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VIA E-MAIL

Dr. Brian King
Director
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Building 71, Room G335
Silver Spring, MD 20993

Re: Effective Use of Civil Monetary Penalties to Control Illegal Marketing of E-Cigarette Products

Dear Director King:

We represent the Campaign for Tobacco-Free Kids ("Tobacco-Free Kids") and write to express our concern about the low level of civil monetary penalties recently sought by the FDA against manufacturers selling unauthorized e-cigarette products. We also write to request a meeting with you and your colleagues about this matter.

According to the latest available data, 14.1% (2.14 million) of high school students and 3.3% (380,000) of middle school students report e-cigarette product use, and 85% of these students use flavored products.[1] Recognizing the highly addictive nature of nicotine and its harm to the developing adolescent brain, FDA has stated that e-cigarette product use among youth remains a "top concern" for the Agency.[2] All flavored e-cigarette products are marketed illegally,[3] and it is critically important that FDA use all of its enforcement tools to address this significant public health problem.

FDA should exercise its existing powers both to remove products lacking marketing authorization from the market, and to impose stiff monetary penalties on companies that persist in violating the law so that others will have the incentive to comply. One important tool that

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[1] *Results from the Annual National Youth Tobacco Survey*, FOOD & DRUG ADMIN., https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey (last updated Dec. 20, 2022).

[2] *Id.* (citing *E-Cigarette Use among Middle and High School Students — United States, 2022*, CENTERS FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf).

[3] To date, the only e-cigarette products to receive FDA authorization are tobacco-flavored products and devices.

Congress has given the Agency to accomplish this task is the civil monetary penalty ("CMP") provision in the Federal Food, Drug, and Cosmetic Act.

We urge FDA to hold manufacturers accountable for making or selling illegal e-cigarette products[4] by asserting, and seeking the statutory maximum for, *multiple* violations of the Family Smoking Prevention and Tobacco Control Act ("TCA"). This would be a change from what we understand to be the current policy of charging manufacturers or sellers with a single violation.

On February 22, 2023, FDA announced that for the first time it had filed CMP complaints against four tobacco product manufacturers for manufacturing and selling e-cigarette products without marketing authorization.[5] While an important and welcomed first step, there are thousands of e-cigarette products being sold illegally. In order for this initiative to be successful, FDA must significantly expand this effort. Because children overwhelmingly favor flavored e-cigarette products, FDA should prioritize its enforcement efforts and aggressively pursue CMPs against manufacturers of flavored products.

In its February 22 press release, FDA stated that it was pursuing the "statutory maximum allowed by law." We agree that these circumstances merit the maximum penalty. However, the Agency charged each of the four manufacturers with only a *single* violation of the TCA, seeking only $19,192—the maximum penalty for a single violation—from each company.[6] We are concerned that seeking a total of only $19,192 from a manufacturer for marketing perhaps thousands of violative products will do little to deter wrongdoers and pressure e-cigarette manufacturers into compliance. In fact, as we explain below, the Agency has authority to charge a manufacturer with multiple violations, up to $1.2 million in a single proceeding. Moreover, under the statute, the Agency may initiate multiple proceedings against a manufacturer that has repeatedly violated the law, as many e-cigarette product manufacturers have.

The plain language of the TCA states that FDA may seek CMPs for *multiple* violations in a single action. This is consistent with how FDA historically has interpreted the statute. The TCA provides that "any person who violates a requirement of this Act which relates to tobacco products shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for *each* such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding." 21 U.S.C. § 333(f)(9)(A) (emphasis added). By law, the individual and collective maximum amounts are inflation-adjusted and have increased to $19,192 and $1.2

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[4] Consistent with FDA's terminology, "e-cigarette products" include e-cigarettes, vapes, e-liquids, e-cigars, e-pipes, and e-hookahs. *See, e.g.*, *How FDA is Regulating E-Cigarettes*, FOOD & DRUG ADMIN. (Sept. 10, 2019), https://www.fda.gov/news-events/fda-voices/how-fda-regulating-e-cigarettes.

[5] *FDA Files Civil Money Penalty Complaints Against Four E-Cigarette Product Manufacturers*, FOOD & DRUG ADMIN. (Feb. 22, 2023), https://www.fda.gov/news-events/press-announcements/fda-files-civil-money-penalty-complaints-against-four-e-cigarette-product-manufacturers.

[6] *Id.*

million, respectively.[7] By specifying the penalty "for each such violation," the TCA allows FDA to charge several violations in one proceeding.

Federal courts have adopted this straightforward interpretation of the statute. In *Orton Motor v. HHS*, the D.C. Circuit upheld FDA's CMP levied against a tobacco seller for three violations of the prohibition on selling cigarettes to underage children.[8] In that case, FDA explained that the TCA allows FDA to charge multiple violations:

> Adopting [the tobacco seller's] view would preclude FDA from finding more than one violation even if an inspection revealed that a retailer made several separate unlawful sales. [The tobacco seller] is similarly wrong in urging that FDA may charge only one violation per transaction. Where Congress wanted to limit the term "violation," it did so expressly.[9]

The D.C. Circuit agreed, holding that FDA could charge three separate violations stemming from two inspections.[10]

FDA's interpretation of the CMP provision of the Safe Medical Devices Act ("SMDA") is also instructive. That provision, which was the model for the CMP provision of the TCA, contains language that is identical to the above-quoted language in the TCA. *See* 21 U.S.C. § 333(f)(1)(A). FDA has charged multiple violations for medical devices brought under this provision. For example, in its complaint against Advanced Bionics for selling defective hearing aids, FDA sought the maximum penalty of $1.1 million. This total penalty reflected the maximum penalty for the 74 separate instances where Advanced Bionics introduced the product to market—*i.e.*, 74 separate violations of the statute.[11]

The plain meaning of the TCA applies with equal force in the context of unauthorized e-cigarette products. Like the multiple violations charged from one inspection in *Orton Motor* and FDA's past enforcement of the SDMA, FDA has the authority to charge multiple violations for one unauthorized e-cigarette product. We thus strongly urge FDA to pursue the statutory maximum allowed by law for *multiple* violations of the TCA for each unauthorized e-cigarette product.

We request a meeting to speak to you further about this important matter. Thank you for

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[7] *See* 45 C.F.R. § 102.3; *see also* 21 U.S.C. § 333(f)(9)(A).

[8] *Orton Motor, Inc. v. United States Dep't of Health & Hum. Servs.*, 884 F.3d 1205, 1214 (D.C. Cir. 2018).

[9] Brief of Respondent at 19, *Orton Motor, Inc. v. United States Dep't of Health & Hum. Servs.*, 2017 WL 1736701, No. 16-1299 (D.C. Cir. May 3, 2017).

[10] *Orton Motor*, 884 F.3d at 1214.

[11] Complaint ¶ 23, *In re Advanced Bionics Corp.*, No. 3:07-cv-01777-M, ECF No. 12-6 (Apr. 14, 2008).

your consideration of this letter.

Sincerely,

/s/ William B. Schultz

William B. Schultz
Andrew N. Goldfarb
Trillium Chang

cc: Dr. Robert Califf, Commissioner
Mark Raza, Chief Counsel
Ann Simoneau, Director, Office of Compliance and Enforcement