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Docket No. FDA-2017-N-6189 **June 29, 2018**
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2017-N-6189 (83 Fed. Reg. 11,818, March 16, 2018) Advance Notice of Proposed Rulemaking on Tobacco Product Standard for Nicotine in Level of Certain Tobacco Products

Dear Commissioner Gottlieb,

We write to you out of concern for the proposal to regulate nicotine levels in cigarettes to "non-addictive" levels. We believe that a proposal to implement reduced nicotine levels in combustible cigarettes is a step towards changing the landscape of tobacco products and 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, there could be a decrease in the likelihood that future generations become addicted to cigarettes and allow more currently addicted smokers to quit. [1]

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[2], 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 agents will react to the criminalization of a personal behavior practiced by roughly 35 million American adults and that has always been legal. In all likelihood, there will be cultural, as well as 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.

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[1] 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.
[2] Euromonitor International, *Cigarettes in the US*, July 2017. http://www.euromonitor.com/cigarettes-in-the-us/report.

It is important to note that the risks of such potential for unintended, real-world consequences has been recognized within FDA – and that these consequences may be mitigated by acceptance and promotion of newer forms of nicotine-containing products.[3] However, 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.

Smoking is, by far, the most common way to use nicotine, as well as the most harmful way to use it. This is why we believe that the reduced nicotine measure could be useful, even if never implemented. It can function as an agency threat that influences the direction of the nicotine market and signal the end of combustible tobacco products as nicotine delivery products. But we think this is more likely to be achieved through innovation in the low-risk alternatives, candid communication of relative risk and a regulatory framework that imposes burdens proportionate to risk and does not distort the market in favor of the more harmful products.

We should always be open to novel strategies to reduce the burden of smoking on both those who smoke and those who don't, but such a sea change in the regulatory landscape of combustible cigarettes is sure to bring on unintended consequences and may distract from more effective policies. Enclosed in this document, please find our Executive Summary followed by a more detailed report on considerations the FDA must address before implementing such regulations.

Sincerely,

Carrie Wade, Harm Reduction Policy Director
R Street Institute

Clive Bates, Founder and Director
Counterfactual

[3] U.S. Food and Drug Administration, "FDA announces comprehensive regulatory plan."

EXECUTIVE SUMMARY

The FDA will have to address a range of issues before implementing a *de facto* prohibition of cigarettes including:

- Assessing the real-world behavioral response strategies of smokers under new market conditions following introduction of a rule. Such responses may include:
    - Use of other combustible products – pipes, cigars, hand-rolling tobacco novel products or deliberately designed workarounds
    - Use of illicitly-traded legally manufactured product or counterfeit products with high nicotine content
    - Illicit manufacturing or adding nicotine to legally available cigarettes
    - Switching to non-combustible products, such as smokeless tobacco
    - Quitting smoking and nicotine use
    - Use of very low nicotine cigarettes
- Use of very low nicotine cigarettes is by far the most extensively studied behavioral responses to such a rule, but it also among the least likely in real-world conditions. This means the *relevant* evidence base for the rule is weak and poorly focused.
- Significant enforcement challenges
    - Likely involvement of organized crime and strengthening criminal networks
    - Stockpiling
    - Importation and internet trade
    - Tampering
    - Corruption and collusion of law enforcement
    - Police-community relations
- Meeting the burden of proof required by the public health test
- The consequences for federal and state tax and master settlement revenues
- The legality and political mandate for such a product standard
- Stakeholder interests including
    - Tobacco growers
    - Supply chain participants
    - Law enforcement and customs
    - State treasuries

FDA is required to assess alternative policies to achieve similar ends with lower cost or impact on stakeholders. We believe that more effective and deliverable alternatives do exist including:

- Supporting migration via consumer choice from smoking to lower risk products including smokeless tobacco, heated tobacco products and e-cigarettes. This requires candid communication of risk; a far less burdensome route to market; and regulatory framework that encourages innovation.
- Imposing toxin standards on emissions from combustible products
- Encouraging differential taxation between combustible products and lower risk alternatives

If lower risk alternatives are widely accessible, and if the FDA strengthens existing tobacco control measures for combustible products we believe that low nicotine standards will be unnecessary.

We believe that the prospect of a reduced nicotine rule works best as an 'agency threat' – a statement of intent about the direction the market should take. FDA retains the 'nuclear option' of introducing the rule should progress be inadequate, but the more feasible and options should be exploited to the maximum first.

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. Indeed, it has long been understood that, "people smoke for the nicotine but die from the tar." [4]

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.[5] 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 regulation or illicit full-nicotine cigarettes.

Although investigators are in the process of conducting trials to explore what happens in practice,[6] high levels of non-compliance,[7] high drop-out rates[8] and signs of compensatory smoking in more dependent users[9] 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, 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

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[4] 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.

[5] 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/.

[6] 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/.

[7] 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/

[8] 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.

[9] 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.

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.

Nicotine reduction acts as a prohibition on cigarettes

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:

> 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.[10]

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% would no longer be whiskey by any common-use definition.

If the FDA follows the most commonly expressed proposal of a 20- to 40-fold reduction of the nicotine concentration in cigarette tobacco,[11] the resulting product would not have the psychoactive rewards that users seek.[12] Accordingly, such a measure would not convert the existing cigarette market to low-nicotine cigarettes as much as it would eliminate the cigarette category altogether. This would be a *de facto* prohibition on a market that supplies 35 million Americans [13] and, in 2016, had retail sales of $94 billion.[14]

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[15] and illicit drugs.[16] 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 of using nicotine, and the most addictive.

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[10] Benowitz, "Nicotine Addiction," 2298. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2928221.
[11] 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/.
[12] 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.
[13] 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, 2017, Figure 8.1. https://public.tableau.com/profile/tina.norris#!/vizhome/FIGURE8_1/Dashboard8_1.
[14] *Cigarettes in the US*. http://www.euromonitor.com/cigarettes-in-the-us/report.
[15] Lisa McGirr, *The War on Alcohol: Prohibition and the Rise of the American State* (New York: W.W. Norton & Co.), 2015, p. 352.
[16] See, e.g., Steve Rolles S, Geroge 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.

Pressure to broaden the scope of the rule

Historically, low nicotine cigarettes have not been commercially viable, even as niche products.[17] 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, 22nd 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-rolling tobacco, cigars and pipes. Recognizing this weakness some proponents of low nicotine cigarettes have suggested widening the rule to most combustible forms of tobacco.[18] 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

A compliance fallacy exists when naïve assumptions are made about how markets will respond to regulation and this problem plagues current projections of the likely outcomes of the FDA's nicotine reduction proposal. This is because 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;
- Smoking cessation – with relapse to different nicotine products.

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[17] See, e.g., Rolf Lutz, "Nicotine Reduction Strategy - The Promise and the Peril," Philip Morris International, September 28, 2016. https://www.pmiscience.com/system/files/publications/gtnf2016_nicotine_reduction_pmi_perspective_rolf_lutz_28092016.pdf.

[18] Neal L. Benowitz, "Comprehensive Nicotine Regulation to End the Combustible Tobacco Epidemic," *Annals of Internal Medicine* 40, Aug. 15, 2017, 170–80.

In any event, 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 – and in trial conditions.[19] 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 that suggests 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.

Thus far, 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.[20] 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.

Accordingly, policymakers that promote a reduced-nicotine strategy must address several tests of credibility, which require 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 that requires FDA to show that the rule is "appropriate for the protection of the public health;" [21]
- Executive Orders[22] that govern good regulatory practice and 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, as well as distributive impacts and equity);
- The Regulatory Flexibility Act,[23] which requires FDA to analyze regulatory options that would minimize significant impacts of a rule on small businesses;
- Unfunded Mandates Reform Act, which requires 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." [24] The impact on tax collection may trigger this.

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[19] 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.
[20] Donny, Denlinger, et al. http://www.nejm.org/doi/full/10.1056/NEJMsa1502403.
[21] Tobacco Control Act of 2009, Section 907(a)(3). https://www.fda.gov/tobaccoproducts/labeling/rulesregulationsguidance/ucm263053.htm.
[22] Executive Order 13563 of January 18, 2011 Improving Regulation and Regulatory Review. https://www.reginfo.gov/public/jsp/Utilities/EO_13563.pdf; and Executive Order 12866 of September 30, 1993 Regulatory Planning and Review. https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf.
[23] The Regulatory Flexibility Act of 1980 (as amended). https://www.sba.gov/advocacy/regulatory-flexibility-act.
[24] 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.

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 enterprise from cartel to street dealer.

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 entirely as follows, specifically 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. [25]

The FDA believes that 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 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. Further, and as previously argued, 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 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 take. It follows that Congress would expect rules that have the equivalent effect to be equally important, and thus reserved for Congress.

The weak political mandate

Given that the 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 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 rule-making of this significance. It should thus 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

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[25] Federal Food, Drug, and Cosmetic Act – Section 907(d)(3), "Tobacco Product Standards." https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm263053.htm.

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 rule-making. Moreover, a broad political mandate is required because the measure will have wide-ranging impact on many stakeholder groups that are 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:

- 35 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.[26] It is not clear from where replacement taxation would come and certainly 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 those who own the corner store. They will be concerned that their business is not simply being transferred to any illicit trade that emerges;
- 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 who may be required to address a growing internet trade in nicotine products and imported cigarettes from Canada or Latin America;
- Law enforcement officers at the community level who are 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 the FBI and DEA that are concerned about organized crime and criminal networks having additional sources of income and greater reach;
- Politicians—the 15 percent of the adult population that currently smokes 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 of achieving the policy goals. And, 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

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[26] 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), iv. https://old.taxadmin.org/fta/tobacco/papers/tax_burden_2014.pdf.

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 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. Thus, such a strategy would still face the same viability challenges as the FDA's alternative but at the very least, it would not run the risk of mandating *more* harm. Further, the FDA already has research in place to inform such a strategy.[27]

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.[28] 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 and 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 glamour or other positive values associated with it. Overall, decreases in the acceptability and other positive attributes associated with smoking are correlated with a decrease in initiation to smoking. However, this has mixed effects on current smokers, as it generally increases the intention to quit and associated quit attempts, while further marginalizing them.[29] 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 of the options available to achieve the desired outcome, which must include a wider assessment of impacts beyond public health.

Creating a credible framework for non-combustible nicotine products

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[27] 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/RulesRegulationsGuidance/ucm297752.htm.

[28] 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.

[29] 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.

Accordingly, 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.[30] 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," which recognizes that 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. [31] However, the commitment is weak and vague. Instead, 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.

THE COERCION PARADOX

The reduced-nicotine proposal would create a forced, state-imposed behavioral change for most of America's 35 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.[32] 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.

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[30] 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.

[31] 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/newsevents/ucm568425.htm.

[32] 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.

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"[33] – 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 the low-risk products that smokers will have to switch to.

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. 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, non-combustible alternatives, such as e-cigarettes, heated tobacco and smokeless tobacco products.

[33] Tim Wu, "Agency Threats," *Duke Law Journal* 60 (2011), 1841. http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1506&context=dlj.