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Alex M. Azar II
Secretary of Health and Human Services
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

July 24, 2019

Dear Secretary Azar,

Re: Regulation of vaping products – a crisis in 2020

In July 2017, we welcomed FDA’s announcement of a comprehensive risk-based strategy for nicotine and tobacco.ⁱ However, we must now to express concern that the FDA’s regulatory approach to e-cigarettes and other vaping products is heading towards a serious crisis by the middle of 2020. We are concerned that excessively expensive, time consuming, and burdensome regulation is about to kill-off or severely degrade one of the most important new technologies for public health in the United States. There are approximately 12 million vapers in the United States and 34 million smokers – each one has a stake in the viability, diversity, and innovation of this industry. We are writing to draw your attention to the causes of the looming crisis and to suggest remedies.

Even after 50 years of progress, smoking remains a devastating burden on American families. According to the Centers for Disease Control and Prevention, more than 16 million Americans live with a smoking-related disease and smoking causes more than 480,000 deaths per year. That is more than HIV, alcohol, illicit drug use, motor vehicle accidents, and firearms *combined*.ⁱⁱ The costs are enormous – over \$300 billion annually for healthcare (\$170 billion) and in lost productivity (\$156 billion).ⁱⁱⁱ The costs in lost life, pain and grief are incalculable. The burdens fall most heavily on disadvantaged groups, with higher rates of smoking among those who are economically deprived, have poor educational attainment, LGBT status, no health insurance, a disability or suffer mental distress^{iv}.

However, since 2009 there has been highly beneficial disruptive innovation in the tobacco/nicotine market and new products, such as e-cigarettes, that pose much lower risks to users are gaining in popularity as alternatives to cigarettes. We are seeing smoking decline in both adults and adolescents at an accelerated rate. This is driven by consumers acting on their own initiative, spending their own money to improve their own health and wellbeing – something every government should encourage. Modeling the effects of e-cigarettes on smoking-related disease suggests that e-cigarettes could save millions of lives, even with pessimistic assumptions about unlikely unintended consequences.

However, it appears that the Federal Government may soon frustrate these highly promising developments and unintentionally protect the cigarette trade from pro-health competition and encourage more smoking, not less. There are four main concerns:

1. The excessive costs and burdens of FDA's pre-market tobacco application (PMTA) process threaten to remove almost all companies and products from the market.
2. Even now, FDA's pre-market tobacco application requirements remain unclear.
3. The court-ordered compression of the time available for compliance with pre-market review requirements threatens an abrupt convulsion in the market.
4. FDA's own scientific resources may be a fatal constraint.

As a result of the intense burdens, the unpredictability of the process and the compressed timetable, we believe that almost all industry participants and products will exit the regulated market – this is a plausible possibility that FDA should examine. The likely effect is that some fraction of the 12 million vapers will revert to exclusive smoking thereby causing a detriment to public health, that a major unregulated black market will form, and that innovation in the lawful regulated marketplace will be severely curtailed, but will continue unabated outside the United States, notably in Canada, China, and Europe, and thus drive further development of a US black market.

A substantial reassessment is now required, and five remedial actions should be undertaken urgently:

1. FDA's Regulatory Impact Analysis (RIA) should be immediately revisited and reviewed.
2. FDA must clarify how it will apply the "public health" test in practice.
3. FDA should develop a viable proportionate route to market for vaping products.
4. FDA should make a strategic reassessment and update its 2017 strategy for nicotine.
5. FDA and other relevant agencies should overhaul their risk communications for tobacco and nicotine.
6. FDA should appeal the Maryland court decision and seek a stay.

We share the widespread concern about the increase in youth vaping between 2017 and 2018, but we counsel against a damaging overreaction to the headlines and recommend a careful reading of the underlying data: most youth vaping is occasional; most regular youth vaping is concentrated in current or former smokers, many of whom may be vaping with the intent (in some cases successful) to reduce or eliminate their smoking. Youth vaping should be addressed with youth-orientated measures – not through excessively burdensome regulatory regime for products that are beneficial to adults and promise to roll-back the epidemic of smoking related disease.

The attached briefing elaborates on these points in greater detail.

We are concerned that the FDA has strayed from its July 2017 announcement whereby it indicated, among other things, that tobacco and nicotine products should be regulated using the 'continuum of

risk', that innovation should be encouraged not stifled, that the review process for new product approvals should be streamlined, and that adult users be given access to lower risk alternative products.

Given the potentially serious impact on public health and the large number of Americans affected, we hope you will agree to meet a small delegation to discuss these points, the likely adverse consequences for public health, and the fundamentals of an appropriate alternative regime.

Yours sincerely,

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Attached:

[Briefing A crisis in 2020: The impact of excessive FDA regulation of vaping products and public health](#)

Copied to:

Acting FDA Commissioner (Ned Sharpless)

Director, Center for Tobacco Products, FDA (Mitchell Zeller)

Acting Director of OMB (Russell Vought)

Senator Lamar Alexander, Chair, Senate Committee on Health, Education, Labor & Pensions

Senator Patty Murray, Ranking Member, Senate Committee on Health, Education Labor and Pensions

Rep. Frank Pallone, Chair, House Committee on Energy & Commerce

Rep. Greg Walden, Ranking Member, House Committee on Energy & Commerce

References

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- ⁱ U.S. Food and Drug Administration, FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death, News release, July 28,2017. [\[link\]](#)
- ⁱⁱ Centers for Disease for Disease Control and Prevention, Health effects of cigarette smoking. Accessed 22 July 2019 [\[link\]](#)
- ⁱⁱⁱ Centers for Disease for Disease Control and Prevention, Economic trends in tobacco. Accessed 22 July 2019 [\[link\]](#)
- ^{iv} Centers for Disease for Disease Control and Prevention, Current Cigarette Smoking Among Adults in the United States. Accessed 22 July 2019 [\[link\]](#)

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1 Introduction

E-cigarettes and other vaping products are used by around 12 million Americans, about five percent of adults. 70% of users say they are using e-cigarettes as a way of cutting down on cigarette smoking and 72% believe that e-cigarettes will help with quitting smoking.¹ Multiple reviews have concluded that though vaping may not be risk-free, it is likely to be *much less risky* than smoking.^{2 3} For many, these products are an important part of their approach to personal health and their wider wellbeing either because they have quit smoking by vaping or because they are in transition from smoking to vaping.

The rate of decline in US cigarette consumption has accelerated coinciding with the rise in vaping. For example, between June 2018 and June 2019, US cigarette volumes fell by more than 10%, driven by rising e-cigarette sales.⁴ This is more than double the long-term rate of decline. Scenario modelling suggests very substantial public health benefits are likely, even under pessimistic scenarios.⁵

Compared with the status quo, replacement of cigarette by e-cigarette use over a 10-year period yields 6.6 million fewer premature deaths with 86.7 million fewer life years lost in the Optimistic Scenario. Under the Pessimistic Scenario, 1.6 million premature deaths are averted with 20.8 million fewer life years lost.

To realize these benefits will require a comprehensive strategy in which these products play a major role. However, the approaching regulatory crisis will cause almost all legitimate companies and vaping products to exit the legal market, while leaving cigarettes widely available.

There is evidence that vapers will respond to excessive and ill-designed regulation, in part, by returning to smoking⁶. There is no justification for this on public health, ethical, legal, or political grounds. On the contrary, it will do considerable harm to public health, increase healthcare costs, and undermine FDA's broader strategy for reducing the impact of smoking on health.

¹ Coleman B, Chang JT, Rostron BL, Johnson SE, Das B, Del Valle-Pinero AY. An Examination of Device Types and Features Used by Adult Electronic Nicotine Delivery System (ENDS) Users in the PATH Study, 2015–2016. *Int J Environ Res Public Health*. 2019 Jul 2;16(13):2329. [\[link\]](#). Approximately 12m vapers; 7m dual users; 3m former smokers; 2m never smokers.

² Abrams DB, Glasser AM, Pearson JL, Villanti AC, Collins LK, Niaura RS. Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives. *Annu Rev Public Health*; 2018. [\[link\]](#)

³ National Academies of Science, Engineering and Medicine (US). The Public Health Consequences of E-cigarettes. Washington DC. January 2018. [\[link\]](#)

⁴ Herzog B. Nielsen: Tobacco All Channel Data Thru 6/15 - Cig Vol Declines Accelerate, Wells Fargo Securities. 29 June 2019.

⁵ Levy DT, Borland R, Lindblom EN, Goniewicz ML, Meza R, Holford TR, et al. Potential deaths averted in USA by replacing cigarettes with e-cigarettes. *Tob Control*. BMJ Publishing Group Ltd; 30 August 2017. [\[link\]](#)

⁶ Pacek LR, Oliver JA, Sweitzer MM, McClernon FJ. Young adult dual combusted cigarette and e-cigarette users' anticipated responses to a nicotine reduction policy and menthol ban in combusted cigarettes. *Drug Alcohol Depend*. 2019 Jul 15;194:40–4. [\[link\]](#)

2 The causes of the forthcoming crisis in the nicotine market

The reasons for concern over FDA’s approach to regulating vaping products are four-fold:

2.1 The excessive costs and burdens of the pre-market tobacco application (PMTA) process threaten to remove almost all companies and products from the market

The extreme burdens of the pre-market application process that will be required to allow vaping products to remain on or introduce new products to the US market have come into sharper focus since final guidance was published in June.⁷ This confirmed FDA’s intention to impose extremely high evidential burdens on companies making vaping products, even though there is already enough evidence for the National Academies of Science, Engineering and Medicine, to conclude:⁸

While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible tobacco cigarettes.

Despite this, e-cigarette manufacturers will be required to go through an extremely expensive and time-consuming approval process to prove this point repeatedly for thousands of individual products. In 2016, FDA estimated that PMTA application costs would be several hundred thousand dollars:⁹

FDA 2016	E-liquids	Devices
First application	\$131,643	\$466,563
Subsequent applications	\$117,486	\$192,654

Experience since 2016 suggests that the likely costs and duration of the application process will far exceed the estimates the FDA made when the rule was scrutinized in 2016. In filings to the Maryland District Court, the affected companies and trade associations set out in some detail the extensive burdens that arise from following FDA’s guidance to industry, rather than the cost estimates made in 2016.¹⁰ One professional analytics company estimates PMTA costs of \$8.7 to \$11.2 million flat costs and \$597,000 per flavor.¹¹

Even using FDA’s 2016 underestimated costs, most companies and products will be forced off the market. These exits will happen because most companies and most product lines are not large enough to carry the extreme costs and burdens of the application process, not because there is anything wrong

⁷ FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS), Guidance to Industry, June 2019 [\[link\]](#)

⁸ National Academies of Science, Engineering and Medicine (US). The Public Health Consequences of E-cigarettes. Washington DC. January 2018. [\[link\]](#) Launch presentation summary (slide 44) [\[link\]](#)[\[link\]](#)

⁹ FDA, Deeming Rule Docket No. FDA-2014-N-0189: Final Regulatory Impact Analysis, 10 May 2016 [\[link\]](#) The PMTA cost is a weighted average and assumes several products will be included in each PMTA (on average, 11 liquids and 6 devices).

¹⁰ See *amicus curiae* briefs to the Maryland Court by the businesses affected – Case 8:18-cv-00883-PWG, American Association of Pediatrics et al versus Food and Drug Administration et al. *Amicus curiae* brief of Right to be Smokefree Coalition, 14 August, 2018 [\[link\]](#); *Amicus curiae* brief of John Middleton Co. & others, 12 June 2019 [\[link\]](#)

¹¹ Cardno Chemrisk, Center for Product Sustainability, Consortium PMTA Efforts and Costs, 1 July 2019. [\[link\]](#)

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with the products or companies. No such burdens and barriers apply to the thousands of cigarette lines already on the market.

2.2 Even now, FDA's pre-market tobacco application requirements remain unclear

Though final guidance to industry has been produced, it essentially provides an exhaustive list of possible evidence the companies could provide, but offers no prioritization and does not attempt to define an efficient pathway to compliance. Despite completing the rule deeming e-cigarettes to be tobacco products in 2016, and despite promising in 2017 to make the pathway to market for vaping product 'more efficient, transparent, and predictable', the FDA has yet to complete its PMTA rule:¹²

"the FDA plans to issue foundational rules to make the product review process more efficient, predictable, and transparent for manufacturers, while upholding the agency's public health mission. Among other things, the FDA intends to issue regulations outlining what information the agency expects to be included in Premarket Tobacco Applications (PMTAs) ..."

In early July 2019, this was still under review by the Office of Management and Budget.¹³ This proposed rule *"would establish content and format requirements to ensure that premarket tobacco product applications contain sufficient information for FDA to determine whether the marketing of a new tobacco product should be authorized"*. Without such a rule, manufacturers and importers continue to operate in the dark – with the Center for Tobacco Products' (CTP's) guidance documents suggesting the burdens will be very high. In particular, FDA has so far failed to explain publicly to applicants how it will apply the "appropriate for the protection of public health" test in practice – taking account of trade-offs between and within adult and adolescent smoking and vaping behaviors.

2.3 The court-ordered compression of the time available for compliance with pre-market review requirements threatens an abrupt convulsion in the market

The damaging excessive burdens and uncertain requirements referred to in 1. and 2. above are compounded by the extreme compression of the timetable for compliance resulting from legal action brought by activist health groups against the FDA.¹⁴ The groups challenged the FDA's use of enforcement discretion to extend the time available for compliance, initially to August 2022. On July 11, 2019, a Maryland district court determined that PMTAs must be submitted by May 11, 2020.¹⁵ Almost all companies will be unable to comply and will exit the market leaving only a few products, mainly marketed by cigarette companies. Given that there are approximately 12 million Americans using vaping products, little attention has been paid to what impact the sharp and near-term contraction of the

¹² U.S. Food and Drug Administration, "FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death, News release, 28 July 2017. [\[link\]](#)

¹³ OMB/OIRA, Premarket Tobacco Product Applications and Recordkeeping Requirements. RIN: 0910-AH44 [\[link\]](#)

¹⁴ American Academy of Pediatrics and others vs. Food and Drug Administration. United States District Court, District of Maryland, Case No. 8:18-cv-883-PWG. Law 360 [\[link\]](#)

¹⁵ United States District Court, District of Maryland, Case No. 8:18-cv-883-PWG, Order of the Court, 11 July 2019. At the time of writing it is unclear whether FDA/DOJ will appeal on the basis that the court has dictated a specific enforcement policy rather than confine FDA's enforcement discretion, which is what the FDA had proposed.

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industry will have on these users. Rational and efficient companies have been waiting for FDA to finalize the guidance (only completed in June 2019) and to deliver on its promise to improve the PMTA process (no meaningful progress to date with a rule not yet published). Long-term studies will be impossible to conduct in the time remaining, and there may be limited laboratory space available to conduct pre-clinical studies.

2.4 FDA's own scientific resources may be a fatal constraint

The PMTA review process not only places very high burdens on applicants, but also on FDA's own scientific and technical resources, and the compression of available time only aggravates that.

The PMTAs completed to date by two companies and actually authorized by FDA have taken more than a year and involved over a million pages of documentation. In its regulatory impact analysis, FDA estimated that the demand for number of product packages applying for marketing authorization would be 5,424 to 6,764 across all newly deemed products. There is no plausible way that FDA can deliver that volume of reviews, *unless the effect of the compliance burdens is so great that it reduces the number of applications to a minimal level*. It is a real concern that FDA may need the burden of application to be disproportionate in order to make the volume of applications manageable. FDA's scientific resources should not be focused on repetitive assessment of broadly similar products and paperwork compliance, but on novel technologies and potential new risks.

3 Likely consequences of a crisis in the vaping market

Since deeming vaping products to be 'tobacco products' in 2016, FDA's approach to vaping has been discriminatory and disproportionate – implicitly favoring cigarettes over vaping products. Whatever the intent, the likely result will be:

1. Some fraction of the 12 million vapers reverting to exclusively smoking at a health cost that would exceed any conceivable benefits from regulating vaping.
2. The formation of a black market of unregulated vaping products (already evident with Juul-compatible pods in response to Juul Labs' voluntary withdrawal of flavored products from brick and mortar retail).
3. Do-It-Yourself nicotine e-liquid mixing at home and as an informal, illegal, and dangerous business.
4. A great deal of dissatisfaction and distress among those affected, who have done nothing but protect their own health, on their own initiative and at their own expense.
5. A significant barrier to innovation that means products on the American legal market are always behind the curve of innovation and inferior to those available outside the United States in jurisdictions with more proportionate regulation.¹⁶ This will be a driver of black-market activity.

¹⁶ In June 2019, Phillip Morris International received PMTA marketing orders for its IQOS heated tobacco product. But the marketing order applies only to the 1st generation IQOS product, which was the product available when the application process started. Outside the United States, the company sells the 3rd generation of the IQOS product.

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When FDA published its deeming rule, it made no assessment of the possible harmful unintended consequences of excessive burdens of regulation of e-cigarettes – including the likelihood of increasing smoking or other undesirable effects. It is now essential that this is addressed before excessive regulatory actions cause more harm than good.

4 A major policy reassessment is now necessary and urgent

For public health reasons, the policy framework for vaping products needs a major reassessment and overhaul. The recommendations set out in the following five sections should be adopted urgently.

4.1 FDA’s Regulatory Impact Analysis should be immediately revisited and reviewed

In particular, FDA should revisit three key aspects of the regulatory impact analysis: (1) estimates of the costs of the PMTA application process; (2) estimates of ‘exit’ from the marketplace due to compliance burdens; (3) impacts of marketplace consolidation on tobacco use, including potentially unintended shifts towards smoking and black-market development. OMB/OIRA should take whatever measures are necessary to ensure the RIA is the most realistic and current possible analysis of the likely impacts. The existing RIA is not fit for purpose and did not assess possible unintended consequences arising from high levels of companies and products exiting the e-cigarette marketplace. Without such an assessment, policy miscalculation is likely and could have serious public health consequences. The administration should not proceed without a full, up-to-date, and realistic assessment of the impact of this policy on millions of Americans who are currently using these products.

4.2 FDA must clarify how it will apply the “public health test” in practice

This test requires the applicant to show that the product is “appropriate for the protection of public health.” Fundamental aspects of this test remain unresolved or unclear to potential applicants. How will it work when there may be decreases in smoking in some groups but increases in vaping in others? In calculating net public health impact, what weight will be given to the difference in relative harms of vaping vs smoking – will these differ by age-group? How will reductions in high smoking-related risks to adults be balanced against increases in much lower vaping-related risks to adolescents? If vaping displaces smoking in adolescents, will that be counted as a benefit or ignored by FDA?

In a recent Wall Street Journal op-ed, the former FDA Commissioner, Scott Gottlieb, argued that cartridge-based products, for example Juul, would be unlikely to receive marketing approval because of “widespread use by kids.”¹⁷ Though he no longer speaks on behalf of FDA, his statements suggest the former Commissioner has a view of how FDA would weigh the various benefits and detriments of such products to adults and adolescents – but this is not explicit to applicants. If the product was denied access to the market, how would its users – adolescent or adult – respond, and therefore what would the public health impact be? As the result of imposing a premarket review process despite the fact that most of the products seeking authorization will have been on the market for several years, the public health impact is what arises from removing them, not the effect of never having allowed them onto the

¹⁷ Gottlieb S. The FDA’s Challenge on E-cigs, Wall Street Journal, 24 June 2019 [\[link\]](#)

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market in the first place. These issues need to be addressed in the PMTA rule before it is finalized. Regulated entities have a right to expect clarity in how regulators will apply rules.

4.3 FDA should develop a viable and proportionate route to market for vaping products

It should not be a requirement for vapor companies to establish the same basic facts over and over again. In discharging its regulatory responsibilities, FDA is obliged to, *inter alia*:¹⁸

...consider, to the extent reasonable, the degree and nature of the risks posed by various substances and or activities within its jurisdiction [...] design its regulations in the most cost-effective way to achieve the regulatory objective [...] consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

In its approach to vaping products, there is little to suggest that FDA has respected these long-established principles of good regulation. There are numerous options for streamlining the PMTA process, but FDA has not adopted the most important:

- **FDA could resolve many aspects of its public health test at the level of the *whole e-cigarette category*.** FDA could accept findings about the overall impact of e-cigarettes on tobacco use in the United States and use this as context for assessing individual products. For example, in modelling of a variety of scenarios to assess the impact of vaping products, under the “*base-case assumptions, the population gains almost 3.3 million life-years by 2070*” and under the “*worst-case assumptions [...] the population gains over 580,000 life-years*”.¹⁹ We expect more advanced modeling to build on these results. It remains unclear how these calculations could be credibly replicated at the individual product level or what evidence would challenge their range of assumptions.
- **FDA should concentrate its limited scientific resources on products that contain novel technologies or present unusual risks.** Under its current approach, it 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 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. For example, a recent review of cancer risk suggests that e-cigarette emissions under normal use conditions have less than 1% of the cancer potency of tobacco smoke²⁰. Little is gained by forcing repeated reassessments of this finding in human studies unless there is some novel technology or risk.

¹⁸ Executive Order 12866 of September 30, 1993 Regulatory Planning and Review [\[link\]](#)

¹⁹ Warner KE, Mendez D. E-cigarettes: Comparing the Possible Risks of Increasing Smoking Initiation with the Potential Benefits of Increasing Smoking Cessation. *Nicotine Tob Res.* 29 March 2018; [\[link\]](#)

²⁰ Stephens WE. Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke. *Tob Control.* 2018 Jan 4;27(1):10–7. [\[link\]](#)

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- **FDA could establish a system of standards for conventional vaping products.** If such standards were met, this would be sufficient to meet most the needs of the pre-market review – these could cover electrical, thermal, chemical and mechanical safety, labelling and testing. Such standards exist elsewhere, notably France.²¹
- **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 approach taken by the European Union), and to address problems with retrospective action if problems arise. Companies will have to submit extensive plans for post-market surveillance. This is a better use of limited financial and personnel resources than extensive pre-market burdens, as it will allow FDA to assess what is going on in the market after a product is introduced. If there are signs that a product is inappropriate for the protection of public health, FDA has the power to revoke or qualify the marketing order, a far more targeted regulatory action.
- **FDA could develop a streamlined process for authorizing incremental improvements in vaping products.** This is especially important when these improvements provide immediate health or safety benefits – there needs to be a minimal barrier to such upgrades.
- **FDA should publish its own guidance to reviewers.** In order not to be arbitrary and discriminatory, FDA needs to make regulatory decisions that are consistent across like products for multiple technical assessors and over time. It is inconceivable that it could do this without internal guidance that ensures consistency.

To mitigate the impact of a crisis, the administration should instruct FDA to develop a credible path to market with burdens that are proportionate to risk and reflect the dominant incumbent position of cigarettes in the market place. In doing so, it should demonstrate that it has a viable operations plan to process the volume of applications it expects without needing very large-scale exit.

4.4 FDA should make a strategic reassessment and update its 2017 strategy for nicotine

FDA's Comprehensive Plan for Tobacco and Nicotine Regulation relies on the availability of a range of noncombustible alternatives to smoking.²² However, it is likely that FDA's excessive and opaque regulatory burdens on alternatives combined with a compressed timetable will render its broader strategy inoperable. For example, FDA's plan to lower nicotine in cigarettes to a minimally- or non-addictive level requires a "landing place" for smokers who need or want to continue using nicotine.²³ These reduced-risk options need to be more attractive to smokers than black market cigarettes or switching to other smoked products. Without a clear and achievable pathway to market for noncombustible products, including vaping products, FDA's plan to move forward with a very low

²¹ Association Française de Normalisation (France) Electronic cigarettes and e-liquids Part 1: Requirements and test methods for e-cigarettes XP D90-300-1 March 2015 [\[link\]](#) Part 2: Requirements and test methods for e-cigarette liquid XP D90-300-2 March 2015 [\[link\]](#) and Part 3: Requirements and emission-related test methods XP D90-300-3 July 2016 [\[link\]](#)

²² U.S. Food and Drug Administration, "FDA's New Plan for Tobacco and Nicotine Regulation," 28 July 2017. [\[link\]](#)

²³ Iowa Attorney General Miller and 17 others, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, response to Advance notice of proposed rulemaking (ANPRM) Docket No. FDA-2017-N-6189 [\[link\]](#) [\[1k2-947r-gewy\]](#), 11 July 2018.

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nicotine cigarette (VLNC) product standard is infeasible. Should it prove impossible to introduce a VLNC standard for practical, political, or legal reasons, it will still be essential to move smokers away from combusted tobacco products at the greatest possible rate – the need for a low risk alternative to smoking will remain just as strong. In the light of developments since July 2017, FDA should make a strategic reassessment of its nicotine plan and update the 2017 strategy for regulating nicotine.

4.5 FDA and other relevant agencies should overhaul their risk communications for tobacco and nicotine

A major threat to FDA's nicotine strategy remains the serious and deteriorating public misperceptions of the relative risks of smoking and vaping and the harms caused by nicotine. Only 2.6% of Americans correctly perceive that e-cigarettes are much less harmful than cigarettes, but 43% perceive them to be as harmful or more harmful, and a further 37% don't know. Over 50% believe, incorrectly, that nicotine in cigarettes is the substance that causes most of the cancer caused by smoking.²⁴

Analysis of risk perception data shows:²⁵

... a consistent pattern and a change in perceived relative harm of e-cigarettes among US adults in both surveys, which showed that a large proportion of US adults perceived e-cigarettes as equally or more harmful than cigarettes, and this proportion has increased substantially from 2012 to 2017.

These misperceptions have serious consequences for human health and there is evidence that these perceptions inform behavior:²⁶

U.S. adult dual users of e-cigarettes and cigarettes who perceive e-cigarettes as less harmful than cigarettes appear to be more likely to switch to exclusive e-cigarette use, more likely to remain dual users, and less likely to switch to exclusive cigarette use one year later than dual users with other perceptions of e-cigarette harm.

It is not surprising that if people believe there is little difference in risk, they would be more likely to stick with cigarettes. FDA and other relevant agencies should review their approach to risk communication and present a plan to improve alignment between public perception and expert risk assessment.

4.6 FDA should appeal the Maryland district court decision and seek a stay

It follows from the preceding discussion that more time is required for the FDA to make the changes proposed and for businesses to prepare. The Maryland District Court has imposed an impractical timetable and, because FDA has not so far recognized that reform is essential, the court has not taken

²⁴ National Cancer Institute, Health Information National Trends Survey (HINTS) 2018. E-cigarettes compared to cigarettes [\[link\]](#); E-cigarettes harm to health [\[link\]](#); Nicotine as a cause of cancer [\[link\]](#)

²⁵ Huang J, Feng B, Weaver SR, et al. Changing Perceptions of Harm of e-Cigarette vs Cigarette Use Among Adults in 2 US National Surveys From 2012 to 2017. JAMA Netw Open. American Medical Association; 2019 Mar 29;2(3):e191047. [\[link\]](#)

²⁶ Persoskie A, O'Brien EK, Poonai K. Perceived Relative Harm of Using E-Cigarettes Predicts Future Product Switching among U.S. Adult Cigarette and E-Cigarette Dual Users. Addiction. 2019 Jul 6;add.14730. [\[link\]](#)

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account of the time it would take to streamline the review process. FDA has been clear that it should be in control of the timetable and enforcement regime and that the court is not scientifically qualified to assess the demands of regulatory regime.²⁷

Under the Circuit Rules, the appellant can seek a stay (preventing the Maryland court's order taking effect) if they can demonstrate (i) the likelihood that the moving party will prevail on the merits; (ii) the prospect of irreparable injury to the moving party if relief is withheld; (iii) the balance of equities tips in favor of the moving party; and (iv) an injunction is in the public interest. This is a strong case for a stay on public interest grounds, on the likely destruction of hundreds of legitimate businesses and harm to functioning and reputation of the FDA. An updated Regulatory Impact Analysis (see 3.1 above) would help to make this case.

FDA has 60 days (i.e. before 9 September 2019) to appeal and to seek a stay of the Maryland court's decision. An appeal is necessary and should allow FDA time to refine its PMTA process, but it should not inhibit FDA's other actions to address youth vaping.

5 The challenge of youth vaping

Though this briefing focuses primarily on adult smokers and vaping, there are widespread and legitimate concerns about the sharp rise in youth vaping between 2017 and 2018 – from 11.7% to 20.8% of high school students. However, for broad public health reasons, it is imperative to avoid a damaging overreaction to these findings. Four important qualifications are necessary to properly interpret the headline data, discussed in the three sections that follow.

5.1 Youth smoking remains the dominant tobacco-related risk

Youth *smoking of cigarettes, little cigars and other combustibles* continues to be a more serious public health issue than youth vaping. Though in 2018 there were more past-30-day high school vapers (20.8%) than smokers (13.9%),²⁸ smoking is, beyond reasonable doubt, much more harmful.

There is evidence that declines in youth smoking have accelerated with the increase in youth vaping:²⁹

There was a substantial increase in youth vaping prevalence beginning in about 2014. Time trend analyses showed that the decline in past 30-day smoking prevalence accelerated by two to four times after 2014. Indicators of more established smoking rates, including the proportion of daily smokers among past 30-day smokers, also decreased more rapidly as vaping became more

²⁷ American Association of Pediatrics et al v. Food and Drug Administration et al. Case 8:18-cv-00883-PWG. Defendants' Remedy Brief, 12 June 2019 [\[link\]](#) Declaration of Mitchell Zeller, 12 June 2019 [\[link\]](#)

²⁸ Gentzke AS, Creamer M, Cullen KA, et al. *Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018*. *MMWR Morb Mortal Wkly Rep* 2019;68:157–164. See Table 1. [\[link\]](#)

²⁹ Levy DT, Warner KE, Cummings KM, Hammond D, Kuo C, Fong GT, et al. Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check. *Tob Control*. BMJ Publishing Group Ltd; 2018 Nov 20. [\[link\]](#)

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prevalent. The inverse relationship between vaping and smoking was robust across different data sets for both youth and young adults and for current and more established smoking.

It is important not to lose sight of the centrality of smoking and other more serious risks facing young people. However, there are also a range of other risks afflicting young Americans. The youth risk behavior surveillance system paints a vivid picture: in the past 30 days, 19.8% had used marijuana, 13.5% had engaged in binge drinking, and of 62.8% of students who drive, 39.2% had texted while driving.³⁰

5.2 Policymakers should drill down below the headlines on youth vaping data

A nuanced reading of the youth vaping data shows that most adolescent vaping was *occasional*, and that *regular* use was concentrated in adolescents who had already been smokers.³¹

Occasional vaping. Of the 20.8% of high school students who had used an ecigarette in the past 30 days, one third had vaped on one or two days and almost half (48.7%) on 5 days or fewer. Vapers who had not previously smoked were much more likely than the average to be infrequent vapers: over half (53%) were vaping on one or two days and 71% on five days or fewer. While not a cause for complacency, it is important to recognize that the headline numbers aggregate very different behaviors.

Regular vaping. 28% (of the 20.8%) were *regular* vapers (use on 20 or more days in past 30). Nine out of ten (89%) of regular vapers had previously smoked. Only 0.6% of high school students were both regular vapers and had not previously used tobacco.

One in seven high school students (13.9%) are smokers³², and typically from poorer backgrounds³³. For them, it is conceivable that there is a harm-reduction effect if their uptake of vaping is displacing their smoking. FDA officials have explicitly recognized this possibility, but FDA refuses to take it into account in its regulatory approach. According to former FDA Commissioner Gottlieb.³⁴

Even if kids are using ENDS [e-cigarettes] instead of cigarettes -- and that migration in part accounts for the decline in youth cigarette use -- that's still not an acceptable trade.

While this may have a certain emotional appeal, it is irrational for a public health regulator to ignore a real-world public health phenomenon in this way. In practice, it would mean that in carrying out its

³⁰ 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 [\[link\]](#)

³¹ Centers for Disease Control, National Youth Tobacco Survey, 2018. [\[link\]](#) Bates, C. Frequency distribution of vaping by tobacco-use history: US National Youth Tobacco Survey, 2018 [\[Table\]](#)

³² Gentzke AS, Creamer M, Cullen KA, et al. Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018. *MMWR Morb Mortal Wkly Rep* 2019;68:157–164 [\[link\]](#)

³³ U.S. Department of Health and Human Services. *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA. 2012 [\[link\]](#) Chapter 4, Section 4 Large social environments [\[link\]](#)

³⁴ Gottlieb, S. Speech: FDA's Nicotine and Tobacco Regulation and the Key Role of Regulatory Science. U.S. Food and Drug Administration, 18 June 2018 [\[link\]](#)

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duties, FDA would be indifferent to public health detriments arising from increases in adolescent smoking caused by its regulatory approach to e-cigarettes. That is not acceptable.

5.3 Adult and parental smoking cessation has benefits for youth

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.

- Adolescents grow into adults and measures taken to ‘protect’ adolescents as youth may do more harm to them as adults – for example policies that obstruct effective options for smoking cessation.
- Youth initiation and risk behaviors are heavily influenced by adult norms, especially parents and older siblings.³⁵
- When adults are harmed from 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.

It is important to address the pattern of risk behavior through the whole course of life with a view to reducing the overall health, welfare and economic burdens of tobacco and nicotine use.

5.4 The response to youth vaping should be youth-focused

Third, the appropriate way to address youth vaping is through education and targeted controls on youth access, not through indiscriminate and excessive regulation that closes down most of the market serving adult users, the population in most serious and immediate danger. A rise in adult smoking caused by excessive FDA actions in the vaping market would be inappropriate for the protection of public health, costly for healthcare providers, and damaging to smokers and their families.

The rise in youth vaping, properly understood, does not justify a near-complete closure of the vaping market through the application of excessively burdensome routes to market for products that are primarily intended for adults and have the potential roll-back the global epidemic of smoking-related disease.

³⁵ Ball J, Sim D, Edwards R. Addressing ethnic disparities in adolescent smoking: Is reducing exposure to smoking in the home a key? *Nicotine Tob Res.* 2018; [\[link\]](#)