



UP IN SMOKE: THE NEED FOR HARM REDUCTION ALTERNATIVES



Dan Savickas and Luke Hogg

UP IN SMOKE: The Need for Harm Reduction Alternatives

By Dan Savickas and Luke Hogg

Introduction

On August 3, 2018, then-Commissioner of the Food and Drug Administration (FDA) Scott Gottlieb issued a statement on the agency's efforts to reduce tobacco-related illness and death. In this statement, Gottlieb pledged that the FDA, along with other Health and Human Services (HHS) agencies, would support the development of "novel nicotine replacement drug therapies (NRTs)."¹ In doing so, the FDA recognized that the more harmful effects of smoking are primarily caused by cigarette smoke rather than by nicotine products generally.

Gottlieb correctly asserted that innovation of NRT products is crucial to harm reduction for smokers and that laws and regulations should "pave the way for products that help currently addicted smokers move away from the deadliest form of nicotine delivery," which is cigarettes.² Scientists, public health officials, and the 70 percent of adult smokers who say they want to quit hailed the announcement as a great step forward for harm reduction.³ Yet, it seems as if the FDA has backtracked on its initial position by threatening the very livelihood of the American e-cigarette market.

Due to outsized fears about youth nicotine addiction, the Trump administration and the FDA have considered banning flavored e-cigarettes. The most stringent proposals suggest that the administration might ban e-cigarettes altogether. While the desire to safeguard the health of our nation's youth is admirable, it is ultimately - in this case - misguided.

NRTs like flavored e-cigarettes have many health benefits for adults who desire to quit smoking traditional cigarettes. Without access to these alternatives, many will be forced to access black market products with potentially deadly side effects, or to return to traditional smoking, a more harmful method of nicotine delivery. The unintended consequences of e-cigarette regulation or an outright ban far outweigh the supposed health benefits espoused by FDA regulators within the administration.

1 Gottlieb, Scott. "Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps the agency is taking to support the development of novel nicotine replacement drug therapies to help smokers quit cigarettes." Food and Drug Administration. August 3, 2018. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-agency-taking-support-development-novel>

2 Ibid

3 Bloom, Stephanie. "Vaping and Harm Reduction: Don't Let the Perfect be the Enemy of the Good." American Council on Science and Health. July 2, 2018. <https://www.acsh.org/news/2018/07/02/vaping-and-harm-reduction-dont-let-perfect-be-enemy-good-1313>

There are also myriad legal issues surrounding any complete or partial bans on vaping products. E-cigarettes are currently categorized as a tobacco product for the purposes of FDA regulation. The FDA is prohibited by law from banning the sale of particular tobacco products or requiring their nicotine production be reduced to zero.⁴ There are also legal requirements that could prevent the administration from barring the sale of electronic cigarettes in corner stores, but not industry-specific shops.

Lastly, bans of this sort never have their intended effect. America has seen this type of failure before. Whether it is the so-called “war on drugs” or the epic calamity that was the prohibition era, efforts to outlaw products that government bureaucrats don’t see the value in inevitably leads to some level of chaos. Given what we know about flavored e-cigarettes at this point in time, there is no reason to initiate such moral panic.

What is Harm Reduction?

Harm reduction is the basic idea that it is more practical for a society to reduce the public harms associated with things like smoking as opposed to taking the antiquated view that we can solve these societal problems through flatly restrictive legislative or regulatory fiat. It is based heavily on the respect for the individual rights of people like smokers.

Furthermore, harm reduction is a significantly more pragmatic approach to social problem solving because it accepts the reality that both licit and illicit drug use are part of our modern society. Harm reduction recognizes these facts and seeks to minimize the harmful effects of these societal problems without castigating those who suffer from addiction. Such an approach has been highly influential in helping stem the tide of both high smoking rates and the opioid epidemic, among other successes.

One of the primary tools of harm reduction practices is providing less harmful alternatives to smoking. This was one of the driving factors behind the development of many NRTs commonly used today. Putting further regulatory barriers in place that would impede the propagation of e-cigarettes would be a devastating blow to the already tremendous progress our country has made in fighting the public health issues that come with cigarettes.

As we’ve seen from research around the rise of other NRTs - such as gums, lozenges, patches, and medicines - abstinence by itself is rarely ever sufficient to break the addictive power of nicotine.⁵⁶ E-cigarettes are simply the latest innovation in harm

4 21 USC 387g

5 Palazzolo, Dominic. “Electronic Cigarettes and Vaping: A New Challenge in Clinical Medicine and Public Health. A Literature Review.” *Frontiers in Public Health*. 2013; 1: 56. November 18, 2013. Doi: <https://dx.doi.org/10.3389%2Fpubh.2013.00056>

6 Results from the National Epidemiologic Survey on Alcohol and Related Conditions (published in the journal *Archives of General Psychiatry* in November 2004) found that nicotine is one of the most addictive substances known to man. It is far

reduction for traditional cigarette smoking.

Asking a nicotine addict to simply “power through it” is akin to demanding that someone suffering from anorexia nervosa simply eat a cheeseburger. The issue is far more complex than that at its very core. The more alternatives we rip from the market in the name of public safety or public health, the deeper we dig the hole of addiction to traditional cigarettes for addicts whose lives may depend on these technologies. This issue is too important to millions of Americans to be treated with a simplistic answer.

No Other Way

While concerns about youth nicotine use are entirely valid and deserve due consideration, many involved in the debate around e-cigarettes seem to be losing sight of the forest through the trees. By only discussing the effects of vaping on our youth, many have completely ignored the massive health benefits that this technology presents for the estimated 34 million American adults who currently smoke traditional cigarettes.⁷

In order to help the aforementioned 70 percent of adult smokers who want to quit -- an estimated 29 million Americans -- lawmakers and policymakers need to recognize, as the FDA used to, that novel NRTs have massive benefits for public health. Vaping is a scientifically proven nicotine replacement therapy and should be treated as such. Until the relevant authorities recognize this fact, we are holding ourselves back.

E-cigarettes are a particularly effective NRT because, as research has shown, “e-cigarettes can substitute the physical, psychological, social, cultural and identity-related dimensions that were previously enjoyed about tobacco smoking, and thus may uniquely support long-term smoking relapse prevention.”⁸ Though the neurological addiction to nicotine is the leading difficulty for smokers trying to quit, many who use traditional NRTs like gum fail in quitting because there are other non-neurological factors that go into a smoking addiction.

For example, many have found that e-cigarettes are more effective than traditional NRTs because they give the user a similar sensation to smoking that no gum or patch can match. The ability to vape a less harmful substance reproduces the physical motions of smoking, helping to address the addiction to the physical act of smoking, while the nicotine “juice” helps to address the neurological addiction to nicotine.

more difficult to overcome an addiction to smoking than alcohol, cannabis, or even cocaine.

⁷ Centers for Disease Control and Prevention. “Smoking & Tobacco Use: Current Cigarette Smoking Among Adults in the United States.” https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm

⁸ Notley, Caitlin et al. “The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention.” *Harm Reduction Journal* 15, Article number 31. 2018. <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0237-7>

On this subject, the FDA's concern ostensibly falls into two main categories. The first is that flavored e-cigarettes will increase nicotine addiction amongst Americans and will, as a result, have harmful public health side effects. The second is that the prominence of fruity flavors is an indication of vaping companies' desire to market to teens and younger children, leading to youth nicotine addiction and providing a gateway to harder substances. Both sets of concerns, although well-intentioned if indeed they do shape the FDA's motive, are again misguided.

Providing current smokers with the tools they need to reduce the harms of smoking should be a primary goal of organizations like the FDA that claim to promote public health. A study conducted by Public Health England (PHE), an executive agency in the United Kingdom Department of Health and Social Care, found that vaping can reduce the harms of smoking by up to 95 percent. As stated by John Newton, Director of Health Improvement at PHE, "It would be tragic if thousands of smokers who could quit with the help of an e-cigarette are being put off due to false fears."⁹ Limiting access to e-cigarettes or particular flavors of e-cigarettes is simply limiting access to potentially life-saving technology for millions of Americans who want to quit smoking.

This naturally leads to the follow-on argument that, even if vaping is healthier than smoking, the prominence of flavors is a hook to younger generations. As then-Commissioner Gottlieb said in April, "We must not only seek to prevent youth from using tobacco in any form; we must also explore evidence-based approaches to address existing youth tobacco use and youth addiction to nicotine."¹⁰

There are a number of problematic implications in this statement. The first is the lumping of traditional cigarettes and e-cigarettes together when Gottlieb says "tobacco in any form." These products are being associated with the same health problems, even though the aforementioned academic studies clearly illustrate that vaping products are significantly less harmful. We will later see the legal ramifications for such an implication and why it would all but rule out a ban of the type Gottlieb is considering.

The second implication is that the increased prominence of e-cigarettes has had a particularly outsized impact on American youth. This is further evidenced by the title under which this quote was released, claiming that youth had become addicted to nicotine "as a result of the epidemic rise in teen use of e-cigarettes." Again, even with the best intentions at heart and the health of America's children in mind, this claim is specious at best.

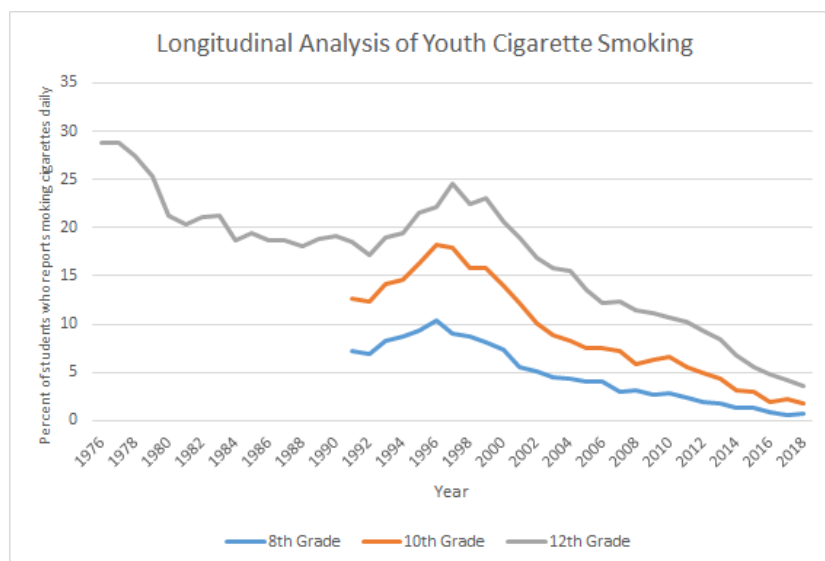
9 Boseley, Sarah. "Public Health England maintains vaping is 95% less harmful than smoking." The Guardian. December 28, 2018. <https://www.theguardian.com/society/2018/dec/28/vaping-is-95-safer-than-smoking-claims-public-health-england>
10 Gottlieb, Scott. "Statement from FDA Commissioner Scott Gottlieb, M.D., on new efforts to advance treatment strategies for helping youth addicted to nicotine as a result of the epidemic rise in teen use of e-cigarettes." Food and Drug Administration. April 1, 2019. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-efforts-advance-treatment-strategies-helping-youth>

Most people are attracted to the flavors because they are less harsh or offer a different sensation. They are a means to quit smoking, not a gateway to it. Such a claim is analogous to asserting that the federal government should ban Mike's Hard Lemonade or any flavored alcoholic beverage because it is somehow marketed towards children. That's simply not the case.

For a more direct illumination of the absurdity of this logic, we need only look back to 2009, when the FDA tried another flavor ban. This was when they implemented a ban on flavored cigarettes of the traditional variety. Before the ban, cigarettes were sold in such flavors as hazelnut, fruit, and cola. As with the current push to prohibit flavored vape "juice," the ban on flavored cigarettes came under the guise of youth protection. The FDA, believing that "sweet-tasting flavors are particularly appealing to youth and young adults," convinced the public that prohibiting flavored cigarettes would prevent more kids from taking up smoking.¹¹

However, according to HHS data on the percentage of students smoking cigarettes, the ban on flavored cigarettes had practically no effect on the already downward trending rate of youth cigarette use.¹² This demonstrates categorically that banning flavored cigarettes had a negligible, if any, impact on youth smoking.

The same is true of vaping. Kids vape underage for the same reason they smoke underage; it's trendy and rebellious. In order to prevent nicotine abuse by our nation's youth, it would be far more effective to treat the issue with actual consideration rather than treating our youth as ignorantly attracted to anything that tastes fruity. Not only is such a perception incredibly naive, but it ignores the reality that the youth vaping issue is a cultural problem that can't be solved with a simple ban.



Source: Department of Health and Human Services Office of Population Affairs

¹¹ Food and Drug Administration. "Menthol and Other Flavors in Tobacco Products." July 20, 2018. <https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-other-flavors-tobacco-products>

¹² Department of Health and Human Services Office of Adolescent Health. "Adolescents and Tobacco: Trends." May 2, 2019. <https://www.hhs.gov/ash/oah/adolescent-development/substance-use/drugs/tobacco/trends/index.html>

The people, on the other hand, who would be most impacted by the ban are not children, but smokers who are desperately searching for alternatives. This will only serve to propel them back into the harmful cycle of addiction to traditional cigarettes and all of the health side effects that come along with that. The FDA's current approach is especially stunning and hypocritical given their aforementioned promise to approve NRTs.

Federal Legal Hurdles

Section 907 of the Federal Food, Drug, and Cosmetic Act (FFDCA) explicitly prohibits the FDA from “banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or requiring the reduction of nicotine yields of a tobacco product to zero.” This presents legal issues for the agency if they try to outright ban e-cigarettes in the manner being suggested by some.

Also, according to Title 21 USC § 387f(d)(3)(A), the FDA may not “prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets.” This would present legal issues for the agency when they try to make a distinction between industry-specific vape shops and other locales.

These statutes are important when you consider how the FDA regulates e-cigarettes and other electronic nicotine delivery systems (ENDS). Take this statement from acting Commissioner Ned Sharpless:

“When FDA’s foundational ‘deeming rule’ went into effect on Aug. 8, 2016, it gave the agency’s Center for Tobacco Products (CTP) regulatory authority over all ENDS, including e-cigarettes, vapes, e-liquids, e-cigars, e-pipes, and e-hookahs. Since late 2016, FDA has worked at maximal speed to regulate this rapidly evolving class of new tobacco products, but our policies and procedures in this area are still evolving.”¹³

For all intents and purposes, the FDA views e-cigarettes and related ENDS as a tobacco product. In fact, in that statement, acting Commissioner Sharpless refers to them as a “rapidly evolving class of new tobacco products.” There is nothing in federal law or in the words and actions of the FDA that would suggest that e-cigarettes could be subject to a different regulatory framework than traditional combustible cigarettes.

This brings the aforementioned Section 907 into play, as it becomes increasingly difficult to see on what legal basis FDA believes it can move towards an outright ban of e-cigarettes. Such overarching bans are explicitly prohibited by law.

13 Sharpless, Ned. “How FDA is Regulating E-Cigarettes.” Food and Drug Administration. September 10, 2019. <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulating-e-cigarettes>

All this brings us once again back to the FDA's assertion that they pledged to support the development of NRTs. This is truly the claim that underlies this entire paper. Not only has the FDA not been true to its word, but it is now running afoul of U.S. law to actively avoid fulfilling the pledge that it made to so many millions of Americans struggling from smoking addiction.

The only exception to this broken promise came in April of 2019, when the FDA approved the sale of a tobacco heating system called IQOS.¹⁴ IQOS functions differently than the e-cigarettes that have been discussed and referenced thus far. IQOS heats the tobacco leaf without burning fire, smoke, or ash. This helps significantly reduce the amount of harmful chemicals that are inhaled from traditional combustible cigarettes.¹⁵ This is the one instance of the FDA actually upholding its end of its promise to approve harm reduction alternatives to smoking.

One of the bases on which FDA approved IQOS is that IQOS products “produce fewer or lower levels of some toxins than combustible cigarettes.”¹⁶ The FDA clarified that this does not mean they are completely safe, but that their sale would be appropriate for the protection of the public's health. This is helpful in clarifying the FDA's standard for what is and what is not suitable for public consumption. Undoubtedly, vaping should fall into this set standard.

The aforementioned Public Health England study revealed that vaping is 95 percent less harmful than smoking. This conclusion was drawn by the lack of sticky tar and other residue left by vaping products compared with traditional combustible cigarettes. As the researchers themselves said:

“We need to reassure smokers that switching to an e-cigarette would be much less harmful than smoking. This demonstration highlights the devastating harms caused by every cigarette and helps people see that vaping is likely to pose only a fraction of the risk.”¹⁷

It certainly seems that e-cigarettes meet that criteria laid out by the FDA to approve a new tobacco product to reduce the harm caused by combustible cigarettes. Most studies that purport to show the risk of e-cigarettes never compare them side-by-side with the risk of smoking, where they pale in comparison.

The FDA might have trouble explaining to the public that it wants to approve products that produce fewer toxins and help adult smokers quit while

14 “FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway.” Food and Drug Administration. April 30, 2019. <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>

15 “What is IQOS?” Phillip Morris International. <https://www.pmi.com/faq-section/faq/what-is-iqos>

16 “FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway.” Food and Drug Administration. April 30, 2019. <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>

17 Boseley, Sarah. “Public Health England maintains vaping is 95% less harmful than smoking.” The Guardian. December 28, 2018. <https://www.theguardian.com/society/2018/dec/28/vaping-is-95-safer-than-smoking-claims-public-health-england>

simultaneously putting an entire e-cigarette industry through the wringer just to keep their products -- which fit this description -- on the market.

This brings us to the second aforementioned legal hurdle the FDA may hit in its attempted vaping ban. If presidential advisor Kellyanne Conway is to be believed in this case, whatever ban does come down from the FDA will hit only corner stores and not industry-specific vape shops.¹⁸

Now, Title 21 USC § 387f(d)(3)(A) comes back into play, where the FDA may not “prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets.” The distinction that Conway is drawing seems to be the very definition of what this provision of U.S. law is trying to prevent. Regardless of intent, this type of ban is flatly illegal. An overarching ban violates tobacco laws that govern the FDA, as would a Conway-esque regulation that shuts corner stores out of the vaping market, while not applying the same standards to traditional shops.

Instead of trying to do mental gymnastics to justify the legality of a ban that would harm so many millions of Americans trying to stave off cigarette addiction, the FDA should just leave well enough alone. The Trump administration’s promise to cut regulatory red tape should apply equally to the FDA, especially when the law is not on the administration’s side.

Lessons from History

In 2009, the Family Smoking Prevention and Tobacco Control Act banned all tobacco flavors other than menthol. The previous chart showed that such a ban had virtually no impact on the downward trajectory of underage smokers. Kids were already moving away from smoking in 2009. This bill piggybacked off of that trend and merely took credit for it. Any amateur statistics student will tell you that is not how you determine correlation, let alone causation.

Furthermore, a 2017 study authored in the American Journal of Preventive Medicine showed that the 2009 flavor ban actually accompanied a positive correlation with the use of menthol cigarettes, cigars, and pipes. The authors conclude that there was a “substitution toward the remaining legal flavored tobacco products.”¹⁹ This confirms what we have known from the start. An outright ban does not get to the heart of the issue, and consumers will find another way to get their fix. This is why the crux of this analysis has focused on harm reduction, not harm elimination.

Naturally, this brings us to the epitome of failed bans on vice behavior throughout American history: Prohibition. Prohibition’s defenders will claim that alcohol

¹⁸ McKay, Tom. “Vape Shops Might Be Exempt From Federal Flavor Ban, If You Believe Kellyanne Conway.” Gizmodo. November 6, 2019. <https://gizmodo.com/vape-shops-might-be-exempt-from-federal-flavor-ban-if-1839675375>

¹⁹ Courtemanche, Charles J, McKayla K. Palmer, and Michael F. Pesko. “Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use.” American Journal of Preventive Medicine. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5401634/>

consumption did decrease during that era, just as those championing flavor bans claim that they will drastically reduce tobacco consumption. This comes from two supposedly definitive studies done decades ago.²⁰ However, there are a number of clarifications that come along with that statistic that must be made. Those clarifications also shed light on the current situation surrounding vaping.

First, despite the outright ban on alcohol during Prohibition, alcohol consumption initially decreased, but only insignificantly. The aforementioned studies show that consumption only went down about twenty percent and was a far cry from anything close to the elimination of alcohol. Much the same, we cannot expect that a flavored vaping ban would eliminate its consumption or even come close to it.

Second, after the initial drop in alcohol consumption, those numbers actually began to rise steadily once illegal and illicit production began. Such production only continued to increase until the end of Prohibition years later.²¹

Just as bootlegged alcohol was often toxic and led to numerous public health issues, so too would bootlegged vaping products, if the government decides to create a black market for them. Research has already indicated that the health issues surrounding vaping are because of the toxins in already-bootlegged products.²² Studies have shown people will search for a substitute, and history tells us people will produce knockoffs. This combination will lead to worse public health outcomes, not better ones.

Lastly, this prohibition greatly raised enforcement costs on the American taxpayer. Funding for the Bureau of Prohibition rose threefold during that time period.²³ Coast Guard spending was also increased. These costs were borne by state and local governments. All this extra cost came for little result, as we have seen the minimal or even adverse impact of prohibition on consumption. Another such vice ban would, no doubt, add to the debt and deficit and become a spending issue in short order, if it were to be enforced fully.

Prohibition has been more than widely viewed as a failure and a proverbial black eye on the record of American liberty.²⁴ It failed at its intended effect and had harmful ramifications for public health and the American way of life. The 2009 tobacco flavor ban also failed to achieve its goal. Instead of trying again with a new product that is actually intended to reduce the adverse effects of combustible cigarettes, lawmakers should give harm reduction a try. The alternative would embody

20 Warburton, Clark. "The Economic Results of Prohibition." (New York: Columbia University Press, 1932); Fisher, Irving. "Prohibition at Its Worst." (New York: Alcohol Information Committee, 1927).

21 Ibid.

22 "Tests Show Bootleg Vapes Are Riddled with Toxins." Occupational Health and Safety. October 2, 2019. <https://ohsonline.com/Articles/2019/10/02/Tests-Show-Bootleg-Vapes-Are-Riddled-with-Toxins.aspx?Page=2>

23 Bureau of Prohibition, Statistics Concerning Intoxicating Liquors (Washington: Government Printing Office, December 1930), p. 2.

24 Thornton, Mark. "Alcohol Prohibition Was a Failure." Cato Institute. <https://www.cato.org/publications/policy-analysis/alcohol-prohibition-was-failure>

Einstein's definition of insanity: trying the same thing over and over expecting different results.

Conclusion

No one can deny the devastation that smoking has inflicted on our nation and our world. There are very few American families that have not been touched in some way, shape, or form by its side effects. Lawmakers cannot be faulted for wanting to address this issue in a meaningful way for the benefit of public health. However, they can be faulted for proposals that will have the opposite impact.

Vaping is certainly not without its drawbacks. None who would seriously claim to tout its benefits would omit such drawbacks from the conversation. However, as an alternative to traditional combustible cigarettes, there is no other comparison currently in existence. Vaping is a tool for harm reduction, not harm elimination. Those struggling with nicotine addiction can get their fix in a way that causes far less harm to the human body with e-cigarettes.

Concerns about the health of children are genuine, but any sweeping ban on flavors, or the product in general, will only sweep up struggling adults as well. This will usher them back into the arms of cigarettes and all of the collateral damage that goes along with them.

Lawmakers should learn from the past and trust the data that is out there. There are no perfect, silver bullet solutions to this problem. However, harm reduction offers the best hope of getting as many adults away from traditional cigarettes and into a relatively healthier lifestyle. This should be the goal of members of Congress and regulators at the FDA. Instead of reverting to Prohibition-era thinking, they should walk down the path of harm reduction for a new way to address public health.