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Dear Mr. Zeller

We were pleased when, in a May 2015 interview in *The New York Times*, you called for a "national debate on nicotine." We agree with you on the need, but that debate has not happened so far. We clearly need a dispassionate discussion of the appropriate priorities, principles and evidence that should guide nicotine policy. With that in mind, we were surprised to see the remarks attributed to you in a different *New York Times* article published Sept. 2, 2016.

> *'In the absence of science-based regulation of all tobacco products, the marketplace has been the wild, wild West,' said Mitch Zeller, the director of the F.D.A.'s Center for Tobacco Products, which is in charge of enforcing the new rule. 'Companies were free to introduce any product they wanted, make any claim they wanted, and that is how we wound up with a 900 percent increase in high schoolers using e-cigarettes and as well as all these reports of exploding e-cigarette batteries and products that have caused burns and fires and disfigurement.'*

We don't think this is a fair reflection of the underlying reality. As a contribution to a debate on nicotine, we would like to make seven clarifying observations.

1. The growth in e-cigarette use – a threat or a threat disruptor?

It is trivially obvious that any newly introduced product is likely to grow from a very low level at its introduction to a high multiple, like 900 percent, over its early years. If a base year of 2009 had been chosen, it would have been 10,000 percent or more. It is more important to interpret what is going on behind these headline numbers: is there a shift in the overall burden of harm? How much of this use is problematic? For example, does it

reflects youthful experimentation or regular use? How much use includes nicotine? Is vaping feeding into an increase in adult smoking? Addressing these questions, as we do in the sections below, leads to a much more positive assessment of vapor technology's impact.

The better way to interpret the growth in e-cigarette use, both generally and among adolescents, is not as the "Wild West," but as the emergence of a disruptive pro-health technology in the most harmful of all consumer markets. It is a *positive* development if the incumbent cigarette trade is disrupted by a new lower-risk technology.

2. The dramatic decline in adolescent smoking changes the burden of risk

Over the period in question, 2011-15, the behavior about which we are most concerned, cigarette smoking, fell dramatically. Current use of cigarettes by high school students fell from 15.8 percent to 9.3 percent, and use of cigars and pipes also fell.

> *Significant linear decreases were observed for current use of cigarettes (15.8% to 9.3%) and smokeless tobacco (7.9% to 6.0%), and significant nonlinear decreases were observed for current use of cigars (11.6% to 8.6%), pipe tobacco (4.0% to 1.0%), and bidis (2.0% to 0.6%).*
>
> Singh T, Arrazola RA, Corey CG, et al. Tobacco Use Among Middle and High School Students — United States, 2011–2015. MMWR *Morb Mortal Wkly Rep* 2016;65:361–367. [link]

The rise in e-cigarette use among adolescents should never be discussed without noting the coincident rapid decline in smoking. It only makes sense to be indifferent to the changes in type of nicotine product used if there is no difference in the relative risk of combustion and non-combustion products. But you have spoken on many occasions of the "continuum of risk." As you rightly said in your commentary on the "tobacco endgame" in the journal *Tobacco Control* in 2013:

> *Anyone who would ponder the endgame must acknowledge that the continuum of risk exists and pursue strategies that are designed to drive consumers from the most deadly and dangerous to the least harmful forms of nicotine delivery*.
>
> Zeller M (2013) Reflections on the “endgame” for tobacco control. *Tob Control 22 Suppl* 1:i40-1. [link]

We agree with this insight. The debate on nicotine needs to be grounded in an understanding of the relative risks of different nicotine products. The data suggests (but cannot not prove) that consumers are doing as you hope: shifting from the most deadly and dangerous to the least harmful.

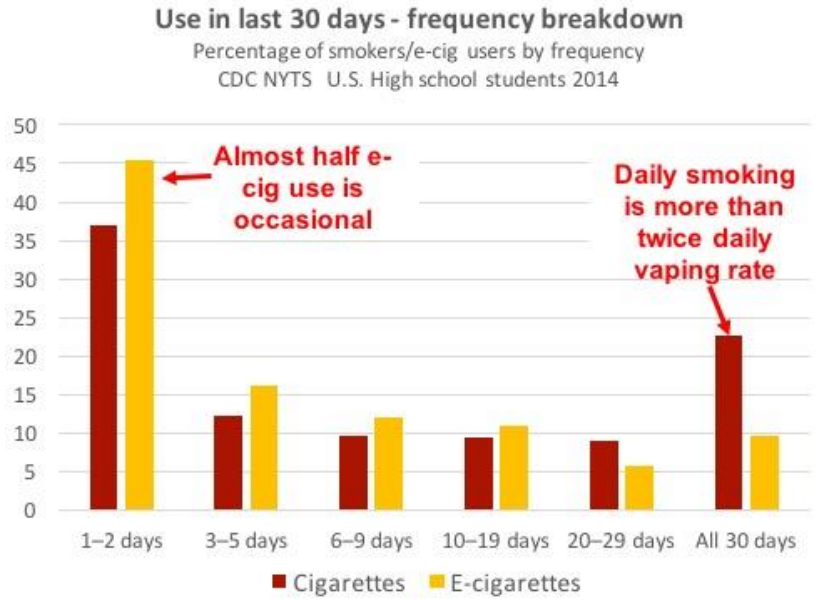
3. The (in)frequency of adolescent e-cigarette use

There has been a recent paper that highlights the frequency distribution within the 30-day smoking-prevalence headline. This has highlighted the occasional nature of most teenage vaping, especially among those who were not also smokers.

Non-smoking high school students are highly unlikely to use e-cigarettes; among those who do, most used them only on 1–2 of the past 30 days. By contrast, current smokers are likely to use e-cigarettes and on many more days.

Warner KE, Johnston LD, O'Malley PM, et al (2016) Frequency of E-Cigarette Use and Cigarette Smoking by American Students in 2014. *Am J Prev Med* 51:179–184. [link]

This paper should be read with the Center for Disease Control and Prevention's analysis showing most adolescent e-cigarette use is occasional. CDC's measure of current use is "used at least once in the last 30 days." But within this very broad measure, there is considerable variation in frequency of use. Daily vaping is *half* as prevalent among 30-day e-cigarette users as daily smoking is among cigarette smokers. The CDC data on the frequency distribution of e-cigarette use within 30 days is plotted on the following annotated chart. This illustrates why unqualified statements about smoking or vaping prevalence based on the "last 30 days" measure can be highly misleading.



4. The limited use of nicotine by adolescent vapers

There is a recent important paper showing that most adolescent vaping does not involve nicotine. The paper, based on the Monitoring the Future survey, provides a warning about simplistic conflation of e-cigarette use and use of nicotine or tobacco products. Respondents reported what substance they vaped the last time they used a vaporizer, such as an e-cigarette. Compared to just using flavorings...

...Nicotine use came in a distant second, at about 20% in 12th and 10th grade and 13% in 8th grade

Conclusions. *These results challenge the common assumption that all vaporiser users inhale nicotine. They (a) call into question the designation of vaporisers and e-cigarettes as ENDS ('Electronic Nicotine Delivery System'), (b) suggest that the recent rise in adolescent vaporiser use does not necessarily indicate a nicotine epidemic, and (c) indicate that vaporiser users*

> *can be candidates for primary prevention programmes. Finally, the results suggest the importance of developing different rationales for the regulation of vaporiser devices as compared to the regulation of substances marketed for vaporiser use.*
>
> Miech R, Patrick ME, O'Malley PM, Johnston LD (2016) What are kids vaping? Results from a national survey of US adolescents. *Tobacco Control* tobaccocontrol-2016-053014.[link]

If there is to be a debate about nicotine use, we should focus analysis on data that relates to the use of nicotine, not on more frivolous behaviors. Perhaps future iterations of CDC's National Youth Tobacco Survey should make this distinction clear, so that it does actually capture nicotine or "tobacco use," as defined in the Tobacco Control Act (Section 101).

5. The situation with fires and explosions

You draw attention to the fire and explosion risk associated with lithium-ion batteries. There are risks with these batteries if misused or short-circuited, and there have been several incidents and some injuries. But this is a common challenge across many types of battery-powered devices. Most of these are not regulated by the Food and Drug Administration. The risks should be addressed through consumer-protection law governing electrical safety that covers all batteries and chargers that elevate this risk.

More importantly for the purposes of a nicotine debate, however, is to put this fire risk in context. Again, comparison with risks associated with smoking is instructive. The U.S. National Fire Protection Association provided an analysis of 2011 data, which reveals the scale of the problem:

> *In 2011, U.S. fire departments responded to an estimated 90,000 smoking-material fires in the U.S., largely unchanged from 90,800 in 2010. These fires resulted in an estimated 540 civilian deaths, 1,640 civilian injuries and $621 million in direct property damage; deaths were down substantially from the year before.*
>
> *Home structure fires dominated all these measures of loss except for fire incidents. In 2011, an estimated 17,600 smoking-material home structure fires caused 490 civilian deaths (19% of all home structure fire deaths), 1,370 civilian injuries and $516 million in direct property damage. The other 72,400 smoking-material fires in 2011 were mostly outdoor fires (60,200 fires in trash, vegetation and other outdoor combustibles).*
>
> John R. Hall, The smoking material fire problem, National Fire Protection Association , July 2013 [link]

This extraordinary carnage arose despite the intervention of regulators and followed the legal requirement for "fire-safe" cigarettes, which was complete in all states by 2011.

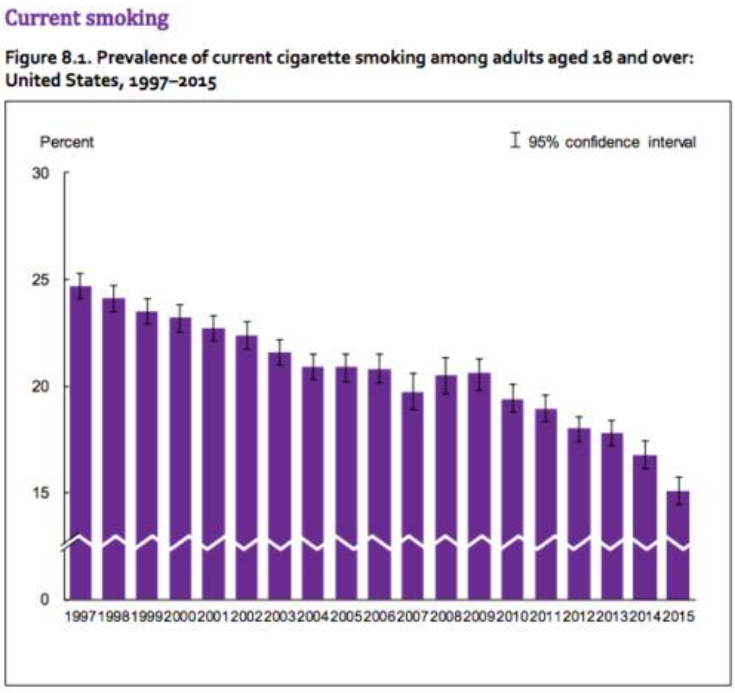
If we were debating nicotine policy, a key point would be to recognize that, to the extent vaping is displacing smoking, we are likely to be experiencing a significant *public health win* in the area of "burns, fires and disfigurement." Again, if we are to draw attention to the

problem of fires arising from e-cigarettes, the risk should be placed in context with cigarettes, the product they aim to displace.

6. The trends in adult smoking

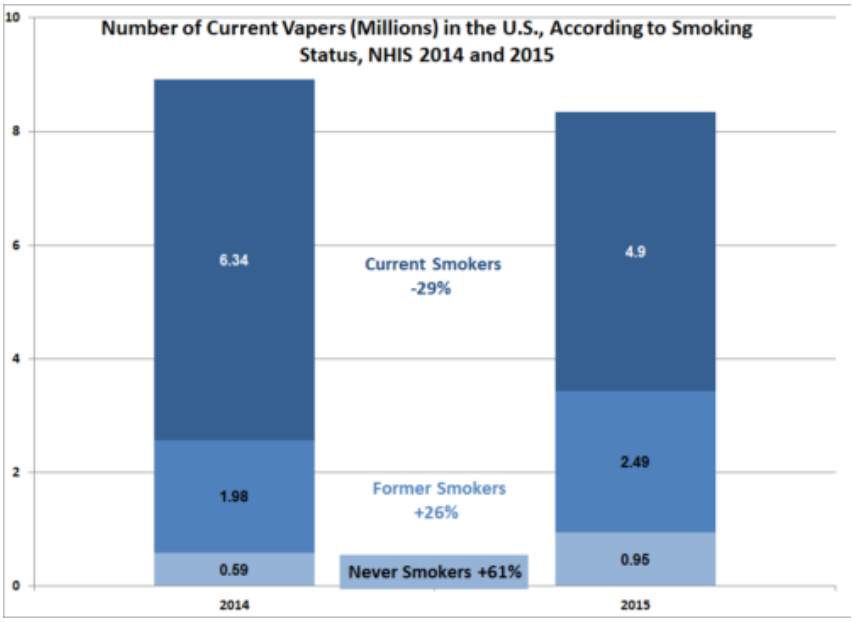
While adolescent e-cigarette use is one part of any debate about nicotine trends, we should keep the main prize in sight – that is, reducing adult smoking prevalence at the greatest possible rate. If our goal is to reduce disease and premature death from tobacco use, it is the changes in adult smoking that are the most vital indicator; smoking adults are the primary at-risk group.

The trends in adult smoking in the United States are exceedingly positive, with a decline coinciding with the rise of e-cigarettes and an especially sharp drop between 2014 and 2015. The chart below shows the trend.



Source: National Center for Health Statistics, *National Health Interview Survey, 1997–2015*, Sample Adult Core component. Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–2015. [link]

Of course, it's not possible to attribute the decline in smoking conclusively to the rise in vaping, due to the cross-sectional nature of the surveys. However, the rise in vaping has coincided with an accelerating decline in smoking; the idea that there is a causal link should at least be maintained as a credible hypothesis. There is no reason to proceed on the basis that this hypothesis is false. Nearly 2.5 million U.S. adult vapers are now ex-smokers, and the data are consistent with dual users migrating to exclusive vaping. The presence of 8.3 million vapers now poses a significant challenge to the cigarette industry's market of 38 million U.S. smokers.



Source: Data - CDC, *National Health Interview Survey, 2015 Data Release* [link]. Analysis - Rodu B. How Many Americans Vape? CDC Data Show Fewer Vapers & Smokers in 2015, Tobacco Truth, July 17, 2015. [link]

7. FDA's approach is "anti-proportionate"

Although you called for a debate in 2015, there still is a pressing need to have a real debate about nicotine, including the potential for vapor and other reduced-risk technologies. While this debate has barely started, let alone run to a satisfactory conclusion, the regulatory reaction from many agencies around the world has been to approach these technologies as a threat, rather than as an opportunity.

Many experts have been troubled at the excessive weight of regulation that is to be placed on e-cigarettes and their vendors by the FDA. This will take place while the most harmful products, cigarettes, have been given what amounts to a free pass through grandfathering and other transitional arrangements. Considering the continuum of risk, the FDA's approach cannot reasonably be described as "proportionate." Even "disproportionate" is an insufficient description; it is not even as though the burdens on e-cigarettes are lower than cigarettes, but just not low enough. In our view, the FDA's approach is best characterized as "anti-proportionate"; the burdens on the much-safer products are far higher than on the most dangerous, and we simply cannot see how that can be justified.

It is wrong to, as the *Times* article does, promote the idea that opposition to the FDA's approach is exclusively from "tobacco-aligned companies." There is a credible public-health argument to take a more risk-proportionate and light-touch approach to regulating nicotine. The FDA has the tools to do this: it could support congressional legislation to change the predicate date for e-cigarettes and then use its powers to set technical standards to

improve the market without destroying most of it. If it takes the right approach, the FDA could become a model for good practice worldwide.

There still needs to be a real debate on nicotine policy. We hope there will be an opportunity to discuss these important issues with you and other experts at the FDLI meeting in October.

With sincere regards,

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