales.⁶³ From the lungs, the nicotine is rapidly absorbed into the bloodstream. Previous studies have demonstrated that higher concentrations of nicotine can lead to systemic adverse effects,

⁵⁶ CDC, “Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products,” updated November 27, 2020, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

⁵⁷ The subset of patients included those with complete information on substances used in ENDS products three months prior to symptom onset.

⁵⁸ Benjamin C. Blount, Mateusz P. Karwowski, Peter G. Shields, et al., “Vitamin E Acetate in Bronchoalveolar-Lavage Fluid Associated with EVALI,” *The New England Journal of Medicine*, December 20, 2019, DOI: 10.1056/NEJMoa1916433.

⁵⁹ CDC, “Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products,” updated February 25, 2020, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

⁶⁰ 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>.

⁶¹ FDA, “Vaping Illness Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Vaping Products and Any Vaping Products Obtained Off the Street,” press release, October 4, 2019, <https://www.fda.gov/consumers/consumer-updates/vaping-illness-update-fda-warns-public-stop-using-tetrahydrocannabinol-thc-containing-vaping>.

⁶² CDC, “Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products,” updated February 25, 2020, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

⁶³ FDA, *Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)*, last updated September 17, 2020, available at <https://www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends>.

including addiction.⁶⁴ The concentration of nicotine in these e-liquids can vary, depending on the manufacturer.⁶⁵ As a result, the level of nicotine absorbed into the user’s blood stream can also vary. Studies have demonstrated that in some instances variability may exist between the labelled concentration of nicotine per solution and the actual measurement of nicotine in that solution.⁶⁶ In addition, several e-cigarette manufacturers have begun using nicotine salts⁶⁷ in their formulations of e-liquids, which are purported to provide a more pleasing sensory experience for the user by masking the harshness of nicotine.⁶⁸ These salts may increase the amount of nicotine the user receives and may allow manufactures to include additional nicotine in the solution.⁶⁹

The deeming rule that extended the agency’s authority over ENDS products also extended to e-liquids.⁷⁰ While tobacco product manufacturers and importers are required to submit ingredient information for finished tobacco products⁷¹ to the FDA, regulations do not currently specify a concentration of nicotine in the e-liquid solution.⁷² FDA has previously discussed the establishment of a potential *nicotine product standard*, which would lower nicotine levels in *combustible cigarettes* to a minimal or non-addictive level.⁷³ In March 2018, FDA issued an advance notice of proposed rulemaking (ANPRM) to seek comments on setting such a potential nicotine product standard, but the agency has not taken further regulatory action since that time.⁷⁴ In addition, FDA has not publicly indicated that it will pursue regulatory action regarding a nicotine product standard for ENDS products.

⁶⁴ Aseem Mishra, Pankaj Chaturvedi, Sourav Datta, et al., “Harmful effects of Nicotine,” *Indian Journal of Medical and Paediatric Oncology*, vol. 36, no. 1 (January 2015), pp. 24-31.

⁶⁵ National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes*, National Academies Press, Washington, DC, 2018, p. 89, https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf.

⁶⁶ Jean-Francois Etter and Aurelie Bugey, “E-cigarette liquids: Constancy of content across batches and accuracy of labeling,” *Addictive Behaviors*, vol. 73 (May 10, 2017), pp. 137-143.

⁶⁷ Nicotine salts are a specific formulation of nicotine that combines a weak base with an acid. See Natalie Voos, Maciej L. Goniewicz, and Thomas Eissenberg, “What is the nicotine delivery profile of electronic cigarettes?,” *Expert Opinion on Drug Delivery*, vol. 16, no. 11 (September 13, 2019), pp. 1193-1203.

⁶⁸ Adam M. Leventhal, Danielle R. Madden, Natalia Perez, et al., “Effect of Exposure to e-Cigarettes With Salt vs Free-Base Nicotine on the Appeal,” *JAMA Network*, vol. 4, no. 1 (January 12, 2021).

⁶⁹ Maciej L. Goniewicz, Rachel Boykan, Catherine R. Messina, et al., “High exposure to nicotine among adolescents who use JUUL,” *Tobacco Control*, vol. 28, no. 6 (November 2019), pp. 676-677.

⁷⁰ Terry McDonald, *The “Deeming Rule”—New Requirement for Tobacco Retailers*, FDA, 2016, <https://www.fda.gov/media/97860/download>, and FDA, *Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization*, January 2020, pp. 41-42., <https://www.fda.gov/media/133880/download>.

⁷¹ A finished tobacco product is one in which all of the components and parts are sealed in a final package intended for consumer use. A component and part sold separately from other tobacco products are considered finished products if they are sold in final packaging. See FDA, *Guidance for Industry: Listing of Ingredients in Tobacco Products*, November 2018, pp. 6, <https://www.fda.gov/media/101162/download>.

⁷² FDA, *Guidance for Industry: Listing of Ingredients in Tobacco Products*, November 2018, <https://www.fda.gov/media/101162/download>.

⁷³ 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>.

⁷⁴ FDA, “Tobacco Product Standard for Nicotine Level of Combusted Cigarettes,” 83 *Federal Register*, March 16, 2018.

Citing some of the health issues mentioned above, Congress held various hearings in the 116th and 117th sessions.⁷⁵ In the 117th Congress, H.R. 3051 would require 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.”⁷⁶ Certain members of the ENDS industry have proposed similar standards. For example, The American E-liquid Manufacturing Standards Association (AEMSA)—a trade association composed of volunteer American manufacturers of e-liquids—published recommended standards for manufacturers. AEMSA has recommended, among other things, that the nicotine content in a final flavored product have a set maximum level.⁷⁷ At least one study, however, has suggested that low concentrations of nicotine in e-liquid may lead users to overcompensate by increasing their use of an ENDS product, thereby potentially negating any benefit of the initial lower nicotine concentration and possibly exposing the user to additional harm from exposure to increased aerosol or HPHCs.⁷⁸

FDA has funded research to determine whether modest differences in nicotine concentration may affect the abuse liability of an ENDS product.⁷⁹ While this research is currently pending, Congress may consider directing FDA or other federal research agencies to expand studies into the potential effects (e.g., compensatory usage, harm due to increased exposure to aerosols, reduction in addiction rates) of reducing nicotine concentration in ENDS products, as such research may help inform future regulatory standards.

Remote Sales

Some have identified remote sales (i.e., non-face-to-face sales) as an opportunity for minors to illegally purchase tobacco products—including ENDS—due to difficulties in enforcing purchasing restrictions. FDA is statutorily authorized to promulgate regulations on remote sales of tobacco products, including age verification requirements.⁸⁰ In 2011, FDA issued an ANPRM regarding remote sales and distribution of tobacco products,⁸¹ but the agency has not taken further regulatory action since that time.

The Prevent All Cigarette Trafficking (PACT) Act of 2009 (P.L. 111-154) amended the Jenkins Act of 1949⁸² and placed certain restrictions on the remote sales of cigarettes and smokeless

⁷⁵ 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, and 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*, 116th Cong., 1st sess., July 24, 2019.

⁷⁶ This bill had been introduced in the 116th Congress as H.R. 4624 (2019).

⁷⁷ AEMSA, *E-Liquid Manufacturing Standards*, January 14, 2014, https://www.aemsa.org/wp-content/uploads/2014/02/AEMSA-Standards_Version-1-8.pdf.

⁷⁸ Lynne Dawkins, Sharon Cox, and Maciej Goniewicz, “‘Real-world’ compensatory behaviour with low nicotine concentration e-liquid: subjective effects and nicotine, acrolein and formaldehyde exposure,” *Addiction*, vol. 113, no. 10 (June 7, 2018), pp. 1874-1882.

⁷⁹ FDA, “*The Effects of E-liquid Nicotine Concentration on the Abuse Liability of ENDS in Current Users*,” October 3, 2019, <https://www.fda.gov/tobacco-products/research/effects-e-liquid-nicotine-concentration-abuse-liability-ends-current-users>.

⁸⁰ FFDCA §906.

⁸¹ FDA, “Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Marketing, and Promotion of Tobacco Products,” 76 *Federal Register* 55835, September 9, 2011.

⁸² See U.S. Government Accountability Office, *INTERNET CIGARETTE SALES: Limited Compliance and Enforcement of the Jenkins Act Result in Loss of State Tax Revenue*, GAO-03-714T, May 1, 2003,

tobacco but stopped short of outright prohibiting them.⁸³ Further, the PACT Act limited the ability of states and local governments to regulate the delivery carriers involved in remote sales—complicating enforcement efforts—and did not place such restrictions on other tobacco products, such as ENDS.⁸⁴

In FY2021, Congress enacted the Preventing Online Sales of E-Cigarettes to Children Act (Title VI of Division FF, P.L. 116-260), which prohibited the remote sale of most ENDS by amending the Jenkins Act to include a definition of ENDS in the definition of cigarettes.⁸⁵ Congress further directed the United States Postal Service (USPS) to promulgate regulations to clarify the applicability of the prohibition on mailing cigarettes to ENDS. The prohibition on mailing cigarettes is to be extended to ENDS immediately after said regulations have been promulgated.

On February 19, 2021, the USPS published a proposed rule that generally extended the prohibition on mailing cigarettes and smokeless tobacco products⁸⁶ to ENDS as defined in the Preventing Online Sales of E-Cigarettes to Children Act.⁸⁷ The proposed rule also included provisions related to “any component, liquid, part, or accessory of an ENDS, regardless of whether sold separately from the device.”⁸⁸ Under this rule, ENDS products would be subject to the same restrictions and exceptions as cigarettes. The comment period for the proposed rule closed on March 22, 2021. In advance of the publication of the final rule, the USPS released a guidance document on April 19, 2021, detailing how, once the final rule is published, mailers of ENDS may prepare applications to apply for the same exceptions as cigarette manufacturers that mail tobacco products.⁸⁹

ENDS User Fees

FDA does not collect user fees from ENDS manufacturers and importers, because the agency is not authorized to assess user fees from ENDS manufacturers and importers. FDA does not have this authorization because Congress did not specify an enumerated class for ENDS products and did not provide a framework by which FDA could potentially assess user fees for ENDS products.⁹⁰ Given recent concerns around ENDS products, the Center for Tobacco Products (CTP) has dedicated a portion of its user fees paid by other tobacco product manufacturers and importers to address ENDS-specific issues. Therefore, some stakeholders 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.

<https://www.gao.gov/assets/gao-03-714t.pdf>.

⁸³ See ATF, *Prevent All Cigarette Trafficking (PACT) Act*, June 28, 2021, <https://www.atf.gov/alcohol-tobacco/prevent-all-cigarette-trafficking-pact-act>.

⁸⁴ PACT Act §2A(e)(5)(A); Tobacco Legal Consortium, “E-Cigarettes and Other Tobacco Products Online: Preventing Sales to Kids,” <https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-guide-online-tobacco-products-kids-2016.pdf>.

⁸⁵ 15 U.S.C. §375.

⁸⁶ See generally 18 U.S.C. §1716E.

⁸⁷ U.S. Postal Service, “Treatment of E-Cigarettes in the Mail,” 86 *Federal Register* 10218, February 19, 2021.

⁸⁸ *Ibid.*

⁸⁹ U.S. Postal Service, “Treatment of E-Cigarettes in the Mail,” 86 *Federal Register* 20287, April 19, 2021.

⁹⁰ FDA, “Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigarettes and Pipe Tobacco,” 81 *Federal Register* 28707, May 10, 2016.

Based on FDA’s interpretation, for ENDS manufacturers to be subject to the tobacco product user fees, Congress would need to provide FDA with the authority to do so. For example, Congress may consider amending both Section 919 of the FFDCA⁹¹ and specific provisions of the Fair and Equitable Tobacco Reform Act of 2004 (FETRA). Although cigarettes and other tobacco products—including snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco—are subject to federal excise taxes,⁹² ENDS products are not subject to such taxes.⁹³ These taxes are a critical component of the FETRA formula;⁹⁴ therefore, if Congress were to amend FETRA and the 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) to make ENDS products subject to federal excise taxes.⁹⁵ Another option for Congress may be to create a new, separate ENDS user fee program.

Some in Congress and the executive branch have recently expressed interest in requiring ENDS manufacturers and importers to pay user fees. Legislation was introduced in the 116th Congress that would have either amended the FFDCA’s current user fee structure (by striking the FETRA provisions to allow for assessment of ENDS user fees)⁹⁶ or created a new, separate ENDS user fee program.⁹⁷ The FY2022 President’s budget request proposes requiring ENDS manufacturers and importers (along with manufacturers and importers of certain other deemed products) to pay \$100 million annually in user fees starting in FY2022.⁹⁸ Based on FDA’s current interpretation, user fees could not be collected from ENDS manufacturers and importers without first enacting authorizing legislation.⁹⁹

Increasing Minimum Age for Purchasing ENDS Products

Some public health stakeholders have been concerned about youth access to tobacco products in general and expressed support for raising the minimum age of purchasing tobacco products from 18 to 21.¹⁰⁰ Numerous scientific studies and Surgeon General Reports have documented that

⁹¹ 21 U.S.C. §387s.

⁹² See generally FDA, “Tobacco Product User Fees: Responses to Frequently Asked Questions”, May 2021, <https://www.fda.gov/media/149512/download>.

⁹³ For more information on why ENDS products are not currently subject to federal excise taxes, see U.S. Government Accountability Office, *Electronic Cigarettes: Effect on Federal Excise Taxes Collected on Traditional Cigarettes is Not Currently Evident*, GAO-15-771, September 2015, <https://www.gao.gov/assets/680/672467.pdf>, p. 16.

⁹⁴ 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*.

⁹⁵ Relevant IRC provisions are found at 26 U.S.C. §§5701-02.

⁹⁶ H.R. 2339, 116th Congress.

⁹⁷ S. 616, 116th Congress.

⁹⁸ FDA, *Justification of Estimates for Appropriations Committee* for FY2022, p. 288, <https://www.fda.gov/media/149616/download>.

⁹⁹ FDA’s interpretation also extends to other newly deemed products (e.g., hookah) not currently subject to user fee assessment. See FDA, *Tobacco Product User Fees: Responses to Frequently Asked Questions*, at <https://www.fda.gov/media/149512/download>.

¹⁰⁰ See, for example, Truth Initiative, “Where we stand: Raising the tobacco age to 21,” October 23, 2017, <https://truthinitiative.org/research-resources/tobacco-prevention-efforts/where-we-stand-raising-tobacco-age-21>.

tobacco product use often begins before the age of 18.¹⁰¹ Nearly 90% of cigarette smokers have tried their first cigarette by age 18, and 98% have tried their first cigarette by age 26.¹⁰²

The Family Smoking Prevention and Tobacco Control Act of 2009 (TCA) required FDA to commission a report on the public health impact of raising the minimum age of tobacco product sales.¹⁰³ FDA contracted with the Institute of Medicine (now known as the National Academy of Medicine) and concluded in a 2015 report that “increasing the minimum age of legal access to tobacco products will likely prevent or delay the initiation of tobacco use by adolescents and young adults.”¹⁰⁴ However, the report noted that “the impact on initiation of tobacco use of raising the minimum age of legal access to tobacco products to 21 will likely be substantially higher than raising it to 19, but the added effect of raising the minimum age of legal access beyond age 21 to age 25 will likely be considerably smaller.”¹⁰⁵

In FY2020 appropriations, Congress amended the FFDCFA to raise the federal minimum age of tobacco product sales to 21. FDA was also required to update its regulations by June 20, 2020, to reflect the new federal minimum age of tobacco purchasing, as well as the federal minimum age verification requirement (the age verification required for individuals younger than 30 years of age).¹⁰⁶ The final rule was required to take effect by September 20, 2020.¹⁰⁷ Although the spring 2021 White House OMB Unified Agenda of Federal Regulatory and Deregulatory Actions indicated that this rule would be published in May 2021,¹⁰⁸ the rule has not been published as of the date of this report.

¹⁰¹ U.S. Department of Health and Human Services, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, Atlanta, GA, January 2014, <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/50-years-of-progress-by-section.html>; National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, Centers for Disease Control and Prevention, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, U.S. Department of Health and Human Services, Atlanta, GA, 2012, <https://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf>.

¹⁰² U.S. Department of Health and Human Services, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, Atlanta, GA, January 2014, <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/50-years-of-progress-by-section.html>.

¹⁰³ TCA §104.

¹⁰⁴ Institute of Medicine, *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products*, The National Academies Press, p. 4-5, Washington, DC, 2015, <https://www.nap.edu/read/18997/chapter/1>.

¹⁰⁵ Institute of Medicine, *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products*, The National Academies Press, p. 4-5.

¹⁰⁶ For more information, see CRS Report R45867, *FDA Regulation of Tobacco Products*.

¹⁰⁷ §603(b) of Division N of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94). FDA has stated that the new age sales restriction is currently in effect. See FDA, “Newly Signed Legislation Raises Federal Minimum Age of Sale of Tobacco Products to 21,” January 15, 2020, <https://www.fda.gov/tobacco-products/ctp-newsroom/newly-signed-legislation-raises-federal-minimum-age-sale-tobacco-products-21>. Congress directed FDA to provide a written notification and justification for the delay in rulemaking to the committees of jurisdiction if the final rule was not promulgated 180 days after enactment.

¹⁰⁸ OMB, “Agency Rule List—Spring 2021: Department of Health and Human Services, Prohibition of Sale of Tobacco Products to Persons Younger Than 21 Years of Age,” <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202104&RIN=0910-AI51>.

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