
Truth Initiative Statement on Harm Reduction

There is a contentious and ongoing debate regarding what role the concept of “harm reduction” should play for smokers who have rejected FDA approved cessation methods or who find those alternatives unattractive. Recently, the term has been seized upon by industry¹ and pro-e-cigarette advocates as a proxy for a vision of a lightly regulated market in nicotine products that provides for continued and robust growth of nicotine as a commercial product. They argue this approach will encourage the development of lower harm alternatives to cigarettes and will therefore improve public health. This same group contends that those who advocate for a more cautious approach are anti-smoker and anti-harm reduction.

We reject this narrative for what it is, a cynical attempt by commercial interests to protect and grow their profits. Indeed, tobacco control advocates have long embraced the concept of harm reduction as traditionally understood in public health. We believe that smokers who choose not to quit nicotine should have less harmful alternatives. We forcefully reject, however, the notion that this requires the further development of a huge commercial market in addictive nicotine products focused on growth and the acquisition of new users, most of whom are youth and young adults. Instead, we argue that a genuine harm reduction approach requires a measured and careful deployment of nicotine alternatives that are tightly focused on helping smokers who otherwise would not quit smoking cigarettes. One with science driven oversight that considers impact on population health. In other words, a regulated harm reduction approach.

Background

Harm reduction, broadly described, is a public health strategy that acknowledges not all people will choose to avoid risky behaviors and seeks to serve those people by providing less risky alternatives. For example, during the height of the HIV/AIDS crisis, harm reduction encompassed a broad population primary prevention strategy encouraging the widespread use of condoms by all sexually active individuals in non-monogamous relationships.^{1, 2} Harm reduction as practiced among the relatively small and highly vulnerable population of intravenous drug users includes providing programs like clean needle exchange, safe consumption sites, and medication assisted treatment.³

Harm reduction with regards to tobacco use has been part of the conversation in tobacco control for decades, and indeed was the subject of a report by the Institute of Medicine in 2001.⁴ It recognizes that, for tobacco users who have not



yet quit, “minimizing harms and decreasing total mortality and morbidity, without completely eliminating tobacco and nicotine use” is an appropriate public health strategy. Ideally, this would include a transition to regulatorily-approved nicotine replacement treatment.

While in the case of substance use disorder, harm reduction, if focused primarily on the health and well-being of the drug user, does not ignore the impact on public health. For example, while medication assisted therapy for substance use disorder is a sound harm reduction policy, no one advocates selling methadone as a consumer product to everyone in convenience stores nationwide. Instead, it is provided in a medically supervised context to limit dangers of abuse and uptake by non-users.

The 2009 Tobacco Control Act (the TCA) adopts a public health harm reduction approach in authorizing the marketing of new tobacco products in the United States. Under the TCA, the FDA should prohibit the marketing of a new tobacco product unless it finds the marketing of the product would be “appropriate for the protection of the public health,” “taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products.”ⁱⁱ TCA § 910(4).⁵ The TCA allows the FDA to put conditions on the marketing of new products so that they comply with this standard. The “appropriate for the protection of the public health” test is not driven by the growth and protection of commercial markets, but by a careful balancing of the impact on the health of current tobacco users AND non-users.

Unfortunately, the TCA did not anticipate the magnitude and rapidity of the introduction of novel tobacco products that were not originally included as regulated products in the law. As a result, e-cigarettes were introduced into the US market without pre-market review. While the TCA allowed for the regulation of such products, it required the FDA to assert jurisdiction before it could proceed. This process, called “deeming,” was not completed until August 2016 – seven years after the TCA was passed and well after the emergence of the e-cigarette as a significant consumer product.⁶ⁱⁱⁱ Further delays occurred in July 2017, when the FDA announced it would postpone pre-market review of e-cigarettes until August 2022 – a full 13 years after the initial law was enacted.⁷ Later, due to litigation from public health groups, this date was moved up to September 2020.⁸ Under the court’s order, if FDA has not completed its review of a product by September 9, 2021 and issued an order authorizing the



marketing of the product, it must come off the market or be subject to FDA enforcement.^{9iv}

Commercial interests eagerly stepped into the regulatory void, creating a multi-billion-dollar business in e-cigarette products whose manufacturers had no incentive or directive to restrict the sale and marketing of these products to adult smokers. The result has been calamitous. In the absence of marketing restrictions, the industry immediately turned its focus to rapidly growing the largest user base possible. Not surprisingly, rather than addressing efforts exclusively to long-term cigarette smokers who want to quit smoking, this included the recruitment of new users who were primarily young people. In fact, Juul's product launch directly copied Big Tobacco's playbook for reaching kids using youth oriented lifestyle advertising.¹⁰ Other companies did the same.¹¹ This strategy also included the proliferation of highly appealing flavors and increasingly addictive products with levels of nicotine exceeding those of a typical cigarette.^{12,13} By 2018, 20.8% of High School students had reported e-cigarette use in the previous month, prompting the Surgeon General to declare the use of e-cigarettes by youth an epidemic.^{14,15} That number surged as high as 27.5% in 2019, and remained at epidemic levels of nearly 20% in 2020 with the behavior now endemic in youth culture.^{16,17} Meanwhile, the usage rate among adults continues to hover around 4%, essentially unchanged from when national surveys began monitoring it in 2014 and with no concurrent significant change in the annual decline of adult smoking rates. In the United States, the "harm reduction" opportunity these products purport to provide has yet to be realized in any meaningful way on a population basis.^{18,19}

Despite this situation, industry and some advocates have hailed the introduction of e-cigarettes as a triumph for tobacco harm reduction.²⁰ Other public health advocates have been concerned about the explosion of youth use and the lack of clear and compelling scientific evidence supporting both their long-term safety and their efficacy in promoting smoking cessation on a population level.^{15, 21} Industry interests have seized on this controversy as an opportunity to reframe the image of "big tobacco," crystalized in the late 90s as marketers of deadly products and adjudicated racketeers, to one of a now reformed industry that presents itself as a champion of public health.²²

Regulated Harm Reduction

We, and many public health authorities, reject the notion that unregulated or lightly regulated commercial markets in nicotine alternatives are equivalent to



harm reduction.²³ The nature of nicotine as a drug is incompatible with an unregulated approach. In the United States, 70 percent of current adult smokers want to quit.²⁴ Recent research shows that most youth and young adult e-cigarette users surveyed also want to quit.²⁵ Nicotine, however, is particularly hard to give up because it leads to physical dependence and withdrawal.²⁶ Moreover, young people are particularly vulnerable to nicotine addiction: Nearly 9 out of 10 adults who smoke cigarettes daily first try smoking by age 18 and 99% first try smoking by age 26.²⁷

The market for cigarettes has historically depended on a strategy of hooking young users and developing them into lifelong addicted users who then become heavy users and generate profits on volume. In fact, a significant majority of nicotine is purchased to stave off the unpleasant effects of nicotine withdrawal by users who wish they had never started in the first place.^{28v} The current US experience suggests that an unregulated e-cigarette market will follow a similar trajectory, with innovation concentrating on increasing addiction liability and product appeal.

Because industry incentives are inevitably to grow and retain markets and nicotine's nature as an addictive drug facilitates long-term, high-volume sales, the tobacco industry should have no part in defining the parameters of a harm reduction approach and their attempts to claim the mantle of harm reduction should be rejected by the public and policy makers.^{vi} Our experience with cigarettes should have permanently put this notion to rest. Even in the face of overwhelming evidence that smoking kills, the industry responded with obfuscation, public relations efforts, distortion of the scientific record, and, even to this day, staunch resistance to any public policy that will shrink the cigarette market.²⁶

Consistent with the above, we endorse a regulated approach to harm reduction that considers both individual health and public health. This approach recognizes that the best way to eliminate tobacco-caused harm is to prevent its use in the first place and, failing that, to eliminate tobacco use as early in life as possible. However, for those that have been unsuccessful at quitting or who choose not to quit nicotine, the death and disease that flow from combustible tobacco use can be significantly reduced if users switch exclusively to evidence-based, regulated, significantly less harmful, non-combustible nicotine delivery products (ideally regulator-approved nicotine replacement therapies) while keeping opportunities for complete nicotine cessation available.



For youth, there is no appropriate role for tobacco or nicotine use regardless of product except for youth who are already nicotine users in the limited circumstance where they are using regulator-approved nicotine replacement therapy (NRT) under medical supervision as a strategy to end all nicotine use. As the FDA considers authorizing the marketing of new tobacco products pursuant to the “appropriate for the public health” standard, we recommend the following considerations inform a regulated approach to harm reduction:

- **Safety:** To the best extent possible given currently available evidence, product manufacturers should be required to establish that products are substantially less harmful than those they are meant to replace. The overall safety profile is especially important if the product is easily available to tobacco naïve users.

E-cigarette advocates often claim that the products are 95% less harmful than conventional cigarettes.^{29,30} However, this assertion is unsubstantiated by quantitative evidence, and while it is true that there is substantial evidence that exposure to toxic substances from e-cigarettes is significantly lower compared to combustible cigarettes, recent studies suggest that is not the end of the story on health impact.³¹ It now appears that e-cigarettes may present their own unique health risks, including to the respiratory and cardiovascular systems.^{32,33} Even e-cigarette manufacturers concede that the medium to long term risks of e-cigarette use are unknown.³⁴ This dearth of evidence on long-term safety should signal caution especially when the delivery mechanism necessitates frequent and long-term inhalation of a foreign aerosol into the lungs.

- **Addiction Liability:** Nicotine is an addictive drug, and its addiction liability varies via delivery mechanism. Cigarettes, because they rapidly deliver high levels of nicotine through the lungs, are particularly addictive.³⁵ While earlier iterations of e-cigarettes were generally unable to deliver high quantities of nicotine efficiently,^{vii} this changed with the introduction of nicotine salts, which allow for higher concentrations of nicotine that can be inhaled more deeply due to lower pH values in e-cigarette liquid; allowing e-cigarettes to deliver nicotine even more effectively than cigarettes.³⁶ This set off a trend towards stronger and stronger e-cigarettes with higher and higher concentrations of nicotine.¹²

Some proponents of the lightly regulated e-cigarette model have argued that public health advocates have overemphasized the problem of youth addiction. We disagree. Nearly 40% of high school e-cigarette users use them on a regular



basis.¹⁷ We know from our research and experience that youth users find addiction to be unpleasant and stressful and want to quit.³⁷ The science also suggests that nicotine alters the developing brain to make it more susceptible to addiction to nicotine and other substances.³⁸

While nicotine addiction may not be associated with the sorts of adverse behaviors we see from those addicted to opioids or methamphetamines, it still imposes physical, emotional, and financial burdens on the user. Simply put, while addiction to nicotine will not kill you if delivered via a safe mechanism, the fact that most people who use it would like to stop and have great difficulty doing so is evidence enough that its costs outweigh its rewards. The physical discomfort of repeated daily symptoms of nicotine withdrawal, the emotional stress of avoiding withdrawal symptoms, and the financial stress of sustaining a long-term addiction are an unnecessary burden placed upon society, all of which contribute to diminished quality of life.

Because of the issues of addiction liability for youth, high nicotine products, and particularly highly-appealing flavored versions of e-cigarettes, are simply not appropriate for approval as new commercial tobacco products pursuant to the public health standard. However, they may be appropriate for regulation as a smoking cessation therapy approved via a drug pathway for those that have been unsuccessful at quitting or who choose not to quit smoking using currently available FDA approved treatments.

- **Appeal:** Flavored tobacco products are highly attractive to youth and flavored e-cigarettes have been a major driver of the youth e-cigarette epidemic: 97% of youth who vape use a flavored e-cigarette.³⁹ There is also evidence that flavors are attractive to some adult smokers.³⁹ However, as the United States experience has shown, while the introduction of a multitude of flavored e-cigarettes has helped drive youth e-cigarette use to unprecedented levels, it has had little impact on overall adult e-cigarette use nor has it resulted in a significant acceleration in the decline of adult smoking rates.¹⁸

Given the actual United States experience with flavored tobacco products, it is clear such products (including menthol), and particularly those with high addiction liability, do not meet the public health standard of the TCA and must be rapidly removed from the market. However, they may be appropriate for approval as a smoking cessation therapy with significant access safeguards under the FDA's authority to regulate drugs.



- **Access:** The model of making highly appealing and addictive e-cigarettes widely available as consumer products with little to no access limitations was clearly a failure in the US market with respect to youth. It is also unclear whether it has been a productive strategy for adult smokers. Despite wide availability in the market, adult e-cigarette use has been largely stable since 2014, with significant changes only at younger ages as users who started when they were youth aged into the young adult cohort.^{18,19} While there is evidence that e-cigarettes may aid smokers to quit smoking by switching completely if done with guidance and instructions to quit, the impact on smoking by simply placing the products in the market as a competitor to cigarettes is less clear, with many studies showing that strategy has negative effects on cessation.⁴⁰

To the extent new tobacco products are authorized by the FDA, authorization should be accompanied by strict requirements that restrict access to adult smokers. Depending on the safety profile, addiction liability and appeal of such products, such measures should include all the following restrictions:

- Adult only retail spaces
 - No internet sales
 - Strict ID check requirements similar to those used for pseudoephedrine
 - Volume of purchase limitations
 - No self-service sales
 - No in-store/window promotional signage near schools
- **Marketing Restrictions:** No nicotine product should be marketed to youth or nicotine naïve individuals. Rather, marketing efforts should focus on adult smokers seeking to quit smoking. The FDA should carefully review manufacturer marketing plans, advertising, and perception studies to confirm the products do not appeal to youth or new users. This should include research confirming lack of appeal among young people. Any marketing authorization should be followed up with post-marketing surveillance to confirm the product has not attracted youth users.

Regulation of Legacy Tobacco Products



A consistent argument from industry and some advocates is that newer, potentially less harmful tobacco products should be able to compete as consumer products with cigarettes and other combustible products.⁴¹ They therefore critique any regulation of newer products as anti-smoker and anti-harm reduction.

First, as an empirical matter, the evidence for the proposition that harm reduction is achieved through product competition is weak. The strongest case for such an approach is the experience of snus in Sweden.⁴² However, in the United States, with a much weaker tobacco regulatory environment and weak restrictions on marketing, the impact of e-cigarettes as a lightly-regulated consumer product has been less clear with regards to smoking cessation.⁴³ Indeed, the strongest evidence for e-cigarettes as a tool for smoking cessation comes from randomized control trials where the use of the product was coupled with counseling and instruction on using the products to quit.⁴⁰ This suggests such products may be more useful as cessation therapies than as consumer competitors.

Second, the argument against regulation of new products is simply an argument that we should continue to repeat the immense policy failures that led to the mass commercialization of the cigarette in the first place. The better conclusion is that cigarettes have been too lightly regulated. That is why we support the FDA's plans to reduce nicotine to non-addictive levels in particularly harmful products, limits of harmful constituents such as tobacco-specific nitrosamines in oral nicotine, and measures to remove all flavors, including menthol, from all combustible products. We also continue to advocate for proven tobacco control strategies such as high taxes, clean indoor air laws, access limitations and prevention education.⁴⁴

Conclusion

Truth Initiative endorses the public health strategy of harm reduction. Indeed, Truth Initiative, along with other tobacco control advocates, has clearly embraced harm reduction in its long-term efforts to encourage the FDA's Center for Drug Evaluation and Research to liberalize the labeling, usage advice, and approval processes for NRT and other nicotine dependence treatments.

We also recognize that there are a significant number of adult smokers who have rejected current cessation therapies or who simply do not desire to quit nicotine. For that group, complete transition to the least harmful nicotine delivery alternative is a desirable and appropriate result. However, the goal of harm



reduction is not to sustain a commercial market for nicotine, but to reduce the morbidity and mortality associated with tobacco use.

We also believe every smoker should be given the support to quit all nicotine should they so desire and that nicotine alternatives should be carefully deployed to prevent creating future generations of nicotine addicts. Harm reduction requires a consideration not only of the comparison to harms of existing products but also a cautious perspective and evaluation of potential harms in the absolute—particularly as new technology presents uncertain long-term health risks. The lessons of the past are clear given the public health failures of bogus “tobacco harm reduction” strategies such as filter tips and low tar cigarettes.⁴⁵ And, while new products, such as e-cigarettes, may be appropriate for a smoker who otherwise would not quit smoking, we should take strong steps to make sure such a product does not appeal to and addict youth.

While it is true that policies restricting nicotine delivery should consider current smokers, this aim can and should be accomplished through more targeted and efficient means than allowing the industry lightly restricted access to addict young people in exchange for vague promises of eventual market transformation. The decades of fraud, malfeasance, and the targeting of youth by purveyors of non-therapeutic nicotine cannot be denied. It will take strong, independent, and public health focused regulatory leadership to end the tobacco epidemic.

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ⁱ This paper uses the word “industry” to connote commercial interests in the business of selling non-therapeutic nicotine. Some advocates seek to separate the “vaping” industry from the larger tobacco industry. This paper will argue that the highly addictive nature of nicotine drives analogous behaviors in both groups.

ⁱⁱ It is important to note this standard specifically contemplates complete cessation of the harmful product not reduction and ongoing dual use of the harmful product and the reduced harm alternative.

ⁱⁱⁱ E-cigarettes were already on the market when the TCA was passed and by 2013 were a quickly growing segment of tobacco product sales.

^{iv} However, FDA has already indicated that due to the volume of submissions received, it is unlikely to meet this deadline for all applications. It also has ^{iv}not clarified whether it will require manufacturers to remove products from the market if they are not reviewed by the September 2021 date.

^v See <https://tobaccocontrol.bmj.com/content/24/2/112> in which leading health economists make this exact argument in urging the FDA to significantly discount the principle of “lost pleasure” in analyzing the “costs” of cigarette graphic warning labels.

^{vi} Maybe reference our consumer perceptions of industry studies here?

^{vii} Some users were able to increase nicotine delivery via increasing the power to the heating element in modifiable vaping devices.