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Testimony for hearing on vaping and e-cigarette safety - November 4, 2019

Dear Ms. Sheridan

We write as a public health and tobacco control specialists based in London (Bates) and Ottawa (Sweanor) with many years of advocacy and policy experience – short biographies are at the end of this letter. We do not have conflicts of interest with respect to tobacco, vaping, or pharmaceutical industries. What happens in New York is always of global significance in tobacco policy and, with that in mind, we would like to contribute testimony to the upcoming hearing on vaping and e-cigarette safety.

We strongly support ‘tobacco harm reduction’ as a public health strategy for reducing the burden of smoking related cancer, heart disease, respiratory illness and other harms associated with smoking. We believe there is strong evidence to encourage vaping as a much lower risk alternative to smoking for people who cannot or do not wish to quit completely. In this testimony, we will cover:

1. Why clearing the market of flavored e-cigarettes will cause harmful unintended consequences;
2. Why the excessive burdens of FDA's regime will also favor the Big Tobacco;
3. Wall Street expects market distortions and concentration in favor of tobacco companies;
4. Understanding the rise in youth vaping – a more nuanced analysis is necessary;
5. Understanding the recent vaping-related lung damage outbreak.

By way of background, we have also included a letter on tobacco harm reduction as a global public health strategy from 72 US and international experts in the field. We hope this illustrates the extent of informed support for this approach. We would be happy to provide any other information.

1 Clearing the market of flavored e-cigarettes will cause harmful unintended consequences

Many states are considering various forms of bans or restrictions on e-cigarettes or flavored products. 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

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](#)]

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:

- The closure, nationally, of thousands of small to medium sized businesses (vape stores and manufacturers)³ as the products they make and sell are mostly flavored. Many 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 – this will *increase* health risks;
- 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 may switch to whatever vaping products are permitted – providing these are pleasurable, affordable and accessible;
- 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 or restraint 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*. To my knowledge, no assessment has been made of how these effects will play out at federal or at state level. FDA has already recognized the adverse impacts of a rapid vaping market contraction⁴ though has shown little sign of doing anything about it.⁵

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 lead to an*

Recommendation. Policymakers contemplating major interventions in the vaping market should assess the likely health, economic, and political consequences – intended and unintended - as they will unfold following any prohibitionist measures. No legislature should be passing new regulation without an objective impact and risk assessment.

2 The excessive burdens of the FDA approval process will also favor Big Tobacco

Restrictive measures taken at state level will be compounded by the federal government’s highly burdensome and discriminatory approach. FDA has not made good on 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 guidance⁷ and the recently published PMTA rule⁸ 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.

Recommendation. Policymakers should recognize that *de facto* prohibition of vaping through excessive regulation and flavor bans will protect the cigarette trade from disruption, promote black markets in vaping products, prolong the epidemic of smoking related disease and shut down pro-health innovation.

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]

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

3 Wall Street expects 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 and state 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. Wall Street 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 Understanding the rise in 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.

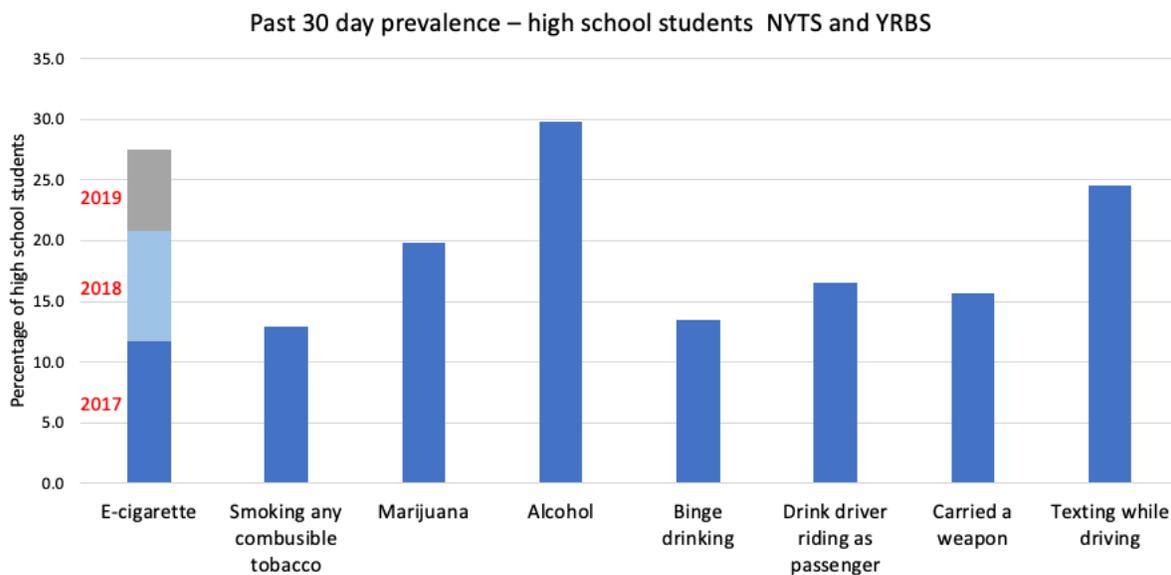
Regrettably, the detailed data needed to analyze the 2019 headline figure in this way have not yet been made available. However, the data is available for 2018 and this provides a useful illustration.¹⁰

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	
	No past tobacco use	Any past tobacco use	No past tobacco use	Any past tobacco use
Frequent e-cig use: ≥ 20 days per month	0.6%	5.2%	88,589	752,298
Infrequent e-cig use: ≤ 19 days per month	4.7%	10.3%	695,388	1,513,724

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

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 system¹¹ 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 harmful 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 would be if an adolescent who vapes takes up smoking and continues for decades, never returning to vaping. This is extremely unlikely in practice. In 2018, 13.9% of high school students had smoked any combustible tobacco in the past 30 days. Given smoking is likely to be a least twenty times as harmful as vaping, this represents a far greater public health risk than more people (25.7% in 2019) doing something much less harmful.

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

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

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 US adolescents currently use cannabis. 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. FDA has adopted a better approach with 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.

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”

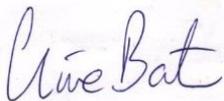
¹⁵ Siegel M. [CDC Finally Admits that Black Market THC Vape Carts are a Major Culprit in Respiratory Disease Outbreak. Rest of the Story](#). The Rest of the Story blog. September 29, 2019.

- 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, 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 these observations 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-threatening regulation imposed by the federal and state governments. We strongly recommend that policymakers should enter this period well-acquainted with the likely harmful consequences and likely benefits to the cigarette trade.

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.

Attachment: Letter from seventy-two specialists in nicotine science, policy and practice to the Director General of the World Health Organisation

Biographies

Clive D. Bates is Director of Counterfactual, a consulting and advocacy practice focussed on a pragmatic approach to sustainability and public health. He has had a diverse career in the public, private and not-for-profit sectors. He started out with the IT company, IBM, then switched career to work in the environment movement. From 1997-2003 he was Director of Action on Smoking and Health (UK), campaigning to reduce the harms caused by tobacco. From 2000, he was closely involved in the development of the Framework Convention on Tobacco Control. In 2003, he joined Prime Minister Blair's Strategy Unit as a senior UK civil servant and worked in senior roles in government and regulators, and for the United Nations in Sudan. He started Counterfactual in 2013.

David T. Sweanor JD is Adjunct Professor of Law and Chair of the Advisory Board of the Centre for Health Law, Policy and Ethics at the University of Ottawa. He has worked on global tobacco and health issues for more than 30 years, helping set many global precedents in Canada. He has also worked globally on tobacco issues with the WHO, PAHO, World Bank and numerous other bodies and spoken and published widely on issues of tobacco and health. His interests extend to a wide range of topics, and in addition to his personal work he funds numerous initiatives. He was the recipient of the Outstanding Individual Philanthropist award for Ottawa in 2016.