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Michelle Marston
Chief of Staff
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By email: [***]

Dear Michelle,

Re: follow up to meeting regarding tobacco & vaping policy (24 September 2019) – a crisis in 2020

Thank you for finding time to see us on September 24, 2019 and for your thoughtful observations and questions. I thought it might be helpful if I summarized some key points by way of follow-up. We discussed five main issues:

(1) clearing the market of flavored e-cigarettes and likely adverse unintended consequences;
(2) the excessive burdens of FDA's PMTA route to market and how to reduce these;
(3) the likely market distortions and concentration in favor of tobacco companies;
(4) the rise in youth vaping and how to address it, and;
(5) the appropriate interpretation of the recent vaping-related lung damage outbreak.

1 Clearing the market of flavored e-cigarettes and likely adverse unintended consequences

The President, Secretary Azar and Acting FDA Commissioner Sharpless announced on 11 September that the Federal Government would use FDA's enforcement discretion to 'clear the market of flavored e-cigarettes'.[1] This means removing from market nearly all e-cigarettes and liquids, as non-tobacco flavors increasingly dominate the market.[2] As with any prohibition, this will not in fact 'clear the market of flavored 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:

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1 Department of Health and Human Services. Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products, Press release. September 11, 2019

2 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]

- The closure of thousands of small to medium sized businesses (vape stores and manufacturers)[3] as the products they make and sell are predominantly flavored. Many of these also provide a market-based supportive service to smokers wishing to take up vaping as an alternative to smoking.
- A transfer of the supply of flavored 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 flavored 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 flavors;
- 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 switch to tobacco flavored e-liquids (as we discussed, this experience is nothing like smoking);
- Some may quit vaping and smoking altogether (though may increase other risk behaviors).

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. This in itself carries risks – black markets may supply adulterated products made in unsanitary, unregulated conditions. 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*. As far as we are aware, no assessment has been made of how these effects will play out. FDA has already recognized the adverse impacts of a rapid vaping market contraction.[4] However, it is possible that FDA sees its role as implementing, rather than challenging, such policies.[5]

Recommendation. The White House should commission a rapid policy review to assess the likely health, economic, and political consequences – intended and unintended - as they will unfold in 2020.

2 The excessive burdens of the PMTA process and how to reduce these

FDA argues that flavored products can return to the market once they have been subject to the FDA's pre-market review (the Pre-Market Tobacco Application – PMTA). However, FDA has not made good on

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[3] Analysis by consultants John Dunham & Company found that in 2018, the US e-cigarette 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.

[4] Zeller M. (Head of Centre 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.

[5] Stephanie Miller. Sandhill Strategy, September 27, 2019: "*When we asked Mr. Zeller [Head of the Center for Tobacco Products, FDA] explicitly whether he was concerned that a total ban of flavored vape products would likely to lead to an increase in combustible cigarette use, he presented an answer that indicated the agency is far more concerned with the means rather than the ends of their public policy approach*." [Sandhill Strategy client e-mail, no link available]

its promise to make the process "efficient, predictable and transparent". We detailed concerns and suggested remedies in a letter to Secretary Azar, which was copied to OMB.[6] Both the final guidance[7] and the recently published PMTA rule[8] describe a regime that is enormously burdensome, opaque, and unpredictable. In court filings, the Vapor Technology Association (VTA) provides a cost estimate:[9]

> *First, preparing a PMTA is an extremely costly and time-consuming endeavor, with estimated costs for only five e-liquid flavors running between $2.5 million and $3.5 million.*

The VTA complaint details numerous changes in the timetable and guidance and shows that even now the 'rules-of-the-road' remain unclear – though companies are required to comply by May 12, 2020.

It is worth considering the combined effect of these measures: the likely removal of flavored products from the market later this year will destroy most of the legitimate companies in the market. Even if they intend to make PMTA applications for flavored products, these businesses will be crippled by cash-flow consequences of perhaps a two-year delay from the time their products are removed from the market to the point they receive FDA approval while their PMTA applications are evaluated. Few companies have the resources to make successful PMTA applications even without the removal of flavored products from the market. Only a handful are likely to be able survive these twin challenges. This will dramatically concentrate the market and reduce competition, choice, and innovation while potentially adding to the public health burdens of tobacco. We believe the PMTA process should be significantly improved, and this is possible without compromising public safety, using the following approaches:

- **FDA could resolve many aspects of its public health test at the level of the *whole e-cigarette category*.** There is too much reinventing the wheel. FDA could make findings about the overall impact of e-cigarettes in the United States and use this as context for assessing individual products.
- **FDA could rely more heavily on post-market surveillance and corrective action.** It would make far more sense to have a relatively straightforward and transparent compliance regime for access to the market (the EU approach), and to address problems with retrospective action if problems arise. Trying to predict the market in advance is impossible: no-one foresaw the rise of Juul, including Juul.
- **FDA could severely limit the use of costly and time-consuming human subject studies**. Expensive and time-consuming human studies could be largely avoided by relying on vapor toxicology as a reasonable proxy for individual risk. Human studies add little relevant knowledge for a regulator.
- **FDA could establish a simplify review by developing a range of transparent *de facto* benchmarks for conventional vaping products**. If such benchmarks were met, this would be sufficient to meet

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6 Letter from Iowa Attorney General Tom Miller, Regulation of Vaping Products: a Crisis in 2020, July 24, 2019.

7 FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems *Guidance for Industry*, June 11, 2019.

8 FDA, Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 FR 50566, September 25, 2019.

9 Vapor Technology Association and Vapor Stockroom versus Food and Drug Administration and Department of Health and Human Services, Eastern District of Kentucky, Verified Complaint, August 14, 2019

most of the assessment needs of the pre-market review. These benchmarks could cover electrical, thermal, chemical and mechanical safety, labelling, and testing – an approach emerging in France.

- **FDA should concentrate its limited scientific resources on products that contain novel technologies or present unusual risks**. Under its current approach, FDA will be using its scarce and highly trained staff to parse millions of pages of routine and repetitive documentation, and its assessments will be driven by the adequacy of paperwork rather than underlying product safety.
- **FDA should publish its own guidance to reviewers**. In order not to be arbitrary and discriminatory, FDA needs consistent assessments: (1) across like products; (2) across multiple technical assessors, and; (3) over time. It is inconceivable that it could do this without internal guidance that ensures consistency. It should publish that guidance. If it does not have it, it should create it.

Recommendation. OMB should commence a substantive engagement with FDA to materially improve the efficiency, predictability and transparency of FDA's pre-market review process. The suggestions in our July letter, summarized above, could be independently assessed and a new approach could replace the current 'anti-proportionate' PMTA regime, whereby extreme burdens are placed on the much safer market entrant (e-cigarettes) and minimal burdens on the harmful incumbent (cigarettes).

3 Market distortion and concentration in favor of the tobacco industry

While many small and medium sized businesses will be wiped out, the tobacco companies are well-placed to benefit from federal interventions in the vapor market. They are effectively hedged against adverse developments in the vapor market by their traditional cigarette businesses and they can cross-subsidize their vapor compliance costs and ride out any delays from their highly profitable cash-generating cigarette trade. The stock analyst community recognizes the likely effects of these measures:

> *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)

4 Youth vaping – a more nuanced analysis is necessary

The headline youth vaping figures have caused alarm: there has been a sharp increase in high school age e-cigarette use: 11.7% in 2017: 20.8% in 2018; and 27.5% in 2019. We do not wish to downplay these numbers and recognize that any rapid rise in a youth risk behavior is troubling. However, the headlines conceal important nuances. In particular, these numbers refer to the proportion declaring at least one puff in the past 30 days. For public health purposes, it is essential to unpack this headline figure

according to how many are vaping frequently (≥20 days per month) and whether the e-cigarette user has already shown a propensity for tobacco use by prior use of cigarettes or other tobacco products. For these users, vaping may be *beneficial* even if we prefer that they use no nicotine products at all.

Regrettably, the detailed data needed to analyze the 2019 headline figure in this way have not yet been made available. However, the data is available for 2018 and this provides a useful illustration.[10]

NYTS 2018 data	Percentage of high school students using e-cigarettes Total = 20.8%		Number of high school students using e-cigarettes Total = 3,050,000	
High school students	No past tobacco use	Any past tobacco use	No past tobacco use	Any past tobacco use
Frequent e-cig use: 20-30 days per month	0.6%	5.1%	88,589	752,298
Infrequent e-cig use: ≤ 19 days per month	4.7%	10.3%	695,388	1,513,724

It is evident from the table that: (1) most vaping is infrequent and therefore does not suggest serious addiction or public health concerns and; (2) among frequent adolescent vapers, there is a strong association with prior tobacco use and therefore at least a potential benefit from vaping. Only 0.6% of high school age vapers are both frequent users and have no prior history of tobacco use.

Youth vaping should also be placed in context with other youth risk behaviors. The Youth Risk Behavior Surveillance system[11] provides insights into adolescent risk-behaviors, such as alcohol use (29.8% in the past 30 days), binge drinking (13.5%), cannabis use (19.8%), carrying a weapon (15.7%), and texting or emailing while driving (24.6%). During the 12 months before the survey, 19.0% had been bullied on school property and 7.4% had attempted suicide. Young people have tried heroin (1.7%), meth (2.5%), hallucinogenic drugs (6.6%) and prescription painkillers without a prescription (14.0%).

While vaping is not benign, it does not loom large in the range of risks facing young Americans today. It does not, for example, cause the violence, road traffic and other accidents, or the sexual vulnerability caused by alcohol use. The most lasting consequence of vaping is if an adolescent who vapes takes up smoking and continues for decades. It is possible that removing flavored products from the market and leaving only tobacco-flavored vaping products could make this transition to smoking *more likely*.

We believe the emphasis on flavors as a driver of youth vaping uptake and the harms arising from e-cigarette flavors is overstated and have set out our reasoning at some length.[12] The same flavors are available in Europe and there has not been significant youth uptake. There are many substances that rise in popularity without flavors: for example, nearly one in five adolescents currently use cannabis.

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[10] Jarvis M, Bates C. Analysis of National Youth Tobacco Survey 2018 data. July 2019. See table with full frequency distribution here.

[11] Kann L, McManus T, Harris WA, et al. Youth Risk Behavior Surveillance — United States, 2017. *MMWR Surveill Summ* 2018;67(No. SS-8):1–114.

[12] Comment from Iowa Attorney General Tom Miller, Regulation of Flavors in Tobacco Products: A Proposed Rule by the Food and Drug Administration, Comment on Docket No. FDA-2017-N-6565 83 FR 12294

Flavors are integral to vaping products and banning almost all flavors is a *de facto* prohibition rather than targeted and proportionate regulation.

Recommendation. 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.

5 Appropriate interpretation of the recent vaping-related lung damage outbreak

An outbreak of severe lung injuries associated with vaping began in mid-July.[13] Though CDC and FDA are maintaining the underlying causes remain unclear, the evidence strongly, if not yet conclusively, points towards ingredients such as Vitamin E acetate added to black market cannabis (THC) liquids to thicken the liquid. FDA has rightly focused its advice on black market THC cartridges.[14] CDC has, however, provided far more generalized advice to avoid all vaping, only emphasizing THC vaping as late as September 28, 2019,[15] by which time many vapers would reasonably assume the lung-injury risk applies broadly to all vaping products and liquids. There are four relevant considerations:

- Providing overly generalized advice can cause two serious risks: (1) that ordinary nicotine vapers will (incorrectly) believe the warnings and risks apply to them and quit vaping, possibly returning to smoking; (2) that the warnings are too vague to deter THC users from accessing the black market, putting users in mortal danger. We believe FDA has adopted the right approach with its more specific warnings.
- The outbreak is recent and confined to the United States and Canada (one possible case) so far. There are about 14 million adult nicotine vapers in the United States and 50+ million worldwide. If these lung injuries are associated with legitimately marketed nicotine liquids, we would have seen it before and in other countries, but we have not seen this syndrome develop elsewhere.
- CDC notes that some users report only using nicotine. However, self-report is highly unreliable. Because the legal status of illicit substances raises issues with parents, school, college or employers,

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13 CDC. Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping. CDC website, September 27, 2019 (ongoing)

14 FDA. Vaping Illnesses: Consumers can Help Protect Themselves by Avoiding Tetrahydrocannabinol (THC)-Containing Vaping Products September 6, 2019. "*While the FDA does not have enough data presently to conclude that Vitamin E acetate is the cause of the lung injury in these cases, the agency believes it is prudent to avoid inhaling this substance. Because consumers cannot be sure whether any THC vaping products may contain Vitamin E acetate, consumers are urged to avoid buying vaping products on the street, and to refrain from using THC oil or modifying/adding any substances to products purchased in stores. Additionally, no youth should be using any vaping product, regardless of the substance"*

15 Siegel M. CDC Finally Admits that Black Market THC Vape Carts are a Major Culprit in Respiratory Disease Outbreak. Rest of the Story. The Rest of the Story blog. September 29, 2019.

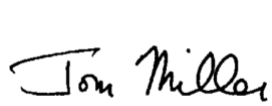
and may attract various sanctions, users have strong incentives not to report illicit drug use. Secondary checks have usually found THC markers present in those initially claiming only to have used nicotine liquids.[16] CDC investigations into other outbreaks rarely identify a single exposure to explain all cases. However, multiple simultaneously-arising and independent causes are highly unlikely, and an epidemiological approach is used to identify the probable causal mechanism.[17]

- There is *no reason* to add these suspect substances to nicotine liquids – they are expensive and serve no useful function in nicotine liquids, whereas it is economically attractive to black market THC liquid suppliers to dilute ('cut') the liquid and then thicken it so that it looks like full strength THC liquid. If nicotine liquids are implicated in the lung damage cases, it would need to be through an entirely separate cause. It is implausible for twin outbreaks to arise in the same geography and at the same time, but with completely separate causes. Misreporting (above) is by far the most likely explanation for the ongoing lack of clarity on the underlying cause, and this may *never* be resolved.

Recommendation. The lung-injury outbreak should be understood by policymakers as *a black-market problem,* not an e-cigarette problem. It arises from the legal status of THC or other illicit substances and the consequential illegal trade, rogue operators and poor production techniques that follow from prohibitions. Although similar devices are used, this is not an issue that arises from using commercially available nicotine vaping products regulated by the FDA, which have been working well as an alternative to smoking. However, the crisis has been used by some to justify emergency restrictions on nicotine vaping products (complete bans or flavor bans), which will, in practice, *increase black market activity*.

In conclusion. We hope the observations above are of interest. We believe the United States is heading for a crisis in this field in 2020 with potentially millions of Americans facing life-threating regulation imposed by the Federal Government. Our recommendations propose that White House staff, on behalf of the President, should enter this period well-acquainted with the potential adverse consequences.

Yours sincerely,



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[16] For example, CDC found: "*In Wisconsin, eight patients initially denied using THC-containing products in interviews, but five (63%) were later found to have used THC through review of medical charts, reinterview, or cross-referencing with friends who were also interviewed as patients*." MMWR, September 26, 2019.

[17] Siegel M. *Despite Increasing Clarity in Role of Illicit THC Vape Carts in Lung Injury Outbreak, CDC Violating Its Own Principles to Blame E-Cigarettes.* The Rest of the Story blog. September 17, 2019.