REYNOLDS
A BETTER TOMORROW

401 North Main Street
Winston-Salem, NC 27101
336.741.2000

July 2, 2026

VIA Email

The Honorable Richard J. Durbin
United States Senate
711 Hart Senate Building
Washington, DC 20510

The Honorable Elizabeth Warren
United States Senate
311 Hart Senate Office Building
Washington, DC 20510

The Honorable Edward J. Markey
United States Senate
255 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Jeffrey A. Merkley
United States Senate
531 Hart Senate Office Building
Washington, DC 20510

The Honorable Richard Blumenthal
United States Senate
503 Hart Senate Office Building
Washington, DC 20510

The Honorable Jack Reed
United States Senate
728 Hart Senate Office Building
Washington, DC 20510

Dear Senators:

We are writing in response to your June 4, 2026,[1] letter regarding the Food and Drug Administration's ("FDA") May 2026 enforcement-priorities guidance for certain electronic nicotine delivery systems ("ENDS") products marketed without premarket authorization.[2] RAI Services Company[3] ("Reynolds") agrees that youth access to nicotine products should be prevented and appreciates the opportunity to share its views on this public health issue.[4] Like you, we believe that ENDS policies best serve public health where there is science-based regulation

[1] Letter from Sens. Richard J. Durbin, Elizabeth Warren, Edward J. Markey, Jeffrey A. Merkley, Richard Blumenthal & Jack Reed to David Waterfield, President & CEO, Reynolds Am. Inc. (June 4, 2026) ("Senate Inquiry Letter").

[2] U.S. Food & Drug Admin., *Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization* (May 2026) ("May Enforcement Guidance").

[3] RAI Services Company is a wholly owned subsidiary of its parent Reynolds American Inc., and it provides corporate and support services to Reynolds American Inc. and its distinct affiliates, including R.J. Reynolds Vapor Company. The term "Reynolds" is utilized here for convenience and refers to Reynolds American Inc. and/or one of its independent subsidiary operating companies, as applicable.

[4] Senate Inquiry Letter at 1–2.

and rigorous enforcement against illicit products—almost all of which come from Chinese manufacturers that evade all FDA review and target youth.[5]

At the outset, we believe it is important to share our core beliefs regarding nicotine products, including ENDS. In fact, many of your publicly stated positions, including many in your letter, are in complete alignment with ours. For example, we agree on the following:

- Youth should not use any nicotine products, including ENDS. Period.
- Adult smokers should have access to alternative and less harmful products, like ENDS, that have demonstrated through substantial scientific evidence that they are appropriate for the protection of public health.
- A lawful, FDA-regulated marketplace—supported by timely, science-based premarket review—best serves public health.
- Illicit imports—particularly misdeclared Chinese vapor products—are a serious issue.
- Interagency enforcement coordination is necessary to tackle the illicit vapor market, and federal agencies should use the full range of enforcement tools against unregulated actors.
    - FDA and the Department of Justice ("DOJ") should act decisively—through robust enforcement (e.g., going beyond Warning Letters or Civil Money Penalties)—to remove unauthorized products that defy regulation and appeal to children.
- It is far past time to pass bipartisan legislation to strengthen enforcement against unregulated tobacco products, including illicit ENDS.

FDA's Historic Inaction Drove an Illicit Market and Led to the Need for Reform

Reynolds agrees with the Senators' core enforcement concern: FDA should do more to address policy failures that have allowed illicit ENDS products—that is, unauthorized ENDS products that evade FDA premarket review, including youth-appealing products primarily

[5] *Durbin Questions FDA, DOJ on Allowing Sale of Unauthorized Vaping Products During Senate Judiciary Committee Hearing on the Prevalence of Youth E-Cigarette Use*, U.S. Senate Committee on the Judiciary (June 12, 2024), available at https://tinyurl.com/468x9jpw ("Sharing photos of several vaping products sold in a shop less than one mile from FDA's headquarters, Durbin asked, **"Not a single one of these products has been authorized by FDA. None of them. These illegal products—clearly designed for kids by their flavors—are being sold in the shadow of FDA's headquarters. How is that allowed to happen?"**) (emphasis in original).

imported from China—to gain a substantial market presence for years.[6] Today, these illicit Chinese products constitute approximately 80% of the American ENDS market.

Illicit products dominate the market because of FDA's inaction—both in terms of product authorization and enforcement. Congress directed FDA to make premarket tobacco product application ("PMTA") decisions "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application...."[7] But, to our knowledge, FDA has never met that deadline. Congress also directed FDA to enforce a regulated marketplace. Yet FDA has allowed illicit ENDS products that evade all FDA review to flood the marketplace.

While illicit ENDS came to dominate the market, FDA repeatedly pointed to its Warning Letters and Civil Money Penalties data—touting the sheer number of letters it had issued and fines it had assessed—to project an image of vigorous enforcement for public-relations purposes.[8]

That record does not withstand scrutiny. FDA long knew that it was having resource allocation issues and routinely testified as such during oversight hearings before Congress.[9] The Agency was responding to a multibillion-dollar illicit market with Warning Letters and Civil Money Penalties—a response not calibrated to the scale of the problem. A coalition of state attorneys general, meanwhile, reported that illicit e-cigarettes are "generating over $11 billion in annual retail sales," account for "more than 80% of all e-cigarette sales nationwide," and are "sold in more than 100,000 retail locations nationwide."[10] The May 2026 Enforcement Guidance acknowledges that reality, noting FDA "lacks the resources to pursue enforcement against every product that has not received authorization."[11]

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[6] *See U.S. Food & Drug Admin. Regulation of Electronic Nicotine Delivery Systems: Background and Selected Policy Issues* at 8–12, Cong. Rsch. Serv. (Apr. 4, 2025) (discussing flow of illicit ENDS products into the United States since 2018).

[7] 21 U.S.C. § 387j(c)(1)(A).

[8] *See* U.S. Food & Drug Admin., *Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products,* available at https://tinyurl.com/2pp6yjb8 ("To date, FDA has issued more than 800 warning letters to firms for manufacturing, selling, and/or distributing new tobacco products without marketing authorization from FDA, with more than 100 of these warning letters to firms manufacturing, selling, and/or distributing for unauthorized non-tobacco nicotine products.").

[9] *Durbin Questions FDA, DOJ on Allowing Sale of Unauthorized Vaping Products During Senate Judiciary Committee Hearing on the Prevalence of Youth E-Cigarette Use*, U.S. Senate Committee on the Judiciary (June 12, 2024), available at https://tinyurl.com/468x9jpw ("Dr. King said that the volume of premarket tobacco product applications (PMTAs) is overwhelming...."); *see also Durbin Calls FDA and DOJ Officials into Washington Office to Receive Briefing on Lack of Enforcement Against Unauthorized E-Cigarettes*, U.S. Senator Dick Durbin of Illinois (Apr. 12, 2024), available at https://tinyurl.com/2us3hufr ("In the meeting, Durbin questioned Dr. King on the FDA's delay in reviewing PMTAs and reminded him that the agency's inaction is leading to more children developing an addiction to e-cigarettes.").

[10] Letter from Brenna Bird, Att'y Gen. of Iowa, et al., to Payment Card Networks at 1–2 (Apr. 14, 2026) ("State Attorneys General Letter").

[11] May Enforcement Guidance at 4.

The historic gap between the Agency's response and the market it was meant to address is stark. For an operator earning millions from illicit ENDS, a Warning Letter or Civil Money Penalty does little to alter the economics that drive the illicit trade. The Agency's acknowledgment that it cannot pursue every unauthorized product underscores why a measured, case-by-case response was never going to keep pace with an $11-billion illicit market. The problem, in short, was the mismatch between the finite measures actually deployed and the magnitude of the conduct FDA was meant to deter.

By any measure, the Agency's efforts to reduce illicit ENDS sales—compared to the scale of the problem—were just a drop in the bucket. And the persistence and continued growth of the illicit trade, including the rise of so-called "nicotine analogues," are the clearest evidence that more is required. As a result of FDA's historic lack of enforcement, U.S. consumers, public health, and law-abiding companies have suffered. Reynolds has long advocated to Congress, FDA, and administrations of both parties for robust enforcement against illicit ENDS products and a clear pathway for rule-following applicants to receive prompt FDA authorization of their ENDS.

Reynolds respectfully disagrees with any suggestion that prioritizing enforcement against illicit and unregulated ENDS products provides a "free pass"[12] to youth-appealing products or authorizes unlawful sales. Distinguishing responsible applicants—those who have invested in scientific research, submitted comprehensive applications that have passed FDA's filing review stage or received supplemental PMTA acceptance—from entities attempting to evade FDA review entirely is not a regulatory loophole; it is a rational and appropriate allocation of FDA's enforcement efforts.[13] Such an approach continues to protect youth by allowing FDA to prioritize enforcement against products it believes have presumptively underage-appealing features—including products depicting cartoon-like fictional characters, disguising their nature as ENDS products, or resembling children's toys, phones, or gaming platforms—and against products that present significant public health or safety concerns, including high nicotine content, serious adverse experiences, lack of child-resistant packaging, or potential fire hazards.[14]

We agree that a well-regulated ENDS marketplace serves a critical public health function: providing adult smokers with scientifically reviewed less-risky alternatives to combustible cigarettes. Reynolds' strategic mission is to offer products to assist in the transition of adult smokers—who are not interested in or having difficulty quitting smoking entirely—from cigarettes to noncombusted alternatives. This objective aligns with FDA's recognition (both in general statements endorsing a continuum of risk for tobacco products and its individual product authorizations) that ENDS and other noncombusted products generally present lower health risks than cigarettes and may enable complete switching or significant reduction in combusted cigarette use resulting in a substantial health benefit.[15] And it follows the aims of the Tobacco Control Act,

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[12] Senate Inquiry Letter at 1.

[13] RAI Servs. Co., *Comment* on Docket No. FDA-2026-D-1817, *Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications—Considerations Related to Youth Risk*, at 32–37 (May 11, 2026) ("Reynolds May 2026 Comment"); *see also* May Enforcement Guidance at 3–5.

[14] May Enforcement Guidance at 4.

[15] *See* U.S. Food & Drug Admin., "*The Relative Risks of Tobacco Products*," available at https://tinyurl.com/3vwymf5j.

which preserves the right of adults to choose to use tobacco products against a public health backdrop that would decrease rates of morbidity and mortality from tobacco use.[16]

With respect to flavors other than tobacco and menthol, the scientific evidence demonstrates that flavor availability can materially increase the number of adult smokers who switch from combustible cigarettes to ENDS.[17] Reynolds believes that a limited set of flavored ENDS—when appropriately named and marketed responsibly to avoid youth appeal by manufacturers that adhere to FDA's rules— can help adult smokers switch while reducing demand for illicit ENDS products.[18]

The Need for FDA Reform Was a Widely Held Consensus View

An important public-health challenge is the illicit ENDS market that expanded while FDA's premarket review failed to provide timely, predictable decisions. The December 2022 Reagan-Udall Foundation operational evaluation of FDA's tobacco program[19]—an independent expert review commissioned by former FDA Commissioner Califf—described "an unintended shift from what was structured by law as a pre-market authorization framework to the reality of a post-market regulatory environment," warning that "millions of products have entered the market without pre-market authorization and remain on the market today." A coalition of state attorneys general reported[20] that illicit e-cigarette products "now account for almost all of the U.S. e-cigarette market," are "generating over $11 billion in annual retail sales," and are "making up more than 80% of all e-cigarette sales nationwide"; that illicit e-cigarettes are "sold in more than 100,000 retail locations nationwide"; and that FDA had "authorized only 41 e-cigarette products for legal sale in the United States" at the time of that letter. These illicit ENDS products bypass FDA's premarket scientific review, are deliberately packaged to appeal to children, are mislabeled to avoid seizure at border patrol, and are distributed through channels lacking robust age verification.

That enforcement-focused position is consistent with Senator Durbin's repeated criticism (as well as Reynolds' oft-repeated point) that FDA and DOJ have allowed thousands of unauthorized e-cigarettes to remain on shelves and have not acted with sufficient urgency to remove products that have not received FDA authorization or, in some cases, without applications even filed. Reynolds agrees with Senator Durbin that the agencies have the legal authority to stop

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[16] *See* 21 U.S.C. § 387 note (The purposes of Tobacco Control Act are, among other things, to "…ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products… [and] to continue to permit the sale of tobacco products to adults…"); *see also* 21 U.S.C. § 387k(g)(2)(B)(ii) (modified risk findings) ("the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users…").

[17] 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*, 25 Nicotine & Tobacco Res. 541, 543 (2023).

[18] Reynolds May 2026 Comment at 1–2, 15–16, 24–25.

[19] Reagan-Udall Found., *Operational Evaluation of Certain Components of FDA's Tobacco Program* 3, 22 (Dec. 2022) ("Reagan-Udall Report").

[20] State Attorneys General Letter at 1–3 & app. A-1.

unlawful manufacturers from flooding the market, and the answer must be action—not mere "signals"—against products that openly defy the law, evade FDA review, and appeal to children.[21] The May Enforcement Guidance likewise recognizes that enforcement resources should be focused on products that present the greatest public-health concerns, including unauthorized products with youth-appealing features, high nicotine content, or other safety risks.[22] Plus, the May Enforcement Guidance commits to establishing a "list" or public directory to be maintained by FDA that will provide more transparency to retailers on ENDS product status; Reynolds and responsible retailers, amongst others, have been advocating FDA to establish this for years. Reynolds continues to share that core enforcement objective: restore a lawful, FDA-regulated marketplace by concentrating enforcement on illicit ENDS products—especially youth-appealing disposables imported from China—while providing clear, timely, science-based review for responsible applicants.[23]

The specific harms uniquely associated with illicit ENDS products demonstrate why such products warrant FDA's enforcement scrutiny. For example, shipments are allegedly misdeclared as unrelated goods (e.g., batteries and flashlights) to evade customs duties and detection; products are made with unreviewed ingredients and without FDA inspection, as are products contaminated with heavy metals, carcinogens, and other dangerous compounds; counterfeit or youth-appealing devices are designed to resemble smartphones, gaming devices, or established brands become accessible; and products are on U.S. shelves with "Made in USA" claims despite being manufactured by Chinese or Hong Kong-based entities.[24]

Inadequate enforcement with respect to the growing illicit market has contributed to changed youth-use patterns, as evidenced by the most recent National Youth Tobacco Survey results showing that current youth ENDS users overwhelmingly used disposable products—almost all illicit ENDS.[25] Notably, although the illicit market has made flavored ENDS products ubiquitous and readily accessible nationwide, youth vaping rates have declined to historic lows—undermining the premise that flavor availability alone drives youth uptake.

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[21] *Durbin Questions FDA, DOJ on Allowing Sale of Unauthorized Vaping Products During Senate Judiciary Committee Hearing on the Prevalence of Youth E-Cigarette Use*, U.S. Senate Committee on the Judiciary (June 12, 2024), available at https://tinyurl.com/468x9jpw.

[22] May Enforcement Guidance at 3–5.

[23] Reynolds May 2026 Comment at 1–3, 32–37; *see also* RAI Servs. Co., *Comment to Docket No. USTR-2025-0001*, at 1–6 (Mar. 11, 2025); *see also* RAI Servs. Co., *Comments on FDA CTP Strategic Plan* (FDA-2023-N-2873), at 3–5 (Aug. 29, 2023); *see also* Reagan-Udall Report at 3, 22; *see also* State Attorneys General Letter at 1–3 & app. A-1.

[24] State Attorneys General Letter at 1–3; Reynolds May 2026 Comment at 21 & n.59.

[25] *See* U.S. Food & Drug Admin., *Results from the Annual National Youth Tobacco Survey (NYTS)*, available at https://tinyurl.com/2s3u9w4u ("The most commonly used device among current [youth] e-cigarette users was disposables (66.3%)"); *see also* Eunice Park-Lee et al., E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024, 73 Morbidity & Mortality Wkly. Rep. 774, 774 (2024), available at https://tinyurl.com/msyj35dr ("The device types used most often by students reporting current e-cigarette use were disposables (55.6%)."); *see also* May Enforcement Guidance at 4 n.11.

Effective youth protection in the ENDS category requires distinguishing between unauthorized products that evade FDA review and FDA-reviewed products subject to regulatory oversight. Illicit ENDS products that bypass FDA review, and use youth-appealing packaging, marketing, and product design present heightened youth-access risks. FDA-reviewed ENDS products can offer adult-smoker transition potential because they are subject to rigorous scientific scrutiny, post-market surveillance, and marketing restrictions. A balanced framework should entail clear standards (e.g., volumetric, nicotine content, battery safety, naming conventions, etc.) for responsible applicants, prompt FDA review, transparent product listings, strong post-market monitoring, and aggressive enforcement against illicit ENDS products that target youth.[26]

Reynolds agrees that youth should not use nicotine products and that FDA and DOJ should act decisively against illicit ENDS products that evade FDA review and appeal to children. The most effective path is to enforce aggressively against those illicit products while allowing FDA-regulated, science-based ENDS products to compete in a transparent marketplace.[27] Reynolds supports the bipartisan legislative efforts you have undertaken with others to strengthen enforcement against illegal tobacco products, including illicit ENDS products, and stands ready to work with Congress, FDA, state attorneys general, retailers, distributors, and other stakeholders to reduce youth access, restore the rule of law to the ENDS category, and advance the public health objective of moving adult smokers away from combustible cigarettes.

Committed to Compliance

Reynolds takes its compliance obligations seriously. Reynolds follows strict product stewardship, product development, and manufacturing quality processes to ensure our products are of the highest quality.[28] As required by the Tobacco Control Act, Reynolds submits PMTAs to FDA for review for every ENDS product that it markets. Indeed, Reynolds has received marketing granted orders for sixteen (16) products in the Vuse portfolio, including FDA's first-ever ENDS marketing granted order through the PMTA pathway. At present, a majority of Reynolds' pending ENDS PMTAs fall within FDA's May Enforcement Guidance framework.

Committed to Underage Access Prevention

Reynolds also maintains programs designed to prevent underage access, including retailer age-verification requirements, participation in We Card, sponsorship of TruAge®, monitoring of FDA compliance-check data, and restrictions on digital access and marketing to age-verified adults.

Moreover, Reynolds is committed to marketing its ENDS products responsibly. Our marketing communications must comply with the Reynolds Marketing Guidelines,[29] and adhere to core principles that exceed what the law requires, including but not limited to: all communications must be truthful and non-misleading; we make no health or modified risk claims

[26] May Enforcement Guidance at 3–5; Reynolds May 2026 Comment at 32–37.

[27] Reynolds May 2026 Comment at 2–3, 36–40.

[28] Reynolds May 2026 Comment at 1–2, 15–16, 24–25.

[29] *See* Reynolds, *Responsible Marketing*, available at https://tinyurl.com/23mw54m8.

unless and until specifically authorized by FDA; and we do not market "up the risk continuum." We also restrict advertising to measured media whose audience is at least 85% age 21 or older (as verified by independent third parties such as Nielsen and comScore), prohibit the use of celebrities or others judged to have special appeal to youth, and bar content depicting underage activities or suggesting that our products are essential to social prominence, success, or sexual attraction. We prohibit the use of social media influencers for marketing, carefully manage our owned channels, and deploy multiple third-party technologies to prevent underage access and keep our marketing oriented toward adult consumers. Our ENDS marketing plans are shared with FDA as part of the PMTA process. And for any product that receives a marketing granted order, the marketing is subject to post-market surveillance and reporting.

Finally, Reynolds is implementing a comprehensive retail compliance program to further restrict youth access to any flavored ENDS products in its portfolio. The compliance program includes (1) mandating scanning of a valid government-issued ID for every purchase of such products, (2) capping sales of such products to four pod packs per adult consumer per day, (3) requiring display of bespoke "Responsible Retailer" style decals at the retail outlet, and (4) enhancing consequences (e.g., monetary and ability to sell under our program) for underage sale violations as reported by FDA. Reynolds believes that these measures will further mitigate against the risk that a retailer may sell these products to underage purchasers.

Reynolds Participates Lawfully and Transparently in the Political Process

Reynolds actively works together with the FDA, engages with regulators and policymakers, and participates in the political and public policy process at both the federal and state levels, in compliance with law, to continue to identify meaningful solutions to provide adult tobacco consumers with access to less-risky products while helping to prevent youth access to those products. In connection with such participation, Reynolds makes the required disclosures to appropriate federal and state regulatory agencies, and those disclosures are available from those agencies. Reynolds rejects any suggestion that lawful civic participation alters its regulatory obligations or FDA's obligation to apply the law.

We appreciate your interest in these matters, and we hope this information is helpful to your understanding of these issues.