## United States Senate

## WASHINGTON, DC 20510

March 6, 2024

Brian Hannasch Chief Executive Officer Circle K Stores, Inc. 1130 West Warner Road, Bldg B Tempe, AZ 85284

Dear Mr. Hannasch:

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: <a href="https://digitalmedia.hhs.gov/tobacco/print\_materials/CTP-250">https://digitalmedia.hhs.gov/tobacco/print\_materials/CTP-250</a>.

Every single 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

Bernard Sanders

United States Senator

Chairman, Committee on

Health, Education, Labor, and

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Pensions

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**United States Senator** 

Chairman, Committee on

Sherrod Brown

Chairman

Finance

Senate Committee on

Banking, Housing, and Urban

Affairs

Richard Blumenthal United States Senator Chairman, Permanent

Subcommittee on

Investigations