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Congress of the United States House of Representatives Washington, VC 20515—0307

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October 4, 2024

Brian King, M.P.H., Ph.D. Director, Center for Tobacco Products U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, Maryland 20993-0002

Brian Boynton Principal Deputy Assistant Attorney General Consumer Protection Branch, Civil Division U.S. Department of Justice 950 Pennsylvania Avenue, N.W. Washington, DC 20530-0001

Dear Dr. King and Mr. Boynton:

The recently announced multi-agency task force, which seeks to bring the collective resources of the federal government to bear against those supplying illegal e-cigarettes, is a potential turning point in the ongoing illicit e-cigarette crisis. To disrupt the actual sale and distribution of illegal e-cigarettes in the market, I request the members of the task force use all resources and authorities at their disposal to hold illicit market actors accountable.

While youth vaping rates are declining, too many children can easily access these flavored illegal products. The result is a growing public health crisis that is likely to harm U.S. consumers and is already contributing to underage tobacco use rates that are far higher than what is acceptable.

Several illicit brands marketed to minors, including Elf Bar, Geek Bar, Esco Bars, Lost Mary, are among the 10 most popular brands with school students based on the recently released 2024 National Youth Tobacco Survey.²

As a Congressman from Arizona, I take seriously the threat these products pose to Arizonans, particularly young Arizonans. While I am hopeful that the task force represents a significant step to finally combat the illicit nicotine crisis, I have yet to see any public actions taken to hold the

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¹ Seven of the ten most popular e-cigarette brands among middle and high school students are illicit flavored disposable products (Elf Bar, Breeze, Mr. Fog, Esco Bars, Fume SMOK, Kangvape, and GeekBar). See Notes from the Field: E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024 Weekly / September 5, 2024 / 73(35);774–778

² Park-Lee E, Jamal A, Cowan H, et al. Notes from the Field: E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:774–778.

largest manufacturers or distributors most responsible for the explosive growth of the illicit ecigarette market.

Every day without action results in more young Arizonans falling victim to addictive products from China.

Just in Arizona, we have two entities, Mi-Pods and Happy Distro, that are among the largest domestic distributors of illicit e-cigarette brands, with the FDA also issuing warning letters for supplying illicit e-cigarette products.³ But even though the distributors operate in plain sight and open defiance of federal law, neither have been subject to civil monetary penalties or any other enforcement actions.

These distributors, and others that are similarly situated, supply illicit products that are manufactured, distributed, and sold without FDA oversight. That means they are supplying products to millions of U.S. consumers without review of product ingredients or additives, manufacturing processes or controls, and product labeling or marketing. In addition to their wholesale operations, many also operate direct-to-consumer websites that sell hundreds of ecigarettes FDA has already cited as misbranded and adulterated in warning letters and import alerts.

Most of the leading manufacturers of illegal e-cigarettes are domiciled in China. Although there may be constraints in enforcing judicial and administrative orders against these foreign companies, these constraints do not apply to the U.S.-based distributors that bring these illegal products to U.S. consumers, nor do they apply in securing our borders against the importation of illegal products.

With the establishment of the multi-agency task force – and the promise of greater coordination between FDA and DOJ – inaction on enforcement is no longer tolerable. The task force must issue impactful enforcement actions immediately to send a clear message to the worst offenders that open defiance of applicable laws and regulations will no longer be permitted.

Thank you in advance for your consideration and I look forward to your response.

Sincerely,

Ruben Gallego

MEMBER OF CONGRESS

³ https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sv3-llc-dba-mi-one-brands-647624-12022022