

WASHINGTON, DC 20510

March 6, 2024

William Sansom Chief Executive Officer H.T. Hackney 502 South Gay Street, Ste 300 Knoxville, TN 37902

Dear Mr. Sansom:

We write to draw your attention to distributor and retailer responsibilities under the *Family Smoking Prevention and Tobacco Control Act (P.L. 111-31)*, and to specifically highlight apparent widespread violations of federal law prohibiting the sale and distribution of unauthorized tobacco products at convenience stores, gas stations, and other retail outlets across the nation.

Under the law, no tobacco product—including electronic nicotine delivery systems such as e-cigarettes or vaping devices, including those containing nicotine not made or derived from tobacco—may legally enter the market for sale without having first received authorization by the Food and Drug Administration (FDA) that the product is "appropriate for the protection of public health" (21 U.S.C. § 387j(c)). To date, only 23 e-cigarettes or vaping devices have been authorized by the FDA—those products can be found here, including a link to a free, downloadable list for printing: <u>https://digitalmedia.hhs.gov/tobacco/print_materials/CTP-250</u>.

<u>Every single</u> e-cigarette or vaping product that is not on this list was not authorized by FDA, making such products illegal and adulterated and misbranded under Sections 902 and 903 of the *Federal Food, Drug, and Cosmetic Act.* Companies distributing or selling any such unauthorized products are subject to enforcement penalties by the FDA, which may include a civil monetary penalty or no-tobacco-sale order. To date, FDA has issued more than 440 warning letters and 88 civil monetary penalties to retailers for the sale of illegal e-cigarettes and vaping products. Retailers and distributors engaged in the sale or distribution of such unauthorized products risk liability.

Despite these statutory requirements, a trip to many convenience stores, gas stations, or similar retail outlets reveals scores of unauthorized e-cigarettes and vaping products being sold. These illegal sales also pose a tremendous public health threat. Today, millions of children use unauthorized e-cigarettes, risking nicotine addiction, respiratory illness, exacerbation of depression and anxiety, and many other harms.

As Chairs of the Senate Judiciary Committee; Finance Committee; Health, Education, Labor, and Pensions Committee; Banking, Housing, and Urban Affairs Committee; and Permanent Subcommittee on Investigations, we are working with the Department of Justice, FDA, and other agencies, to ensure adequate enforcement of federal laws to protect public health and prevent the unauthorized sale of tobacco products. We strongly encourage your company to ensure compliance with federal laws to prevent youth use of harmful tobacco products and protect your company from liability.

Sincerely,

Richard J. Durbin United States Senator Chair, Senate Committee on the Judiciary

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Bernard Sanders United States Senator Chairman, Committee on Health, Education, Labor, and Pensions

Ron Wyden United States Senator Chairman, Committee on Finance

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Sherrod Brown Chairman Senate Committee on Banking, Housing, and Urban Affairs

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Richard Blumenthal United States Senator Chairman, Permanent Subcommittee on Investigations