Youth vaping and the dangers of over-reaction – a letter to the FDA

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Scott Gottlieb, MD
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Letter from Iowa Attorney General Miller and others, including me, to Scott Gottlieb, FDA Commissioner. See PDF at the link below:

Re: Youth tobacco and nicotine use – proportionate and responsible reaction

This is a letter and 7-page briefing to set out issues with youth vaping and to caution against over-reaction. For the fully referenced version, please see the PDF at the link above. The main text is below.

Scott Gottlieb, MDCommissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring,
MD 20993-0002
14 November 2018
Dear Commissioner Gottlieb

Re: Youth tobacco and nicotine use – proportionate and responsible reaction

We share your widely reported concern about the rise in e-cigarette use among adolescents. At the same time, we remain hopeful that by encouraging smokers who cannot or who choose not to quit to switch to e-cigarettes, we may be able

substantially to reduce premature mortality due to smoking, which remains the #1 risk factor in the US and in the world. With so much to gain from e-cigarette use by smokers, we write to urge FDA to take carefully calibrated and proportionate action in response. We hope you will consider the possible resulting harm to public health that could arise from disproportionate intervention, given the relative harms of cigarettes and e-cigarettes, the interactions between youth vaping and smoking, and between adult use and youth use.

We understand and recognize the possible trade-off you have highlighted between vaping products as an "off-ramp" for adult smokers and an "on-ramp" to nicotine use for youth, potentially leading to smoking. There are also a number of other trade-offs and complexities with risks of unintended harmful consequences that need to be factored in to policy on youth tobacco use. A half million annual American deaths from cigarette smoking are an immediate, stark, and preventable tragedy that should be fully factored in to a rational risk-benefit analysis. We hope FDA will consider the following points before taking further action:

- *It is essential to distinguish between adolescent occasional use and regular or daily use and to focus policy on addressing the latter, while not over-reacting to the former.*
- *The most intensive adolescent e-cigarette users are far more likely to also be smokers. They may potentially benefit from e-cigarette use. There is no ethical basis for ignoring public health harm reduction benefits to those under 18.*
- *The risks of vaping should not be exaggerated, and any policy response should be proportionate to risk. Even though there will be residual uncertainty about the long-term health risks until these products have been used for several decades, we know enough now to be confident that these products pose little direct risk to either adults or adolescents compared to smoking or to many common youth risk behaviors.*
- *Vaping by youth is primarily a concern only to the extent it will lead to cigarette smoking, and there is little evidence suggesting that vaping itself causes regular smoking. Regular use of vapor products is a concern because it could be indicative of emerging dependence. If young people become dependent on nicotine through*

vaping, then removal from the market of the products they are using could lead to unpredictable behavioral responses, including uptake or increase of smoking – the outcome that FDA and the public health community seeks to avoid.

- *It is not possible to separate neatly the interests of adults and adolescents. Parental and role-model smoking is a major risk factor for youth initiation. Young people suffer significant harm when a parent or other significant people in their lives die or are incapacitated by smoking-related disease. All adolescents grow to become adults and their wellbeing is a product of risks and opportunities available through the life-course. Young people have a stake in the adult society they will grow into.*
- *Even if FDA can identify causal connections between product characteristics, such as flavors, and uptake of youth vaping, there are further difficulties in establishing the effects of any intervention on youth behavior and whether this will cause net harms or net benefits.*
- *FDA's comprehensive strategy for nicotine has a clear long-term objective to protect young people from initiating with the most harmful products. But this strategy is highly contingent on the availability of appealing and effective alternatives to smoking. A hasty response that does not consider the harm reduction potential for adults could render FDA's broader strategy inoperable.*

We hope that FDA will pause to reflect before taking further action in the vaping market. We would welcome your response to the points raised. We would also welcome the opportunity to discuss this difficult issue with you in person. To that end, we would like to request a meeting at your convenience.

A longer briefing is attached. This provides some background on the points above.

Yours sincerely

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Briefing: FDA action to address youth vaping: issues to consider

The Secretary of Health and Human Services, Dr. Alex M. Azar, and the Commissioner of the Food and Drug Administration, Dr. Scott Gottlieb, have set out concerns about a rise in youth e-cigarette use. Any sharp rise in a youth risk behavior should be a reason for concern and for an appropriate policy, regulatory, and communications response. But it should not be a reason for hasty or excessive reaction, which may lead to harmful unintended consequences. The points below suggest reasons for proceeding with care and with careful regard for the evidence and ethics involved.

1. It is essential to differentiate between youth experimental and regular use. *FDA should distinguish carefully between different patterns of*

youth e-cigarette use. For health policy purposes, there is a major difference between occasional or experimental use and regular (20 or more days per month) or daily use. The latter should be the focus of policy and represents a much smaller population than headline figures for past 30-day prevalence. The latest published data from 2018 shows less than 3 percent of age 15-17 youth using e-cigarettes on 10 or more days per month. Regrettably, this study does not report a breakdown to show daily use, which would be where concern about 'nicotine addiction' would be most justified – but daily use is likely to be between 1 and 2 percent – and Juul use is a subset of this. We also note that Juul use has been found to be more concentrated among higher SES youth.2 It may be that for many occasional users, Juul is a transient teenage fad with no material long-term health consequences. However, the availability of vaping alternatives may be a real benefit for young smokers likely to persist with smoking to adulthood, and these would tend to come from poorer homes. It is possible that FDA intervention in youth vaping could disproportionately harm poorer adolescents and adults.

2. Regular vaping is concentrated in smokers for whom it may be beneficial. *Even if 1-2 percent of adolescents were using e-cigarettes daily, this cannot simply be assumed to represent a public health detriment. It is important to be clear about the tobacco use characteristics of those users. If they are also current, former, or likely combustible tobacco product users, then the use of e-cigarettes may be beneficial and reduce the health burden compared to a situation where no e-cigarettes are available. There is evidence that young tobacco users do resort to using e-cigarettes for harm reduction purposes. In the most recent analysis of youth data, more intensive e-cigarette use was highly concentrated among combustible tobacco users:*

> *It remained rare in 2015 for tobacco naïve youth to have reported using e-cigarettes on 10 or more days in the past month (less than 0.1%)*

Changes in the pattern of tobacco and nicotine use can be deceptive. An increase in 'dual use' among more heavily committed smokers may have the effect of increasing the adolescent vaping prevalence without reducing the smoking prevalence. Though this may create the appearance of an overall worsening situation, it may, in fact, be an improvement if it means more

dependent cigarette users are embarking on a pathway away from smoking by starting to vape as well. Careful examination of the underlying causes of changes in headline data is essential.

***3. FDA should focus on the behaviors that cause the greatest harm – primarily smoking**. We agree with the National Academies' assessment of relative health risks:*

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

Most immediately, that means that FDA's efforts should be focused on reducing smoking in any age group, including adolescents. It is concerning, therefore, that FDA's recent regulatory and communications actions have been largely focused on one of the least harmful forms of nicotine use, e-cigarettes, with very little visible action on cigarettes, cigarillos, and teenage smoking. For example, cigarette manufacturers have not been instructed to prepare plans to reduce teenage cigarette access and use, though such plans are required of the leaders in the vaping market. However, in 2017 there were 2.3 million current teenage combustible tobacco product users compared to 2.1 million e-cigarette users. The smoking problem has not gone away, but FDA's effort appears to be dominated by focus on reducing the use of safer alternatives.

***4. FDA should be truthful and proportionate about nicotine and smoking risks**. The harms of nicotine are not the primary public health problem either immediately or over years and decades of use. It is widely accepted that nicotine has dependence-forming potential, depending on how it is administered, and that it poses some risks to those with certain pre-existing conditions. However, there is only weak and contested evidence of other material harms arising from nicotine use itself. The evidence that nicotine harms the developing adolescent brain is weak and based mainly on studies of rodents, which cannot readily demonstrate human impairment. If there are any effects, these do not appear to be noticeable in human populations, as they have not been found in the large populations of smokers and ex-smokers who have been exposed to nicotine from an early age over many decades. For both ethical and pragmatic reasons, FDA and others should adopt a strictly truthful and non-misleading approach to risk*

communication and 'dial down' the rhetoric about nicotine, for example in the Real Cost campaign. This is not just because it risks misleading adults, but because it may also lead young people to conclude, falsely, that nicotine is the main harmful agent in tobacco use and that there is no difference between the risks of vaping and smoking. Such misrepresentations and misperceptions are harmful if they cause users to choose more dangerous tobacco product.

***5. The (low) risks of vaping need to be placed in context with other youth risk behaviors**. If there has been a recent rise in more casual or experimental use of ENDS and/or Juul among tobacco naïve users, some perspective is needed to respond appropriately and proportionately. Though we agree that, ideally, no adolescents should use any nicotine products, we should recognize that risk behaviors are and always have been a feature of life for many adolescents. Nicotine use, while unwelcome, should be considered alongside the range of risks and challenges faced by young people. Even if unpublished data shows that past-30-day vaping has reached 20 percent, then this should be placed in context with other risk behaviors recorded in surveys of youth:*

In the past 30 days	High school students
Alcohol use	29.8%
Binge drinking (as defined)	13.5%
Marijuana use	19.8%
Drove after drinking (% of drivers)	5.5%
Drove after marijuana use (% of drivers)	13.0%
Rode with a driver who had been drinking	16.5%
Texted or emailed while driving	39.2%
Carried a weapon (e.g. gun, knife, club)	15.7%
In the past year	**High school students**
Involved in physical fight	23.6%
Threatened or injured with a weapon	6.0%
Physically bullied on school property	19.0%
Electronically bullied	14.9%
Felt sad or hopeless	31.5%
Considered suicide	17.2%
Made suicide plan	13.6%

In this context, e-cigarette use, especially non-daily use, is a relatively minor risk among youth and should not a basis for hasty or excessive regulatory action that may lead to harm to adults or sub-groups of vulnerable youth. Adolescent health and wellbeing should be an important theme in public health, but this should be focused by the broad needs and welfare of the

individual, not driven by the specialization, powers and resources of product-specific federal agencies.

***6. It is unethical to ignore or deny harm–reduction opportunities for young people**. Almost every adult would prefer adolescents not to use nicotine in any form. However, the reality is that 3.6 million adolescents were using tobacco or nicotine products in 2017, and this cannot be avoided or wished away. It is difficult to concur with FDA's stated view that the differences in risks arising from different forms of adolescent tobacco or nicotine use are not a relevant consideration in youth-orientated tobacco and nicotine policy. According to Commissioner Gottlieb:*

> *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.*

The danger of FDA conducting regulatory policy as if the distinction in risk between smoking and vaping is of no relevance to the health, wellbeing and life-chances of young people is that FDA will pursue sub-optimal policies that cause more youth smoking and more harm than otherwise would be the case. It is hard to see how an approach that denies harm reduction benefits to young people can be ethical or appropriate for the protection of public health.

***7. It is not realistic to separate the interests of adults and adolescents in tobacco policy**. In its public statements, FDA has drawn a distinction between the interests of adults and adolescents. In practice, it is not possible to divide these populations and their respective interests so neatly for tobacco policy purposes.*

- *Parental smoking and adult role-modelling are important risk-factors and predictors for youth smoking initiation. By modelling a different, far less harmful behavior, adult vaping and associated smoking cessation is likely to have a beneficial effect on youth smoking initiation and prevalence.*
- *The loss of a parent or close relative to smoking-related disease is a significant detriment to most young people. Likewise, adult ill-health*

imposes costs on the family in terms of lost economic activity and increased caring responsibilities. Harm reduction for adults has collateral benefits for a whole family, including its younger members.

- *Adolescents grow into adults, and today's youth have an interest, not necessarily acknowledged, in having better options for their future. The serious harms of tobacco or nicotine use are not instantaneous and mainly develop over many decades of use. They are an outcome of the pattern of tobacco use over the life-course – almost all of the premature mortality risk of smoking is avoided by stopping smoking by age 35. So, opportunities to stop smoking in the first two decades of adult life are especially valuable and continue through the whole life-course.*

8. FDA does not have an evidence base to justify banning flavors on public health grounds and may do net harm if it does. *FDA should not impose widely cast bans on e-liquid flavors or flavor categories as these are integral to the appeal of the vaping experience and this appeal is the basis of the harm reduction potential of vaping products. Attorney General Miller et al. responded to FDA's flavors ANPRM consultation arguing that FDA did not yet have the means to make sound policy judgements in this area and that it was at least as likely to cause detriments to public health as benefits.. This comment concludes:*

> *To summarize, the chain of reasoning required to justify rule-making to prohibit particular flavors, flavor categories or flavor descriptors in non-combustible products is extremely challenging, with the real possibility that FDA intervention could cause harm both to adults and young people if it makes misjudgments about: (1) the effects of vaping on health, and (2) the effect of flavors on vaping. FDA would need to show that vaping itself is a source of net harm (this is unlikely) and show that particular flavors or descriptors were increasing uptake and contributing to harm (this is difficult). Finally, it would need to show its proposed intervention would be proportionate and effective, and not prone to excessive unintended consequences (for this there is no credible evidence). The FDA does not have a reliable case at any point in this chain of reasoning.*

Even if Juul flavors like mango have become popular among youth, it is not possible to establish whether the popularity of mango is causing the popularity or Juul or the popularity of Juul is causing the popularity of mango

– or some of each. Either way, FDA cannot be sure if the popularity of ENDS, including Juul, is having a detrimental or beneficial effect on youth through displacing smoking. Finally, it has no basis for assuming that interventions like flavor bans will have their intended result and be appropriate for the protection of public health. The possibility of harmful unintended consequences remains real even if FDA uses its pre-market review enforcement discretion to secure de facto flavor prohibitions without going through the disciplines of rule-making. The question is not whether FDA has powers to impose bans flavors, but whether it should, and how it would know if it was causing harm.

9. There is no logic to constraining e-cigarette flavor choices only to tobacco and menthol*. One major cigarette company, Altria, has voluntarily restricted its e-cigarette product range to tobacco and menthol flavors. While any company has the right to remove products from the market, there is little to suggest this will be beneficial to public health and it should not be adopted as policy by FDA. Generations of young people have taken up cigarette smoking using almost exclusively tobacco and menthol flavors. There is no obvious logic to restricting e-liquid flavors to only those that mimic the most dangerous tobacco products and have been the main basis for initiation in the past – and no justification of such a move has been provided. The majority of users are trying over time to migrate away from traditional tobacco flavors to put the experience of smoking behind them.*

10. Overall, e-cigarettes are likely to be beneficial at population level under all but the most implausible assumptions*. Multiple independent simulation models are consistent in showing that under all but the most implausible scenarios, the availability of vaping products will result in a net population benefit. For example, see Abrams et al, (2018); Warner and Mendez (2018); Levy et al, (2016), Levy et al, (2017). It is unlikely that the as yet unpublished NYTS data for 2018 would change this. Though there are associations (i.e. correlations) between e-cigarette and cigarette use, this is because there are 'common liabilities' (attributes of the individual, household or social situation) that incline young people both to smoke and to vape – and therefore these behaviors are seen together. However, even if a modest gateway effect is assumed, it is highly unlikely to overwhelm the wider population benefits of introducing reduced-risk alternatives to*

smoking onto the market . For further information, this data is discussed in greater depth by Abrams and colleagues. It follows, therefore, that disproportionate or ill-conceived intervention in this market could cause harm – and that such harms would not necessarily be confined to adults.

11. FDA should not be deflected from its broader nicotine and tobacco strategy by a spike in teenage vaping*. FDA wishes to create a fundamental shift in the recreational nicotine market from addictive combustion products to much safer non-combustion products. AG Miller and others responded to the FDA's ANPRM on a setting a nicotine standard to highlight the common need for effective alternatives to smoking in a range or scenarios. We share the concern that excessive restrictions on vaping products would compromise FDA's wider goals by denying many smokers effective alternatives to smoking.*

> *If a nicotine standard is introduced, it will create a significant impact on the personal behaviors of many millions of Americans. The key question is how will smokers respond to a change in the nicotine content in cigarettes? From a public health perspective, 'healthy' behavioral responses (becoming nicotine-abstinent or switching to low-risk, non-combustible nicotine products) will be in competition with 'harmful' behavioral responses (smoking reduced-nicotine cigarettes, smoking smuggled and/or counterfeit cigarettes, smoking other forms of tobacco, pursuing "do-it-yourself" modifications to products). Smokers will make their decisions based on the choices available to them, taking account of price, ease of access and legality, product appeal, and the relative ease of substituting an alternative product or behavior for tobacco smoking. It is important, therefore, that the low-risk and lawful options are highly competitive compared to the more harmful alternatives so as to maximize adoption of positive behavioral responses to a nicotine standard.*

To summarize, FDA should keep its nerve and react proportionately and dispassionately to new data on adolescent vaping. A hasty regulatory over-reaction to what amounts to relatively low-risk behavior could undermine a major public health opportunity for tobacco harm reduction by rendering vaping products unattractive, ineffective and/or inaccessible. FDA should not ignore the benefits of vaping to adolescent smokers and concentrate excessively on protecting non-users from what is a minor risk compared to

smoking or other youth risk behaviors.

FDA should not try to separate the interests of adolescents and adults and treat these differently – their interests are directly connected through the family and because harms from tobacco use evolve over the life course and do not become significant and irreversible until middle age.

There is little to suggest that e-cigarette interventions under consideration will work and some reason to believe they would cause unintended harms to both adults and to youth. FDA needs a more nuanced approach to intervening in this market as it risks doing harm by prolonging smoking and erecting regulatory defenses around the cigarette trade.