

# United States Senate

COMMITTEE ON  
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

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November 13, 2019

President Donald Trump  
The White House  
Washington, D.C. 20500

Dear Mr. President:

Recent reports indicate that the Food and Drug Administration (FDA) will issue guidance restricting the sale of certain e-cigarette flavors, which could have a devastating effect on the e-cigarette industry and force many small businesses to shut down.<sup>1</sup>

The costs of a ban on most e-cigarette flavors will almost certainly be substantial. Many stakeholders in the e-cigarette industry are small businesses—over 10,000 according to some estimates<sup>2</sup>—so an outright ban on the most popular flavors purchased by adults will likely force them to close. The closure of these small businesses, including the loss of thousands of jobs, could essentially destroy this estimated \$9 billion industry.<sup>3</sup>

Although major restrictions on the sale of e-cigarette flavors will have a significant financial impact on this industry, reporting indicates that the guidance under review at FDA and the Office of Information and Regulatory Affairs (OIRA) was designated as not “economically significant.”<sup>4</sup> The “economically significant” designation, which applies to any action that is likely to have an annual effect on the economy of \$100 million or more, ensures a thorough review by both the FDA and OIRA of the costs and benefits.<sup>5</sup>

Aside from the significant monetary costs of the flavor restrictions, there is also a significant cost to the public health. Many adults have quit smoking by switching to e-cigarettes, a product that is 95 percent less harmful according to Public Health England,<sup>6</sup> and they rely on

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<sup>1</sup> Josh Wingrove and Gerald Porter Jr., *Vape Shops Likely to Be Exempted in Planned FDA E-Cig Curbs*, Bloomberg, Nov. 6, 2019, <https://www.bloomberg.com/news/articles/2019-11-06/vaping-shops-likely-to-be-exempted-in-planned-fda-e-cig-curbs>.

<sup>2</sup> John Kartch and Adam Sabes, *Vape Flavor Ban Will Devastate Main Street Businesses Nationwide*, Americans for Tax Reform, Nov. 4, 2019, <https://www.atr.org/vape-flavor-ban-will-devastate-main-street-businesses-nationwide>.

<sup>3</sup> @GoPaulBlair, Twitter (Oct. 29, 2019, 7:54 AM), <https://twitter.com/gopaulblair/status/1189193784229355520>.

<sup>4</sup> Office of Mgmt. & Budget and Gen. Serv. Admin., Exec. Office of the President, *Pending EO 12866 Regulatory Review, RIN: 0910-ZA56, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (Screenshot on file with Comm. Nov. 5, 2019, 5:41 PM), retrieved from <https://www.reginfo.gov/public/do/eom12866SearchResults?pubId=&rin=0910-ZA56&viewRule=true>.

<sup>5</sup> Exec. Order No. 12866, 58 Fed. Reg. 190 (Oct. 4, 1993), <https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf>.

<sup>6</sup> Press Release, *PHE publishes independent expert e-cigarettes evidence review*, Public Health England, Feb. 6, 2018, <https://www.gov.uk/government/news/phe-publishes-independent-expert-e-cigarettes-evidence-review>.

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flavors that this guidance threatens to restrict or make harder for them to obtain. If former smokers cannot access products that they have used to kick the habit, they could very well return to less healthy alternatives like smoking cigarettes or purchasing illicit products on the black market. That outcome would be a public health disaster.

Under your leadership, the regulatory burden faced by businesses has been greatly reduced. You have successfully implemented policies that reduce government interference in the private sector and help small businesses flourish. Further, you have also led much-needed efforts to stop federal agencies' use of guidance documents to circumvent the formal rulemaking process. However, a costly guidance document from the FDA restricting e-cigarette flavors would be inconsistent with those significant achievements.

I am supportive of regulations that ensure the safety of consumer products, and common-sense efforts that prevent youth access to e-cigarettes. But I am strongly opposed to far-reaching, unchecked government action that stifles innovation and restricts adults' freedom to choose safer alternatives to smoking. As your administration finalizes this anticipated guidance, I respectfully urge you to consider to the long-term costs and public health consequences this type of policy could have on Americans.

Sincerely,



Ron Johnson  
Chairman