

# **Reducing nicotine in cigarettes**

## **Challenges and opportunities**

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## Challenges and opportunities

*“There are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns – the ones we don't know we don't know. [...] it is the latter category that tend to be the difficult ones.”*

Donald Rumsfeld, 2002

## Table of Contents

<b>1</b>	<b>Introduction .....</b>	<b>3</b>
<b>2</b>	<b>Summarizing FDA strategy .....</b>	<b>4</b>
<b>3</b>	<b>The challenge of nicotine reduction and nicotine-seeking behavior .....</b>	<b>5</b>
<b>4</b>	<b>Issues FDA will need to address .....</b>	<b>6</b>
4.1	A rule reducing nicotine to non-addictive levels is a cigarette prohibition in practice .....	6
4.2	The pressure to broaden the scope of the rule .....	7
4.3	The compliance fallacy - people will not act as expected or desired .....	8
4.4	The research base does not address the key policy questions .....	8
4.5	The weak legal mandate.....	10
4.6	The weak political mandate.....	10
4.7	Fierce, diverse and legitimate stakeholder opposition .....	11
<b>5</b>	<b>Alternative and complementary approaches.....</b>	<b>12</b>
5.1	Reduce toxins relative to nicotine.....	12
5.2	Taxation.....	12
5.3	Other tobacco control measures.....	12
5.4	Creating a credible framework for non-combustible nicotine products .....	13
<b>6</b>	<b>The coercion paradox .....</b>	<b>13</b>
<b>7</b>	<b>The real value of the reduced nicotine rule – an agency threat .....</b>	<b>14</b>
<b>8</b>	<b>Conclusion.....</b>	<b>14</b>
	<b>About the authors .....</b>	<b>16</b>

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## 1 Introduction

On July 28, 2017, the recently appointed Commissioner of the U.S. Food and Drug Administration, Dr. Scott Gottlieb, committed the U.S. Food and Drug Administration (FDA) to introduce a new guiding philosophy for the regulation of tobacco and nicotine. The associated news release sets 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>

Such a focus on nicotine rather than tobacco is an effort 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 non-addictive levels, we could decrease the likelihood that 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 – whether people will switch to other forms of smoking, access illicitly traded cigarettes, switch to vaping or heated tobacco products, quit smoking, engage in other risk behaviors, or develop an innovation designed to exploit the commercial opportunity the regulation would create. Nor do we know how those affected as consumers, suppliers and law-enforcement will react to criminalizing the personal behavior of 38 million Americans that has always been legal – there will be a cultural response as well as millions of individual responses.

It is quite possible that teenagers, as hoped, will simply stop smoking or never get hooked In the first place. However, it is also possible that they will see access to full-nicotine cigarettes as a badge of teenage honor, and source them from the black market where they will encounter criminal enterprise with a willingness to supply them with anything. The FDA cannot know which one will predominate.

The risks of unintended real-world consequences has been recognized within FDA. Showing appropriate caution, Dr. Gottlieb charged the FDA 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 rule-making:

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<sup>1</sup> U.S. Food and Drug Administration, "FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death, News release, July 28,2017. [\[link\]](#)

<sup>2</sup> U.S. Food and Drug Administration, "FDA's New Plan for Tobacco and Nicotine Regulation," July 28, 2017. [\[link\]](#)

<sup>3</sup> Euromonitor International, *Cigarettes in the US*, July 2017. Executive Summary. [\[link\]](#)

*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* insights into the way the market will respond and likely nature and extent of unintended consequences. The likely outcome of this initial dialogue will be a list of unanswered, and perhaps unanswerable, questions about what effects, good or bad, that such a huge intervention would have.

In this report, we explore some of the issues facing FDA and proponents of this strategy and suggest a way forward.

## **2 Summarizing FDA strategy**

In taking this approach, the FDA is not trying to eliminate the use of nicotine, but rather to reshape the landscape of nicotine 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 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. FDA's strategy can be summarized under four main headings:

- 1. Make the most harmful form of nicotine use, cigarette smoking, non-addictive*

By lowering nicotine levels in cigarettes to sub-addictive levels, 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 market place*

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 non-combustible 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 in place by deferring enforcement of the most demanding requirements of the Tobacco Control Act for e-cigarettes until 2022.

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<sup>4</sup> U.S. Food and Drug Administration, "FDA announces comprehensive regulatory plan. to shift trajectory of tobacco-related disease, death, News release, July 28,2017. [\[link\]](#)

### 3. *Improve the pharmaceutical smoking-cessation products*

FDA will review its approach to authorizing pharmaceutical smoking cessation medication to ensure 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 a cost in additional smoking. FDA implies it will look into rebalancing these trade-offs in favor of smoking cessation.

### 4. *Protect youth from any nicotine use*

Finally, the FDA proposes a range of strategies for preventing 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 uptake of teenage vaping has contributed to the unusually rapid decline in teenage smoking since 2010. FDA has correctly identified 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 operationalizing the strategy.

## 3 The challenge of nicotine reduction and nicotine-seeking behavior

Proponents of nicotine reduction must overcome a major underlying problem based on what we know of smoking; it is primarily a nicotine-seeking behavior. It has long been understood that:<sup>5</sup>

*“people smoke for the nicotine but die from the tar.”*

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 the smoke is diluted or fewer cigarettes are available because they are more expensive, smokers compensate – usually by subconsciously adjusting smoking intensity by taking more puffs or more intensive puffs per cigarette.<sup>6</sup> If it is not possible to obtain an adequately satisfying nicotine exposure through adjusting smoking behavior, then it is possible to use different nicotine products – those not covered by the reduced nicotine rule regulation or illicit full-nicotine cigarettes.

Although investigators are in the process of conducting trials to explore what happens in practice,<sup>7</sup> high

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<sup>5</sup> Mike Russell, Low-tar medium nicotine cigarettes: a new approach to safer smoking. *BMJ* 1976;1:1430–3. [[link](#)]

<sup>6</sup> Benowitz NL. Nicotine Addiction. *N Engl J Med*. NIH Public Access; *Clinical aspects of nicotine addiction* 2010 Jun 17;362(24):2295–303 [[link](#)]

<sup>7</sup> See. e.g., Donny EC, Denlinger RL, Tidey JW, Koopmeiners JS, Benowitz NL, Vandrey RG, et al. Randomized Trial of Reduced-Nicotine Standards for Cigarettes. *N Engl J Med*. Massachusetts Medical Society; 2015 Oct;373(14):1340–9. [[link](#)]; and Benowitz NL, Dains KM, Hall SM, Stewart S, Wilson M, Dempsey D, et al. Smoking Behavior and Exposure to Tobacco Toxicants during 6 Months of Smoking Progressively Reduced Nicotine Content Cigarettes. *Cancer Epidemiol Prev Biomarkers*. 2012;21(5). [[link](#)]

levels of non-compliance,<sup>8</sup> high drop-out 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 sub-addictive levels, compensation by changing puffing intensity is unlikely to be viable – the user would need to absorb too much smoke. The most likely form of compensatory behavior is simply not to use these products at all, and seek nicotine from other products.

## 4 Issues FDA will need to address

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

### 4.1 *A rule reducing nicotine to non-addictive levels is a cigarette prohibition in practice*

The main reason why 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<sup>11</sup>:

*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.*

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% would no longer be whiskey by any common-use definition. Such a change in the alcohol content fundamentally changes the product itself, because 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.

If the FDA follows the most commonly expressed proposal<sup>12</sup> of a 20- to 40-fold reduction of the nicotine concentration in cigarette tobacco, the resulting product would not have the psychoactive rewards that

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<sup>8</sup> Bandiera FC, Ross KC, Taghavi S, Delucchi K, Tyndale RF, Benowitz NL. Nicotine Dependence, Nicotine Metabolism, and the Extent of Compensation in Response to Reduced Nicotine Content Cigarettes. *Nicotine Tob Res.* Oxford University Press; 2015 Sep;17(9):1167–72. [[link](#)]

<sup>9</sup> Mercincavage M, Wileyto EP, Saddleson ML, Lochbuehler K, Donny EC, Strasser AA. Attrition during a randomized controlled trial of reduced nicotine content cigarettes as a proxy for understanding acceptability of nicotine product standards. *Addiction.* 2017; [[link](#)]

<sup>10</sup> Nardone N, Donny EC, Hatsukami DK, Koopmeiners JS, Murphy SE, Strasser AA, et al. Estimations and predictors of non-compliance in switchers to reduced nicotine content cigarettes. *Addiction.* 2016 Dec;111(12):2208–16. [[link](#)]

<sup>11</sup> Benowitz NL, “Nicotine Addiction,” *The New England Journal of Medicine* 362:24 pg. 2298 17 June 2010. [[link](#)]

<sup>12</sup> 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. [[link](#)].

users are seeking.<sup>13</sup> Accordingly, such a measure will not be converting the existing cigarette market to low-nicotine cigarettes, but rather eliminating 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 alcohol<sup>16</sup> and illicit drugs<sup>17</sup>. There are differences, the reduced nicotine proposal is a ban on *a drug delivery system*, not the drug *per se*. But it happens that this is by far the most common way of using nicotine, and the most addictive.

#### **4.2 The 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 1989-1993 Phillip Morris U.S. introduced nicotine-free NEXT, MERIT and Benson & Hedges variants. These failed, even after a \$200 million investment. Ten years later, Vector Tobacco Inc. tried and failed again 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, 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-rolling tobacco, cigars and pipe tobacco. Recognizing this weakness some proponents of low nicotine cigarettes have suggested widening the rule to most combustible forms of tobacco<sup>19</sup>. Even with broadening the scope of the measure 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.

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<sup>13</sup> Benowitz NL and Henningfield JE, “Establishing a Nicotine Threshold for Addiction—The Implications for Tobacco Regulation, *The New England Journal of Medicine* 331 (July 14, 1994), 123-25. [\[link\]](#)

<sup>14</sup> 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. [\[link\]](#)

<sup>15</sup> Euromonitor International, *Cigarettes in the US*, July 2017. Executive Summary. [\[link\]](#)

<sup>16</sup> McGirr L. *The War on Alcohol: Prohibition and the Rise of the American State*. 2015. 352 p.

<sup>17</sup> Rolles S, Murkin G, Powell M, Kushlick D, Saunter N, Slater J. *Counting the Costs: The Alternative World Drug Report*, 2nd edition. Transform Drug Policy Foundation, Bristol, UK; 2016. [\[link\]](#)

<sup>18</sup> See, e.g., Rolf Lutz, “Nicotine Reduction Strategy - The Promise and the Peril,” Philip Morris International, September 28, 2016. [\[link\]](#)

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

### **4.3 The compliance fallacy - people will not act as expected or desired**

A compliance fallacy exists when naïve assumptions are made about how markets will respond to regulation. This problem plagues current 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 intervention, the greater the scope for unintended harms to overwhelm the good intentions of regulators. And this is particularly true in a market driven by physiological dependence. In light of this, here are some of the likely responses available to consumers:

- The stockpiling of conventional cigarettes or trade with stockpilers
- The import of conventional cigarettes for personal use through the internet
- A switch to other combustible products: hand-rolling tobacco, pipes, cigars or little cigars
- Procurement of legitimately made or counterfeit nicotine cigarettes via the black market
- Procurement of counterfeit low-nicotine cigarettes that, in fact, have high nicotine content
- Addition of nicotine liquid to low-nicotine cigarettes
- Dual use or concurrent use of VLNC and other nicotine products
- A rise in fraudulent solutions and quack remedies
- Use of vaping, heated tobacco and smokeless tobacco products
- Quitting smoking and nicotine altogether – 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.

### **4.4 The research base does not address the key policy questions**

Thus far, much of the research on the nicotine reduction strategy has focused on what happens when consumers use these products – and in trial conditions.<sup>20</sup> Though the work is extensive and of high quality, it is unlikely much of this work will have practical value because the vast majority of consumers will not respond this way—which is to say that they are no more likely to take up these alternative forms of low-nicotine smoking than they are to drink low-alcohol whiskey. There is no evidence that suggests people will use these products, there is no reason to believe they will, and experience to date suggests they will not.

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<sup>20</sup> See for example National Institutes for Health research program U54 DA031659 and 47 related grants totaling spending of \$58,238,110 from 2011-15 [[link](#)]



The major trials on low-nicotine products have involved recruiting volunteers willing to be the subjects of experiments, giving them free products, paying them to join the trial and incentivizing them to stay the course.<sup>21</sup> These conditions could not be more different than those real-world behavioral influences that shape the economic behavior of participants in a consumer market, with a wide range of alternative strategies available to them.

Policymakers promoting a reduced nicotine strategy have to address several tests of credibility – requiring assessment of the likely real-world costs, benefits, risks and alternative options. These include:

- The public health test of the Tobacco Control Act section 907<sup>22</sup> that requires FDA to show that the rule is “appropriate for the protection of the public health”.
- Executive Orders<sup>23</sup> that govern good regulatory practice require 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; distributive impacts; and equity)
- The Regulatory Flexibility Act<sup>24</sup> requires FDA to analyze regulatory options that would minimize significant impacts of the rule on small businesses.
- Unfunded Mandates Reform Act<sup>25</sup> requires FDA to prepare a written statement, which 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." The impact on tax collection may trigger this.

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 done. The system is highly complex, and includes highly heterogeneous consumers, the entire supply chain from farm to convenience store for cigarettes and numerous alternatives alternatives, connections to international markets, law enforcement agencies and criminal enterprise from cartel to street dealer.

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<sup>21</sup> Donny EC, Denlinger RL, Tidey JW, Koopmeiners JS, Benowitz NL, Vandrey RG, et al. Randomized Trial of Reduced-Nicotine Standards for Cigarettes. *N Engl J Med.* Massachusetts Medical Society; 2015 Oct;373(14):1340–9. [[link](#)]

<sup>22</sup> Tobacco Control Act of 2009, Section 907(a)(3) [[link](#)]

<sup>23</sup> Executive Order 13563 of January 18, 2011 Improving Regulation and Regulatory Review [[link](#)] and Executive Order 12866 of September 30, 1993 Regulatory Planning and Review [[link](#)]

<sup>24</sup> Regulatory Flexibility Act of 1980 as amended. [[link](#)]

<sup>25</sup> Unfunded Mandates Reform Act of 1995, Section 202(a) [[link](#)]

#### 4.5 *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<sup>26</sup> specifically prohibits the FDA from certain actions in this area of rulemaking:

*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*

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

In terms of Congressional intent, the chapeau to the clause above is helpful - 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 take. It follows that Congress would expect rules that have the equivalent effect to be equally important, and, to follow the logic, to be reserved for Congress.

#### 4.6 *The weak political mandate*

Given that FDA’s strategy brings it close to, and arguably breaches, the legal constraints Congress placed on FDA’s rule-making discretion in 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 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.

We argue that, in advancing this measure, FDA is taking Congress literally but not seriously. We believe FDA should refrain from pedantic action and recognize that Congress expects to authorize rule-making of this significance.

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. It is insufficient both legally and democratically to rely on a negative mandate – namely that such a proposal does not infringe the letter of an exclusion clause that may not properly have captured Congressional intent or have envisaged rule-making. One reason why a broad political mandate is required is that the measure will

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<sup>26</sup> Federal Food, Drug, and Cosmetic Act – Section 907(d)(3) Tobacco Product Standards [[link](#)]

have many impacts on many stakeholder groups that are outside the normal business of food and drug regulation.

#### **4.7 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:

- 38 million American smokers and particularly challenging or sympathetic sub-groups of smokers – for example, 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 revenue of \$41.6 billion<sup>27</sup>. It is not clear where replacement taxation would come from – if it came from non-combustible nicotine products it could reduce switching and divert more smokers to the illicit cigarette market.
- Supply chain participants from tobacco multinationals to the corner store. They will be concerned that their business is not simply being transferred to the illicit trade.
- U.S. tobacco growers for the American market. There will be little point in growing low-nicotine tobacco as there is unlikely to be much demand for it.
- Customs and Borders Protection officers. They may be required to address a growing internet trade in nicotine products and imported cigarettes from Canada or Latin America
- Law enforcement officers at community level concerned about a new class of offenses that will apply to previously law-abiding citizens, draw on resources, potentially create new tensions or corruption opportunities.
- Law enforcement agencies such as FBI and DEA concerned about organized crime and criminal networks having additional sources of income and greater reach.
- Politicians. 15 percent of the adult population 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 FDA to map the full range of stakeholders and the impacts on these groups, but this will be necessary if it is to justify the rule. There is almost very little research that would inform a full stakeholder analysis.

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<sup>27</sup> On average, federal and state excise taxes account for approximately 44% of the retail price of cigarettes. See e.g., “The Tax Burden on Tobacco,” *Orzechowski and Walker Historical Compilation* 49 (2014), Tax Year Highlights. page IV. [\[link\]](#)

## 5 Alternative and complementary approaches

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

### 5.1 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 to selectively reduce toxins relative to nicotine. This is the opposite of 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. Thus, such a strategy would still face the same viability challenges as the FDA's alternative but at the very least, it not run the risk of mandating *more* harm. Further, the FDA already has research in place to inform such a strategy<sup>28</sup>

### 5.2 Taxation

The approach taken to reducing 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 US could raise taxes for tobacco to levels found elsewhere. In 2015 the World Health Organization reported in 2015 that the most popular cigarette brand in 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 price in US<sup>29</sup>. Economically, the approach of reducing nicotine to non-addictive levels is similar to raising taxes to unaffordable levels. Both function as a strong disincentive to smoke and ultimately a *de facto* prohibition, both are vulnerable to diversion to black market. The advantage of taxation is that can be applied more gradually and may not result in rapid contraction of tax revenues.

### 5.3 Other tobacco control measures

As well as 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 glamour or other positive values associated with it. Overall, decreasing the acceptability and other positive attributes associated with

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<sup>28</sup> FDA. 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 [[link](#)]

<sup>29</sup> WHO. Report on the Global Tobacco Epidemic, 2015 Appendix II: tobacco taxes and prices. Prices at purchasing power parity exchange rate. Pages 135, 139 [[link](#)]

smoking is correlated with a decrease in initiation to smoking, while having mixed effects on current smokers – increasing the intention to quit and quit attempts while further marginalizing them as well<sup>30</sup>. 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 of the options available to achieve the desired outcome – including a wider assessment of impacts beyond public health.

#### **5.4 Creating a credible framework for non-combustible nicotine products**

The superior and more urgent strategy is to promote the migration of smokers from combustible to non-combustible ‘alternative nicotine delivery systems’ by *choice*. We have described options to improve FDA’s approach in this regard in earlier publications<sup>31 32</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 good awareness of the relative risks of smoked and smoke-free products
- Taking an approach to the “public health test” that recognizes that excessive caution can result in population harm through lost opportunities to stop smoking
- Reducing the burdens of application for innovations, especially innovations that increase safety, usability, and user awareness.

The FDA did place some emphasis on the last strategy<sup>33</sup> by delaying enforcement of PMTAs to 2022, promising to clarify guidance and to use standards to reduce the burdens on applicants. However, this commitment is weak and vague. The FDA needs to focus on a simple and risk-proportionate route to market for non-combustible consumer nicotine products. This is a prerequisite for its reduced nicotine strategy and, if successful, will render the strategy unnecessary.

## **6 The coercion paradox**

The reduced nicotine proposal would create a state-imposed forced behavior change for most of America’s 38 million adult smokers. The degree of coercion involved, and predictable backlash, is a

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<sup>30</sup> Castaldelli-Maia JM, Ventriglio A, Bhurga D. Tobacco Smoking: From ‘glamour’ to ‘stigma’. A comprehensive review. *Psychiatry and Clinical Neurosciences*. 2016; 70:24-33 [\[link\]](#)

<sup>31</sup> Bates CD, Lehrer E, Sweanor DT. Reshaping American Tobacco Policy: Eight federal strategies to fight smoking and ignite a public health revolution, February 2017 [\[link\]](#)[\[PDF\]](#)

<sup>32</sup> Bates CD. Rethinking nicotine: implications for U.S. federal tobacco policy – A discussion paper. June 2017 [\[link\]](#)[\[PDF\]](#)

<sup>33</sup> FDA, FDA’s New Plan for Tobacco and Nicotine Regulation. 28 July 2017 [\[link\]](#)

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>34 35</sup>.

These alternatives need to be good enough 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.

## 7 The real value of the reduced nicotine rule – an agency threat

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. Reducing nicotine in cigarettes could be a good measure to talk about and prepare for, but it may not be necessary to go further and actually do it. In more formal terms, it could perform the function of an ‘agency threat’<sup>36</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 an agency threat, FDA will need to act as if it is trying to create a viable proportionate regulatory framework for low-risk alternatives. The main benefit of the reduced nicotine rule is that it requires FDA to fix the regulatory framework for the low-risk products that smokers will need to, or choose to, switch to.

## 8 Conclusion

The reduced nicotine strategy is best understood as a declaration of intent or statement of direction aimed to significantly reduce tobacco-related disease and death. It is a huge intervention with wide-ranging consequences that will be hard to assess with confidence in advance and may become chaotic when introduced. This policy option is one of several that should compete for regulatory and scientific resources and political capital. It should be evaluated against alternative strategies meeting the objectives of degrading the appeal of smoking and providing low-risk alternatives.

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<sup>34</sup> Benowitz NL, Donny EC, Hatsukami DK. Reduced nicotine content cigarettes, e-cigarettes and the cigarette end game. *Addiction*. 2016 Jan;112(1):6–7. [[link](#)]

<sup>35</sup> Hatsukami DK, Luo X, Dick L, Kangkum M, Allen SS, Murphy SE, et al. Reduced nicotine content cigarettes and use of alternative nicotine products: Exploratory trial. *Addiction*. 2016 Jan;112(1):156–67. [[link](#)]

<sup>36</sup> Tim Wu, Agency Threats, 60 DUKE L.J. 1841 (2011) [[link](#)]

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 a way that supports 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 'nuclear option' of tobacco regulation is deployed or not, the priority is to provide a risk-proportionate route to market for low-risk non-combustible alternatives, such as e-cigarette, heated tobacco and smokeless tobacco products.

## About the authors

**Clive Bates** is director of Counterfactual, a consulting and advocacy practice focused on a pragmatic approach to sustainable development, energy policy and public health that he founded in 2013. Clive had a diverse career in the public, private and nonprofit sectors. After securing a degree in engineering from Cambridge University, he worked in information technology for IBM before moving on to work as an energy specialist with several environmental nonprofits. From 1997 to 2003, he was the United Kingdom's director of Action on Smoking and Health, campaigning to reduce the harms caused by tobacco. In 2003, he joined Prime Minister Tony Blair's Strategy Unit as a civil servant and worked in several roles in the public sector in the United Kingdom and for the United Nations in Sudan. This report was written 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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Carrie's scientific background in the biological mechanisms of opioid addiction led to her interest in how public-health initiatives can prevent incidence of addiction and reduce the negative societal and personal consequences that result from substance use. Her work with the Baltimore Harm Reduction Coalition solidified her goal to promote reasonable and efficient drug policies. Carrie received her bachelor's in neuroscience and Ph.D. in pharmacology from the University of Minnesota and a master's in public health from Johns Hopkins University.