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Senators' Letter To FDA Commissioner Gottlieb Perpetuates Misconceptions About E-Cigarettes

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In a letter to Dr. Scott Gottlieb, the new commissioner of the Food and Drug Administration, eleven Democratic senators previewed the pressure that he will face as he addresses policy reform regarding electronic cigarettes.

"We encourage you to prioritize efforts to prevent tobacco-related disease and keep tobacco products out of the hands of children," wrote the senators recently, echoing a goal that Gottlieb too had endorsed during his confirmation hearing.

Toward that aim, they urged Gottlieb to "stand up to special interests" and oppose a recent FDA decision to delay by three months the deadline for regulating e-cigarettes, battery-powered devices that are estimated by Britain's Royal College of Physicians to be at least 95 % less risky than conventional cigarettes because they deliver nicotine without the carcinogenic and toxic tar.

Will a letter from a small group of lawmakers exert much impact on FDA practice?

WASHINGTON, D.C. – APRIL 05: FDA Commissioner-designate Scott Gottlieb testifies during a Senate Health, Education, Labor and Pensions Committee hearing on April 5, 2017 at on Capitol Hill in Washington, D.C. (Photo by Zach Gibson/Getty Images)

It's doubtful. For one thing, the agency and the Department of Health and Human Services have considerable latitude in executing tobacco policy reform. What's more, funding for the Center for Tobacco Policy (CTP), the engine room of tobacco product regulation, is funded by the tobacco industry through generous statutory user fees, not appropriated dollars.

But the senators' letter is important nonetheless as a window into a larger, national discussion about e-cigarettes that is rife with misunderstandings, warped facts, and alarmism.

Some background. In the spring of 2016, the FDA issued a "deeming rule" bringing e-cigarette devices and associated nicotine liquids under the jurisdiction of the Tobacco Control Act and requiring each product to be authorized by FDA.

It was clear from the outset that the cost of filing an application for approval would be excessive. FDA itself estimates application costs of between $286,000 and $2.6 million for devices and between $182,000 and $2.0 million for liquids – and there are tens of thousands of devices and liquids.

This high cost is combined with great uncertainty about the how FDA would make its decisions and therefore whether it is worth risking an application.

Taken together, these burdens would devastate the e-cigarette market and crush hundreds of decent small businesses – as many as 99% would exit. It would harm consumers using e-cigarettes as an alternative to smoking and protect the cigarette trade from competition. Even worse, the chilling effect on innovation would keep smokers inhaling lethal tar.

Delaying compliance would give new leadership at FDA and HHS precious time to evaluate issues raised by the deeming rules and to consider alternative regulatory approach. And support for new rules is strong among other politicians, the Attorney General of Iowa, respected public health experts, the vaping industry, and vapers themselves.

A promising option to replace some of the deeming rules is a product standards regime.

Instead of filing applications for each product variant, FDA would set product standards to establish clear and transparent rules for access to the market. Standards could be defined to control any chemical, mechanical, thermal or electrical risks for e-cigarettes; define schedules of prohibited or limited ingredients; and establish good manufacturing and quality control practice. Existing bans on sales to teens and on sales by vending machine would be retained.

There is precedent for a standards approach. Last year, the Medicines and Healthcare Products Regulatory Agency issued minimum standards for the safety and quality of all e-cigarettes and refill containers (otherwise known as e-liquids). The European Union has adopted a regime based on standard-setting and notification rather than product-by-product authorization. The United States now has an opportunity to adapt and improve upon the approach taken by the Europeans.

Yet senators claim that a pause for reconsideration will have "dangerous consequences" for the teens "deliberately targeted" by an industry that plies them with flavors such as "cookies and cream" and "cotton candy." This sentiment mirrors familiar activist talking points in which a predatory industry uses child-like flavors to hook kids on vaping and ultimately to get them to smoke. It's a compelling story, but it just isn't true.

In adolescents, daily or regular vaping is highly concentrated among those who smoke – this explains the 'strong association' between vaping and smoking that the senators draw attention to. But it arises because the same things that incline young people to smoke also incline them to vape. It does not mean the vaping causes the smoking. In reality it means that vaping is likely functioning as an *alternative* to smoking, and is partly responsible for the rapid decline in smoking among teenagers since 2010 when e-cigarettes first started becoming popular.

According to the University of Michigan Monitoring the Future survey, cigarette smoking among 12th graders fell from 19.2 percent in 2010 to 10.5 percent in 2016, a rate of decline four times as rapid as the average over the previous 35 years. It is more likely than not that the surge in vaping has a beneficial impact on teenage health by reducing smoking.

There is no evidence that particular flavors exert such a large pull on teenagers that they cause them to start vaping when they otherwise would

not. It is true that once they use these products teenagers say they like the flavors, but that is what we should expect – we would be more alarmed if they were vaping while disliking the flavors!

A 2015 survey published in the Journal of the American Medical Association publicized the obvious finding that teenagers who already vape like the flavor. But there was little reporting of the less obvious but more interesting finding: that teens are using e-cigarettes to reduce harm to themselves, to quit smoking and to protect those around them (see Table 2), and that taken together, these protective motivations are the main reason teens vape.

Finally, the vast majority of American vapers are adults and their health matters. Many have been smoking for decades and it is their health that is in the greatest peril. By 2015, 2.5 million vapers were former smokers – a very encouraging sign.

As with teens, we have seen a rapid decline in adult smoking since 2010. The National Health Interview Survey shows a decline in adult smoking from 20.6 percent in 2010 to 15.8 percent in 2016, representing an acceleration of the previous rate of decline and despite a change of sampling methodology in 2016. In good news, the CDC just reported that e-cigarettes are the most popular device used for smoking cessation (35.3%), more popular than both the nicotine gum and patch combined (25.4%).

The senators, to their credit, give credence to the possibility of a harm reduction benefit – the idea that nicotine can be delivered to smokers in a safer way. Their mistake is in believing that the FDA's current deeming rules are the way to realize it.

The lesson, as ever, is that bad facts drive bad policy. E-cigarettes, and other reduced risk products, are breakthroughs in public health. They must be regulated for safety, surely, but in a manner that facilitates ongoing product improvement and puts them on the fastest track possible into the hands of the millions of American smokers.

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