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R STREET POLICY STUDY NO. 115  
October 2017

## REDUCING NICOTINE IN CIGARETTES: CHALLENGES AND OPPORTUNITIES

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### INTRODUCTION

In a July 28 announcement, Dr. Scott Gottlieb, recently appointed as the 23<sup>rd</sup> commissioner of the U.S. Food and Drug Administration (FDA), committed his agency to introduce a new guiding philosophy for the regulation of tobacco and nicotine. The associated news release set out the agency's desire for a "new comprehensive plan for tobacco and nicotine regulation" and for an "approach [that] places nicotine, and the issue of addiction, at the center of the agency's tobacco regulation efforts."<sup>1</sup>

The focus on nicotine, rather than tobacco, is an effort to address the underlying cause of smoking-related diseases and deaths – that is, that people smoke tobacco primarily to consume nicotine. By lowering nicotine levels in cigarettes to nonaddictive levels, we could decrease the likelihood that

1. U.S. Food and Drug Administration, "FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death, News release, July 28, 2017. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm>.

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future generations become addicted to cigarettes and allow more currently addicted smokers to quit.<sup>2</sup>

This approach is at least *internally* coherent and it could work if several major assumptions about how the market will react to this measure turn out to be correct. However, this is a very dramatic intervention in the \$94 billion U.S. market for cigarettes<sup>3</sup>, in which the main product, traditional full-nicotine cigarettes, would effectively be removed from the market.

The severe challenge for FDA is that it really does not know, and perhaps cannot know, how the market will react to such an intervention. Nor do we know how those affected as consumers, suppliers and law enforcement will react to the criminalization of a personal behavior practiced by roughly 38 million Americans and that has always been legal. In all likelihood, there will be both cultural and personal responses. For example, it is quite possible that, as hoped, teenagers will simply stop smoking or never get hooked in the first place. However, it is also possible that they will simply source full-nicotine cigarettes from a resultant black market. The bottom line is that the FDA cannot know which one will predominate.

2. U.S. Food and Drug Administration, "FDA's New Plan for Tobacco and Nicotine Regulation," July 28, 2017. <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm568425.htm>.

3. Euromonitor International, *Cigarettes in the US*, July 2017. <http://www.euromonitor.com/cigarettes-in-the-us/report>.

The risks of such potential for unintended, real-world consequences has been recognized within the FDA. Showing appropriate caution, Gottlieb charged the agency to “begin a public dialogue” about lowering nicotine levels in combustible cigarettes and to consider the potential for unintended consequences that may arise from such rulemaking:

I’ve also asked CTP [Center for Tobacco Products] to explore the potential for any adverse effects from reducing nicotine levels, especially the possibility of a black market for higher nicotine products. And we need to understand what role, if any, the availability of newer forms of nicotine delivery may play in reducing those adverse effects.<sup>4</sup>

Very little of the research undertaken so far provides any insight into the way the market will respond, nor does it help to elucidate the nature and extent of unintended consequences. For this reason, the outcome of this initial dialogue will likely be a list of unanswered, and perhaps unanswerable, questions about what effects, good or bad, such a huge intervention might have. For these reasons, the present study seeks to explore some of the issues facing the FDA and proponents of the nicotine-reduction strategy and to suggest a potential way forward.

## SUMMARIZING THE FDA STRATEGY

In pursuing a nicotine-reduction strategy, the FDA is not trying to eliminate the use of nicotine, but rather to reshape the landscape of its use in order to eliminate the most harmful delivery systems—traditional cigarettes—while encouraging smokers to quit or switch to much lower-risk nicotine products. In doing so, the FDA correctly recognizes that exposure to the toxic products of tobacco combustion—not nicotine itself—is the cause of harm. However, it sees toxicity as the *proximate* cause of disease, with the *underlying* cause being the addiction to nicotine when delivered by cigarettes as the ultimate reason for harmful exposure, and the reason young people become dependent smokers after a period of experimentation.

Accordingly, the FDA’s strategy can be summarized under four main headings:

1. Make the most harmful form of nicotine use, cigarette smoking, nonaddictive.

By lowering nicotine levels in cigarettes to subaddictive levels, the FDA would remove the most important reason for smoking – the psychoactive effects of nicotine. This, it hopes, would prevent uptake among teenagers and would

cause adults to quit smoking or switch to smoke-free nicotine products.

2. Ensure high-quality, low-risk alternative nicotine products are available in the marketplace.

Adult users of nicotine should be able to switch to satisfactory, low-risk and widely available alternatives that are appropriate for the protection of public health – vapor products, heated tobacco products, smokeless tobacco or other forms of noncombustible nicotine delivery. In order to meet this anticipated demand, the FDA will need to develop a more streamlined and proportionate regulatory system based on straightforward standards and clearer guidance with respect to its approval system, the Pre-Market Tobacco Application (PMTA). It has extended the time available to put this system in place by deferring enforcement of the most demanding requirements of the Tobacco Control Act (TCA) for e-cigarettes until 2022.

3. Improve pharmaceutical smoking-cessation products.

FDA will review its approach to authorizing pharmaceutical smoking-cessation medication to ensure that these are as effective as possible in helping smokers who wish to quit. It is possible that risk-aversion about the abuse liability (addictiveness) of such products has constrained their effectiveness as smoking-cessation medications, but at the cost of additional smoking. The FDA implies it will look into rebalancing these tradeoffs in favor of smoking cessation.

4. Protect youth from any nicotine use.

Finally, the FDA proposes a range of strategies to prevent youth smoking, including possible bans on flavors or flavor descriptors that it suggests might entice young people to take up nicotine use. The evidence for this is very poor, and it is quite possible that an uptake of teenage vaping has contributed to the unusually rapid decline in teenage smoking since 2010. The FDA correctly identifies that flavors might play an important role in attracting smokers to vaping and seeks views on this.

The intent of these combined strategies is to reframe tobacco control through a focus on nicotine and addiction, rather than on cigarettes themselves. However, this package will have far-reaching consequences that must be carefully considered before this strategy is made operational.

## NICOTINE REDUCTION AND NICOTINE-SEEKING BEHAVIOR

Proponents of nicotine reduction must overcome a major underlying problem, based on what we know of smoking; namely, that it is primarily a nicotine-seeking behavior.

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4. U.S. Food and Drug Administration, “FDA announces comprehensive regulatory plan.”

Indeed, it has long been understood that, “people smoke for the nicotine but die from the tar.”<sup>5</sup>

A fundamental feature of nicotine-seeking behavior is that smokers will try to achieve a satisfactory nicotine exposure in whatever way they can. Accordingly, if the nicotine in combusted smoke is diluted or fewer cigarettes are available because they are more expensive, smokers compensate—usually by subconsciously adjusting smoking intensity to take more puffs or more intensive puffs per cigarette.<sup>6</sup> If it is not possible to obtain an adequately satisfying nicotine exposure through adjusted smoking behavior, then it is possible to use different nicotine products—those not covered by the reduced-nicotine rule—or illicit full-nicotine cigarettes.

Although investigators are in the process of conducting trials to explore what happens in practice,<sup>7</sup> high levels of noncompliance,<sup>8</sup> high dropout rates<sup>9</sup> and signs of compensatory smoking in more dependent users<sup>10</sup> suggest very low nicotine cigarettes (VLNC) will prompt a wide range of compensatory responses.

In the case of a rule that reduces the nicotine to subaddictive levels, compensation by changing puffing intensity is unlikely to be viable, as the user would need to absorb too much smoke. The most likely form of compensatory behavior, then, is simply not to use these products at all, and instead to seek nicotine from other products.

## ISSUES THE FDA WILL NEED TO ADDRESS

A wide range of potential issues and objections need to be considered if this shift in policy is to be a viable one.

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5. Mike Russell, “Low-tar medium nicotine cigarettes: a new approach to safer smoking,” *The BMJ* 1 (1976), 1430–33. <http://www.bmj.com/content/1/6023/1430>.

6. Neal L. Benowitz, “Nicotine Addiction,” *The New England Journal of Medicine* 362:24 (June 17, 2010), 2295–303. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2928221>.

7. See, e.g., Eric C. Donny, Rachel L. Denlinger, et al., “Randomized Trial of Reduced-Nicotine Standards for Cigarettes,” *The New England Journal of Medicine* 373: 14, (Oct. 1, 2015), 1340–49. <http://www.nejm.org/doi/full/10.1056/NEJMsa1502403>; and Neal L. Benowitz, Katherine M. Dains, et al., “Smoking Behavior and Exposure to Tobacco Toxicants during 6 Months of Smoking Progressively Reduced Nicotine Content Cigarettes,” *Cancer Epidemiol Prev Biomarkers* 21:5 (May 2012). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3348427>.

8. See, e.g., Frank C. Bandiera, Kathryn C. Ross, et al., “Nicotine Dependence, Nicotine Metabolism, and the Extent of Compensation in Response to Reduced Nicotine Content Cigarettes,” *Nicotine Tob Res.* 17:9 (September 2015), 1167–72. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4542742>.

9. See, e.g., Melissa Mercincavage, E. Paul Wileyto, et al., “Attrition during a randomized controlled trial of reduced nicotine content cigarettes as a proxy for understanding acceptability of nicotine product standards,” *Addiction* 112:6 (June 2017), 1095–1103. <http://onlinelibrary.wiley.com/doi/10.1111/add.13766/abstract>.

10. Natalie Nardone, Eric C. Donny, et al., “Estimations and predictors of non-compliance in switchers to reduced nicotine content cigarettes,” *Addiction* 111:12 (December 2016), 2208–16. <http://onlinelibrary.wiley.com/doi/10.1111/add.13519/abstract>.

## Nicotine reduction acts as a prohibition on cigarettes

The main reason people smoke cigarettes is for the nicotine. After all, the purpose of a cigarette and the reason for its commercial success is its delivery of nicotine as a mild psychoactive drug that provides reward and modulates mood:

Nicotine induces pleasure and reduces stress and anxiety. Smokers use it to modulate levels of arousal and to control mood. Smoking improves concentration, reaction time, and performance of certain tasks.<sup>11</sup>

In view of this, a cigarette with nicotine lowered to a minimal level does not provide these functional rewards and no longer meets the common definition of a cigarette, just as whiskey with alcohol reduced to 1 percent would no longer be whiskey by any common-use definition. Such a change in the alcohol content would alter the product itself in fundamental ways. After all, part of the essence of whiskey is its alcohol content. Like cigarettes, whiskey also provides a sensory experience, flavors and aromas that make whiskey what it is. These characteristics are necessary in whiskey, but they are not sufficient without the alcohol.

Thus, if the FDA follows the most commonly expressed proposal of a twentyfold to fortyfold reduction of the nicotine concentration in a tobacco cigarette,<sup>12</sup> the resulting product would not have the psychoactive rewards that users seek.<sup>13</sup> Accordingly, such expansive measure would not so much convert the existing cigarette market to low-nicotine cigarettes as it would eliminate the cigarette category altogether. This would be a *de facto* prohibition on a market that supplies 38 million Americans<sup>14</sup> and, in 2016, had retail sales of \$94 billion.<sup>15</sup>

In fact, there is little evidence that prohibitions of established products have worked at all well, at least in the absence of a superior alternative. For this reason, advocates of nicotine reduction should heed the lessons learned from other attempted prohibitions—like, for example, those on

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11. Benowitz, “Nicotine Addiction,” 2298. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2928221>.

12. In 2015, a World Health Organization advisory group recommended a standard of no more than 0.4mg/g nicotine of dry tobacco, as compared to the 15–20mg/g found in conventional products. See e.g., World Health Organization, *Advisory note: global nicotine reduction strategy*, WHO Study Group on Tobacco Product Regulation, 2015. [http://www.who.int/tobacco/publications/prod\\_regulation/nicotine-reduction/en](http://www.who.int/tobacco/publications/prod_regulation/nicotine-reduction/en).

13. Neal L. Benowitz and Jack E. Henningfield, “Establishing a Nicotine Threshold for Addiction—The Implications for Tobacco Regulation,” *The New England Journal of Medicine* 331 (July 14, 1994), 123–25. <http://www.nejm.org/doi/full/10.1056/NEJM199407143310212>.

14. National Center for Health Statistics, “The National Health Interview Survey Early Release Program: Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–2016, 2016, Figure 8.1. [https://www.cdc.gov/nchs/data/nhis/earlyrelease/Earlyrelease201705\\_08.pdf](https://www.cdc.gov/nchs/data/nhis/earlyrelease/Earlyrelease201705_08.pdf).

15. *Cigarettes in the US*. <http://www.euromonitor.com/cigarettes-in-the-us/report>.

alcohol<sup>16</sup> and illicit drugs.<sup>17</sup> It should be noted that there are differences, as the reduced nicotine proposal is a ban on a drug-delivery system, and not the drug per se. However, the delivery system in question happens to be by far the most common way to use nicotine, and the most addictive.

### Pressure to broaden the scope of the rule

Historically, low-nicotine cigarettes have not been commercially viable, even as niche products.<sup>18</sup> For example, between 1989 and 1993, Phillip Morris U.S. introduced nicotine-free Next, Merit and Benson & Hedges variants. These failed, even after a \$200 million investment. A decade later, Vector Tobacco Inc. again tried and failed when they introduced their Quest variation in eight U.S. states. Similarly, in 2015, 22<sup>nd</sup> Century Group launched “Magic Zero” in Spain, which is a nicotine-free cigarette produced with genetically modified tobacco. It has not yet become a commercial success.

One reason for the unpopularity of these products is that they are competing with regular nicotine content cigarettes. It is conceivable that if VLNCs were the only available product, people would switch. However, the FDA’s nicotine-reduction proposal is currently limited only to cigarettes, which means that smokers will continue to have other options to consume nicotine—including in other combustible tobacco products, such as hand-rolled tobacco, cigars and pipes. Recognizing this weakness, some proponents of low nicotine cigarettes have suggested broadening the rule to most combustible forms of tobacco.<sup>19</sup> Even if the scope of the measure is broadened, it is difficult to imagine dependent smokers using their own money to pay for very low nicotine cigarettes under realistic market circumstances when these products provide none of the physiological rewards provided by nicotine.

### The compliance fallacy

Naïve assumptions about how markets will respond to regulations tend to yield a compliance fallacy. This problem plagues projections of the likely outcomes of the FDA’s nicotine-reduction proposal. Any regulation that radically changes a familiar, widely used product is a major intervention—and in this case, a far larger one than any other tobacco control policy has ever attempted. The larger the interven-

tion, the greater the scope for unintended harms to overwhelm regulators’ good intentions. This is particularly likely to be true in a market driven by physiological dependence. In light of this, here are some of the likely responses available to consumers:

- Stockpiling conventional cigarettes or trading with stockpilers;
- Importing conventional cigarettes for personal use through the internet;
- Switching to other combustible products: hand-rolled tobacco, pipes, cigars or little cigars;
- Procuring legitimately made or counterfeit nicotine cigarettes via the black market;
- Procuring counterfeit low-nicotine cigarettes that, in fact, have high nicotine content;
- Adding nicotine liquid to low-nicotine cigarettes;
- Using VLNC with other nicotine products concurrently;
- Rising use of fraudulent solutions and quack remedies;
- Using vaping, heated tobacco and smokeless tobacco products;
- Smoking cessation – with relapse to different nicotine products.

What is certain is that a reduced-nicotine standard will alter the behavior of millions of consumers, perturb the supply chain and stimulate innovation (whether legitimate or criminal) in products and commerce.

### Outstanding key policy questions

Thus far, much of the research on the nicotine-reduction strategy has focused on what happens when consumers use VLNCs under trial conditions.<sup>20</sup> Though the work is extensive and of high quality, it is unlikely much of it will have practical value, because the vast majority of consumers are no more likely to take up these alternative forms of low-nicotine smoking than they are to drink low-alcohol whiskey. Currently, there is simply no evidence to suggest people will use VLNCs and thus there is no reason to believe they will. In fact, on the contrary, experience to-date suggests they will not.

To date, the major trials on low-nicotine products have involved recruiting volunteers willing to be the subjects of

16. Lisa McGirr, *The War on Alcohol: Prohibition and the Rise of the American State* (New York: W.W. Norton & Co.), 2015, p. 352.

17. See, e.g., Steve Rolles S, George Murkin, et al., *Counting the Costs: The Alternative World Drug Report* 2nd edition, Transform Drug Policy Foundation, 2016. <http://www.countthecosts.org/alternative-world-drug-report-2nd-edition>.

18. See, e.g., Rolf Lutz, “Nicotine Reduction Strategy - The Promise and the Peril,” Philip Morris International, Sept. 28, 2016. [https://www.pmiscience.com/system/files/publications/gtnf2016\\_nicotine\\_reduction\\_pmi\\_perspective\\_rolf\\_lutz\\_28092016.pdf](https://www.pmiscience.com/system/files/publications/gtnf2016_nicotine_reduction_pmi_perspective_rolf_lutz_28092016.pdf).

19. Neal L. Benowitz, “Comprehensive Nicotine Regulation to End the Combustible Tobacco Epidemic,” *Annals of Internal Medicine* 40, Aug. 15, 2017, 170–80.

20. See, for example, National Institutes for Health research program U54 DA031659 and 47 related grants totaling spending of \$58,238,110 from 2011-15. <http://grantome.com/search?q=U54+DA031659>.

experiments, giving them free products, paying them to join the trial and offering incentives to stay the course.<sup>21</sup> These conditions could not be more different from those real-world behavioral influences that shape the economic behavior of participants in a consumer market, who have a wide range of alternative strategies available to them.

Accordingly, policymakers who promote a reduced-nicotine strategy must address several tests of credibility, which requires assessing the likely real-world costs, benefits, risks and alternative options. These include:

- The public health test of the Tobacco Control Act, Section 907, which requires the FDA to show that the rule is “appropriate for the protection of the public health;”<sup>22</sup>
- Executive orders<sup>23</sup> that govern good regulatory practice and require the FDA to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, as well as distributive impacts and equity);
- The Regulatory Flexibility Act,<sup>24</sup> which requires the FDA to analyze regulatory options that would minimize significant impacts of a rule on small businesses;
- The Unfunded Mandates Reform Act, which requires the FDA to prepare a written statement that includes an assessment of anticipated costs and benefits before issuing “any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.”<sup>25</sup> The proposed rule’s impact on tax collection could trigger this provision.

There is very little understanding of how this complex system will react to a reduced-nicotine rule in practice, or even how an assessment could be made. For example, there are few insights into the likely size of the black market that such

a measure would create, or even into how such an assessment could be undertaken. This is because the system is highly complex and includes a largely heterogeneous population of consumers, the entire supply chain from farm to convenience store for cigarettes and numerous alternatives, connections to international markets, law-enforcement agencies and criminal enterprises from cartels to street dealers.

### The weak legal mandate

Currently, there is no positive congressional mandate that requires or even encourages the FDA to reduce nicotine in cigarettes. On the contrary, the Tobacco Control Act, Section 907, which appears in its entirety as follows, expressly prohibits the FDA from certain actions in this area of rule-making:

#### **Limitation on Power Granted to the Food and Drug Administration. Because of the importance of a decision of the Secretary to issue a regulation**

A. 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

B. requiring the reduction of nicotine yields of a tobacco product to zero, the Secretary is prohibited from taking such actions under this Act.<sup>26</sup>

The FDA believes it has a mandate only because these limitations do not specifically extend to its proposals to reduce nicotine to very low levels. In this way, it draws its authority from the *absence of a constraint*, rather than a specific endorsement of such action. Its proponents claim it is neither an attempt to ban cigarettes, nor to reduce nicotine levels to zero. Yet it has the same practical effect. Further, and as previously argued, a cigarette with a subaddictive level of nicotine is no longer, in essence, a cigarette.

In terms of congressional intent, the chapeau to the clause is helpful, as it refers to the “importance of a decision” having the effect of banning cigarettes or reducing nicotine yields to zero, and reserves such decisions for Congress to make. It follows that Congress would expect rules that have the equivalent effect to be equally important, and thus reserved for Congress.

21. Donny, Denlinger, et al. <http://www.nejm.org/doi/full/10.1056/NEJMsa1502403>.

22. Tobacco Control Act of 2009, Section 907(a)(3). <https://www.fda.gov/tobacco-products/labeling/rulesregulationsguidance/ucm263053.htm>.

23. Executive Order 13563 of Jan. 18, 2011 Improving Regulation and Regulatory Review. [https://www.reginfo.gov/public/jsp/Utilities/EO\\_13563.pdf](https://www.reginfo.gov/public/jsp/Utilities/EO_13563.pdf); and Executive Order 12866 of Sept. 30, 1993 Regulatory Planning and Review. [https://www.reginfo.gov/public/jsp/Utilities/EO\\_12866.pdf](https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf).

24. The Regulatory Flexibility Act of 1980 (as amended). <https://www.sba.gov/advo-cacy/regulatory-flexibility-act>.

25. Unfunded Mandates Reform Act of 1995, Section 202(a). <https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/legislation-and-regulations/unfunded-mandates-reform-act>.

26. Federal Food, Drug, and Cosmetic Act – Section 907(d)(3), “Tobacco Product Standards.” <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm263053.htm>.

## The weak political mandate

Given that the FDA's strategy brings it close to, and arguably breaches, the legal constraints Congress placed on the FDA's rulemaking discretion through the Tobacco Control Act, it is highly likely that Congress will wish to reassert its authority over such decisions—even if the courts do not find that the FDA has exceeded its authority. If Congress feels its policy intent is not being taken seriously, then it can amend the act, pass a bill or attach riders to budget appropriations in ways that prevent this course of action.

By continuing to advance this measure, the FDA takes Congress literally but not seriously, and the agency would do well to recognize that Congress expects to authorize rulemaking of this significance. The agency should therefore be cautious in its attempt to circumvent congressional authority.

More importantly, in a liberal democracy, an intervention of this magnitude should not proceed without an explicit affirmative political mandate for a particular and well-defined proposal. Both legally and democratically, it is insufficient to rely on a negative mandate. In other words, unlike the current proposal, an effective strategy should not hinge on the infringement of the mere letter of an exclusion clause that may not properly have captured congressional intent and/or have envisaged rulemaking. Moreover, a broad political mandate is required because the measure will have wide-ranging impact on many stakeholder groups outside the normal purview of food and drug regulation.

## Fierce, diverse and legitimate stakeholder opposition

In addition to such legal and legislative challenges, the landscape of stakeholders likely to be hostile to such a proposal will be powerful and well-resourced. Key stakeholder constituencies include:

- *The 38 million American smokers:* Particularly, members of subgroups who face notable challenges, such as those with psychiatric conditions, illicit drug users, the prison population, veterans or senior citizens.
- *Federal and state treasuries:* In 2014, federal, state and municipal taxation and Master Settlement payments on cigarette sales generated \$41.6 billion of revenue.<sup>27</sup> It is not clear what replacement revenue streams could be found. If those revenues came from taxes on noncombustible nicotine products, the effect could be to reduce switching and divert more smokers to the illicit cigarette market.

27. On average, federal and state excise taxes account for approximately 44 percent of the retail price of cigarettes. See e.g., "The Tax Burden on Tobacco," *Orzechowski and Walker Historical Compilation* 49 (2014), iv. [https://old.taxadmin.org/fta/tobacco/papers/tax\\_burden\\_2014.pdf](https://old.taxadmin.org/fta/tobacco/papers/tax_burden_2014.pdf).

- *Supply chain participants:* From tobacco multinationals to those who own corner stores, many stakeholders will be concerned that their business is simply being transferred to any illicit trade that emerges.
- *Domestic market tobacco farmers:* There will be little point in growing low-nicotine tobacco, as there is unlikely to be much demand for it.
- *Customs and Border Protection officers:* They may be required to address a growing internet trade in nicotine products or imported cigarettes from Canada or Latin America.
- *Community-level law enforcement:* They are likely to be concerned about the challenges of enforcing a new class of offenses that apply to previously law-abiding citizens, draw on resources and potentially create new tensions or opportunities for corruption.
- *Federal law-enforcement agencies:* Agencies like the FBI and Drug Enforcement Administration could be concerned about organized crime and criminal networks having additional sources of income and greater reach.
- *Politicians*—The 15 percent of the adult population who currently smoke represents a significant share of the electorate. Such a strong federal government intervention will engage "small government" activists and populists.

It remains a challenge for the FDA to map the full range of stakeholders and the impacts on these groups, but this will be necessary if it is to justify its rule. Further, there is very little extant research that would inform a full stakeholder analysis.

## ALTERNATIVE AND COMPLEMENTARY APPROACHES

Not only does the FDA have to show that the reduced-nicotine rulemaking is viable and that overall benefits exceed costs, but it also has to compare it with other options and show that this is the best means to achieve these policy goals. If the goal of the policy is to make smoking less attractive and ultimately unviable, there are more efficacious alternatives.

### Reduce toxins relative to nicotine

Given that the primary danger in cigarettes is the toxins and not the nicotine, and that smokers are seeking the nicotine and not the toxins, a better strategy could be selectively to reduce toxins relative to nicotine. This is the opposite of a nicotine-reduction strategy but it conforms better to the normal regulatory practice of reducing toxicity and raising purity. This would mimic the strategy that the tobacco companies have pursued for many years, wherein they identify harmful

agents and remove them either at the source or through filtration. Many of these product prototypes have been created, but none have proven an acceptable alternative to products currently on the market. This is likely because to make specific toxin reductions mandatory changes the character and flavor of the products in ways that are off-putting to smokers. Such a strategy would still face the same viability challenges as the FDA's alternative but, at the very least, would not run the risk of mandating *more* harm. Further, the FDA already has research in place to inform such a strategy.<sup>28</sup>

## Taxation

The approach taken to reduce the appeal of smoking does not have to involve product standards. It could instead involve taxation – and it is possible to argue that this route has not been exhausted in the United States. For example, the United States could raise taxes for tobacco to levels found elsewhere. In 2015, for example, the World Health Organization reported that the most popular cigarette brand in the United Kingdom retailed for 8.35 pounds (\$11.10), with total taxes representing 82.16 percent of the price, compared to \$6.23, with total taxes of 42.54 percent of the price in the United States.<sup>29</sup> Economically, the approach of reducing nicotine to nonaddictive levels is similar to raising taxes to unaffordable levels. Both function as a strong disincentive to smoke and ultimately a *de facto* prohibition. Thus, both are vulnerable to diversion toward a black market. The advantage of taxation, however, is that it can be applied more gradually and may not result in rapid contraction of tax revenues.

## Other tobacco control measures

In addition to raising prices, much of tobacco control consists of degrading the value of smoking by making it less acceptable and more inconvenient, and by diminishing any glamor or other positive values associated with it. Overall, decreases in the acceptability and other positive attributes associated with smoking are correlated with decreased initiation to smoking. However, this has mixed effects on current smokers. It generally increases the intention to quit and associated quit attempts, while further marginalizing smokers.<sup>30</sup> The FDA and proponents of the reduced-nicotine approach will not only need to show that their proposal is viable, but also that it is the best option available to achieve the desired

outcome, which must include a wider assessment of impacts beyond public health.

## A CREDIBLE FRAMEWORK FOR NONCOMBUSTIBLE NICOTINE PRODUCTS

Accordingly, the superior and more urgent strategy is to promote the migration of smokers from combustible to noncombustible “alternative nicotine delivery systems” *by choice*. We have described options to improve the FDA's approach in this regard in earlier publications.<sup>31</sup> These changes should include:

- Reducing the costs and unnecessary paperwork burdens of applications;
- Clarifying and simplifying the requirements for pre-market approval of new products;
- Using product standards to provide clarity on what is expected of manufacturers;
- Dealing with as many issues as possible at the category level to reduce wasteful repetition;
- Taking a more proactive approach to risk communication so that consumers have better awareness of the relative risks of smoked and smoke-free products;
- Taking an approach to the “public health test” that recognizes excessive caution can result in population harm through lost opportunities to stop smoking;
- Reducing the burdens of application for innovations, especially those that increase safety, usability and user awareness.

By delaying enforcement of PMTAs to 2022, promising to clarify guidance and to use standards to reduce the burdens on applicants, the FDA has placed some emphasis on this last strategy.<sup>32</sup> However, the commitment is weak and vague. Instead, the FDA needs to focus on a simple and risk-proportionate route to market for noncombustible consumer nicotine products. This is a prerequisite for its reduced-nicotine strategy and, if successful, will render the strategy unnecessary.

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28. See, e.g., U.S. Food and Drug Administration, *Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act*, March 2012. <https://www.fda.gov/TobaccoProducts/Labeling/RegulationsGuidance/ucm297752.htm>.

29. World Health Organization, “Appendix II: Tobacco Taxes and Prices,” 2015, 135 and 139. [http://www.who.int/tobacco/global\\_report/2015/appendix2.pdf?ua=1](http://www.who.int/tobacco/global_report/2015/appendix2.pdf?ua=1).

30. See, e.g., João Mauricio Castaldelli-Maia, Antonio Ventriglio, et al., “Tobacco Smoking From ‘glamour’ to ‘stigma’: A comprehensive review,” *Psychiatry and Clinical Neurosciences* 70:1 (January 2016), 24–33. <http://onlinelibrary.wiley.com/doi/10.1111/pcn.12365/full>.

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31. See, e.g., Clive Bates, Eli Lehrer, et al., “Reshaping American Tobacco Policy: Eight federal strategies to fight smoking and ignite a public health revolution,” *The Counterfactual*, February 2017. <https://www.clivebates.com/reshaping-american-tobacco-policy-eight-proposals-for-the-trump-administration>; and Clive Bates, “Rethinking nicotine: implications for U.S. federal tobacco policy – A discussion paper,” June 2017. <https://www.clivebates.com/documents/FDAREformJune2017.pdf>.

32. U.S. Food and Drug Administration, “FDA's New Plan for Tobacco and Nicotine Regulation,” Press Release, July 28, 2017. <https://www.fda.gov/tobaccoproducts/new-sevents/ucm568425.htm>.

## THE COERCION PARADOX

The reduced-nicotine proposal would create a forced, state-imposed behavioral change for most of America's 38 million adult smokers. The degree of coercion involved, and predictable backlash, is a major vulnerability for such a policy. For the effects of such coercion to be remotely acceptable and manageable, it will be important to have good full-nicotine low-risk alternatives—vapor products, heated tobacco and smokeless products—available for smokers to migrate to. This approach is gaining support among proponents of the reduced-nicotine concept.<sup>33</sup> These alternatives need to be sufficiently good substitutes for smoking and acceptable to almost all users—something that may be achievable over the next 10-20 years, given a pro-innovation regulatory regime.

But therein lies the paradox: if the products are good enough substitutes for smoking, then the coercive approach becomes unnecessary, and markets and consumer preferences will generate the necessary transition. When the alternatives are good enough, the need to reduce nicotine in cigarettes diminishes and the benefits decline.

## THE REAL VALUE OF THE REDUCED-NICOTINE STRATEGY

As with nuclear weapons, a major regulatory intervention does not have to be used to be useful.

It may be that the prospect of reduced-nicotine cigarette regulation is an important driver of change, but primarily by virtue of the supporting changes that are required to make it viable and the signaling effect it has on the industry. In more formal terms, it could perform the function of an “agency threat”<sup>34</sup> – a measure that signals a direction and regulatory intent (in this case, the endgame for combustion), and can be deployed if the regulated industries fail to follow this direction. To work as an agency threat, the prospect of the reduced nicotine measure has to be credible. It follows that to be successful either as a measure that is implemented or as a threat, the FDA will need to appear to create a viable proportionate regulatory framework for low-risk alternatives. The main benefit, then, of the reduced-nicotine rule is that it requires the FDA to fix the regulatory framework for those low-risk products that smokers will have to switch to.

## CONCLUSION

The reduced-nicotine strategy is best understood as a dec-

laration of intent or statement of direction aimed to reduce tobacco-related disease and death significantly. It is a huge intervention with wide-ranging consequences that will be hard to assess with confidence in advance and may become chaotic once introduced. However, this policy option is only one of several that should compete for regulatory and scientific resources and political capital. Accordingly, it should be evaluated against alternative strategies that degrade the appeal of smoking and provide low-risk alternatives.

If the coercive reduced-nicotine strategy is to retain any credibility at all, it will be necessary to have alternative low-risk nicotine delivery systems readily available, so that these products can play a significant role in the behavioral response to the rule. These low-risk alternatives should also be regulated proportionately and in ways that support diversity and innovation, rather than creating excessive regulatory barriers to entry that would establish a new tobacco-industry oligopoly.

Reduced-nicotine policy can be useful as a threat and to set direction, even if never implemented. Whether this option of tobacco regulation is deployed or not, the priority is to provide a risk-proportionate route to market for low-risk, noncombustible alternatives, such as e-cigarettes, heated tobacco and smokeless tobacco products.

33. Neal L. Benowitz NL, Eric C. Donny, et al., “Reduced nicotine content cigarettes, e-cigarettes and the cigarette end game,” *Addiction* 112:1 (January 2016), 6-7. <http://onlinelibrary.wiley.com/doi/10.1111/add.13534/full>; and Dorothy K. Hatsukami, Xianghua Luo, et al., “Reduced nicotine content cigarettes and use of alternative nicotine products: Exploratory trial,” *Addiction* 112:1 (January 2016), 156-67. <http://onlinelibrary.wiley.com/doi/10.1111/add.13603/abstract>.

34. Tim Wu, “Agency Threats,” *Duke Law Journal* 60 (2011), 1841. <http://scholarship.law.duke.edu/cj/viewcontent.cgi?article=1506&context=dj>.

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Clive contributed to this report as part of Counterfactual's advocacy program without additional funding. Clive Bates and Counterfactual have no competing interests with respect to e-cigarette, tobacco or pharmaceutical industries.

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