The US vaping flavour ban: twenty things you should know

A blog by Clive Bates at the Counterfactual 4 November 2019



Introduction

American vapers and vaping businesses will shortly enter a period of chaos and existentially threatening regulation. First will be a ban on almost all flavours — everything except tobacco flavour and possibly menthol and mint. That is likely to shut down nearly every vape shop and e-liquid company that isn't part of a tobacco company. Then by 12 May next year, any surviving vaping companies and will have to comply with the hugely burdensome, opaque and unpredictable pre-market tobacco application process. Going into 2020, the industry will be in crisis and vapers and smokers will be in danger of losing one of the most important innovations of the century.

This blogpost focuses on the first of these – the ban on flavours. Here are twenty things you should know about the US vaping flavour ban.

For the web version, please see: The US vaping flavour ban: twenty things you should know

The twenty things you should know about the US flavour ban

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1 What is happening about flavoured vaping products in the United States?

On 11 September 2019, the US Federal Government <u>announced</u> it was intending to 'clear the market of flavored e-cigarettes'.

"The Trump Administration is making it clear that we intend to clear the market of flavored ecigarettes to reverse the deeply concerning epidemic of youth e-cigarette use that is impacting children, families, schools and communities," said Health and Human Services Secretary Alex Azar. "We will not stand idly by as these products become an on-ramp to combustible cigarettes or nicotine addiction for a generation of youth."

FDA argues (with bizarre pedantry) that this is not 'a flavours ban' because the products are already technically illegal. This is because all vaping products on the US market have not been subject to premarket authorisation (a requirement FDA established in 2016 with a hopelessly unrealistic deadline that this should be done by August 2018). It just that the FDA has chosen not to enforce the law and so any product that was on the market at 8 August 2018 can stay (subject to several other requirements) without expecting enforcement action. This is because the FDA uses 'compliance policy' to decide what laws it will enforce and also as a way of making *de facto* policy. The last update on compliance policy for these products was March 2019: Modifications to Compliance Policy for Certain Deemed Tobacco

Products. FDA, in consultation with the White House, plans to update this sometime soon to implement a new policy.

The revised compliance guidance was submitted to OMB for review on 25 October 2019 – see the <u>notice</u> and <u>scheduled stakeholder meetings</u>.

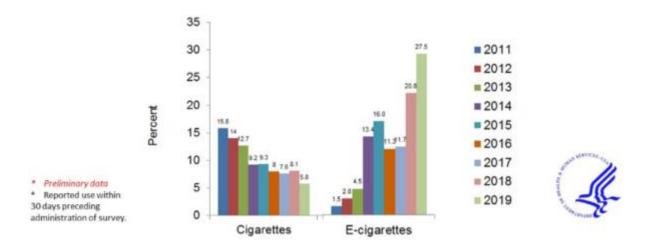
The current political debate centres on whether to allow or to ban menthol and mint flavours. Apparently, the White House hopes this will soften the likely political backlash from 14m adult vapers as the US approaches an election year. It is not for me to discuss that.

2 Why is this happening now?

This policy was announced in the context of two aggravating factors:

1. The <u>cynical and false conflation</u> of regular nicotine vaping with an outbreak of serious lung injuries arising from the use of adulterated black market cannabinoid products (<u>CDC</u>). This has created an intensified peak to the moral panic surrounding vaping, even though – beyond any reasonable doubt – it has nothing whatever to do with vaping regular nicotine e-liquids. The lung injuries are a result of a contaminated adulterated and illegal supply chain for cannabinoid vapes. Nevertheless, the confusion has triggered several states into emergency action against vaping products.

2. An early and (of course) incomplete <u>release of youth vaping data</u>, which showed high school past-30-day vaping rates had risen to 27.5% in 2019 (20.8% in 2018 and 11.7% in 2017). As these numbers have risen



Any sharp rise like this is bound to cause alarm. But as we will see later, these aggregate numbers betray a more complex underlying picture.

3 The big question: does the FDA have any idea what it is doing?

The question is, and always has been: does FDA have the faintest what it is doing and whether its interventions will do more harm than good?

The answer is, and always has been: no, it has no idea what it is doing and, yes, its interventions will inevitably do more harm than good.

The reason is that FDA does not have a **coherent analytical framework** for considering the role of vaping on public health, including its interactions with youth and adult smoking, and no idea how to evaluate the impact of massive prohibitionist interventions like *clearing the market of flavored vaping products*.

3.1 What does an analytical framework for evaluating vaping policy measures look like?

I last blogged about this in December 2017: Regulating e-liquid flavors – is the U.S. regulator more likely to do harm than good and how would it know? This was based on a letter and briefing to the then-FDA Commissioner, Scott Gottlieb. The letter is from an informal group of public health advocates led by the Attorney General of Iowa, Tom Miller, and it includes me. The questions raised then remain unanswered now.

The heart of the problem is evaluating and trading possible harms and benefits to adolescents and to adults arising from the likely displacement of smoking by vaping in <u>both</u> adolescents and adult populations. How do you include the adolescents that benefit from vaping in the analysis? How much weight do you give to one additional adolescent who starts vaping compared to one adult who quits

smoking using vaping? How do you know what the effect of an intervention like a flavour ban is? Banning a product used by millions is not the same as the product never existing or becoming somehow uninvented.

In the <u>letter</u> mentioned above, we suggested that 10 questions should be used to interrogate policy on vaping flavours.

- 1. Is the flavor used in a combustible or non-combustible product?
- 2. Is the cause for concern an actual flavor or the way it is described (or both)?
- 3. Are all flavors, whole flavor categories or specific flavors the cause for concern?
- 4. How will the subset of flavors that have a particular role in attracting youth be identified?
- 5. Does a flavor preference create a change in behavior to increase e-cigarette use?
- 6. What is the behavior of concern and what is a distraction?
- 7. Would youth uptake of e-cigarettes caused by flavors be harmful or beneficial to health?
- 8. How are trade-offs between potential harms and potential benefits to youth addressed?
- 9. How will beneficial impacts for adults be reconciled with any potential impacts on youth?
- 10. What impact would a rulemaking intervention by FDA have?

I do not think FDA has the slightest idea how to address the challenges that such a framework presents. So, to refer back to the title, I believe that FDA is more likely to do harm than good, and what's more, it wouldn't know what effect its intervention was having. The conclusion drawn in that letter remains valid:

In this complex landscape of multiple behavioral pathways, how will it be possible to assess unintended harmful consequences of a policy designed to reduce the appeal of e-cigarettes? [...]. It is unclear how FDA could design interventions that only address (minor) harms without compromising the likely (substantial) benefits. It would first need to know the disposition of harms and benefits attributable to flavors (as discussed in 2-9 above). Then it would need to assess how a flavor-related intervention would modify the behavior, and the patterns of harms and benefits. Then it would need to be confident that its intervention would reduce harm rather than increasing it.

4 Kiddie-flavours are now defined as all flavours except tobacco flavour – but it wasn't always that way

The Federal government is now defining all flavours, other than tobacco flavour, as somehow implicated in the 'American youth vaping epidemic'. This is a remarkable expansion of the problem definition and is based on very little evidence.

But it wasn't always this way...

4.1 Campaign for Tobacco-Free Kids is against 'kid-friendly flavors'

You may recall that Campaign for Tobacco-Free Kids started out highlighting flavours like 'Gummy Bear', 'Cotton Candy' etc. The story was that these descriptors or sweet flavours were 'kiddie appealing' and designed to lure kids into lifelong tobacco use. See, for example, the CTFK report, The Flavor Trap (2017).

In recent years, there has been an explosion of sweet-flavored tobacco products, especially e-cigarettes and cigars. These products are available in a wide assortment of flavors that seem like they belong in a candy store or ice cream parlor – like gummy bear, cotton candy, peanut butter cup, cookies 'n cream and pop rocks for e-cigarettes



The list above (from The Flavor Trap slide show) has no basis in evidence, by the way. The report does nothing to define 'kid-friendly' (or adult-friendly). There is nothing to suggest that these 'kid-friendly flavors' actually do appeal to youth substantially more than they appeal to adults. Many adults like sweet tastes and many like frivolous branding. And there is nothing to show that these flavours have been designed with youth-appeal in mind. My guess is that Campaign for Tobacco-Free Kids just defined kid-friendly as anything "a bit childish, quirky or humorous in our opinion".

4.2 Food and Drug Administration also targets 'kid-appealing' flavors

The FDA also built its case for action on flavours on what former Commissioner Gottlieb called (July 2017) 'obviously kid-appealing flavors'.

To take one example, I have real concerns about kids' use of e-cigarettes, and I know many others share those concerns, especially those products marketed with **obviously kid-appealing flavors**. [...]

We will re-double our efforts to protect kids from all nicotine-containing products. This has to include looking at the role of kid-appealing flavors, because kids shouldn't be using any of these products.

Though it was apparently obvious to Dr Gottlieb what is and is not a kid-appealing flavour, it is not actually obvious at all. Why would childish flavours appeal to adolescents? Aren't they trying to dump the trappings of childhood and reinforce their identity as adults?

FDA made much of its <u>tough cop role</u> in cracking down on e-liquids mimicking kid-orientated food brands...



4.3 Enter Juul to ruin the kiddie flavours story

When Juul took off in late-2017, this 'kid-appealing' narrative failed. This is because the Juul flavours were not obviously youth-orientated or presented in a way that appeals to youth. Until September 2019, the Juul US site offered the following flavours: Classic Tobacco, Virginia Tobacco, Mint, Menthol, Creme, Fruit, Mango, Fruit and Cucumber. In what way are these 'youth' flavours?

The last four of these have now been withdrawn voluntarily by Juul. Note how sedate and unchildlike the packaging and presentation is – see Juul here. (And below from another online retailer).



4.4 So the Campaign for Tobacco-Free Kids redefines 'appeal to youth'

So it was necessary for anti-vaping activists to be able to blame <u>both</u> Juul and flavours in order (i) to punish Juul for its astonishing success as an alternative to smoking, (ii) to campaign for flavour bans (a form of vaping prohibition) and, (iii) to maintain consistency with their previously-held but evidentially-untenable position.

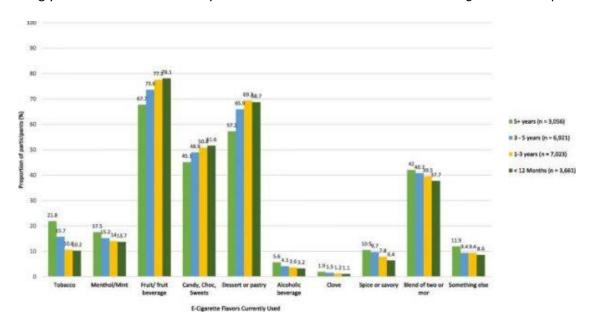
The answer: to define Juul flavours as kid-appealing. Simple. Suddenly CTFK moved to defining kid-appealing flavours as effectively anything made by Juul and then anything that was not tobacco flavour.

Juul is sold in flavors that appeal to youth, including mint, menthol, fruit, crème, mango and cucumber

... but you won't find any of these flavours on its earlier lists of supposedly kid-appealing flavours.

5 Flavours are an important part of the appeal to adults

Take this study... these fruit, candy and dessert flavoured products are highly favoured by adults too... and interest in tobacco flavour has been declining over time. Consumers see the vaping experience as increasingly a different and better way to consume nicotine and flavours are *integral* to that experience.



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. [link]

6 Flavours as a whole are attractive to adolescents (but this is trivially obvious)

It is trivially obvious that 'flavours' as a whole are appealing – they are integral to the product. Just as pizza toppings are an appealing addition to a pizza base, so flavours give vaping products a large part of their character.



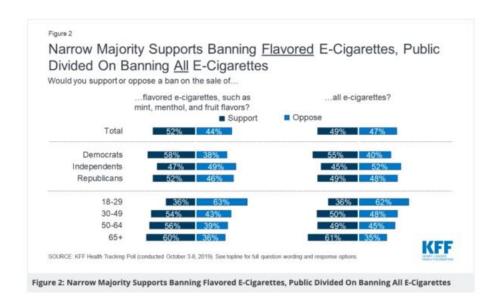
So it is true that if regulators eliminated nearly all flavours there would be less adolescent and adult-use (at least from legal suppliers) because they have taken away a key part of the product. In the same way, I would expect a decline in pizza sales if you could only buy a pizza base or a simple Margherita.

A regulator, legislator or activist who wants to ban all or nearly all flavours is essentially imposing a prohibition of the product because they are removing its 'essence' or one aspect of its essence, the other being nicotine.

7 Activists have moved from targeted youth-orientated measures to indiscriminate prohibition

Activists have discreetly moved from arguing **some** flavours or flavour-descriptors may be appealing to adolescents to arguing that **all** flavours (except tobacco flavour) appeal to youth. It's as though they have moved from merely wanting to ban pizza with pineapple in the topping to banning everything that isn't a pizza base or a Margherita. If you ban (almost) everything, you are sure to make the product less appealing to everyone. In doing so, they have moved from a targeted approach, which was unsupported by evidence and in conflict with reality, to an indiscriminate prohibition for which you can be fairly sure of some effect. The proposed flavour ban is close to a *de facto* prohibition of vaping products.

In fact, it is likely that support for a ban on flavours is just a proxy for support for complete vaping prohibition. Polling by KFF showed the following:



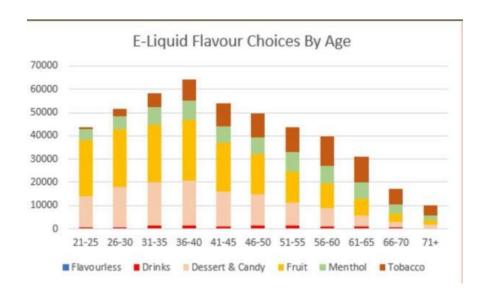
If 52% support banning flavours and 49% want to ban all e-cigarettes, that suggests that approximately 94% of those who want flavours banned also want the whole product banned.

I have long been convinced that the activists involved have the same objective, but are not prepared to come out and call for a straight prohibition. So they have set about achieving it by other means: regulation, taxation and disinformation. They are now very close to achieving their goal. But the results will be more smoking, a slower decline in the cigarette business, a black market and home mixing. Why they are doing this is a subject for a future blog.

8 But don't kids like (non-tobacco) flavours more than adults?

It might be objected that non-tobacco flavours appeal more to kids than they do to adults. But it is obvious why. Firstly, because tobacco flavour may be more appealing to adult vapers who are entrenched smokers and tobacco may be more familiar to them – the chart below shows preferences for tobacco flavour increases with age – though also, by implication, number of years as a smoker. Secondly, a great deal of money has been spent informing adolescents that tobacco is dangerous, gross, anti-social and nasty.

The data below are from the online age-verified US retailer <u>Electric Tobacconist</u> (with thanks). The x-axis shows the age distribution of purchases and the y-axis is the number of units (e-liquids, pre-filled pods, carts) sold between 1 Jan 2019- 31 August 2019 in the United States.



Flavour choices and volumes by age group

While it is clearly true that adults have proportionately greater preferences for tobacco flavour, and this increases with age, the chart also shows that dessert, candy, fruit and menthol dominate adult preferences at any age.

Note that most sales are made in the age-group (31-45) where smoking cessation delivers the most substantial risk reduction and public health benefit. See section 19 below

9 Research suggests broader causes for youth vaping uptake than flavours

A recent review summarised the evidence in its introduction. It is clear there is a lot more to why young people take up vaping than flavours (though flavours may also be a factor)...

Early studies on the reasons that youth and adults use e-cigarettes relied heavily on focus groups (Choi, Fabian, Mottey, Corbett, & Forster, 2012; Pepper & Brewer, 2014; Pokhrel, Herzog, Muranaka, Regmi, & Fagan, 2015), while later studies examined whether reasons to use e-cigarettes are associated with patterns of use (Adkison et al., 2013; Bold, Kong, Cavallo, Camenga, & Krishnan-Sarin, 2016; Kong, Morean, Cavallo, Camenga, & Krishnan-Sarin, 2015; Pepper, Ribisl, Emery, & Brewer, 2014; Tan, Lee, & Bigman, 2016). Common reasons to use e-cigarettes cited by youth and adults were curiosity, peer influences, and ability to use anywhere (Bold et al., 2016; Choi et al., 2012; Kong et al., 2015). Adults also cited more goal-directed reasons, such using them to quit or reduce cigarette smoking and being less harmful than cigarettes (Adkison et al., 2013; Bold et al., 2016; Pepper et al., 2014). Additional youth-specific reasons were that e-cigarettes were "cool", had appealing flavors, were easy to hide, were cheaper, and did not smell like cigarettes (Bold et al., 2016; Choi et al., 2012; Kong et al., 2015). Previous research assigned these reasons to general categories, such as "general interest" and "social norms", to organize related items. For example, "social norms" is commonly assigned

as the larger category that cites friends/peers/family using e-cigarettes and e-cigarettes can be used anywhere (Bold et al., 2016; Kong et al., 2015; Tan et al., 2016).

Nicksic NE, Snell LM, Barnes AJ. Reasons to use e-cigarettes among adults and youth in the Population Assessment of Tobacco and Health (PATH) study. *Addict Behav*. 2019 Jun 1;93:93–9. [link]

<u>Nicksic et al.</u> concluded that there were two broad factors driving of e-cigarette use by both adults and adolescents – with several sub-factors organised under these:

This study found two overarching factors, "alternative to cigarettes" and "larger social environment", which combine sub-categories to explain main motivators of e-cigarette use.

For example, this study found that sub-categories, including peer influences and social norms, were strongly related to one another through EFA, and are part of a larger, latent organizing factor that we called the "larger social environment". This factor also included media, advertising, and socializing influences, a category of responses that speaks to ways in which youth and adults look for cues to use and integrate information from many sources to make decisions about tobacco use. The larger category of "alternative to cigarettes" encompasses not just goal-directed use (e.g., to quit cigarette smoking), but also perceptions about where the product could be used, how acceptable use is, and how use might affect health.

In this 'factor analysis' of PATH data, "It comes in flavors I like" was merely the sixth most prominent factor in the "alternative to cigarettes" category (see <u>Table 1</u>):

- 1. They don't smell
- 2. They might be less harmful to me than cigarettes
- 3. They might be less harmful to people around me than cigarettes
- 4. Using them help people to quit smoking
- 5. They are more acceptable to non-tobacco users
- 6. It comes in flavors I like/liked
- 7. [...] several other factors of lower prominence

In the wider social environment category, flavours were of little importance to youth. But other factors did play a role – the top five were:

- 1. The advertising appeals/appealed to me
- 2. People in the media or other public figures use/used them

- 3. People who are important to me use/used them
- 4. Liked socializing while using an e-cigarette
- 5. They are/were affordable

However, if a regulator banned nearly all flavours in a non-marginal change – effectively a prohibition – these factors would surely change. "I can only get them in tobacco flavor" would be likely to become a negative factor in the "alternative to cigarettes" category – a pro-cigarette measure.

10 Other research focuses on the initial choice of flavour but this offers a poor explanation for youth vaping

Two recent studies have highlighted that the choice of the first flavour is associated with future use.

first use of flavored e-cigarettes, cigars, hookah, and smokeless tobacco was associated with subsequent use of those products at wave 2 among young adults and adults aged 25 years and older;

first flavored use of a cigarette, e-cigarette, any cigar, cigarillo, filtered cigar, hookah, and any smokeless tobacco documented at wave 1 was associated with current regular use of those products among young adults and adults aged 25 years and older at wave 2 compared with first use of a nonflavored product;\

Villanti AC, Johnson AL, Glasser AM, Rose SW, Ambrose BK, Conway KP, et al. Association of Flavored Tobacco Use With Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015. JAMA Netw Open. 2019 Oct 2;2(10):e1913804.[link]

And:

Adolescents who vaped e-cigarettes in nontraditional flavors, compared with those who exclusively vaped tobacco-flavored, mint- or menthol-flavored, or flavorless e-cigarettes, were more likely to continue vaping and take more puffs per vaping occasion 6 months later

Leventhal AM, Goldenson NI, Cho J, Kirkpatrick MG, McConnell RS, Stone MD, et al. Flavored Ecigarette Use and Progression of Vaping in Adolescents. Pediatrics. 2019 Oct 28;e20190789. [link]

The trouble with such studies is that they don't tell us whether the first flavour actually *caused* the subsequent behaviour or whether it tells us something about the person who made the initial choice. For example, if they chose tobacco flavour, was it because they were already a smoker? It is difficult to tell what is causing the associations detected in these studies: as always, you would need more information on the whole pattern of tobacco use and transitions of the individuals involved to begin to guess. But let me make some observations anyway:

- 1. The use of traditional flavours (by which they mean tobacco and menthol flavours) could be more common among adolescents who smoke just as they are among adults it may be that they are torn between vaping and smoking but as a result, are less likely to be vaping at a later stage as they are using other tobacco products
- 2. It is possible that those using traditional flavours were less adventurous or committed and just bought the most recognisable product from a convenience store. Those with greater interest and commitment may have been better informed about their options and more exploratory in finding flavours that suited them
- 3. It is possible that users are expecting or wanting a 'clean taste' and something that distinguishes vaping and smoking. The tobacco flavour would be like having tobacco-flavoured toothpaste. In addition, young people have been told that tobacco is harmful, gross, nasty and anti-social so it wouldn't be a surprise to see some avoiding it. A weird extension of this line of thought would be for regulators to insist on flavours that people didn't for example, why not insist on the addition of onion flavour if the aim is to make the flavours unattractive?
- 4. It may be a good thing that vaping persists among those using flavours *if this is an alternative to smoking*. Many adults like flavours precisely because it distances the vaping experience from smoking.
- 5. Extremely large generalisations are at work here: they have essentially divided the vaping flavour market into three segments: tobacco flavours, menthol flavours, and thousands of other flavours.

Finally, studies like this are examining a narrow question – associations between flavours and subsequent use. By design, they are not looking for other causes.

11 Why not just ask adolescents why they vape?

A researcher can certainly learn *something* by asking users why they do something. But think about smoking for a minute.

If you ask people why they smoke you would get answers like 'it helps me relax and concentrate' or 'I like the taste' or 'I need the buzz' (I'm guessing here). But we know that smoking is associated with poverty, poor educational attainment, mental health problems, parental smoking, other substance use, delinquency and that it may have deeper underlying causes, such as stress or depression. How many smokers would give these factors as reasons if asked? We have to be careful with how people explain their behaviour because they may simply be unaware of where it comes from.

The most widely cited example of this type of study is Ambrose et al.

This study extends a recent national report on youth use of flavored tobacco products by examining first use of flavored product among ever users by products and flavorings as a reason for noncigarette tobacco use. Consistent with national school-based estimates, this study confirms widespread appeal of flavored products among youth tobacco users.

Ambrose BK, Day HR, Rostron B, Conway KP, Borek N, Hyland A, et al. Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014. JAMA. American Medical Association; 2015 Nov 3;314(17):1871. [link]

The most frequently quoted finding in Ambrose et al. is that more than 80% of those asked agreed that "I use e-cigarettes because they come in flavors I like", which was the top reason given. See this annotated extract from Table 2 in Ambrose et al. with the highlighted finding in red.

Ambrose et al, JAMA, 2015 Reasons for Use	% (95% CI) e-Cigarettes (n = 418) ^c
I use [product] because they come in flavors I like	81.5 (77.9-85.0)
I use [product] because they are affordable	47.8 (42.9-52.6)
I use [product] because I can smoke/use them at times when or in places where smoking cigarettes isn't allowed	58.9 (54.1-63.7)
I use [product] because I like socializing while using them	40.3 (34.9-45.8)
I use [product] because it doesn't bother non-tobacco users	53.9 (48.1-59.8)
I use [product] because they might be less harmful to me than cigarettes	79.1 (75.2-83.0)
I use [product] because they might be less harmful to people around me than cigarettes	78.1 (74.3-81.8)
I use [product] because they don't smell	58.7 (54.2-63.2)
I use [product] because they help people to quit smoking cigarettes	59.5 (54.6-64.5)
I use [product] because people who are important to me use them	34.9 (30.6-39.2)
I use [product] because people in the media or other public figures use them	36.1 (31.5-40.7)

But also notice the cluster marked in yellow – these are harm reduction or pro-health reasons for vaping, and virtually no attention has been paid to them. Perhaps taken together they amount to the most important reason? Indeed they do. For a poster for SRNT 2017, Shiffman and Sembower aggregated harm reduction motivations from the same data used by Ambrose et al.

Table 1. Top 3 reasons for using e-cigarettes

Reason for Use ("I use e-cigarettes because")	% (95% CI)
Harm Reduction (to self and others)	88.2 (85.3-91.1)
They might be less harmful to me than cigarettes	79.1 (75.2-83.0)
They might be less harmful to people around me than cigarettes	78.1 (74.3-81.8) - p=0.002
They come in flavors I like	81.5 (77.9-85.0)
They help people to quit smoking cigarettes	59.5 (54.6-64.5)
Harm reduction is the most frequently endorsed reason, significantly m	ore than flavors

Shiffman S., Sembower MA, PATH Data: Harm Reduction is Teens' Top Reason for Using e-cigarettes.

Poster SRNT 2017, Pinney Associates [link]

Harm reduction reasons, when aggregated, are the most cited reason for vaping – a full 88% give one or both harm reduction justifications.

But I have a deeper concern about a literal interpretation of what adolescents say about flavours. Consider how you would *not* answer 'yes' to the statement 'I use e-cigarettes because they come in flavors I like" given that choice is presented and you are not constrained to one answer. What if they didn't come in flavours you like?

Obviously, before becoming a vaper, you don't know what the flavours are like. So to be driven to vape by flavours an adolescent would need to be driven by the appeal of flavour descriptors.

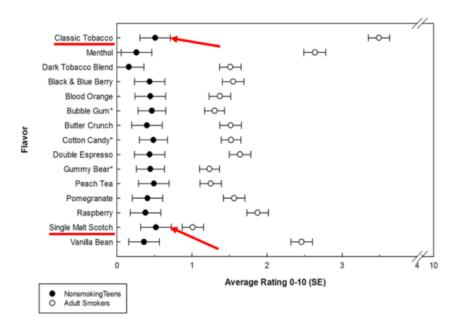
12 Do flavour descriptors attract teenage non-users? Hardly at all.

A study done for the e-cigarette manufacturer NJOY addressed this question experimentally – and attracted <u>quite a debate</u> (which the author, Saul Shiffman, won convincingly).

Nonsmoking teens' interest in e-cigarettes was very low (mean = 0.41 ± 0.14 [SE] on 0-10 scale). [...] The e-cigarette flavors tested appealed more to adult smokers than to nonsmoking teens, but interest in flavors was low for both groups.

Shiffman S, Sembower MA, Pillitteri JL, Gerlach KK, Gitchell JG. The impact of flavor descriptors on nonsmoking teens' and adult smokers' interest in electronic cigarettes. *Nicotine Tob Res* 2015; published online Jan 7 [link][release].

Interest really was *very low* – a score of 0.41 out of ten. Ironically, the two highest-scoring flavours among teens were Classic Tobacco and Single Malt Scotch (though the differences from other flavours were non-significant). The important finding is that flavours are not a big deal to the uninitiated.



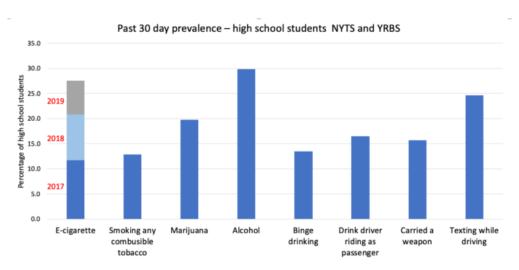
13 Does teenage vaping justify banning (almost all) vaping products? What is the precedent?

It should not be taken as a given that adult products that appeal to adolescents should be banned. For many, it is part of being a teenager to sample the forbidden fruits of adulthood and it happens. But we do respond to youth experimentation by banning other potentially harmful adult products just because adolescents use them.

- **Alcohol**. Take alcohol past-30 day youth prevalence was 29.8% in 2017 see Youth Risk Bevhavior Surveillance MMWR). Yet alcohol has far greater potential to harm teenagers than vaping through violence, road traffic and other accidents, and sexual vulnerability.
- Cannabis. What about cannabis? Cannabis is moving towards legalisation in many states, yet 19.8% of high school students were past-30-day users in 2017 (see <u>Youth Risk Behavior</u> <u>Surveillance survey</u>)
- Smoking. Or, wait a minute, what about smoking? In 2018, use of any combustible tobacco product (i.e. smoking) was 13.9% of high school students. Has anyone suggested banning cigarettes because teens prefer cigarettes to, say, premium cigars or pipe tobacco? (see NYTS MMWR). No, they have not.

We generally do not allow adolescent experimentation to bend adult choices out of shape.

Though it has risen sharply, vaping is not out of the ordinary compared to the prevalence of other risk behaviours. But crucially, it does not actually pose much risk. Given smoking is likely to be at least 20 times the risk of vaping then the total harm associated with 13.9% (2018) smoking any combustible is much greater than 27.5% vaping.



Data is from Youth Risk Behavior Surveillance and National Youth Tobacco Survey.

13.1 Is there really an epidemic of youth nicotine addiction?

The anti-vaping campaigners like to characterise the use of vaping products by American adolescents and a "youth vaping epidemic" or an "epidemic of youth nicotine addiction". As I argue in the next section you cannot really say anything credible about youth vaping without knowing in detail the frequency distribution (how many days in the past 30 did each student use e-cigarettes) and what their wider pattern of tobacco is (especially whether they are smokers or like to smoke). I have discussed the claim for an epidemic in detail here: The great American youth vaping epidemic. Really?

But there is one further piece of evidence to bring to the analysis. How many adolescent vapers show signs of dependence? Simply using a vaping product does make the user a 'nicotine addict'. British experts analysed the US N database and drew the following conclusion:

Data from the NYTS do not support claims of a new epidemic of nicotine addiction stemming from use of e-cigarettes, nor concerns that declines in youth tobacco addiction stand to be reversed after years of progress. Among current e-cigarette users who had never tried tobacco products, responses consistently pointed to minimal dependence.

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; [link]

I am not saying there is no problem. Just that those demanding massive invasive interventions that put up to 14 million American adult vapers at risk need a broader justification grounded in the way we manage youth risk behaviours.

13.2 What could be done instead?

Policymakers should respond to reasonable concerns about youth vaping through measures that are proportionate to risk and targeted at youth. This would mean measures to control:

- Access stricter age restrictions and verification, retailer compliance, control over retail settings
 (for example, sale only permitted in age-restricted environments such as vape stores or with
 strong online age verification)
- Marketing control of advertising themes, placement and time; restrictions on branding and flavor descriptors designed to appeal to adolescents; restriction of flavor descriptors to literal and informative descriptions.

14 Could measures against vaping flavours make things worse <u>for</u> <u>adolescents</u> (as well as adults)?

The answer is *yes*. We have seen adolescent vaping rise sharply since 2017 – from 11.7% in 2017 to 20.8% in 2018 to 27.5% in 2019. But these figures are for any use of the product in the past 30 days. We should demand much closer inspection of these aggregates in two particular ways:

- 1. We should want to know how often young people are vaping and focus our concern on the most frequent.
- 2. We should want to know if more frequent teen vapers might be using other tobacco products. If the more frequent vapers are typically also smokers or have smoked in the past, vaping may be *protective* and beneficial for them by displacing smoking

The data to make those estimates are available for 2018 – set out here – but not 2019. They can be summarised as follows (defining 'frequent' as vaping on 20 or more days in the past 30)

Breakdown of 20.8% high school students who vaped in the past 30-days (2018)

	Never used tobacco	Prior tobacco use
Frequent use ≥20 days per month	0.6%	5.2%
Infrequent use ≤ 19 days per month	4.7%	10.3%

The breakdown reveals several important findings. In 2018:

- Most teen vapers (72%) are not frequent users (15% of students)
- Most teen vapers (75%) are prior tobacco users (15.5% of students)
- Few teen vapers (<3%) are both tobacco naïve and frequent users (0.6% of students)
- Most of the teen frequent vapers (90%) are prior tobacco users (5.2% of students)

So by a <u>large</u> majority, the frequent vapers are also the ones who are already using tobacco. *For them, vaping may be beneficial in several ways...* it can help them quit smoking; it can divert them from starting smoking; it might reduce how much they smoke, and it is there for them if they want to quit smoking by switching to vaping later.

15 FDA does not care if vaping works as an alternative to smoking *for adolescents* – and this is deeply unethical

FDA, HHS, Trump, CTFK etc have no way of navigating these issues – they simply cannot say whether a flavour ban will be harmful or beneficial to adolescents because they do not accept the need to understand the inter-relationship of smoking and vaping behaviours in the most intensive users. Former FDA Commissioner Gottlieb even made this explicit in what I think is a quite astonishingly unethical statement (emphasis added).

No child should use any tobacco product. We've seen cigarette use decline among kids, while ecig use has grown sharply. This is happening even as overall rates of tobacco use among kids has declined, according to recent data.

This is still not acceptable, even if the trends are moving in a more positive direction of reduced overall use of tobacco products. Even if kids are using ENDS instead of cigarettes — and that migration in part accounts for the decline in youth cigarette use — that's still not an acceptable trade.

Parents who see their children using e-cigs and say, "well at least my child isn't smoking," should take no comfort.

No child should be using any tobacco product.

Scott Gottlieb, FDA's Nicotine and Tobacco Regulation and the Key Role of Regulatory Science, 18 June 2018 [link]

In my view, this argument is outrageous. Just because an agency believes young people should not smoke or vape does not mean that is how it plays out in the real world. Public health is about dealing with the world as you find it – not giving instructions to people who are not listening, not interested in your views and are unimpressed by your authority. But that doesn't mean a regulator is absolved of responsibility for the *consequences* (good or bad) of its actions.

In making this statement, Gottlieb was saying that FDA doesn't care if vaping is reducing smoking and, therefore, ignoring a big public health benefit that has been a goal of US policy for decades (e.g. see Healthy People 2020]. But there is also a dangerous corollary – that is that FDA doesn't care if measures they take against vaping have the effect of *increasing smoking among adolescents*. That is what is so despicable about this lofty attitude – indifference to the group most at risk – and elitist bias.

16 Is there an elitist bias at work here?

Yes, there is a justifiable suspicion that the political weather is being made by 'soccer moms' – the worried well-off – with concerns about kids who would never have smoked taking up vaping, especially Juul. There is almost nothing to worry about here... these kids will stop vaping when they are ready,

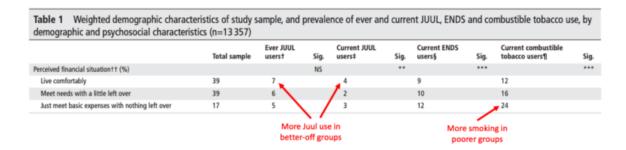
vaping is not that harmful and they will never progress to smoking. We hear much less from poor families, of course (and Democrats have shown little interest in them). These are the kids who would be likely to smoke and for whom vaping could be a *protective* alternative. They are in fact avoiding a large risk – and as we saw above, the frequent vapers are dominated by those with a propensity to use tobacco products.

Professor Lynn Kozlowski highlights possible class bias in explaining why moral psychology plays drives so much controversy in this area. In the statement above, FDA overweights the minor risk to what Kozlowski terms the 'good' kids and ignores the potential benefit to the 'bad' kids.

<u>Disgust</u> at contaminating the "purity" of youth, especially "good," low-risk youth, with any tobacco/nicotine products opposes harm reduction, as does contempt for violating so-called community values and disrespecting authority. Support for harm reduction arises from <u>anger</u> at failing to provide reduced harm to "bad," high-risk individuals and denying them the "liberty" to decide.

Kozlowski LT. Minors, Moral Psychology, and the Harm Reduction Debate: The Case of Tobacco and Nicotine. *J Health Polit Policy Law*. Duke University Press; 2017 Dec 1;42(6):1099–112. [link]

A study on who uses Juul found that Juul was more likely to be used in better-off families, whereas smoking is concentrated in the poorer families.



Vallone DM, Bennett M, Xiao H, Pitzer L, Hair EC. Prevalence and correlates of JUUL use among a national sample of youth and young adults. Tob Control; 2018 Oct 29 [link]

17 Does adult vaping have benefits for kids?

Yes, of course. Unsurprisingly, adults and adolescents do not live as entirely separate populations. In particular, their interests are connected through the family.

- Youth smoking initiation and other risk behaviours are heavily influenced by adult norms, especially by parents and older siblings. When adults switch from smoking to vaping they are likely to have a net positive role-model effect, reducing the risk of smoking uptake
- When adults are harmed by smoking, the whole family is harmed: through lost economic activity, increased caring burdens, or through grief and distress.

- Young people in a smoking household can be exposed to second-hand smoke in the home and vaping may also avoid pre-natal smoking exposures.
- Adolescents grow into adults and measures taken to 'protect' adolescents when they are young may do more harm to them as adults – vaping has 'options value' to young people

It is not possible or desirable to separate youth interests from those adults. Adult smoking creates 'collateral damage' to adolescents and policies that unduly restrict adult options to quit smoking will have negative impacts on youth.

18 What are the likely marketplace consequences of a flavour ban?

18.1 Perverse and chaotic consequences

As with any prohibition, a flavour ban will not in fact 'clear the market of flavoured e-cigarettes', it will provoke a series of market and consumer responses, some of which may cause more harm than good. There are 14 million adult vapers in the United States and they have so far attracted little official attention or political concern, but it is important to ask: what will they do?

The likely consequences include:

- The closure of thousands of small to medium-sized businesses (vape stores and manufacturers) as the products they make and sell are predominantly flavoured. Many of these also provide a market-based supportive service to smokers wishing to take up vaping as an alternative to smoking. Analysis by consultants John Dunham & Company found that in 2018, the US ecigarette industry created \$24.46 billion in economic activity, supported 166,007 jobs (direct, indirect and induced) and consisted of 380 liquid manufacturers, 2,012 vape shop manufacturers and 11,469 specialist retail outlets ("vape stores"). See court testimony of John Dunham.
- A transfer of the supply of flavoured products from legitimate American businesses to highly professional consumer-facing Chinese internet-based suppliers (see Fast Tech, for example);
- The development of a new and flourishing black market in flavoured nicotine e-liquids manufactured by amateurs, opportunists, and criminal enterprise;
- Migration of users to the existing unregulated sub-culture of DIY mixing of nicotine and food flavours;
- Vapers or dual users may revert to smoking or the use of other tobacco products and current smokers who would otherwise switch to vaping in the future may remain as smokers;
- Some may switch to tobacco flavoured e-liquids (as we discussed, this experience is nothing like smoking);
- Some may quit vaping and smoking altogether (though may increase other risk behaviours).

This closure of legitimate businesses will be accompanied by the development of black markets that will supply both adults and teens with no discipline regarding age. Black market suppliers bring additional risks – black markets may supply adulterated products made in unsanitary, unregulated conditions (as we have seen with the recent outbreak of lung injuries). Many participants in this trade are likely to expose adolescents to other black-market products (liquids containing THC, meth and other illicit drugs and other illicit products). It is conceivable that this will increase the overall risks *to both adults and adolescents*.

Yet no assessment has been made of how these effects will play out.

FDA has already recognised the adverse impacts of a rapid vaping market contraction. Referring to a mass exit of e-cigarette products from the market, Mitch Zeller, the head of Centre for Tobacco Products at FDA highlighted the danger:

"[...] 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.

Mitch Zeller. Declaration to the US District Court for the District of Maryland <u>Case 8:18-cv-00883-PWG Doc 120-1</u>, para 15. June 12, 2019.

18.2 A win for Big Tobacco – thanks to tobacco control

There is no real doubt this is a win for Big Tobacco – tactically if not strategically.

- Tobacco company vaping sales risks are to some extent hedged by cigarette sales and, in Altria's case, by iQOS. There is no equivalent hedge for pure vaping companies.
- The vaping flavour ban will massacre nearly all Big Tobacco's competitors in the recreational nicotine space vapour is a flavours business. State and local bans that go further serve the same cause.
- The extreme burdens and regulatory risk of the FDA's ludicrous PMTA process which will cut in next year will bayonet the remaining wounded not killed off by the flavours ban.
- Only tobacco companies have the cigarette-generated cash to withstand the cash flow
 consequences of flavour bans that can only be reversed by high-cost and high-risk PMTAs on a small
 number of high volume products few companies have the muscle to do extensive compliance
 activity (with highly uncertain outcomes) while their main products are not generating revenue.
- In the chaotic and confusing wake of the adulterated THC cart lung injury fiasco, a growing band of public health commentators (including Michael Bloomberg see tweet below) are running with a

line that smoking and vaping are of equivalent risk (and that it is a marketing trick to pretend otherwise).



Too many Americans fall victim to the marketing tricks used by big tobacco to convince us that vaping is safer than regular cigarettes.

It's part of why we launched @noflavoredecigs. Thank you to @mikiebarb and The Daily for telling this story.

In doing so, they renormalising smoking and denormalising vaping. No tobacco company would ever dare to make this audacious and evidence-free claim in support of its lucrative core product – the cigarette. Mike Bloomberg probably doesn't realise it, but he is one of <u>Big Tobacco Little Helpers</u>.

Wall Street seems convinced too:

The Trump Administration and FDA announced it will move towards an e-cigarette flavor ban, excluding traditional tobacco flavors. While the timing of such action appears to be weeks away, the impact on our coverage could be a softening of the e-cig headwind that had been driving accelerating cigarette declines.

Vivien Azer, Cowen Equity Research, September 11, 2019

Our recent survey revealed: Almost 50% of retailers believe the removal of flavors in e-cigs won't help reduce youth usage of e-cigs as kids are more likely to turn to the black market/D.I.Y. for product [...] The majority of retailers believe that removing non-tobacco e-cig flavors (esp mint/menthol) would be positive for combustible cigs (>70%) & oral nicotine (~60%) and negative for e-cigs (85%).

Bonnie Herzog, Wells Fargo Securities, September 18, 2019

19 What if we actually wanted to to do the right thing for adolescents?

Take a look at the main causes of death for Americans by age group (the figure below is from CDC <u>here</u> and <u>here</u>). The top table shows the top three causes of death by age group. The lower chart drills down to show the causes of death by unintentional injury.



According to CDC (YRBS):

In 2016 in the United States, 74% of all deaths among persons aged 10–24 years resulted from four causes: motor vehicle crashes (22%), other unintentional injuries (20%), suicide (17%), and homicide (15%)

19.1 Road accidents

The most important teenage killer is unintentional accidents of which the majority are motor vehicle accidents. That suggests a focus on driving under the influence, avoiding rides with drunk drivers, distracted driving (texting), better driving skill and enforcement of rules-of-the-road.

A whole journal is devoted to <u>Traffic Injury Prevention</u> but we do not seem to hear much in the news about it.

19.2 Suicide and mental health

Next highest is suicide -6,252 deaths between age 15-24 in 2017. Suicide should be seen as the most brutal tip of an iceberg of mental health problems and misery. The numbers are truly awful. The figures are documented in the Youth Risk Behavior Survey (data for 2017).

During the 12 months before the survey:

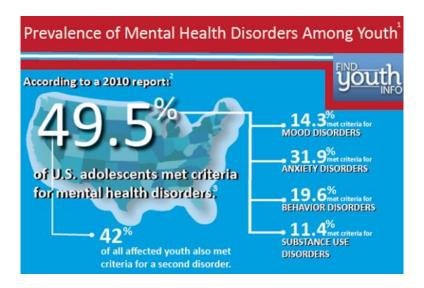
19.0% had been bullied on school property and 7.4% had attempted suicide.

- 17.2% of students had seriously considered attempting suicide
- 3.6% of students nationwide had made a plan about how they would attempt suicide.
- 2.4% of students nationwide had made a suicide attempt resulting in an injury, poisoning, or overdose that had to be treated by a doctor or nurse

Analyses based on the question ascertaining sexual identity indicated that nationwide, 5.4% of heterosexual students; 23.0% of gay, lesbian, and bisexual students; and 14.3% of not sure students had attempted suicide

CDC Youth Risk Behavior Surveillance, 2017

The scale of the mental health problem is daunting (even allowing for loose definitions of mental health disorders) – see youth.gov



It is quite likely that vaping and smoking are overrepresented in teenagers with mental health problems as it is with adults (according to CDC, about 35% of adults with serious psychological distress smoke compared to 13% without such problems). So why is so much attention given to youth vaping a relatively innocuous behaviour?

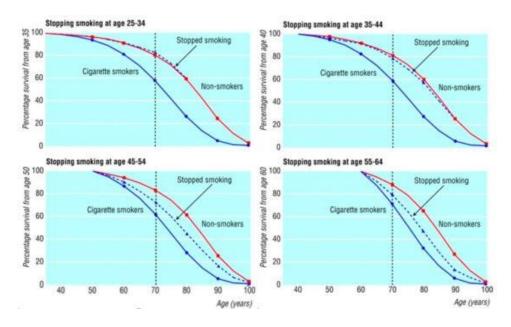
If you really want to do the right thing for adolescents, then *start with the person* and what is going on in their life. Do not start with a particular form of substance use, nicotine, that in practice isn't that harmful and may itself be a symptom of deeper problems. The reason this doesn't happen is that money flows to stopping the nicotine use not to helping the person.

19.3 Homicide

Guns and gangs. You know what you need to do.

19.4 Adults and smoking

The table above shows cancer and heart disease emerging as the big killers in middle age (45-64) – this is why the high levels of vaping among adults age 35-45 is so welcome and important. Quitting smoking before age 40 avoids nearly all the long term mortality risk of smoking (see British Doctors' Survey below). The charts below show survival probability (y-axis) by age (x-axis) for lifelong smokers (blue) and non-smokers (red). The dotted line is the survival probability for smokers varying in each of the four charts by the age at which they stopped smoking. It diverges only after age 44.



Doll R, Peto R, Boreham J, Sutherland I. Mortality in relation to smoking: 50 years' observations on male British doctors. *BMJ*. 2004 Jun 26;328(7455):1519. [link]

The chart is useful for several reasons...

- 1. It shows the importance of quitting smoking before the age of 40. This is where the largest gains in life-expectancy are achieved and this is exactly where adult vaping plays a role. By 40 most smokers who wanted to quit and were going to quit easily will already have done so. Vaping is a new strategy available to those most at risk.
- 2. It reminds us of the body's resilience someone quitting at 40 may have smoked for 25 years. That is definitely not without risk, but the charts suggest that the big risks accumulate with decades of sustained smoking with the median lifelong smoker losing about 10 years of life between age 73 and 83. If vaping is much less risky than smoking, then what would these curves look like for vaping?
- 3. For adolescents who are committed smokers, it shows there is time to quit. A 15-year-old smoker today may not be interested in switching to vaping but if the products continue to improve over the next 20 years, then he or she may switch later. I would be surprised if any

American adolescents smoking today are still smoking at age 40. If we allow the vaping products to progress they will render smoking obsolete and will do this in time to ensure this generation of youth avoids almost all of the burden of smoking-related disease. Vaping is a huge latent public win in the making.

20 Could the anti-vaping moral panic actually be a cause of youth vaping?

The most astonishing amount of publicity for teenage vaping has been generated by those notionally opposed to it. The press coverage has been immense and outraged. Weighty editorial boards have been worked up into a frenzy of indignation. Public health organisations have been running strange science-free campaigns (The Real Cost). Congress has vented its fury. Even President Trump has been drawn in.

I wrote about a moral panic gripping the United States in April last year <u>The US media is losing its mind</u> over vaping and Juul – the questions a credible journalist should ask – and it has only got worse since.

Often the anti-vaping publicity is ridiculous and generates satirical responses. The video below shows a truly embarrassing attempt at appropriating heavy metal culture by the anti-vaping campaign Truth Initiative followed by videos mocking it and the Truth Initiative.

Please see video content on the blog - here

What is the chance that this level of adult panic is, in fact, driving the very behaviour it is worrying about? It is hard to prove and of course not a question asked by anyone with the resources to answer it. But surely seeing Matthew L. Myers, President of Campaign for Tobacco-Free Kids on the television sounding like an Old Testament prophet is an unmissable invitation to do whatever it is that he is so upset about?

Other material

Please suggest good sources and I will list them here:

- Are flavors really 'hooking another generation of kids'? (February 2017).
- A response to the FDA's (advanced notice of proposed rulemaking (ANPRM) on Flavors (2018): Regulation of Flavors in Tobacco Products
- Caution against excessive reaction to youth vaping (November 2018): <u>Youth tobacco and</u> nicotine use – proportionate and responsible reaction
- Warn the White House of unintended perverse consequences from a flavor ban (October 2019): Follow-up to a meeting on vaping and tobacco policy – a crisis in 2020

About the author

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