

Statement before the House Labor, Health, Education Appropriations Subcommittee On E-cigarettes: An Emerging Threat to Public Health

Putting Teen Vaping in Perspective: Balancing protection of youth with health of smokers

Sally L. Satel MD Resident Scholar American Enterprise Institute Lecturer in Psychiatry, Yale University School of Medicine

October 16, 2019

The American Enterprise Institute (AEI) is a nonpartisan, nonprofit, 501(c)(3) educational organization and does not take institutional positions on any issues. The views expressed in this testimony are those of the author.

I am grateful to Chairwoman Rosa DeLauro, Ranking Member Tom Cole, and members of the subcommittee for inviting me to offer my view on this vital public health issue.

I am resident scholar at the American Enterprise Institute and a lecturer at Yale University School of Medicine. My medical expertise is in addiction psychiatry. I also serve on the current National Advisory Board of the Substance Abuse and Mental Health Services Administration. I have worked part time in mental health and methadone clinics in the District. I spent last year in Rust Belt Appalachia (southeastern Ohio) studying the opioid crisis.

Today, I would like to comment on electronic cigarettes and commercial nicotine vaping in the context of two recent developments. The first is the rash of about 1,300 cases of lung injuries and 26 deaths (as of October 11) linked to vaping. The second development is the imposition of non-tobacco flavor bans on e-cigarettes and vaping products. The facts show that the bans would do nothing address the lung injuries and deaths.

I want to emphasize the crucial importance of distinguishing between the cannabisrelated products responsible for causing pulmonary illnesses and deaths from nicotinecontaining commercial vaping products, which have not caused been identified as the source.

I also highlight the serious unintended consequences imposed upon adult vapers by flavor bans that are aimed at discouraging teen use.

Without question, we must reduce teen vaping but other, non-prohibitionist solutions can help achieve that imperative. We must not impede vital access to vaping products for the 11-14 million adult vapers who might otherwise smoke instead or for the 38 million smokers who could switch to vaping if they cannot quit smoking by other means.

Vaping-Induced Lung Injury

For weeks, the Food and Drug Administration (FDA) has been communicating to the public the dangers of vaping street-bought THC. Most recently, on October 4, the agency released a statement with a headline warning people to "stop using THC vaping products."¹ According to the FDA, "The best way to avoid potentially harmful effects is to not use THC, including through e-cigarette, or vaping, products...[T]he latest findings from the investigation into lung injuries associated with e-cigarette use, or vaping, suggest products containing THC play a role in the outbreak."

The lung injury problem is a story of the dangers of the black market, not of vaping. Earlier this month, a California cannabis lab tested counterfeit vapes and found high levels of dangerous chemicals, including vitamin E acetate (a cutting agent used to stretch the amount of THC in vape cartridges), pesticides, and hydrogen cyanide.²

Consumers have been using commercially available vaping devices and nicotine products for

10 years without a single recorded death or any surge of illnesses...until this summer. What we are observing today is consistent with a relatively acute contamination.

Thus, warning smokers in a blanket manner not to vape is a hazard to smokers who have already switched to e-cigarettes and now risk return to smoking combustible cigarettes. After all, vaping is a generic term for an activity that uses a device to inhale substances in aerosolized (droplet) form. FDA's emphasis on THC cartridges targets the actual problem.

The key lesson here is that the tragic cases of lung injury and death are completely separate from the commercially sold vaping products intended to help smokers relinquish cigarettes. Risk communication and policies targeted at THC, not global warnings against vaping, are needed.

Flavor Bans

Background:

On September 11, the Trump administration announced its intention to ban all nontobacco flavored e-cigarette vapes from the market. The impetus for the news was the release of preliminary data from the National Youth Tobacco Survey showing that more than one in four high school students ³ had used an e-cigarette ("vaped") within the past month in 2019, with most using flavored products. A week later, the Monitoring the Future Survey revealed that 11.7 percent of high school seniors ⁴ reported vaping on 20-30 days out of the past month in 2019. Both results represented increases over the year before. (Notably, however, earlier data show that current and former smoking students are far more likely to fall into the frequent-use category than are never-smoking teens.)

These worrisome data spurred the administration to curb the sale of vaping liquid with fruit and candy flavors in order to dissuade teens from use. The ambient alarm surrounding lung illness and deaths – particularly in light of erroneous impression that e-cigarettes played a role --surely contributed to the impetus behind decisions to ban.

As of October 9, Massachusetts, Michigan, Montana, New York, Oregon, Rhode Island, and Washington have moved to ban most flavored nicotine vaping products. The California Department of Public Health recently warned against all vaping devices, and the governor of Massachusetts issued a four-month ban on all vaping products. Los Angeles County voted last week to ban flavored tobacco products, and <u>dozens of other California cities</u>⁵ have enacted or are considering similar legislation.

The problem with bans:

1. As I have explained, a ban on flavors is completely irrelevant to the outbreak of lung disease. Eliminating flavored nicotine e-liquids will not prevent further cases of lung disease because those products had nothing to do with the outbreak.

2. Under a non-tobacco flavor ban, a sizeable number of vapers will resume smoking – after all, cigarettes will remain untouched on convenience store shelves and that is where many will head. Others will seek out counterfeit enterprises. Others will seek out counterfeit enterprises, as Mitchell Zeller, head of the FDA's Center for Tobacco Products, confirmed in in a declaration to a Maryland court this June.⁶ "Dramatically and precipitously reducing availability of these products could present a serious risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products," he wrote.

Generally, bans push users to patronize underground marketplaces, which are breeding grounds for the worst manufacturing practices and products including tainted nicotine liquids, defective batteries, and heating coils.

Adult Smokers – The intended consumer:

The central fact is that vaping is much less hazardous than smoking. This is a relative statement - vaping *reduces* harm, but does not obliterate it completely. Classic harm reduction efforts include giving clean needles to heroin users and disseminating condoms and pre-exposure prophylaxis (PrEP),⁷ and imparting information on safe sex practices for populations at risk for HIV/AIDS. Such practices are widely endorsed by the public health establishment

But it is difficult to endorse nicotine harm reduction with the enthusiasm it warrants if one doubts that vaping is actually reducing harm.⁸ Indeed, a thick haze of misinformation about e-cigarettes that has obscured their value. These have included unwarranted claims of e-cig-induced heart attacks ⁹ and "popcorn lung" (obstruction of the smallest pulmonary airways), and nicotine as a cause of cancer.¹⁰

Accordingly, public opinion regarding their relative safety and value as quit devices has turned negative over the years.

Fortunately, evidence points to significantly less hazard, due to the fact that e-cigarettes do not burn tobacco as do conventional cigarettes. The latter release 7,000 chemical compounds including 70 known human carcinogens. In contrast, electronic cigarettes heat a solution of nicotine, propylene glycol, glycerin, flavorings, and water. Although they release some toxins, the overall toxicological profile is far less hazardous than that of cigarette smoke.

One representative analysis from 2018, using data from the Food and Drug Administration and published in the *Journal of the American Medical Association* shows that e-cigarettes emit only a fraction of the exposure of known tobacco-related toxicants that result from smoking.¹¹ Some toxicants are present in much lower levels in e-cigarette aerosol while others are completely undetectable.¹²

To be sure, epidemiologists need to continue monitoring vapers for the development of

possible long-term health effects of regularly inhaling propylene glycol, glycerin, and flavors. This uncertainty is a compelling reason for non-smokers to reject vaping. But it should not stop smokers who have failed to quit smoking or don't want to, especially if they haven't been helped by FDA approved forms of nicotine replacement such as gum or the patch.

Vaping is now the most popular ¹³ and successful ¹⁴ product for quitting smoking relative to nicotine patches or gum. And in response to the prediction that the 11- 14 million vapers have "re-normalized" smoking in America, reassurance is at hand: the U.S. adult smoking is at 14 percent,¹⁵ the lowest level ever recorded.

Flavors, especially fruity ones, are a key element of the appeal of vaping to adult smokers. Such fruit and candy flavors, which were initially created in do-it-yourself fashion by independent vapers,¹⁶ are in great demand by adults and thus now dominate the market.¹⁷ In 2018, the largest flavor preference survey of adult vapers in the United States found fruit and dessert flavors to be the most popular by far; only a minority of the nearly 70,000 participants used tobacco flavors, and their use has decreased over time.¹⁸ In large-scale consumer surveys ¹⁹, adults who vape overwhelmingly report that non-tobacco flavors and flavor variability ²⁰ matter to them and help keep them away from smoking.

In sum, vaping products are intended to help smokers relinquish cigarettes. They help adult smokers to quit smoking and are substantially less dangerous than smoking.

As with any public health intervention, the unintended consequences of regulatory policies aimed at teen vaping must be kept in the forefront of our thinking. To appreciate why curbing adult access has such significant public health implications, we need to acknowledge the vast health benefits of vaping for smokers.

Teens:

Fortunately, the predictions that vaping would serve as a "gateway" into smoking for has not materialized. Teens now smoke cigarettes at the lowest rates in history and have experienced unprecedented decreases in smoking prevalence precisely during the period of vaping's popularity. Further, data from National Youth Tobacco Survey reveal that frequent vaping (e.g. use on 20 or more days of the past 30) is not common in teens who had not already used tobacco. Specifically, vaping occurred in 0.1 percent of never tobacco users in 2017 and 1.0 percent in 2018.²¹ Data from 2019 are pending and might show an increase.

If a gateway were present, we should see more smoking among teens. Yet, smoking among high school students has dipped to a new low this year, with 5.8 percent report having smoked at least once in the preceding month-- a pattern suggesting that vaping serves more as an off-ramp from smoking than as an entryway for teens. ²² By comparison, in 2014, the first year of vaping's use by significant numbers of students,

smoking prevalence was twice as high. Just two decades ago, well over a third of high school seniors had smoked in the past 30 days. The biggest risk of all for kids – cigarette smoking – is becoming vanishingly small.

Claims that nicotine damages the teen brain rest on shaky empirical grounds. For one, many of the studies were conducted in rodents, making them difficult to translate into humans. Second, those done in teens examined smoking not pure nicotine. Any effects found could be attributed to products of combustion, not nicotine per se. Third, and most compelling to me, is the fact that decades ago a much higher percentage of teens smoked and they more likely to smoke many more days per month than teens today. However, if nicotine exposure caused brain damage, we surely would have observed it in that much larger and much more intensely nicotine-exposed cohort.

To be sure, the absence of a documented gateway effect and the exaggerated claim regarding nicotine-induced brain damage do not diminish the importance of reducing teen vaping, but they should reduce alarm among parents and policy-makers.

Pragmatic Considerations

It is difficult, if not impossible, to make vaping less appealing to kids by banning non-tobacco flavors without simultaneously making it less compelling to adults.

Therefore, in my view, the heavy and relentless focus should be on strengthening barriers to teen access to nicotine vaping products. The FDA has an extensive program for preventing and combatting use. Here are several other options, many of which have received a lot of attention already, including a law raising the age of tobacco purchase and consumption to age 21. Congress should exercise its power to raise the age of tobacco purchase and consumption to 21.

Other interventions include banning TV ads and print advertising except in adult-only publications or media (in which adults are >85 percent of audience). No longer should juvenile terms such as "candy," "bubble gum," "cotton candy," "cake" or variants, packaging that resembles juice boxes, soft drinks, soda, cereal, candy, or desserts, or packaging that uses cartoons or cartoon characters be allowed.

Enforcement should also close loopholes by banning sales on third-party marketplaces, such as Alibaba, Amazon, and eBay where third party sales from unregulated, unlicensed tobacco product distributors are not age verified. In addition, a "Three Strikes and You're Out" rule should be adopted, providing that any retailer accumulating three violations in three years for selling nicotine vapor products to minors loses the right to sell nicotine vapor products. Also, more rigorous age verification practices involving software or technology should be instituted for all online sales and all brick and mortar sales. These are only some of the more aggressive approaches that can be deployed.

Conclusion

The purview of public health is the nation's entire population of vulnerable people, not exclusively its youth. That includes adult smokers, particularly those who smoke at disproportionately high rates, namely, people suffering mental illness, working class men and women, those who live in rural areas, Native Americans, lesbian, gay and bisexual adults, and military veterans.²³

We must not allow the intense focus on teen use – warranted though it is – to divert almost all attention from the benefits of vaping for adult smokers who are dying at the rate of 480,000 per year from a terrible habit.

Benefits to smokers unappreciated: Intrinsic to the controversy we confront today is the fact that the benefits of vaping to smokers are not widely appreciated. Optimal analysis of the risks and benefits of vaping to population as a whole – a public health imperative – simply cannot proceed unless the significant advantages of vaping to smokers are taken into account.

And when the known realities are considered, it becomes clear that we are on an irrational path: we condone smoking, an indisputably dangerous activity, as we impose bans on non-tobacco flavors which will the therapeutic power of much lower risk alternative for smokers.

Harmful unintended consequences of bans: A non-tobacco flavor ban, let alone an outright ban on all vaping, will almost surely harm adults who have already switched or those who could do so in the future, as well as teens who claim they are addicted to nicotine.

Reject a false choice: Regrettably, the vaping issue has been cast as a contest between the health of teens and the health of smokers. But we should not succumb to this false choice. We can protect teens through more aggressive barriers to access. At the same time, we can save smokers' lives and combat the leading cause of preventable death in the world by preserving adult smokers' access to a valuable smoking-cessation method.

³ <u>https://www.usatoday.com/story/news/politics/2019/09/11/donald-trump-wants-to-ban-flavored-vapes-discourage-young-people-from-e-cigarettes/2284270001/</u>

⁴ Miech R, Johnston L, O'Malley P. et al., Trends in adolescent vaping, 2017-2019. *New England Journal of Medicine*. 2019 September 18 at <u>https://www.nejm.org/doi/full/10.1056/NEJMc1910739</u>

⁵ https://californiahealthline.org/news/states-target-vaping-with-bans-in-california-the-action-is-local/

⁶ Zeller M. (Head of Center for Tobacco Products, FDA) "[...] mass market exit of such products would limit the availability of a potentially less harmful alternative for adult smokers seeking to transition or stay away from combustible tobacco products. Dramatically and precipitously reducing availability of these products could present a serious risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products, even if particular ENDS products ultimately receive marketing authorization and return to the market later. Declaration to the US District Court for the District of Maryland Case 8:18-cv-00883-PWG Doc 120-1, para 15. June 12, 2019.

⁷ A combination of two HIV medicines (tenofovir and emtricitabine)

⁸ Compare the US with the U.K.'s National Health Service which explicitly <u>encourages</u> smokers to use ecigarettes.

⁹ <u>https://www.usatoday.com/story/news/health/2019/07/17/vaping-heart-attacks-false-claims-sexual-harassment-allegations/1676473001/</u>

¹⁰ Refuting proposition <u>https://blog.dana-farber.org/insight/2018/07/nicotine-cause-cancer/</u>

¹¹ Goniewicz ML, Smith DM, Edwards KC, et al., Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes. *JAMA Open Network*, Dec. 14, 2008 at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2718096

¹² See also <u>https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review</u> and excellent lecture by Lynne Dawkins PhD <u>https://www.clivebates.com/lynne-</u>dawkins-e-cigarettes-an-evidence-update/

¹³ <u>https://www.cdc.gov/pcd/issues/2017/16_0600.htm</u>

¹⁴ <u>Hajek P</u>, et al.,. A randomized trial of e-cigarettes versus nicotine-replacement therapy. *New England Journal of Medicine*. 2019 Feb 14;380(7):629-637 at <u>https://www.ncbi.nlm.nih.gov/pubmed/30699054</u>
¹⁵ https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html

¹⁶ <u>https://www.inquirer.com/opinion/commentary/vaping-flavor-e-cigarettes-teen-smoking-</u> 20190921.html

¹⁷ Russell C, McKeganey N, Dickson T, Nides M. Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J. BioMed Central;* 2018 Jun 28;15(1):33.

¹⁸ Russell C, McKeganey N, Dickson T, Nides M. Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J. BioMed Central*; 2018 Jun 28;15(1):33.<u>https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0238-6</u>

¹⁹ <u>https://www.forbes.com/sites/jacobsullum/2014/07/17/survey-shows-adults-who-use-e-cigarettes-to-quit-smoking-prefer-allegedly-juvenile-flavors/#7c33c85f8fc1</u>

²⁰ Farsalinos K, Romagna G, Tsiapras D, et al., Impact of flavor variability on electronic cigarette use experience: an internet survey. *International Journal of Environmental Research and Public Health*. 2013 December 17; *10*(12), 7272-7282. <u>https://www.mdpi.com/1660-4601/10/12/7272</u>

¹ <u>https://www.fda.gov/news-events/press-announcements/statement-consumer-warning-stop-using-thc-vaping-products-amid-ongoing-investigation-lung-</u>

illnesses?utm_source=Eloqua&utm_medium=email&utm_term=stratcomms&utm_content=pressrelease &utm_campaign=CTP%20News%3A%20Vaping%20Update%20-%2010419

² <u>https://www.businessinsider.com/study-counterfeit-vapes-contain-vitamin-e-pesticides-and-hydrogen-</u>cyanide-2019-10

²¹ Jarvis MJ, West R, Brown J. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey reveal about high school e-cigarette use in the USA? (Preprint). Qeios. 2019 Oct 2 at <u>https://www.qeios.com/read/article/384</u> (awaiting review)

²² Levy DT, Warner KE, Cummings KM, et al., Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check. *Tob Control*, Nov. 2018

at <u>https://tobaccocontrol.bmj.com/content/early/2018/10/31/tobaccocontrol-2018-054446</u>). See also <u>https://www.fda.gov/news-events/press-announcements/trump-administration-combating-</u> <u>epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non</u> (this shows last 30 days smoking); shows off ramp exceeds on ramp: <u>https://vaping.org/progressive-policy-institute-vaping-most-effective-</u> <u>tool-for-quitting/; https://rodutobaccotruth.blogspot.com/2019/02/teen-smoking-to-vaping-is-more-</u> <u>frequent.html</u>

²³ <u>https://www.lung.org/our-initiatives/tobacco/reports-resources/sotc/by-the-numbers/top-10-populations.html</u>