September 22, 2022

Dr. Brian King
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD. 20993-0002

Re: FDA enforcement policy toward illegal synthetic nicotine products

Dear Dr. King:

We write to express our concern that FDA is pursuing an enforcement policy toward new synthetic nicotine e-cigarette products that is entirely inconsistent with the amendment to the Food, Drug & Cosmetic Act, enacted in March as part of H.R. 2471, the Consolidated Appropriations Act, 2022,[1] giving FDA authority to regulate such products as tobacco products and mandating application of the premarket review process to those products.

The intent of Congress and the statutory language is clear: the goal of Congress was that FDA would take whatever enforcement action is necessary: a) to ensure that any product that now uses synthetic nicotine and that had previously received a marketing denial order (MDO) or refuse-to-file letter for a tobacco-derived version of the product not remain on the market after May 14, 2022; b) to ensure that any synthetic nicotine product for which a premarket tobacco product application (PMTA) was not submitted by May 14, 2022 not remain on the market after that date; and c) to remove from the market on or after July 14, 2022 any synthetic nicotine product that had not received a marketing order, whether or not a PMTA had been submitted. FDA has not taken the action necessary to accomplish any of these goals. Noting that H.R. 2471 created a "brief transition period," Senator Patty Murray (D-Wash.), chair of the Health, Education, Labor and Pensions Committee, said, "Dangerous nicotine products shouldn't be on the market totally unregulated just because of an outdated legal loophole – and now they won't be."[2] House Energy and Commerce Committee Chairman Frank Pallone (D-N.J.) also noted the short transition period in praising inclusion of the synthetic nicotine provision in H.R. 2471.[3]

[1] Pub. L. No. 117-103, 136 Stat. 49.
[2] https://www.help.senate.gov/chair/newsroom/press/omnibus-includes-provision-to-protect-kids-and-families-from-unregulated-synthetic-nicotine-products
[3] https://energycommerce.house.gov/newsroom/press-releases/pallone-applauds-inclusion-of-provision-to-close-synthetic-nicotine-loophole.

FDA's enforcement policy is contributing to the continued widespread availability of flavored tobacco products to young people, as documented in recent press reports[4] and through scores of examples of such products available in retail outlets throughout the nation, as collected by the Campaign for Tobacco-Free Kids.[5] Instead of taking the actions necessary to require that synthetic nicotine products without marketing orders come off the market, including those with pending premarket applications, FDA is insulating from enforcement, for an indefinite period, many synthetic nicotine products which are now illegal to sell or market, including all products for which marketing applications are pending. FDA's enforcement policy is defeating the purpose of the legislation and allowing flavored products harmful to the health of young people to continue to proliferate.

In applying the premarket review process to new synthetic nicotine products, H.R. 2471 created a "transition period" for products already on the market, which allowed products to remain on the market, free of possible FDA enforcement, for 120 days after enactment, if they submitted a PMTA within 60 days of enactment.[6] The transition period for products for which no application was submitted expired on May 14, 2022, and the transition period for products for which applications were submitted, ended on July 13, 2022. The statute provides that manufacturers may "continue to market" their products during the transition period.[7] The language leaves no doubt that, after the end of the transition period, manufacturers who "continue to market" their products without premarket orders are violating the law.[8] The statute also clearly states that the end of the transition period applies to products with pending applications.[9] Since the transition period for some products expired on May 14 and for others on July 13, and FDA acknowledges that no marketing orders have been granted for any synthetic nicotine products,[10] FDA and the U.S. Department of Justice, which plays a key role in FDA enforcement activities, are obligated to take all steps, including filing all enforcement actions, necessary to prevent the continued marketing of synthetic nicotine e-cigarettes, regardless of whether the products are the subject of pending PMTAs.

That Congress intended FDA to take action against companies that continue to market their synthetic nicotine products after July 13 without premarket orders is further demonstrated by statements by Congressional leaders concerning the expiration of the July 13 deadline. On July 13, as the transition period came to a close, Senators Dick Durbin (D-Ill.) and Susan Collins (R-Me.) wrote to Commissioner Califf expressing bi-partisan concern about FDA's meager

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[4] *See e.g.* Chris Kirkham et al., *New 'candy' e-cigs catch fire after U.S. regulators stamp out Juul's flavors*, Reuters (Aug. 16, 2022), https://www.reuters.com/business/healthcare-pharmaceuticals/new-candy-e-cigs-catch-fire-after-us-regulators-stamp-out-juuls-flavors-2022-08-16/.

[5] Campaign for Tobacco-Free Kids, "One Year After Deadline for FDA Action, Flavored E-cigarettes Remain Widely Available and America's Kids Remain at Risk," September 9, 2022 (Tobacco-Free Kids Release). https://www.tobaccofreekids.org/press-releases/2022_09_09_fda-deadline

[6] Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, Division P, Title I, Subtitle B, § 111(d)(2), 136 Stat. 49, 789-90 (2022).

[7] *Id.* § 111(d)(2)(B), 136 Stat. 790.

[8] *Id.* § 111(d)(3), 136 Stat. 790.

[9] *Id.*

[10] Brian King, FDA, *Perspective: Update on FDA Review and Enforcement of Non-Tobacco Nicotine Products* (Aug. 3, 2022) https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-update-fda-review-and-enforcement-non-tobacco-nicotine-products ("To date, no non-tobacco nicotine product has received a marketing granted order.").

enforcement of the premarket review requirements as to new e-cigarettes and the adverse impact of FDA's lack of enforcement on children attracted to these products.[11] Senators Durbin and Collins noted the new statutory language on synthetic nicotine and wrote: "The agency has another deadline – July 13, 2022 – to *clear the market* of all unauthorized e-cigarettes that use synthetic nicotine. The law gives FDA the clear authority *and duty* to remove all unauthorized synthetic nicotine e-cigarettes from the market."[12]

It should be understood that H.R. 2471 was passed against the backdrop of repeated Congressional expressions of dissatisfaction with FDA's enforcement of premarket review as to tobacco-derived nicotine e-cigarettes, particularly the agency's failure to meet the court-ordered deadline of September 9, 2021 for decisions on PMTAs submitted for such products.[13] For example, Rep. Raja Krishnamoorthi (D-Ill.), Chairman of the House Subcommittee on Economic and Consumer Policy, wrote to then-Acting Commissioner Janet Woodcock on September 10, 2021,[14] seeking her assurance that FDA would take enforcement action against e-cigarette products remaining on the market after the September 9 deadline:

> You also told the Subcommittee that any product whose PMTA application FDA failed to rule on by September 9, 2021, could be subject to immediate enforcement action because those products are "only on the market under enforcement discretion by the FDA" [citation omitted]. We request your confirmation that you will follow through and immediately start enforcing the law against every company selling e-cigarettes without a marketing order.

On March 9, 2022, a few days before President Biden signed H.R. 2471 into law, 17 United States Senators sent a bi-partisan letter to Commissioner Califf[15] objecting to FDA's delays in completing premarket review of tobacco-derived e-cigarettes, noting that six months after the court-ordered September 9, 2021 deadline, "FDA has not completed its reviews" of e-cigarette products "and is permitting unreviewed products to remain on the market, leaving children at risk of getting hooked on these e-cigarettes." The Senators explained that FDA lack of enforcement was inconsistent with the statutory scheme:

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[11] https://www.durbin.senate.gov/imo/media/doc/Final_RJD-SMC_FDA%20Synthetic%20Letter.pdf

[12] *Id.* at 1 (emphasis added).

[13] The new legislation also was passed following criticism of FDA's enforcement failures by the public health community. Indeed, the medical and public health groups who brought the lawsuit against FDA resulting in the September 9, 2021 deadline sought, and received from the Court, a modification of the original Remedial Order that requires FDA to provide periodic status reports on its review of the e-cigarette products with the largest market shares. Letter Order, *American Academy of Pediatrics v. FDA*, PWG-18-883, ECF 201 (D. Md. Apr. 15, 2022). In modifying the Remedial Order, the Court observed that "the popular products used by young people remain on the market unreviewed, which is inconsistent with the purpose of this Court's judgment" establishing the deadline. *Id.* at 2 (footnote omitted). The Court further observed that "FDA does not appear to have enforced the premarket review requirements against *any* product still awaiting a [Premarket Tobacco Product Application] decision, including products with the greatest market share and those most used by youth." *Id.* n.2 (quoting Plaintiffs' Motion) (emphasis in original).

[14] https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-09-10.RK%20to%20Woodcock-FDA%20re%20PMTAs.pdf.

[15] https://www.durbin.senate.gov/newsroom/press-releases/durbin-senators-to-fda-commissioner-agency-is-six-months-past-court-ordered-deadline-to-regulate-e-cigarettes

> Now that FDA is six months past the court deadline, these unreviewed products are only being permitted to stay on the market due to the agency exercising enforcement discretion. It makes no sense, and runs contrary to the Tobacco Control Act's statutory framework, that products that have not been granted authorization are being allowed to stay on the market and attract new, young users.[16]

Rep. Debbie Wasserman Schultz (D-Fla.), Rep. Diana DeGette (D-Colo) and 53 other Members of Congress sent a similar letter to FDA in March expressing concern about the agency missing the court-ordered deadline. In addition, in May of this year, Senator Durbin reacted to an FDA court filing revealing that the agency would not complete its review of PMTAs for tobacco-derived products until July, 2023 by leading a bi-partisan group of Senators on a letter to FDA urging the agency to "cease FDA's enforcement discretion on unreviewed e-cigarettes by immediately removing these products from store shelves until their review is completed."[17] In an earlier speech on the Senate Floor, Senator Durbin had called FDA's enforcement policy of taking no action against companies while their PMTAs were pending "just wrong" and "exactly the opposite of the intent of the law."[18] On June 30, 18 Members of Congress wrote to Commissioner Califf that "[c]urrent FDA policy has allowed e-cigarettes, including flavored products, to remain on the market while undergoing premarket review . . ." calling it "a significant public health risk given the rates of youth e-cigarette use." There is no question that the widespread availability of a dizzying variety of flavored e-cigarettes at retail outlets throughout the country remains a serious threat to young people.[19] Indeed, a new analysis from Truth Initaitive shows that since the missed September 9, 2021 deadline nearly 2.5 million youth and young adults (aged 15-24) have initiated e-cigarette use. This includes up to 1.2 million youth aged 15-17 and over 500,000 underage young people 18-20 years old. [20]

Against this backdrop of Congressional dissatisfaction with FDA's enforcement policies for e-cigarettes, the intent behind H.R. 2471's synthetic nicotine provision was to prevent FDA from doing for synthetic nicotine e-cigarette products what it had done for tobacco-derived products – allowing them to remain on the market for an indefinite period, including while FDA considers their PMTAs. Thus, H.R. 2471 must be understood as imposing a limit on the exercise of FDA's enforcement discretion as to synthetic e-cigarettes. In that legislation, Congress stepped in and imposed its own deadline on FDA, after which FDA must act to clear the market of e-cigarettes still lacking marketing orders, regardless of whether their PMTAs are still pending. In short, FDA can take whatever time it needs to review these PMTAs, but it must act to protect young people from these products during the review period.

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[16] https://www.durbin.senate.gov/newsroom/press-releases/durbin-senators-to-fda-commissioner-agency-is-six-months-past-court-ordered-deadline-to-regulate-e-cigarettes

[17] https://www.durbin.senate.gov/newsroom/press-releases/durbin-senators-to-fda-commissioner-remove-all-unauthorized-e-cigarettes-from-market-immediately

[18] https://www.durbin.senate.gov/newsroom/press-releases/durbin-im-calling-on-fda-to-immediately-halt-its-enforcement-discretion-and-remove-all-unauthorized-e-cigarettes-from-the-market#:~:text=This%20is%20just%20wrong.%20This%20is%20exactly%20the%20opposite%20of%20the%20intent%20of%20the%20law.

[19] Tobacco-Free Kids Release, Sept. 9, 2022.

[20] https://truthinitiative.org/press/press-release/new-truth-initiative-data-show-25-million-youth-and-young-adults-started-using

Unfortunately, however, your August 3 "Update on FDA Review and Enforcement of Non-Tobacco Nicotine Products" and the September 8 "FDA Continues to Implement Law Regarding Non-Tobacco Nicotine Products" indicate that FDA is prepared to defy the intent of Congress and will allow synthetic products for which PMTAs are pending to continue to threaten young people for an indefinite period, just as FDA has done with respect to tobacco-derived nicotine products. There is little doubt that Congress, in enacting H.R. 2471, did not intend for these products to remain on the market, immune from FDA enforcement, during this period of review. Although the updates indicate that FDA has issued refuse-to-accept letters and sent some warning letters to companies that have products on the market but failed to submit PMTAs,[21,22] as well as for products sold to underaged buyers, there is no indication that those warning letters are having any impact on clearing the market of illegal products, let alone all products for which no application was submitted. There is also no indication that warning letters have been sent for any of the huge number of products for which applications were timely submitted but have not received marketing orders. Further, no FDA communication has clearly stated that new tobacco products without marketing authorization, including those with pending applications, must come off the market immediately.

It is time for FDA to assure Congress, and the public, that it intends to enforce the law as to synthetic nicotine e-cigarettes consistent with the dictates and intent of Congress. FDA must expressly state that it will take strong action regarding all products for which no application was filed; it must also state that it will not exercise across-the-board enforcement discretion with respect to the products for which PMTAs are pending and that it and the U.S. Department of Justice are prepared to bring appropriate enforcement actions against such products if they remain on the market without the legally-required marketing orders.

Thank you for your consideration of our views.

Sincerely,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Truth Initiative

CC: Dr. Robert Califf, Commissioner, U.S. Food and Drug Administration

[21] The August 3 Update indicates that 17 warnings letters were sent on August 1 to companies that failed to file PMTAs but remain on the market. Given the continued widespread availability of flavored products, particularly disposable products, this number of warning letters is entirely inadequate to bring the proliferation of products under control. In addition, FDA has given no indication that it has sent any warning letters to manufacturers of products that received MDOs or refuse-to-file letters and then introduced the same products as synthetic products. All such products became illegal to sell on May 14, 2022 unless they received a marketing order – and to date, none have received one. Appropriations Act § 111(d)(2)(C), 136 Stat. 790.

[22] CTP News, "FDA Continues to Implement Law Regarding Non-Tobacco Nicotine Products (Sept. 8, 2022).