

July 2023

GAMECHANGER:

SHIFTING FROM TOBACCO CONTROL TO ENDING THE INDUSTRY'S INFLUENCE FOR GOOD

EXECUTIVE SUMMARY

"Endgame" refers to a set of policies and strategies to move toward the end of commercial tobacco and nicotine use, with the exception of Food and Drug Administration-approved medications. Policies to achieve this commercial tobacco-free future decrease the access, appeal, and addictiveness of products;² increase cessation interventions and services;3 and denormalize all tobacco use,4 ultimately relegating it to a behavior of the past. These policies are not prohibition policies, as they do not call for immediate or near-term removal of all commercial tobacco product sales, nor are they directed against individuals who use tobacco. Instead, they are a set of strategies aimed at manufacturers, distributors, and retailers without targeting or criminalizing consumer use or purchase.

Truth Initiative – which has had a long-standing vision of "a future where commercial tobacco and nicotine addiction are a thing of the past" – supports policies designed to accelerate progress toward a future free from commercial tobacco and the predatory influences of the tobacco industry. Ending tobacco must start with shifting the societal mindset that assumes and accepts tobacco's continued long-term presence to one that rejects its use entirely. In other words, moving beyond "tobacco control" to the end of tobacco.

WHY THE U.S. NEEDS AN ENDGAME STRATEGY

Despite significant progress in reducing and denormalizing commercial tobacco in American society, smoking remains the country's number one preventable cause of death and disease, causing more than 480,000 deaths⁹ each year and costing more than \$240 billion annually in healthcare spending and nearly \$185 billion in lost productivity from smoking-related illnesses.¹⁰

The tobacco industry's introduction of new non-combustible tobacco products, especially

e-cigarettes, has dramatically changed the product landscape. While the tobacco industry has suggested e-cigarettes could help move adult smokers away from combustible tobacco products, ⁴¹ they have instead become the most popular tobacco products among youth and have so far not accelerated adult quitting rates. ⁷ Far from being part of the solution to end smoking, as the tobacco industry claims, these products have instead distracted from endgame conversations that long preceded the introduction of e-cigarettes.

A shift toward endgame policies is now gaining momentum.⁵ For example, recent CDC data showed that 62.3% of adults supported a policy ending the sale of menthol cigarettes and more than 57.3% of adults supported a policy eliminating the sale of all tobacco products.³⁵ Public support is translating into adoption of several types of endgame policies at the local, state, and even federal level, such as local restrictions on the sale of all flavored tobacco products and proposed federal rules to end the sale of menthol cigarettes and flavored little cigars and plans to cap nicotine levels in combustible products.

ADDRESSING DISPARITIES

Endgame strategies will do much to reduce tobacco-related health disparities that exist among groups who have long been targeted by the tobacco industry, including Black Americans and other minorities, LGBTQ+ individuals, those dealing with mental illness, and low-income individuals. Geographic disparities also exist for states with fewer tobacco control policies in place compared to the rest of the U.S. Federal endgame policies can help level the playing field and all strategies must be intentional in addressing disparities.

WHAT IS ENDGAME?

Truth Initiative supports a combination of strategies to help current tobacco users quit and prevent people from starting to use tobacco products.

Near-term priorities

- Implement flavor restrictions for all tobacco products at the federal level
- Restrict points of sale
- Reduce nicotine levels in combustible tobacco products
- · Improve cessation access

Medium-term to long-term priorities

- Cap nicotine levels and delivery in all tobacco and nicotine products
- Develop new cessation interventions
- Phase out sales to younger generations
- Restrict commercial sales of cigarettes and some/all other smoked tobacco products

IMPORTANT CONSIDERATIONS FOR THESE STRATEGIES

- Before these types of policies can be implemented, critical considerations must be taken into account to ensure success of these policies and to reduce unintended consequences.
- First and foremost, access to cessation services must be expanded to help people currently smoking and using nicotine to stop.
- Ensure that endgame policies are written so they are not aimed at individual consumers but rather at tobacco and nicotine product manufacturers, distributors, and retailers.

- A coordinated approach that includes many different policies will be needed to achieve endgame.
- Provide strong public education about these policies and develop buy-in in close connection with impacted communities.
- · Plan for educating retailers.

ACTION ITEMS FOR THE PUBLIC HEALTH COMMUNITY TO ACCELERATE PROGRESS

Truth Initiative advocates that the public health community take the following actions:

- Begin thinking in terms of endgame not tobacco control
- Educate policymakers, the public, and consumers about what endgame is AND isn't.
- Governments must redouble their efforts to implement policies that best serve their communities and build toward the end of commercial tobacco.
- The FDA must act quickly to finalize the menthol cigarette and flavored cigar rules to remove them from the market and proceed with plans to cap nicotine levels in combustible products.
- Prepare for tobacco industry attacks and misdirection and hold the industry accountable for their role in continuing youth and young adult tobacco use.
- Develop research on communication and messaging strategies to motivate public support and counter industry attacks.

BACKGROUND AND INTRODUCTION

The concept of "endgame" is a strategy to move to a time when commercial tobacco and nicotine use – with the exception of FDA-approved medications – are no longer used.¹ Policies to achieve this commercial-market tobacco-free future decrease the access, appeal, and addictiveness of products;² increase cessation interventions and services;³ and denormalize all tobacco use,⁴ ultimately relegating it to a behavior of the past. Once considered a radical notion, this movement is gaining increasing momentum among public health experts, policy makers, and the general public.⁵

Truth Initiative's long-standing mission has been to achieve a culture where young people reject smoking. To account for the rise in e-cigarettes and other non-therapeutic nicotine products, all of which are used by youth and young adults in large numbers, ^{6,7} we expanded our mission in 2020 to achieve a culture where young people reject smoking, vaping, and nicotine. Moreover, our vision has long been "a future where commercial tobacco and nicotine addiction are a thing of the past." So, it should come as no surprise that Truth Initiative supports policies designed to accelerate progress toward a future free from tobacco and the predatory influences of the tobacco industry, and bring tobacco and nicotine use and their consequences to conclusion.⁸

SOCIETAL IMPACT OF SMOKING AND NICOTINE USE

Smoking remains the number one preventable cause of death and disease, causing more than 480,000 deaths annually and costing our country more than \$240 billion annually in healthcare spending and nearly \$185 billion in lost productivity from smoking-related illnesses and health conditions.¹⁰

Health effects of tobacco use

- Cigarettes: Cigarette use is associated with a wide range of diseases from cancers of nearly every part of the body, to cardiovascular and respiratory diseases such as heart disease and COPD.¹¹
- E-cigarettes: While e-cigarettes produce fewer of the toxins found in cigarette smoke, the long-term effects of e-cigarette use are unknown, and the most recent evidence suggests that e-cigarettes may pose their own unique health harms including to the respiratory and cardiovascular systems.
 E-cigarettes, like combustible cigarettes, are highly addictive and come with ever increasing levels of nicotine.¹²
- In 2021, among adults who currently used tobacco, 18.1% of them used two or more products. Of those, 31.4% used both e-cigarettes and cigarettes.¹³
 One systematic review found that dual use of

e-cigarettes and cigarettes is at least as harmful, or possibly more so, than exclusive smoking.¹⁴

How many people use tobacco?

- In 2021, 46 million adults (18.7%) were current users of any tobacco product, including 35.65 million (14.5%) adults who used combustible tobacco products, and 11.1 million (4.5%) adults who used e-cigarettes.¹³
- Among youth in 2022, 3.08 million youth (11.3%)
 reported current use of any tobacco product,
 including 1 million (3.7%) who used any combustible
 product, and more than 2.5 million (9.4%) youth who
 were current e-cigarette users.⁷
- 70% of adult smokers indicate they want to quit but only 7.5% are able to successfully quit.¹⁵ In 2019, more than half of middle and high school students who current use e-cigarettes reported seriously thinking about quitting, and nearly as many (52.9%) reported trying to quit in the last year.¹⁶

Tobacco's impact on disparities

There is a vast body of evidence that the tobacco industry has long targeted African Americans, the LGBTQ+ community, women, and other minority

groups,¹⁷ as well as those with low incomes and low levels of education.¹⁸

- Nearly 9 in 10 Black Americans who smoke use menthol cigarettes, which are easier to smoke and harder to quit.¹⁹
- As of 2020, American Indian and Alaska Native high schoolers have the highest current cigarette smoking rate of any other race or ethnicity at 16.2%, compared to 5.8% overall.²⁰
- Transgender youth currently used tobacco products at higher rates than cisgender youth, including 4X

- higher cigarette use and 3X higher e-cigarette use.²¹ Additionally, In 2021, LGB young people currently vaped at higher rates than their heterosexual peers (19.8% vs. 13.2%).²²
- As of 2019, overall smoking rates have not declined as quickly for women as for men. Since 1965, smoking rates among women have dropped by about 59%, compared with a 66% drop among men.²³
- 18.3% of adults living in low-income households smoke, compared to 12.3% of adults living in middle-income households, and 6.7% of adults living in high-income households.¹⁸

A NEW APPROACH IS NEEDED

Despite meaningful progress in reducing and denormalizing tobacco and nicotine in American society, its use remains stubbornly persistent. Much can be explained by its addictive properties (consistently enhanced by industry), 24 but it is also true that although cigarette use has been marginalized over the past decades, many - including some in public health - tolerate the idea that tobacco and the tobacco industry will always be with us. Others subscribe to the notion (perpetrated by industry) that tobacco use is a marker of freedom of choice.²⁵ By definition, the term "tobacco control" serves to legitimize this thinking. Current regulatory approaches aim to manage or minimize the problem rather than ending it. These policies served a necessary and critical role in beginning the denormalization of tobacco and saved many lives through smoke-free air policies, increased prices through taxation of tobacco products, and funding tobacco prevention and cessation programs.^{2,3} It is important to remember that nearly 50 years ago when smoke-free air policies were first introduced,26 they were considered daring and thought to have gone too far. Now, in many parts of the country it is unthinkable to eat a meal at a restaurant while people are smoking. While these types of policies laid the foundation for tobacco control, we cannot and should not wait another 50 years to see the vision of

a tobacco-free future realized. It is important now to build upon them and take bolder steps that will move us quickly toward the end of tobacco and nicotine.

In recent years, some states and localities have taken strong steps to move toward the end of tobacco and nicotine products. At least 121 jurisdictions have prohibited all flavored tobacco sales within their borders²⁷ and the U.S. Food and Drug Administration (FDA) recently proposed rules to remove menthol cigarettes and flavored cigars from the market.²⁸ The FDA has also indicated it will propose a rule to cap nicotine levels in cigarettes to non-addictive levels.²⁹ These steps are critical but insufficient on their own to fully realize the vision of a tobacco-free society.

It is important to note that no one policy will achieve endgame on its own. A combination of policies and an integrated approach is needed. The policies Truth Initiative advocates for include: removing all flavored tobacco products from the market, and capping nicotine levels in all tobacco products (except FDA-approved tobacco cessation drugs). Policies that make tobacco less appealing and less addictive are critical to help current tobacco users quit and prevent new people from starting to use tobacco products. These types of policies seek to not simply manage tobacco but to relegate it to a practice of the past much like the use of lead paint or asbestos – harmful products which would not be tolerated

today even in regulated amounts. The efforts of the tobacco industry to maintain their current customers and attract new ones with non-combustible products have caused much debate and ultimately distracted from endgame conversations that long preceded the introduction of e-cigarettes. As the tobacco industry tries to reinvent itself as part of the solution with

products to keep people addicted to nicotine and prolong its market in the U.S. and around the world, so too must public health move toward a long-term vision and institute polices that will prevent industry reinvention and put us back on track to denormalize and extinguish demand for these dangerous and addictive products.

A WORD ON LANGUAGE

For the purposes of this paper, we use the term "endgame" to describe a set of objectives and future state. We know various groups use different terms, and that sometimes "endgame" means different things to different people. When we use the term endgame in this paper, we are referring to a package or set of policies and strategies to move to a time

when commercial tobacco and nicotine, with the exception of FDA-approved medications, are no longer used. We know that a policy stance needs an effective communications strategy, and work is needed to determine the best messaging to motivate our society to think differently and develop strategies and policies to address the issue differently.

WHY ENDGAME?

Truth Initiative supports these policies because focusing on stronger endgame policies has the potential to save millions more from premature tobacco-related addiction, disease, and death. As we outline below, these policies have and are gaining public support; will do much to reduce tobacco-related disparities; and will serve to quickly reduce the addiction, death, and disease caused by nicotine and tobacco products and move us toward a time when tobacco and nicotine products are simply part of the past.

PUBLIC SUPPORT TO END TOBACCO

Ending tobacco must start with shifting the societal mindset that assumes and accepts tobacco's continued long-term presence to one that rejects its use entirely. In other words, moving beyond "tobacco control" to the end of tobacco.

This change in mindset is gaining acceptance, with recent polling showing that the public supports stronger endgame policies than we once thought both in the U.S.^{15,31} and abroad.³² Recent literature reviews demonstrate that endgame policies are gaining popularity and many already have strong support.³³

For example, according to a study in Spain, when asked at what age parents want their child to start using tobacco or nicotine products, a resounding 97.6% answered "never." ³⁴ In the U.S., recent CDC data showed that 62.3% of adults supported a policy prohibiting the sale of menthol cigarettes and more than 57.3% of adults supported a policy prohibiting the sale of all tobacco products. ³⁵ Canada, the United Kingdom, and the European Union have already prohibited the sale of menthol cigarettes. ³⁶

ENDGAME POLICES ARE ON THE RISE

Public support is translating into adoption of several types of endgame policies in the U.S. at local, state, and even the federal level as well as abroad. For example, many localities have adopted strong or comprehensive flavor restrictions.³⁷ Some counties and cities, like San Francisco and Philadelphia, have adopted policies designed to reduce the number of tobacco retailers in their jurisdictions.³⁸ At the federal level, the FDA has repeatedly announced plans to issue a rule to reduce nicotine levels in cigarettes to non-addictive levels, a proposal that even 10 years ago was thought to be too radical to consider.²⁹ Internationally, New Zealand recently passed a package of laws that caps the number of tobacco

retailers in the country and enacted a policy to raise the legal age of sale by one year every year, which has the effect of permanently preventing the sale of tobacco to anyone born after a certain year – in the case of New Zealand, no one born after 2008 can be sold cigarettes.³⁹

ENDGAME POLICIES CAN HELP ADDRESS DISPARITIES

For large populations that have been left behind with respect to tobacco policies, endgame strategies must be intentional in addressing disparities. We know that the tobacco industry uses product design and marketing to target specific populations. 40 It has historically, as well as recently, aggressively interfered in the political process in order to prevent local entities from enacting policies to protect their constituencies. 41,42 For example, Black Americans have long been targeted by the tobacco industry with menthol cigarettes and as a result 85% of Black Americans who smoke, smoke menthols. 43 Black Americans who smoke are also more likely to die from smoking-related disease than Hispanics and Non-Hispanic whites. 44 Similarly, tobacco-related health disparities exist in the LGBTQ+ population²¹ and Native American populations;²⁰ among those with mental illness;45 those with low levels of education; and those with low socioeconomic status. 18 Regional differences can also exacerbate inequities. States with persistently higher rates of smoking, poorer access to health care, and lower income also tend to have fewer tobacco control policies in place compared to the rest of the U.S.46 Federal endgame policies can help level the playing field so that all populations reap the benefits these policies bring in terms of reduced tobacco use, addiction, disease, and death.

THE INDUSTRY'S ROLE

The tobacco product landscape has changed dramatically in recent years due to the tobacco industry's so-called "innovation" in engineering products that deliver higher and more easily administered levels of nicotine to users, with e-cigarettes in particular, skyrocketing in popularity among youth and young adults.⁴⁷ While the tobacco industry suggested these products could help move

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smokers away from combustible tobacco products, 48 that is not what has happened.

The promise of non-combustible products as a means to dramatically accelerate adult smoking cessation has not been realized. While some adult smokers use these products to quit, the vast majority do not.⁴⁹ Most smokers who use these products continue to smoke at the same time.⁴⁹ The simultaneous use of multiple tobacco and nicotine products does not significantly reduce risks, and in the case of those who would have quit, simply prolongs their use of tobacco and nicotine products.⁵⁰ We know that there is no safe level of tobacco use, particularly combustible tobacco products,⁵¹ and in the tobacco space, the objective of "harm reduction" – a normally legitimate public health tactic – has been hijacked to be an industry co-opted profit strategy.⁵²

This discussion of harm reduction has benefited the industry, divided the public health community, and sapped energy from government and public resolve to end the impacts of tobacco use. The industry has used new products to shift focus from endgame policies that would promote continued and irreversible business decline to ones that shift business from older to newer products, and which maintain and even grow the total market for tobacco and nicotine consumption. As a result, e-cigarettes are the most popular tobacco products among youth⁷ while most adult smokers are not using them. Among those who do, most are not using them to quit tobacco use altogether.⁴⁹

Further, protests and false promises to the contrary, the tobacco industry is not abandoning combustible cigarettes in any way. Cigarettes remain by far the products with the largest market share (more than 80% for the Big Tobacco companies in the U.S.⁵³) and there are still 249 billion cigarettes sold each year in the U.S.⁵⁴ In 2021, the industry spent \$8.06 billion on advertising and promotional expenditures for cigarettes alone.⁵⁵ The industry continues to aggressively fight any policies that would reduce combustible tobacco use - actions contrary to their many advertisements espousing that they are working toward change and have become part of the solution. 48 These industry confusion and obfuscation strategies distract important attention from the goals of moving society away from tobacco and nicotine use in an effort to change the public narrative to embrace newer forms of tobacco and nicotine addiction as a more "healthy" and socially acceptable form of consumption with little to no harms.⁵⁶

This is simply not true nor is it an acceptable substitute for the end of tobacco and nicotine. It is important to note that while e-cigarettes and other nicotine-containing tobacco products may not be as harmful as combustible products when directly compared to each other, they are not "safe," have unique harm profiles independent of combustible tobacco, and pose particular health risks for youth.⁵⁷ A recent literature review found that use of e-cigarettes has been associated with increased odds of chronic cough, phlegm and bronchitis, as well as asthma diagnoses.⁵⁸ Other studies show that e-cigarettes may cause injury to the small airways of the lungs and are associated with diseases like pneumonia and interstitial lung disease and decreased immune cell function in the lungs. 59,60 E-cigarette use is also associated with elevated cardiovascular risks and increased risk of stroke at a younger age than for traditional cigarette smokers.61 The carbonyl compounds created from common solvents in e-liquid are associated with increased

At least **121 jurisdictions** have prohibited all flavored tobacco sales within their borders.

risk of blood clots and atherosclerosis.⁶² While more research is needed to determine the long-term effects of e-cigarette use, there is more than sufficient evidence to show that young people and non-tobacco users should not start using them.

Moreover, nicotine itself is known to carry health risks. Nicotine can increase risk of cardiovascular, respiratory, and gastrointestinal disorders. 63 It also is associated with decreased immune response and impacts on reproductive health.63 Most strikingly, nicotine is harmful to developing brains and its use during adolescence can disrupt the formation of brain circuits that control attention, learning, and susceptibility to addiction.⁶⁴ We know that the earlier one is exposed to nicotine in adolescence, the harder it is to quit. 65 Nicotine may also alter brain chemistry in ways that make adolescent brains more susceptible to other addictive drugs.⁶⁴ Studies have also shown that nicotine can worsen anxiety symptoms, intensify feelings of depression, and increase stress levels.66

It is easy to see why a strategy which equates a product - e-cigarettes or nicotine pouches for example – with the accepted public health strategy of harm reduction would be attractive to an industry that had been struggling for years with declining sales and negative public perceptions. However, it is not a strategy that public health should settle for as a weak substitute for the much bolder vision of a society free from tobacco harm and nicotine addiction. Harm reduction may have a temporary role in allowing some smokers to completely switch to less harmful products on their way to quitting tobacco and nicotine products altogether. However, that does not mean that products that are not appropriate for the protection of public health should be allowed on the market with little to no regulation, and the tobacco industry must not be permitted to corrupt the strategy of harm reduction in order to grow the market for nicotine products and/or maintain their bottom line.

It is critical to take action now to move toward ending tobacco and nicotine addiction because public health efforts to control tobacco have been insufficient to counter the tobacco industry's success in making their products appealing, highly visible, easy to access, and maintaining a favorable policy environment. Current approaches continue to leave millions of individuals, especially those suffering from existing health disparities in our nation, at risk and with significant negative health outcomes as well as significant societal impacts.

WHAT ARE ENDGAME POLICIES?

Ending tobacco will take a combination of near, medium, and long-term strategies. Some policies can be put into place more quickly while others will take time both in terms of public readiness as well as availability of sufficient and evidence-proven cessation services to help people quit. State and local endgame policies will vary depending on political will and the presence or absence of existing tobacco policies. Below are near and long-term policies to move toward endgame.

NEAR-TERM PRIORITIES

1. Implement flavor restrictions: At the federal level, the FDA must quickly finalize and implement rules to prohibit the marketing of menthol-flavored cigarettes and flavored cigars and complete its work through the premarket tobacco product application (PMTA) process to keep non-tobaccoflavored e-cigarette and nicotine products off the market. The FDA can also issue product standards to eliminate all characterizing flavors (except for tobacco flavor) in all products. This includes concept flavors and ingredients that create a heating or cooling sensory experience to mimic menthol or other flavors. At the state and local level, communities can accelerate the elimination of flavored products by passing and implementing more comprehensive sales restrictions on flavored products (where they are not preempted). Federal and state/local strategies are required in tandem to mitigate industry efforts to thwart policies at all levels.

Encouragingly, these policies are gaining increasing attention across the country. Flavor policies have been implemented as sales restrictions at the state and local levels with

121 local comprehensive policies restricting the sale of flavored tobacco, and two strong state policies already in place. However, even with those in place, only 3.31% of the U.S. population is covered by comprehensive policies.²⁷ It is critical to continue to expand such policies in additional states and localities as they achieve readiness for these bold steps. We recognize that some areas may be ready to take such policies on in the near future, but for others, it will take time to build the cessation infrastructure, educate the public and retailers, and build community buy-in.

At the federal level, the FDA must quickly implement product standards that prevent cigarettes and cigar products from having characterizing flavors. These standards must be finalized and implemented as soon as possible. The federal government needs to also continue to work to issue product standards that remove characterizing flavors, other than tobacco flavor, from all products, excluding FDA-approved nicotine replacement therapies (NRT) or other cessation drugs. Evaluation of these policies indicates that more comprehensive policies that include all flavors and all products have better outcomes. Further, evaluation of flavor restrictions in other countries, as well as current domestic policies, shows that such policies reduce youth use of tobacco products; increase quit attempts and successful quitting among adults who smoke; and decrease not only sales of the restricted products, but decrease overall sales of tobacco products.

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menthol cigarettes and more
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all tobacco products.

2. Restrict points of sale: States and localities can limit the sales of all tobacco products to adult-only stores where youth are not allowed to enter, and more importantly, drastically reduce the number of tobacco outlets and prohibit tobacco outlets from being close to youth-sensitive areas like schools and parks.

Policies to restrict sales such as adult-only retailer requirements and capping the number of tobacco outlets are measures that states and localities (when not pre-empted) can put into place. For example, in Bloomington, MN, they passed a law to begin the process of sunsetting tobacco licenses. Starting June 30, 2022, the city no longer issues any new tobacco licenses. so when a store with a tobacco license closes. that license is eliminated. We know that retailer density is a predictor of youth and young adult smoking. 67,68 As the number of tobacco retailers increase, so does exposure to tobacco advertising and promotion, and the ease of accessing tobacco and nicotine products. Further, reducing availability of tobacco retail outlets can help those who wish to guit.69

An estimated 380,000 retailers sell tobacco products in the U.S. To put this into perspective that is 28 times more tobacco retailers than there are McDonald's restaurants.70 The number of tobacco retailers in a given area also contributes to tobacco-related health disparities, since tobacco retailers are disproportionately located in more heavily populated areas with a greater number of minority and low-income populations. For example, in Philadelphia, one study showed that low-income areas have 69% more tobacco retailers per person and more tobacco retailers within 500 and 1,000 feet of schools than highincome neighborhoods.⁷¹ In Washington, DC, little cigars and cigarillos and menthol tobacco products are cheaper in Black and some young adult neighborhoods.⁷² Recently, some localities have implemented caps on the number of retailer licenses they will allow, including Philadelphia, which saw a 20.3% reduction in tobacco retailers. especially in lower-income districts.73

San Francisco, which capped the number of tobacco retailer licenses, saw a 24% reduction in tobacco retail licenses with a 32% reduction in the lowest-income neighborhoods. 74 Some localities have enacted policies to restrict tobacco sales to adult-only facilities, which can be effective in reducing tobacco use. 33

3. Reduce nicotine levels in combustible tobacco products: Implement the planned FDA rule to reduce nicotine in cigarettes and other combustible tobacco products to non-addictive levels.

Capping the nicotine in combustible tobacco products at non-addictive levels will also make significant contributions in lowering the number of people who initiate smoking, help people quit, and reduce tobacco-related mortality. In fact, the FDA estimated that a nicotine cap in cigarettes would result in approximately 5 million additional smokers quitting smoking within one year of implementation and, by the year 2100, more than 33 million people – especially youth and young adults – would be prevented from becoming regular smokers, resulting in more than 8 million fewer tobacco-related deaths through the end of the century.⁷⁵

4. Improve cessation access: Federal, state, and local government agencies, as well as private insurers, should make cessation interventions as accessible as possible, including coverage for multiple quit attempts per year with no copays. Further, the FDA should quickly approve existing nicotine replacement therapies (NRT) for long-term use.

We know that other endgame policies will be less effective without improved access to cessation services. Quitting is difficult. It takes the average smoker 11 quit attempts before successfully quitting. The seven FDA-approved cessation drugs, as well as counseling and other behavioral interventions, can be very effective in helping tobacco users quit. It is important that people wishing to quit smoking have access to proven, safe, and effective drugs for the duration of their quit journey.

There are still **249 billion** cigarettes sold each year in the United States.

MEDIUM-TERM TO LONG-TERM ENDGAME PRIORITIES

These policies could take longer to put into place due to political and public readiness and/or the development of additional evidence to support them.

- 1. Develop new cessation interventions: It has been 17 years since a new drug has been approved for cessation, and additional effective cessation behavioral interventions and FDA-approved drugs are needed. 76 The FDA must create clearer pathways through FDA Centers such as the Center for Drug Evaluation and Research or the Center for Devices and Radiological Health (CDER and CDRH) for products and interventions that are proven to help people guit and have been approved as treatments. The pharmaceutical industry and others should continue to develop these tools and the FDA should facilitate an expedited approval pathway to the market. Although the FDA recently issued guidance on developing nicotine replacement therapy drug products,⁷⁷ more must be done.
- 2. Cap nicotine levels and delivery in all tobacco and nicotine products: The FDA should issue product standards to reduce the level of nicotine in all tobacco and nicotine products. The agency has already indicated that it will do so for cigarettes, but all tobacco products should be restricted to non-additive levels of nicotine.

The United Kingdom (UK), the European Union (EU), and Canada all restrict the level of nicotine allowed in e-cigarettes to 20 mg of nicotine/ml.^{71,78,79} While that level is still addictive and only applies to e-cigarettes, it is approximately half the level of nicotine found in the average e-cigarette in the U.S. There is currently no federal limitation on nicotine levels in any tobacco or nicotine product sold in the U.S. E-cigarettes sold in the U.S. contain anywhere

from 25mg/ml to 61mg/ml. For example, JUUL, Vuse, and similar cartridge e-cigarettes usually contain 5% nicotine (approximately 50mg/ml). A recent study showed that U.S. sales of e-cigarettes with greater than 5% nicotine have grown from 5% in 2017 to 81% in 2022.80

The UK and EU also restrict the maximum volume of nicotine-containing e-liquid refill bottles to 10 ml. The FDA's product standards should also be designed to limit the industry's ability to manipulate the e-liquid or other nicotine delivery (such as by using nicotine salts or otherwise manipulating the pH of nicotine, increasing the power of the battery, or the heating capacity) that allows a higher level of nicotine to be delivered. State and local jurisdictions can implement sales restrictions to limit the level of nicotine sold in their jurisdictions. For example, Massachusetts restricts the sale of e-cigarettes to those with a nicotine content of 35mg/ml or less, except in adult-only retail tobacco stores and smoking bars.⁸¹

3. Prohibit sales to younger generations: "Tobacco-Free Generation" or "Nicotine-Free Generation" policies are gaining momentum. These policies raise the minimum legal age for tobacco product sales by one year every year to phase out legal commercial tobacco and/or nicotine sales, effectively making it so that no one born after a specified date can be legally sold tobacco or nicotine.

In December 2022, New Zealand passed a law that will prevent those born after 2008 from ever being able to legally buy cigarettes. Importantly, New Zealand enacted several other policies at the same time to bolster this policy, including reducing the number of tobacco retailers to 600 in the country and reducing nicotine levels in cigarettes to non-addictive levels.⁸² In the U.S., in 2020, Brookline, MA, passed a Tobacco and Nicotine Free Generation law that prevents anyone born after January 1, 2000 from purchasing tobacco or vaping products.⁸³ Unsurprisingly, the tobacco industry and its partners sued Brookline. However, that lawsuit was dismissed by the Massachusetts Superior Court, opening the door for other cities in Massachusetts to consider

similar policies. At the state level, versions of Tobacco- or Nicotine-Free Generation bills have been introduced in the Nevada, California, and Hawaii state legislatures.

4. Restrict commercial sales of cigarettes and all other combustible tobacco products: Two
California cities have already taken the step
of prohibiting sales of all tobacco and nicotine
products within their jurisdictions and at least five
additional jurisdictions are currently considering
such a policy.⁸⁴

Despite protestations from the tobacco industry and their proponents, banning tobacco sales in various jurisdictions is not akin to prohibition from the 1920s – which we discuss further below. Furthermore, there is no evidence to suggest that bans would result in catastrophic retail losses, underground sales, or any of the other dire warnings promulgated by pro-tobacco audiences. Indeed, in Beverly Hills and Manhattan Beach, CA, where this policy has been in place for more than two years, no retailers have gone out of business since the policy was implemented.

IMPORTANT CONSIDERATIONS FOR ENDGAME POLICIES

Before these types of policies can be implemented, there are some critical considerations to take into account to ensure success of these policies and to reduce unintended consequences.

- First and foremost, access to cessation services
 must be expanded to help people currently
 smoking and using nicotine to rid themselves
 of their addiction for good. Infrastructure
 for cessation services needs to be built and
 expanded, especially in communities most
 impacted by tobacco.
- Endgame policies must be written so that they
 are not aimed at individual consumers but rather
 at tobacco and nicotine product manufacturers
 and retailers. Endgame policies must focus on the
 products themselves and policies should be written
 so that the violators are the manufacturers and

- retailers, not people who use, possess, or purchase tobacco or nicotine products.
- A coordinated approach that includes many different policies will be needed to achieve endgame. There is no silver bullet.
- Strong public education must be provided about the endgame policies under consideration to develop buy-in with members of the community who have been most impacted by the tobacco industry's marketing and targeting tactics and are suffering from higher levels of tobacco and nicotine use, and tobacco-related health issues. Implementing policies without such education and buy-in from the community and policymakers can backfire and leave communities susceptible to tobacco industry arguments that aim to confuse, obfuscate, or mislead the public about these policies and twist the debate over endgame policies to their advantage.
- Plans for educating retailers must be part of any endgame policy implementation. Retailers must not only be educated about the policies themselves, but also be provided with tools and ideas to replace tobacco sales with other products that may be more beneficial to the community and support their business.
- It is important to understand the tobacco and nicotine policy landscape before moving forward.
 It may be advantageous for some communities to address combustible tobacco first, and then turn to non-combustible and nicotine products. In other communities, there may be strong support for bolder policies, and that should be acted upon in the immediate.

\$8.06 billion on advertising and promotional expenditures for cigarettes alone.

WHAT TOBACCO AND NICOTINE ENDGAME POLICES ARE NOT

Just as important as detailing what endgame policies are is explaining what they are not. Endgame policies are not prohibition policies, in that they do not call for immediate or near-term prohibition of all commercial tobacco product sales, despite the goal of eventually eliminating commercial tobacco product use. The goal of these policies is to reduce the appeal, addictiveness, and availability of these products; to denormalize their ubiquity, desirability, and social acceptance; and to move populations to increasingly opt not to use them. These denormalization policies will not completely eliminate tobacco from the shelves for some time, but will increasingly reduce consumer demand and increase the use of cessation services, interventions, and therapies for those who need them.

The tobacco industry claims that an endgame strategy would return us to the time of 1920s alcohol prohibition and illicit markets. However, these scare tactics are vastly overblown. Firstly, as we have advocated above, these policies are aimed at the manufacturers and retailers, not those who use tobacco products. Unlike alcohol prohibition in the 1920s, these policies are not intended to criminalize use or possession. Further, researchers have concluded that the likelihood of an illicit market would be relatively small, particularly if cessation services are increased, and other safeguards are put into place. 85 The simple fact is that the tobacco industry has always labeled tobacco taxes, flavor restrictions, and policies that remove nicotine as "prohibition." 86 In none of those cases is that true tobacco products still remain on the market under each of those policies, but they are more expensive, less appealing, and less addictive - all of which deter young people and people who have not used tobacco or nicotine from trying such products and encourage people who currently use tobacco or nicotine to quit. Done properly, a comprehensive collection of endgame policies will instead make tobacco something that people simply do not want.

ACTION NEEDED ON ENDGAME POLICIES

In order to truly achieve a culture where young people reject tobacco, vaping, and nicotine and realize our vision of a future where commercial tobacco and nicotine addiction are a thing of the past, we must set bold targets and hold ourselves accountable to them.

Truth Initiative advocates that the public health community take the following actions to accelerate progress:

- Begin thinking in terms of endgame not tobacco control. Changing our mindset from merely managing tobacco to one where we recognize that tobacco no longer needs to be a part of our culture is a critical first step in changing our outlook and our work. This will require determining the best way to message this new thinking to the public, so that we can not only educate about endgame and what it means, but inspire the public to adopt these policies that will make tobacco and nicotine a thing of the past.
- 2. Educate policymakers, the public, and consumers about what endgame is and what it isn't. As we noted above, the public's tolerance for tobacco and nicotine products and the continued development of more products that addict our kids is low and we must harness that momentum. We have already seen examples of how this has been implemented in California and Massachusetts with their flavored tobacco sales prohibitions, as well as in places like Brookline, MA, Beverly Hills, CA, and now in New Zealand.
- 3. Similarly, we must hold the tobacco industry accountable for its role in perpetuating tobacco use among youth and young adults and diverting attention from new endgame measures. We must remind policymakers and the public of the lengths the tobacco industry has gone to market to youth, Black Americans, the LGBTQ+ community, those dealing with mental illness, and low-income and low-socioeconomic individuals. More recently, one tobacco manufacturer has been held accountable by the U.S. government for

violating U.S. sanctions and selling cigarettes and other tobacco products to North Korea. ⁸⁷ Similarly, just like cigarette manufacturers before them, e-cigarette maker Juul has been held accountable by many state governments for its egregious actions in misleading consumers and marketing its products to youth. We must take advantage of this and other opportunities to remind the public and policymakers of the true intentions of these companies and take action now.

- 4. Governments at the state and local levels must redouble their efforts to implement the policies that best serve their communities and build toward the end of tobacco. This will involve different policies for different communities based on the foundations already laid in those communities. For some communities it will initially take steps such as implementing comprehensive smoke-free laws, raising taxes, increasing tobacco product prices, and continuing to increase funding for prevention and cessation measures. Other communities with those measures already in place should be ready to take stronger next steps toward endgame. Regardless of where any particular community is starting, this is a journey we all should be on.
- 5. At the federal level the FDA must act quickly to finalize the menthol cigarette and flavored cigar rules to get those products off the market, and to quickly move forward with its plans to cap the nicotine levels in combustible products.
 - a. Additionally, the FDA must work through the PMTA process and through new rulemaking to remove all flavored tobacco and nicotine products from the market, except for FDAapproved cessation products. This is the most equitable way to ensure that all people can benefit from endgame policies.
 - The FDA must work expeditiously to propose and finalize a nicotine standard for all combustible products and move toward nicotine standards for all tobacco and nicotine products.

An estimated **380,000 retailers** sell tobacco products in the U.S. To put this into perspective that is **28 times** more tobacco retailers than there are McDonald's restaurants.

- 6. Prepare for tobacco industry attacks and misdirection. We know that the tobacco industry has fought (and will continue to fight) these policies tooth and nail. The public health community must develop research, arguments, and adequate funding to counter industry's misinformation around these policies.
 - a. The industry often states that flavor policies will increase unnecessary interactions with police for Black Americans. While over-policing and over-incarceration is a huge issue in our country that must be addressed, 157,000 Black Americans have died prematurely between 1980-2018 due to menthol cigarettes.88 In order to reverse this trend, bold action must be taken. At the same time, it is critical that laws are written to hold tobacco manufacturers and retailers accountable - not consumers. Likewise, it will be important to engage and work with credible community leaders to prevent conflating the challenge of addressing racial inequities in our society with the targeting of certain populations by the industry and the resulting harms suffered by them.
 - b. We must also be wary and ready to counter distractions that the industry uses to prolong its business, such as the co-opting of harm reduction and policies that only serve to grow the nicotine market and increase the tobacco industry's bottom line. We must reclaim the narrative around harm reduction as a toolbox with many potential actions to limit harms and not a product strategy as defined by the industry.

CONCLUSION

While recent history has seen steady decreases in cigarette smoking in both youth and adults, with both at all-time lows, smoking and related deaths and harms remain at unnecessary and unacceptable levels. Futher, the last decade has brought increases in youth and young adult tobacco and nicotine use with the youth e-cigarette crisis at the heart of that reversal in progress. We must move quickly to take advantage of the reduced prevalence of cigarette smoking, turn the tide on youth e-cigarette and nicotine use, and make progress to reduce all tobacco and nicotine product use.

Tobacco-related death, disease, and consequences of addiction are still a major public health problem and are responsible for significant drags on our economy in the form of lost productivity and medical costs, increasing the burden on governments, the private sector, and households of people who use these products.

It took 50 years to implement smoke-free laws, which still only cover 61.1% of the U.S. population.⁸⁹ We simply cannot afford to spend another half-century to slowly enact endgame policies that in many cases only benefit a portion of the country. Some endgame policies are within our reach, and we need to harness the energy and implement them as soon as possible so that we can begin reaping their benefits, improving the health of those who use tobacco and nicotine, and making great strides toward the end of tobacco.

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