

Rethinking nicotine: implications for U.S. federal tobacco policy

A discussion paper

**Clive Bates
Director, Counterfactual
United Kingdom**

June 2017

Version 1.1

Rethinking nicotine: implications for U.S. federal tobacco policy

Executive summary	3
1 The case and basis for a new approach	4
1.1 The challenge: introducing risk-based regulation of tobacco and nicotine	4
1.2 How should the government respond?.....	4
1.3 Relevant factual basis to underpin reform.....	5
1.4 Policy intent	6
1.5 Principles for regulation.....	7
1.6 Weaknesses in the current FDA approach to vapor and other low-risk products.....	7
1.7 Developing a better approach to tobacco and nicotine regulation.....	9
2 Take emergency action to prevent needless destruction of the consumer vapor market ..	9
3 Move to a transparent standards-based regime for low-risk products.....	11
4 Put consumer interests first with truthful and candid communication of risk	13
5 Make appropriate use of the public health test	14
6 Retain the current approach to combustible tobacco products	16
7 Conclusions.....	16
Appendix 1: trends in youth tobacco and nicotine use	17
About the author.....	18

Version 1.1 of 20 June 2017 has the addition of Appendix 1.

Rethinking nicotine: implications for U.S. federal tobacco policy

Executive summary

- This discussion paper focusses on the appropriate framework for United States tobacco and nicotine policy *at the federal level*. Other important aspects of policy – taxation, clean indoor air, point of sale – are predominantly addressed at the state or local levels and are not addressed in detail here.
- The emergence and rapid uptake of low-risk tobacco and nicotine products, such as e-cigarettes, as alternatives to smoking creates the possibility of deep and rapid public health gains through ‘tobacco harm reduction’, the substitution of high-risk products by low-risk products. This opportunity arises because it is the products of combustion in tobacco *smoke* rather than nicotine that cause the serious smoking-related diseases. Recent U.S. experience has been positive with sharp declines in adult and youth smoking since 2010.
- The current U.S. federal regulatory regime did not anticipate the rise of low-risk tobacco products on the scale seen recently and does not differentiate adequately according to risk. Under the new framework, very high regulatory burdens will be applied to the lowest-risk products and low burdens applied to the highest risk. The effect of proceeding on this track is likely to be the elimination of most of the products and most of the firms in the vaping and smokeless tobacco market. This could cause a resurgence of smoking and related harms.
- There are options to change direction as manifested in the 2016 Final Deeming Rule by amending the law in Congress. Alternatively, and more pragmatically, through the use of administrative discretion by FDA and DHHS, for example to interpret the law differently and reissue guidance, withdraw draft rules, delay enforcement, or an agreement to settle one or more of the legal challenges to the Deeming Rule.
- A regulatory scheme should be proportionate and non-discriminatory. It should recognize benefits as well as risks. It should be designed to limit harmful unintended consequences arising from regulatory interventions. Regulation should promote beneficial innovation and avoid misplaced risk-aversion. Regulators should aim to be truthful and candid, and never try to modify behavior through misleading the public or any at-risk group.
- The proposed direction is as follows:
 - Take emergency action to pause or withdraw the most burdensome aspects of the regulatory regime, primarily the Pre-Market Tobacco Product Application (PMTA) authorization regime and the new smokeless tobacco nitrosamine rule. Retain other controls on newly deemed products.
 - Shift from a case-by-case authorization system to one that relies primarily on proportionate standards addressing chemical, electrical, mechanical and thermal risks, manufacturing standards, labelling and packaging and marketing as appropriate. This could be done through formal rule-making and/or through guidance in the shorter term. For products that comply with standards and are properly notified, the PMTA would become less burdensome tending towards a formality as reliance on standards increased.
 - Adopt a series of measures to better align public perception of relative risk with reality, including by approving category-wide messages that are agreed to be true and fair reflection of risk and exempting these from enforcement under misbranding provisions of the TCA. Federally funded research into tobacco-related risks should be communicated with a duty of care and candor to the public.
 - Take a more balanced approach to the public health test in the Tobacco Control Act so that uncertainty does not become a barrier to better regulation and a cause of harmful inertia. FDA could make category-wide determinations about the public health test, e.g. for smokeless tobacco and e-cigarettes.
 - Retain the current approach to combustible tobacco products, including the means to control smoke toxicity, reduce abuse liability, challenge harmful innovations and assess modified risk claims.

1 The case and basis for a new approach

1.1 The challenge: introducing risk-based regulation of tobacco and nicotine

The U.S. federal regulatory framework for consumer nicotine products is based primarily on the Family Smoking Prevention and Tobacco Control Act (TCA) of 2009¹; a deeming rule bringing most tobacco and consumer nicotine products under the TCA²; rules and regulations made under the TCA for example covering product standards³ or marketing practices⁴; extensive implementation guidance⁵; and enforcement practice⁶. The Food and Drug Administration (FDA) is the regulator and its role is administered by the Center for Tobacco Products.

This framework is now facing significant challenge following the emergence of new low-risk tobacco and nicotine products and rising interest in the concept of tobacco harm reduction. The National Tobacco Reform Initiative⁷ has proposed a significant rethink of U.S. tobacco policy, including the following:

Establish a more rational tobacco, nicotine, and alternative products regulatory framework based on their relative risks, and that is adaptable to the increased speed of innovation in new technology development.

1.2 How should the government respond?

The first step is to recognize how unsatisfactory the regulatory framework is at present. In terms of burdens, it is an *inversion* of a rational framework, with much greater costs, burdens and regulatory uncertainty applied to the far-safer products – e-cigarettes, heated tobacco products, and smokeless tobacco – than cigarettes. In contrast, almost all cigarettes on the U.S. market today have benefitted from various exemptions when the Tobacco Control Act came into effect or subsequently. There are broadly two procedural approaches to remedy this disparity:

- *Changing the law through Congress* – this could involve relatively minor amendments to the Tobacco Control Act to address its most pressing shortcomings or a more ambitious overhaul, or both over time.
- *Changing the way the law is applied* – this would be done through administrative action at the initiative of the FDA or Department of Health and Human Services (HHS) using their discretion under the law or by settling one or more of the legal challenges to the deeming rule with a consent decree.

On 1 May 2017, FDA and Department of Justice used filings in ongoing legal actions to pause enforcement for deeming rule measures entering into force on or after 10 May 2017 by three months⁸ indicating that the new administration would like “*additional time to more fully consider issues raised by the final rule*”

¹ Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”) 22 June 2009 [\[link\]](#) Amending the Federal Food, Drug and Cosmetics Act 21 U.S. Code § 387 [\[link\]](#)

² Food and Drug Administration (FDA), Deeming Tobacco Products To Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 81 FR 28973, 10 May 2016 [\[link\]](#)

³ For example, Tobacco Product Standard for N-Nitrosomonocotine Level in Finished Smokeless Tobacco Products – Proposed Rule, 82 FR 8004, 23 January 2017 [\[link\]](#)

⁴ For example, Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco. 75 FR 13225 [\[link\]](#) 19 March 2010.

⁵ Food and Drug Administration. Center for Tobacco Products: *Guidance* [\[link\]](#)

⁶ Food and Drug Administration. Center for Tobacco Products: *Compliance, Enforcement and Training* [\[link\]](#). See Effective and Compliance Dates Applicable to Retailers, Manufacturers, Importers, and Distributors of Newly Deemed Tobacco Products [\[link\]](#) [\[PDF\]](#)

⁷ Terry M, Seffrin J, Cummings M, Erickson A, Shopland D. Ending Cigarette Use By Adults In A Generation Is Possible: Executive Summary National Tobacco Reform Initiative, March 2017 [\[link\]](#)

⁸ FDA. Web statement 3 May 2017 [\[link\]](#)

Rethinking nicotine: implications for U.S. federal tobacco policy

Following his appointment to the role of FDA Commissioner, Dr Scott Gottlieb gave an initial indication of his openness to tobacco harm reduction approaches in his first remarks to FDA staff⁹.

Among these and many other opportunities, there's probably no single intervention, or product we're likely to create in the near future that can have as profound an impact on reducing illness and death from disease as our ability to increase the rate of decline in smoking. We need to redouble efforts to help more smokers become tobacco-free. And, we need to have the science base to explore the potential to move current smokers – unable or unwilling to quit – to less harmful products, if they can't quit altogether. At all times, we must protect kids from the dangers of tobacco use.

1.3 Relevant factual basis to underpin reform

- **Nearly all tobacco-related risk arises from combustion.** Essentially, all of the serious harm attributable to tobacco use arises from *smoking* and exposure to tobacco smoke. Nicotine is not harmless but not particularly harmful compared to the toxic products of combustion formed in high temperature reactions in tobacco smoke. Given what is known of the physical and chemical processes involved, the toxicity, exposure and biomarker data^{10 11 12 13 14} and the observable relief in acute conditions¹⁵, we can be confident *beyond reasonable doubt* that exclusive e-cigarette use is much less harmful than smoking. The Royal College of Physicians provides a nuanced perspective on relative risk for practitioners and policy-makers¹⁶.

Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.

- **No significant gateway or adverse population effects have been found.** Concerns have been raised about negative population effects (gateway effects, prolonging smoking, promoting relapse). There is no compelling evidence of a gateway effect from vaping to smoking of any material magnitude and very few studies define this concept or have a methodology that would detect it¹⁷. If anything, the observational data are more consistent with e-cigarettes functioning as an 'exit' and having a positive effect at population level – U.S. adult¹⁸ and teenage smoking¹⁹ have fallen unusually rapidly over the period in which e-cigarette use has risen.

⁹ FDA. Dr. Gottlieb's First Remarks to FDA Staff, 15 May 2017 [\[link\]](#)

¹⁰ Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks, *BMC Public Health* 2014;**14**:18. [\[Link\]](#)

¹¹ Glasser AM, Collins L, Pearson JL, Abudayyeh H, Niaura RS, Abrams DB, et al. Overview of Electronic Nicotine Delivery Systems: A Systematic Review. *Am J Prev Med.* 2016 Nov 30 [\[link\]](#)

¹² Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Therapeutic Advances in Drug Safety* 2014;**5**:67–86. [\[Link\]](#)

¹³ O'Leary R, MacDonald M, Stockwell T, Reist D. Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices. University of Victoria, BC: Centre for Addictions Research of BC.; 2017 [\[link\]](#)

¹⁴ Shahab L, Goniewicz ML, Blount BC, Brown J, McNeill A, Alwis KU, et al. Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users. *Ann Intern Med.* 2017 Feb 7;**24**:442–8. [\[link\]](#)

¹⁵ Polosa R. Electronic cigarette use and harm reversal: emerging evidence in the lung. *BMC Med.* England; 2015;**13**(1):54. [\[link\]](#)

¹⁶ Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction.* 28 April 2016 (Section 5.5 page 87) [\[link\]](#)

¹⁷ Public Health England (UK). E-cigarettes: an evidence update 19 August 2015. [\[link\]](#)

¹⁸ National Center for Health Statistics, National Health Interview Survey, 1997–2015, Sample Adult Core component. Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–2015. [\[link\]](#)[\[data\]](#) Accessed 17 May 2017.

¹⁹ Singh T, Arrazola RA, Corey CG, et al. Tobacco Use Among Middle and High School Students — United States, 2011–2015. *MMWR Morb Mortal Wkly Rep* 2016;**65**:361–367. [\[link\]](#) 15 April 2016

Rethinking nicotine: implications for U.S. federal tobacco policy

- **Low-risk products may work as consumer alternatives to smoking.** These low-risk products in some but not all cases are able to substitute for smoking by meeting the needs of nicotine users who cannot or do not wish to quit using nicotine. The viability of e-cigarettes and other low risk nicotine products as alternatives to smoking will develop with continuing innovation, given a supportive policy, fiscal and risk communications framework. E-cigarettes have become a popular alternative to smoking for up to 9 million Americans and around 2.5 million vapers are now *former* smokers (2015 data)²⁰.
- **Regular use of e-cigarettes by adolescents is occasional or concentrated among smokers and potential smokers.** Much of this use is experimental and occasional and regular use is concentrated in smokers²¹, and adolescents report mostly using e-liquids without nicotine²². It is possible that recent rapid declines in youth smoking may be partly attributable to vaping substituting for smoking, and so are beneficial. Young smokers express interest in using e-cigarettes to quit smoking or to reduce harm²³. See [Appendix 1](#) for data charts.
- **No material risk to bystanders.** There is no compelling evidence of material risk to bystanders arising from vaping²⁴ – though it may be a nuisance or irritating to some. There are no products of combustion in the aerosol and no ‘sidestream’ vapor – e-cigarettes do not release vapor between puffs.
- **Risk perceptions.** The understanding of comparative risk of cigarettes and smokeless tobacco or e-cigarettes of the general public and tobacco users is highly misaligned with the available science base and expert opinion^{25 26}. These misperceptions diminish the incentive to switch from high-risk to low-risk products.

1.4 Policy intent

Before defining regulatory measures, it is important to ask what harms or risks regulation is designed to mitigate and/or what opportunities is it aiming to facilitate? The goals of federal regulation should be as follows and in this order of priority:

1. Reduce smoking-related disease and other harms by displacing smoking through complete cessation or use of low-risk nicotine products. Reduction of harms should be the objective given primacy over all others.
2. Encourage innovation that will do more to reduce smoking-related harm in future.
3. Reduce risks to users of e-cigarettes or other reduced-risk products to the extent possible without compromising the two goals above. For public health, it is worth tolerating additional risk in low-risk products (e.g. heated tobacco products) if it makes them more appealing to users of high-risk products (cigarettes).
4. Discourage initiation of reduced-risk products in those who would never otherwise use nicotine – recognizing this is a relatively minor problem at present and interventions may have unintended consequences if they prevent young people who *would* otherwise smoke using e-cigarettes instead of cigarettes. Measures designed to prevent young people using e-cigarettes should not be uncritically assumed to be beneficial.

²⁰ CDC, National Health Interview Survey, 2015 Data Release [\[link\]](#), Analysis by Rodu B. How Many Americans Vape? CDC Data Show Fewer Vapers & Smokers in 2015, Tobacco Truth 17 July 2016 [\[link\]](#)

²¹ Villanti AC, Pearson JL, Glasser AM, Johnson AL, Collins LK, Niaura RS, et al. Frequency of youth e-cigarette and tobacco use patterns in the U.S.: Measurement precision is critical to inform public health. *Nicotine Tob Res.* December 2016 [\[link\]](#)

²² Miech R, Patrick ME, et al. What are kids vaping? Results from a national survey of US adolescents. *Tob Control*; 2016 [\[link\]](#).

²³ Shiffman S, Sembower MA. PATH Data: Harm Reduction is Teens' Top Reason for Using e-cigarettes, SRNT Poster, March 2017 [\[link\]](#)

²⁴ Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks, *BMC Public Health* 2014;**14**:18. [\[link\]](#)

²⁵ Majeed BA, Weaver SR, Gregory KR, Whitney CF, Slovic P, Pechacek TF, et al. Changing Perceptions of Harm of E-Cigarettes Among U.S. Adults, 2012-2015. *Am J Prev Med.* Elsevier; 2016 Oct;0(0):1922–8. [\[link\]](#)

²⁶ National Cancer Institute, HINTS, FDA Survey 2015. E-cigarettes [\[link\]](#); Smokeless tobacco [\[link\]](#)

1.5 Principles for regulation

- **Proportionality.** Regulation should be risk-based and proportionate. The current approach to e-cigarettes is *disproportionate* given the small risks and potential health benefits.
- **Non-discrimination.** Regulation should be non-discriminatory, treating products with similar risks the same way and products with different risks differently.
- **Unintended consequences.** Regulation should recognize the potential positive health value of consumers replacing high-risk with low-risk products. It follows that regulators should therefore also recognize the related potential unintended consequences of making this switch more difficult or less attractive to smokers.
- **Duty to be truthful and candid.** To support informed choice, regulators should be concerned with truthful non-misleading and candid communication. It is not acceptable to mislead either adults or minors in an attempt to modify their behavior, including misleading by omission, or by misleading with literally factual information (“contains toxins”) that distorts the relative risk perception for users.

1.6 Weaknesses in the current FDA approach to vapor and other low-risk products

The main problems with the current regulatory framework are as follows²⁷:

- **Opaque and uncertain approval criteria.** The criteria for passing the Pre-Market Tobacco Product Application (PMTA) authorization process are expressed in highly generalized terms. The draft guidance has not yet been finalized, and it is not clear to most companies how their applications will be judged or what they need to do to achieve success. This ambiguity also leads to further concern that the process is open to political or advocacy pressure. Many firms will be unable to raise capital while facing such regulatory and political risk and will choose to exit rather than commit resources to an expensive process with an uncertain outcome.
- **Excessive cost and negligible benefits.** The PMTA process, which will be required for all vaping products, is too costly and the premarket burdens too great. FDA estimates application costs of between \$286,000 and \$2.6 million for devices and between \$182,000 and \$2.0 million for liquids²⁸ and some industry estimates are significantly higher. Given companies may have hundreds or thousands of product variants, many with small sales volumes, and limited regulatory compliance staff, this will cause a radical contraction (95-99.9% - estimates vary) in the products and firms competing in the market. Despite the high costs of its intervention, FDA did not quantify benefits arising from the deeming rule, and critics argue that the claimed benefits are negligible, achievable by other means or are actually detriments²⁹. Neither did FDA attribute any public health benefit to vaping and so did not evaluate harm that an excessively burdensome regulatory intervention may cause, for example through the loss of diversity in the vaping market leading to increased smoking through reduced switching or relapse³⁰. Such costs, had they been evaluated realistically, would dominate the cost-benefit analysis and destroy the case for the rule.
- **Barrier to innovation.** The regulatory cost of modifying products is so high that it will place a brake on innovation – and will stop the experimental ‘try it and see what works’ approach to innovation. As of 8 August

²⁷ For more detail on these weaknesses see: Bates CD, Lehrer E, Sweanor D, Reshaping American Tobacco Policy Eight federal strategies to fight smoking and ignite a public health revolution, February 2017. [\[link\]](#) Full report PDF [\[link\]](#)

²⁸ FDA. Deeming rule: Regulatory Impact Analysis. May 2016 – Table 11 covers e-liquids, Table 12 covers devices [\[link\]](#)

²⁹ This case is made in filings in legal action against the FDA’s deeming rule: Nicopure Labs et al vs Food and Drug Administration et al, Motion for Summary Judgement, 8 July 2016 [\[link\]](#) Brief of *amici curiae* of Clive Bates and other in support of plaintiffs’ motion for summary judgement, 5 August 2016 [\[link\]](#)

³⁰ FDA, Deeming Rule Docket No. FDA-2014-N-0189: Final Regulatory Impact Analysis, 10 May 2016 [\[link\]](#)

Rethinking nicotine: implications for U.S. federal tobacco policy

2016, it has become against the law to make any modifications to e-cigarettes, including obvious safety or other beneficial improvements, without receiving an authorization following submission of a PMTA.

- **Discrimination compared to cigarettes.** Cigarettes on the market on 15 February 2007 were ‘grandfathered’ and could stay on the market when the Tobacco Control Act entered into force on 22 June 2009 with a further concession for products modified between 15 February 2007 and 22 March 2011. There are no similar provisions ensuring continuity in the market for e-cigarettes or other newly deemed products.
- **Inadequate risk communication.** Truthful and properly-understood risk communication, including statements that would better inform consumers, are obstructed by an onerous and opaque process (MRTP – Modified Risk Tobacco Product application) for establishing validity of claims on a product-by-product basis. No MRTP orders have been made so far³¹, even though it is beyond reasonable dispute that products with no combustion are far safer than products with combustion. The absence of credible information on relative risk is compounded by mandatory warning labels that do not offer realistic or useful consumer information.
- **The challenge of the public health test.** At several points in the TCA, the applicant or FDA are required to consider a ‘public health test’ – whether the introduction of a product or measure could increase smoking initiation or decrease smoking cessation and is “appropriate for the protection of public health.” Though this sounds reasonable, this test is open to widely diverging interpretation depending on what degree of certainty is called for. Applied with excessive loss aversion, the public health test can provide a pretext for intransigence and may create risks by denying smokers safer alternatives because of an unrealistic burden of proof. The public health test, properly conceived and applied, does allow balancing of adverse and beneficial population effects. For example, highly beneficial effects to middle aged adult smokers who switch must be recognized.
- **FDA as a bottleneck.** The number of newly deemed products currently on the market that could require authorization runs to hundreds of thousands. Even with a radical contraction of the market precipitated by the burdens of the deeming rule itself, FDA’s Center for Tobacco Products will struggle to process several thousand PMTA applications. It is unclear what sort of scientific personnel FDA will find to do the tedious but technical work of evaluating the paperwork. FDA’s own human resources challenge may render the current system unviable unless the market undergoes a radical contraction and concentration likely to be dominated by tobacco companies as the most likely survivors. Since March 2011, FDA has had a large backlog of Provisional Substantial Equivalence applications to process and has made hardly any progress. That experience suggests FDA has not coped with its regulatory duties as they were *prior to the deeming rule*. This experience does not provide an encouraging precedent.
- **Overall weakness.** The Tobacco Control Act was designed with three main purposes in mind: (1) to control and suppress tobacco marketing; (2) to slow or prevent innovation in tobacco products; (3) to be highly risk-averse about supposedly safer tobacco products. When the TCA was conceived, there was raised awareness of the false implicit claims of ‘low tar’ and ‘lights’. Further, it was expected that reduced-risk products would be ‘safer cigarettes’ and it would be necessary to judge if a small reduction in risk gave a disproportionately false reassurance that it was safe to continue to smoke³². The text of the Act and culture of the FDA interact to create a highly burdensome and risk-averse framework that forms a poor basis for exploiting the public health opportunities for tobacco harm reduction.

³¹ FDA. Summary of MRTP Application Actions accessed 14 May 2017 [\[link\]](#). By 14 December 2016, thirty-three MRTP applications had been received, none approved.,

³² See the Findings by Congress that underpin the Tobacco Control Act – notably Findings 33, 34, 36-43 [\[link\]](#)

1.7 Developing a better approach to tobacco and nicotine regulation

There are various elements that can be drawn together to make a strong overall response:

- Take emergency action to prevent needless destruction of the existing vapor marketplace and removal of products that people are using to quit and stay off smoking
- Move to a transparent standards-based regime
- Insist on truthful and candid risk communication by HHS agencies including FDA and CDC
- Make appropriate use of the public health test

These approaches are explored further in the sections below.

2 Take emergency action to prevent needless destruction of the consumer vapor market

The first element is to put a brake on the current approach before the damage and unpredictable consequences intensify. Manufacturers and importers have until 8 November 2018 to file a valid PMTA for each product that was on the market as of 8 August 2016 to be able to continue lawfully marketing said product. After a further 12 months, tobacco products on the market without authorization will be subject to enforcement. New products require a PMTA, so the market is currently frozen and approaching a destructively disruptive regulatory deadline. The suggested emergency measure would provide the same sort of relief for newly deemed non-combustible products (e-cigarettes and other noncombustible nicotine consumer products, etc.) that was provided for cigarettes in 2009 and could be implemented in several ways:

- **Option 1: use administrative discretion to delay enforcement by four years.** This approach could be used to buy time while a standards approach is introduced (see below). A short enforcement delay has already been applied, confirming the administration has the necessary powers³³. This enforcement discretion would apply only to the requirement to have submitted and approved a PMTA (under Section 910), not to all the other measures set out below that are applied through the deeming rule. The FDA could justify delaying enforcement based on non-discriminatory or proportionate treatment in relation to cigarettes, or because of issues raised in legal actions. A variation on this proposal is that the Department of Justice with FDA would decline to contest some or all of the legal challenges to the deeming rule and reach a settlement³⁴. Other administrative options may be considered³⁵. FDA could commission independent legal advice on the full range of administrative flexibilities available to the Secretary.
- **Option 2: Congress could change the predicate date.** Congress could amend the TCA to set a predicate date of 8 August 2016 (the effective date of the deeming rule) for some or all of the products that were deemed to be tobacco products and therefore subject to the jurisdiction of the Act and FDA. This would mean that products

³³ FDA. Web statement 3 May 2017 [\[link\]](#)

³⁴ Stier, J, Miller HI. Promote Health by Not Defending the E-Cigarette Ban, National Review 16 May 2017 [\[link\]](#)

³⁵ There are legal theories that support other administrative flexibilities: [changing the predicate date](#) as part of a deeming rule on the basis that the original Act only applied to cigarettes, smokeless and hand rolling tobacco; [selective deeming](#) (an approach considered to exclude premium cigars) to apply to a subset of vapor products, for example, those placed on the market after 8 August 2016, [limited deeming](#) to apply only a subset of the TCA provisions (not the PMTA requirement), [light touch PMTA](#) using rule-making to create an easier pathway; [“undeeming”](#) to place the intervention on hold pending further study and rule making; [selective enforcement](#) discretion to disapply disproportionate or discriminatory requirements.

Rethinking nicotine: implications for U.S. federal tobacco policy

on the market at this time would be 'grandfathered'. Implementing this requires amendments to Sections 905 and 910 of the Tobacco Control Act³⁶ – this would remove the requirement for pre-market review (PMTA) for products on the market at 8 August 2016 but would leave other measures in place. The Cole-Bishop Bill introduced into Congress³⁷.

- **Retain the other measures.** Whatever approach is used to remove the PMTA requirement, other obligations made under the deeming rule should go in to effect. The deeming rule brought in a number of restrictions and reporting requirements other than the requirement for pre-market authorization. These measures would be retained³⁸ and reassessed, as appropriate, with the introduction of standards.
 - Ban on sales to customers below age 18
 - Ban on free samples – though this should not apply in vape shops or smoking cessation settings
 - Ban on sales by vending machine
 - Product packages and ads must contain the addictiveness warning statement: “*WARNING: This product contains nicotine. Nicotine is an addictive chemical.*” However, note that this is a gross simplification of ‘addictiveness’ of uncertain value and the required size of this warning is excessive.
 - Ingredient listing and disclosure of harmful and potentially harmful constituents (HPHCs)
 - Provision of tobacco health documents
 - Registration of establishments,
 - Labelling with business contact, quantities and restriction to sale only in the United States
- **Formally withdraw the proposed NNN rule for smokeless tobacco following the comment period.** This rule, introduced on 23 January 2017, would reduce the content of a nitrosamine (NNN) to less than one part per million on a dry weight basis³⁹. There are challenges to the underlying justification^{40 41} and credible concerns that the standard is unachievable for most (>95%) of the smokeless tobacco market⁴². If an excessively stringent standard does shut down most of the US smokeless tobacco market there will be unpredictable consequences for tobacco use. These include the possibility of increased uptake of smoking and greatly increased harm as smokeless users respond to changed supply of their preferred products. This danger has not been recognized in the FDA’s supporting analysis for the rule. The rule is open for comment until 10 July 2017.
- **Weigh the pros and cons of including cigars in relief from the PMTA process.** The deeming rule also brought cigars and several other *combustible* products under the jurisdiction of the TCA. Should these products have the same kind of grandfathering waiver as cigarettes? A waiver would allow continuity in the cigar market equivalent to that granted for cigarettes. Not allowing it may increase uptake of cigarettes or stimulate illicit trade activity. The Secretary should consider the principles and politics at stake but ensure that restrictions that are applicable to cigarettes are applied to cigars, for example in relation to flavors.

³⁶ FDA. Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”) 22 June 2009 [\[link\]](#) Amending the Federal Food, Drug and Cosmetics Act 21 U.S. Code § 387 [\[link\]](#)

³⁷ HR 1136 FDA Deeming Authority Clarification Act of 2017. 115th Congress (2017-2018) “The Cole-Bishop Bill” [\[link\]](#)

³⁸ FDA. Effective and Compliance Dates Applicable to Retailers, Manufacturers, Importers, and Distributors of Newly Deemed Tobacco Products, January 2017 [\[link\]](#)[\[PDF\]](#)

³⁹ FDA. Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products, 82 FR 8004-8053, FDA-2016-N-2527 23 January 2017 [\[link\]](#)

⁴⁰ PN Lee. Comment on the Food and Drug Administration (FDA) Proposed Rule: Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products, P N Lee Statistics and Computing Ltd, [\[link\]](#)

⁴¹ Altria Client Services. Comment on the Food and Drug Administration (FDA) Proposed Rule: Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products, Comment and Request for Extension from Altria Client Services LLC [\[link\]](#)

⁴² Rodu B. Problems Multiply for Proposed FDA Smokeless Tobacco Rule, Tobacco Truth, 29 March 2017 [\[link\]](#)

3 Move to a transparent standards-based regime for low-risk products

The emergency intervention above would provide some relief and limit damage to the vaping market, but it does not provide a longer-term and coherent framework for regulating these products. The strategic change required is to move away from a regime based on an opaque, burdensome and costly case-by-case authorization procedure – often for products that are nearly identical within firms and across the market. Instead, a regime based on *standards* and *notification* should be adopted. This is broadly the regulatory philosophy adopted by the European Union, though U.S. regulators should be able to improve significantly on the European Union’s specific standards⁴³.

- **Use standards to mitigate the broad range of risks.** Standards could be established to manage risks.
 - chemical, electrical, thermal and mechanical risks – and related testing methods for devices, liquids and other consumables
 - schedules of prohibited or limited ingredients, contaminants or products of thermal decomposition
 - manufacturing standards and quality control
 - labelling and consumer information
 - any controls on advertising, sponsorship or promotion
- **Use standards to give clarity to producers and consumers.** Manufacturers and importers would know what is expected of them and regulatory uncertainty would be reduced; the supply chain and service industries can gear up to meet standards with high quality and lower cost; consumers would know what to expect and would be appropriately reassured; the process is less open to arbitrary or discriminatory decision-making; standards can evolve through public deliberation and can progressively tighten as firms and regulators acquire experience; standards can be adapted and retrospectively applied to the existing products on the market.
- **Implement proportionate standards using the rule-making powers of the TCA.** The Tobacco Control Act contains rule-making procedures at Section 907⁴⁴. This may be a lengthy procedure, but it is possible to act quickly by creating *de facto* standards through guidance.
- **Use guidance to create *de facto* standards in the interim.** One option would be to propose standards in guidance and allow compliance with these standards to inform a fast-track PMTA process. There is draft already guidance available for PMTA applications for ENDS (electronic nicotine delivery systems)⁴⁵. This could be amended or replaced to create *de facto* standards prior to the rule-making process. The use of interim guidance would also allow experience to accumulate prior to firm rule-making.
- **Internal standards will be required to manage the PMTA process – make them visible.** FDA may be concerned that it cannot set standards because it does not have a scientific basis to set them. Even without explicit standards, FDA will still need to develop internal standards for operational use within the assessment process. These will be required to ensure non-discriminatory and consistent decision-making across thousands of assessments and many assessors. This proposal is that such standards such be made explicit and visible to applicants. This simple measure would be a first pragmatic step to building a full standards regime, but would generate material public health benefits, while reducing burdens on producers and the FDA. A basic standard-setting regime would be valuable if it simply removed outliers, contained known risks or took action against firms with inadequate quality control.

⁴³ Bates CD. What is wrong with the Tobacco Products Directive for vapour products, The Counterfactual, 22 May 2015. [\[link\]](#)

⁴⁴ FDA. Section 907 of the Federal Food, Drug, and Cosmetic Act - Tobacco Product Standards [\[link\]](#)

⁴⁵ Pre-market Tobacco Application. FDA information [\[link\]](#). FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry. May 2016 [\[link\]](#)

Rethinking nicotine: implications for U.S. federal tobacco policy

- **Draw on experience of standards developments within and outside the United States.** The American E-liquid Manufacturing Standards Association (AEMSA) has developed a standard for e-liquids and related manufacturing processes⁴⁶ and several respected American businesses have adopted this. The most highly evolved non-US standards to date have been developed by the French national standards body AFNOR for devices and liquids, and related testing measures⁴⁷. There have been e-cigarettes standards initiatives in the UK⁴⁸ and now the EU standardization body (CEN) is developing an e-cigarettes standard⁴⁹. The WHO's technical advisory group has recommended standards for smokeless tobacco and novel tobacco products⁵⁰. There are many relevant electrical standards.⁵¹ There are ISO standards for child-resistant packaging⁵² - though a standard is already implemented in US law. The UK's Committee on Advertising Practice produced useful guidelines on advertising provide a reasonable balance of interest between protection of minors and promotion of new low-risk products to smokers⁵³.
- **Use standards to contain the burdens on FDA resources.** The use of a standards-based approach would radically reduce the paperwork burdens both on businesses and FDA's assessors. This approach means that FDA's scientific capacity is focused on the technical process of standard-setting rather than on checking thousands of applications for paperwork quality and errors. It would also mean the deeper PMTA case-by-case assessment regime is reserved for truly novel products and novel risks that would fall outside
- **Use standards to reduce the burdens of the PMTA process to manageable and predictable level.** Under the current TCA, the introduction of standards does not substitute for the PMTA authorization process under Section 910 – and does not therefore automatically solve the problem of the destructive burdens of PMTA on the vaping or other markets in low-risk products. There are two approaches to this: either amend the law to make compliance with the standards sufficient to allow the product onto the market; or within the constraints of the existing law, have a PMTA process that amounts in practice to a notification regime for products that comply with standards (i.e. the standards are regarded as sufficient to meet the PMTA requirement). There should be a trade-off between the assurance given by standards and the demands for case-by-case assurance via the PMTA, given both are designed to achieve the same purpose.
- **Retain an authorization regime for novel products and risks.** There may be important innovations in future for which existing standards are inappropriate or insufficient, or where novel risks are created but with significant offsetting benefits. For such developments a proportionate PMTA process could be appropriate.

⁴⁶ AEMSA E-liquid manufacturing standard Version 2.3.2 - March 8, 2017 – accessed 17 May 2013 [\[link\]](#)

⁴⁷ AFNOR (France) Electronic cigarettes and e-liquids Part 1: Requirements and test methods for e-cigarettes XP D90-300-1 March 2015 [\[link\]](#), XP D90-300-2 Part 2: Requirements and test methods for e-cigarette liquid XP D90-300-2 [\[link\]](#) March 2015, XP D90-300-3 Part 3: Emissions testing requirements and methods, July 2016 [\[link\]](#)

⁴⁸ BSI PAS 54115:2015 Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products - Manufacture, importation, testing and labelling - Guide [\[link\]](#) July 2015

⁴⁹ European Centre for Standardisation, CEN/TC 437 - Electronic cigarettes and e-liquids [\[link\]](#)

⁵⁰ See especially: WHO Study Group on Tobacco Product Regulation Report on the Scientific Basis of Tobacco Product Regulation: WHO Technical Report Series, no. 951, 2008 [\[link\]](#), no. 955. 2010. [\[link\]](#); no 989. 2015. [\[link\]](#)

⁵¹ International Electrotechnical Commission (IEC) standards. For example: IEC 60335-1 2010 (safety of appliances) [\[link\]](#); IEC 60335-2-29:2016 (safety of battery chargers) [\[link\]](#); IEC 62133-1&2:2017 (safety of portable batteries) [\[Part 1: Nickel\]](#)[\[Part 2: Lithium\]](#); IEC 61558-1:2005 (safety of AC adaptors) [\[link\]](#); IEC 61000 series (electromagnetic compatibility) [\[link\]](#)

⁵² ISO 8317 Child resistant packaging [\[link\]](#)[\[guide\]](#)

⁵³ Committee on Advertising Practice (UK), UK Code of Broadcast Advertising: 33. E-cigarettes Broadcast [\[link\]](#); UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code): 22. E-cigarettes [\[link\]](#)

4 Put consumer interests first with truthful and candid communication of risk

Public perceptions of relative risk are significantly misaligned with reality⁵⁴. Only 5.3% of Americans believe (correctly) that e-cigarettes are ‘much less harmful’ than cigarettes, 37% believe they are the same or worse and 34% don’t know. Only 11% agree that some forms of smokeless tobacco are less harmful than cigarettes – in fact, all forms of smokeless tobacco on sale in the United States are much less harmful than cigarettes. These misperceptions distort consumer choices and may cause inappropriately risk-averse policy responses if they influence policy-makers. In both cases, these misperceptions are potentially harmful to health if they deter smokers from switching to less harmful products or promote relapse. Possible remedies include:

- **Retain the Modified Risk Tobacco Product approval route but do not rely on it.** The MRTP product-by-product validation of marketing claims is necessary (a route by which a novel or a product-specific claim can be assessed) but far from sufficient as this creates a barrier to truthful risk communication. In essence, an MRTP application will only be made if it is in the commercial interest of a tobacco company to incur the expense of making the application. This is a poor basis on which to provide members of the public with information vital to their health. True and fair communication of risk should not only come from a company awarded an MRTP order but should be a broader mission for the government and its responsibility to citizens.
- **Reform the MRTP process.** The MRTP application process suffers from the same or worse opaque and arbitrary decision-making and unclear or moveable success criteria that afflict the PMTA process. This was clear in a 2016 decision on an MRTP application for a snus product, which apparently required the applicant to prove there was no risk – an impossible burden - and left large warnings in place for negligible risks for which evidence of any harm is at best tenuous⁵⁵. The process should focus on truthful and non-misleading communication of the relative risk compared to smoking. If bold warnings are to be retained on the pack is a the risks need to be material and the warning a proportionate response – we do not warn about every conceivable risk in consumer products. The impact of denying reasonable risk communication about less harmful products to smokers should be weighed in assessing the public health test in MRTP applications.
- **Introduce officially-approved risk communications for reduced-risk products.** FDA and CDC could agree appropriate risk communication statements for major product categories (e-cigarettes, smokeless, heated tobacco) and allow these to be used on packaging and in advertising at the discretion of the manufacturer under guidance provided by FDA. FDA could state that it will not take enforcement action for such statements as they are deemed true and non-misleading commercial speech. This could be implemented as guidance to Section 903 of the Tobacco Control Act⁵⁶. FDA has already considered category-wide warning messages. In 2015, after four years of deliberation, FDA inappropriately rejected a 2011 petition to change a misleading warning for a meaningful reduced risk message for smokeless tobacco products as follows⁵⁷:

Specifically, the Petitioners request that the "WARNING: This product is not a safe alternative to cigarettes." (current warning) be changed to "WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes." (proposed warning).

⁵⁴ National Cancer Institute, HINTS, FDA Survey 2015. E-cigarettes [\[link\]](#); Smokeless tobacco [\[link\]](#)

⁵⁵ FDA Perspective: Lessons Learned from the First Review of Modified Risk Tobacco Product (MRTP) Applications, [\[link\]](#) and critique: Rodu B. FDA Rejects Plea to Correct Smokeless Tobacco Warnings; A Closer Look at Flawed Interpretations, 21 December 2016 [\[link\]](#)

⁵⁶ FDA. Tobacco Control Act 22 June 2009. S.903 *Misbranded Tobacco Products* [\[link\]](#)

⁵⁷ FDA. Docket FDA-2011-P-0573, Initiate a Rulemaking Procedure to Adjust the Text of a Smokeless Tobacco ("ST") Product Warning Label Statement [\[link\]](#) Petition denied 11 May 2015. Citizen Petition from RJ Reynolds Tobacco Company.

Rethinking nicotine: implications for U.S. federal tobacco policy

However, in rejecting this petition, FDA made no assessment of the negative impact of the existing warning, which is literally true but misleading, and the objection to the proposed alternative was highly convoluted.

- **Establish a Code of Practice on Risk Communication for federally funded research.** Though the statements made or authorized by regulators for use by companies would be influential, the communications of academics or advocates routinely make news and shapes public perceptions via the media. Some of this communication lacks the care or caution that information about mortal risks demands, and some may be aiming for headlines to attract attention or funds. FDA and NIH or other funding bodies could address this with academics or advocates in receipt of federal funds by producing a Code of Practice on Risk Communication that grantees would be expected to adhere to. This would not be a curtailment of academic freedom, but an obligation to act responsibly that came with federal funds and a duty of care to the public. It would attempt to curtail irresponsible commentary on research, for example exaggerating the risks from trace concentrations of toxins, misrepresenting minor physiological responses to nicotine as evidence of harm, lacking an explicit comparison or contrast with smoking, or overstating the relevance of animal or *in vitro* studies. Such commentary can have harmful real-life consequences if it alters public perceptions of risk and modifies behavior as a result – and federal funds should not be implicated in causing harm. FDA could appoint a ‘consumer champion’ to adjudicate on violations of the Code of Practice.
- **Set targets for federal agencies to better align public perceptions with reality.** The Department of Health and Human Services could establish performance targets for its major agencies (FDA, CDC, Office of the Surgeon General) to align risk perceptions with realistic expert assessments of comparative risk between non-combustible and combustible nicotine or tobacco products.

5 Make appropriate use of the public health test

Because its interpretation is open to ambiguity, the public health test in the Tobacco Control Act⁵⁸ can be used as a barrier to pro-health innovation and, depending how it is applied, it may be a cause of excessive and harmful risk aversion towards the introduction of new and much safer products⁵⁹. For example, the test has the following formulation for its application to the PMTA process (section 910.c.4).

***Basis for Finding.** For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account:*

- A. the increased or decreased likelihood that existing users of tobacco products will stop using such products; and*
- B. the increased or decreased likelihood that those who do not use tobacco products will start using such products.*

The question is ‘with what degree of certainty should this test be met?’ There are major challenges in meeting this with a high level certainty:

- At the level of a single product, there it is impossible to have certain prior knowledge of how it will fare in the marketplace, who will use it, for what purpose, for how long and what they will do next.

⁵⁸ See use of this test in the following sections: Tobacco Control Act, 2009 s.910c.4 *Application for Review of Certain Tobacco Products: Basis for finding* [\[link\]](#); s.911g.4 *Modified Risk Tobacco Products: Marketing* [\[link\]](#); s.907a.3.B *Tobacco product standards: determinations* [\[link\]](#); s906.d.1 *General Provisions Respecting Control of Tobacco Products: Restrictions* [\[link\]](#)

⁵⁹ Bates CD, Lehrer E, Sweanor D, Reshaping American Tobacco Policy Eight federal strategies to fight smoking and ignite a public health revolution, February 2017. [\[link\]](#) Five: Stop using the public health test to protect the cigarette trade PDF [\[link\]](#)

Rethinking nicotine: implications for U.S. federal tobacco policy

- At the level of whole categories, there is heated disagreement about the population impact of the products, with highly contested interpretations of studies purporting to reveal ‘gateway effects’ or similar. All such studies, and this test, require a ‘counterfactual’ (what would happen in the absence of the product) and this is extremely hard to know in advance – for example, people who use e-cigarettes may otherwise have smoked.
- The population impact is not solely a function of the characteristics of a given product, but a wide range of behavioral influences including pricing and tax, media commentary, policies such as clean indoor air, and tastes, and fashion. These are beyond the control of the applicant and may be unpredictable.

Given this *unavoidable* uncertainty, the test is open to wide interpretation and represents a source of regulatory risk for producers. It provides opportunity for activists to use pedantic interpretations of this test to pursue a prohibitionist agenda and block access to market of low-risk products and related claims.

The key to proper application of this test is the reasoning of the decision-maker, the Secretary (with day to day authority devolved to the CTP). This reasoning could be approached as follows:

- **Give equal weight to possible population harms arising from blocking beneficial products or claims.** The test should be applied *symmetrically*, recognizing the uncertainties cut both ways and that *not* authorizing a low-risk product or modified risk claim because of uncertainties about population impacts could be harmful. The test requires the Secretary “*to take into account*” (i.e. the requirements are not absolute) “*the increased or decreased likelihood*” of adverse or beneficial changes in tobacco use (i.e. the requirement for symmetrical appraisal is built into the test)
- **Use individual risk to determine the burden and strength of evidence required on population effects.** The test could be addressed in two stages. First, focus on individual risk, then on population risk. The first stage would change the burden of proof for the second. If the individual risk is much lower (i.e. a non-combustible product), then FDA would need to be compelling evidence of adverse population effects to block the product or reduced risk claims. If, on the other hand, the individual risk was not much lower than smoking (i.e. a safer cigarette or other combustible product) then the applicant would need compelling evidence that no adverse population effects would arise to justify access to the market.
- **FDA could determine the population test at category level.** The test could be applied at a category level, not a product level. It is virtually impossible to resolve the test at the level of a single product. FDA should make a determination of which categories qualify *as a whole* as appropriate for protection of public health. It could do this by recognizing the risk-use equilibrium concept⁶⁰ or by recognizing that rapid switching to a low-risk alternative may be preferable to total abstinence if it happens sooner⁶¹. Given the cigarette category has been allowed significant grandfathering and never had to face such tests, it would be non-discriminatory to make broad determinations that much safer product categories are consistent with the test.
- **Evaluate using post-market surveillance.** The test could be retained, but assessment made through *post-market* surveillance. This is likely to be only practical at the category level and even then with some difficulty in defining the counterfactual (what would have happened in the absence of the product). This would allow measures to be adopted to address and suppress any adverse effects or, in the event of serious impacts emerging, withdrawal of the product or category.

⁶⁰ Kozlowski LT, Strasser AA, Giovino GA, Erickson PA, Terza J V. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. *Tob Control*. BMJ Group; 2001 Sep;10(3):201–3. [\[link\]](#)

⁶¹ Phillips C V. Debunking the claim that abstinence is usually healthier for smokers than switching to a low-risk alternative, and other observations about anti-tobacco-harm-reduction arguments. *Harm Reduct J*. England; 2009 Jan;6:29. [\[link\]](#)

Rethinking nicotine: implications for U.S. federal tobacco policy

- **Prioritize truth-telling.** There is no a case to withhold truthful and non-misleading risk information about products because of objectives to change behavior – for example to mislead the public about smokeless tobacco risks compared to smoking due to concerns that people will be reassured about using smokeless tobacco⁶². The public health test should not be used to justify the suppression of truthful risk communication.

6 Retain the current approach to combustible tobacco products

The Tobacco Control Act was largely designed with combustible products in mind, and with the prospect that reduced risk *combustible* products, so-called safer cigarettes, might come to market. The framework for regulation of combustible tobacco products allows for the following:

- Assessing public health benefits or detriments arising from innovation in combustible products
- Reducing toxic agents in cigarette smoke
- Reducing abuse liability
- Reducing appeal to minors
- The validation of claims about modified risk

At this time, the Tobacco Control Act provides an adequate framework for regulating combustible products and this should not be a focus of reform efforts.

7 Conclusions

The regulation of low-risk tobacco and nicotine products is heading for a crisis that will have the unintended effect of protecting the cigarette trade and harming health. However, the incoming administration has an opportunity to turn a looming crisis into a public health success. Here are the main ideas:

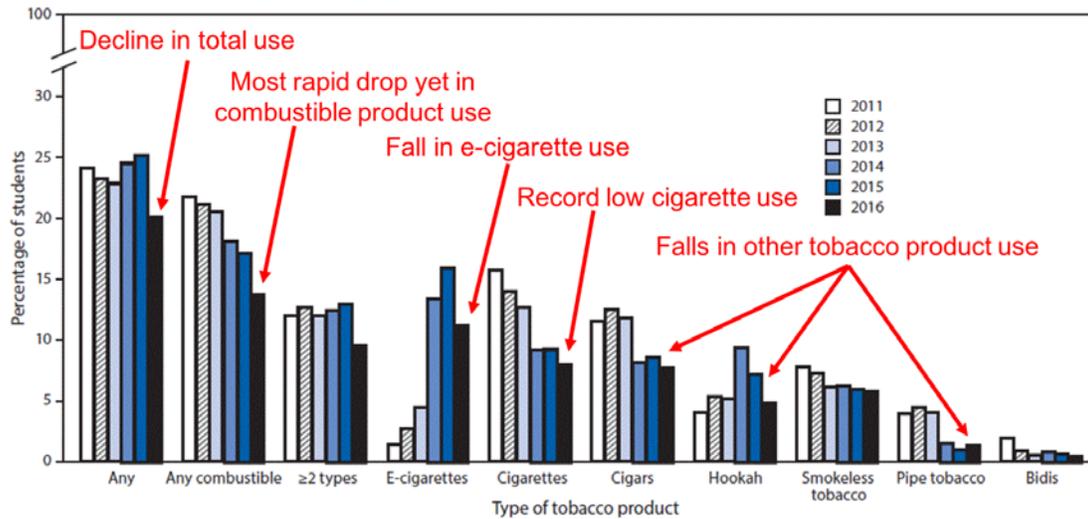
- The first step should be an ‘emergency’ intervention to stabilize the market and to protect the interests of existing consumers by introducing a substantial (four-years) delay in enforcement of requirements to complete a PMTA for vaping products and to cancel the proposed smokeless tobacco standard for NNN.
- Following such action, administrative reforms can be undertaken within the FDA to configure a regulatory framework under the Tobacco Control Act that would enhance opportunities for tobacco harm reduction based on clear regulatory principles and policy objectives.
- The key is to find a practical way to use the flexibilities of the Tobacco Control Act to reduce excessive regulatory burdens by replacing an opaque and burdensome authorization procedure with a transparent proportionate standards-based regime.
- Rather than rely on tobacco manufacturers to determine what risk communication should be provided to the public, FDA as regulator could approve (or waive enforcement action on) statements that clearly communicate relative risks of different categories of tobacco and nicotine products.
- The combination of reducing regulatory burdens in order to release the public health potential of a highly competitive low-risk alternative to cigarettes is a ‘win-win’ and it should appeal across the political spectrum.
- All the protections that the FDA offers to young people would be retained under this system. The approach outlined above is from a public health perspective – a focus on the reduction of smoking-related disease.

⁶² Kozlowski, Sweanor D. Withholding differential risk information on legal consumer nicotine/tobacco products: The public health ethics of health information quarantines. *Int J Drug Policy*. Elsevier; 2016;32:17–23. [\[link\]](#)

Appendix 1: trends in youth tobacco and nicotine use

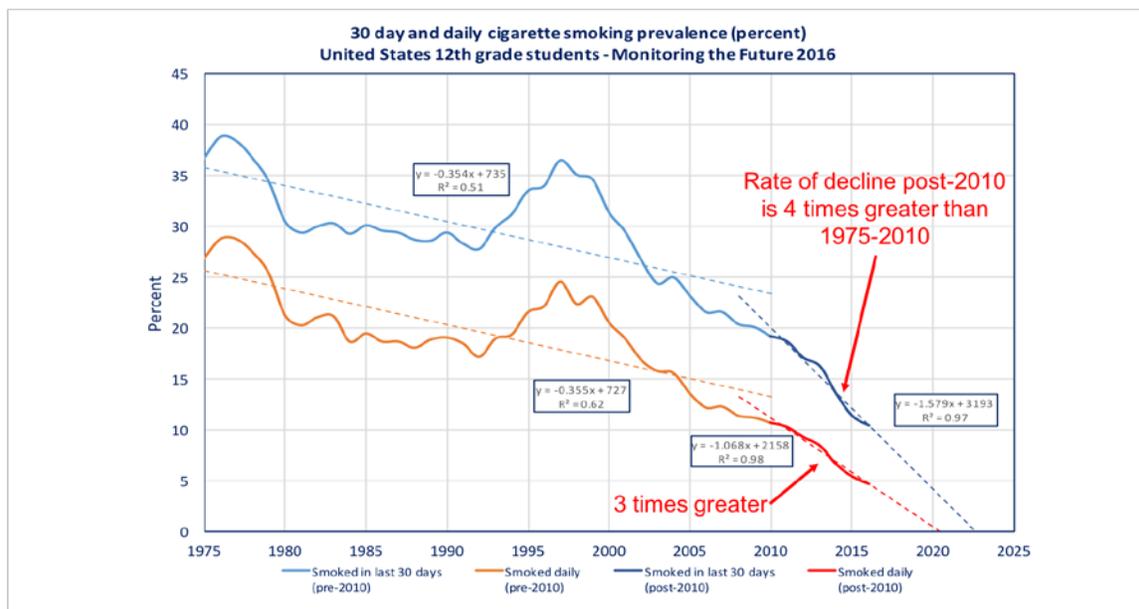
The two charts that follow are annotated to show salient features of the most recent data on youth smoking in the United States. The first chart is from the National Youth Tobacco Survey, published June 2017⁶³.

FIGURE 1. Estimated percentage of high school students who currently use any tobacco products,* any combustible tobacco products,[†] ≥2 tobacco products,[‡] and selected tobacco products – National Youth Tobacco Survey, United States, 2011–2016^{¶,**,††}



* Any tobacco product use is defined as past 30-day use of electronic cigarettes, cigarettes, cigars, hookahs, smokeless tobacco, pipe tobacco and/or bidis.

The second is from the 2016 University of Michigan Monitoring the Future survey, which has a time series dating back to 1975 for 12th grade smoking⁶⁴.



⁶³ Jamal A, Gentzke A, Hu SS, Cullen KA, Apelberg BJ, Homa DM, et al. Tobacco Use Among Middle and High School Students - United States, 2011-2016. *MMWR Morb Mortal Wkly Rep.* 2017 Jun 16;66(23):597–603. [\[link\]](#)

⁶⁴ Miech RA, Johnston LD, O'Malley PM, Bachman JG, Schulenberg JE. Monitoring the Future national survey results on drug use, 1975-2016: Data tables. Table 2 - Trends in Prevalence of Use of Cigarettes. University of Michigan; Ann Arbor: 2016. [\[Tables\]](#) [\[Dataset\]](#).

About the author

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. He has 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.