

# **Reshaping American Tobacco Policy**

**Eight federal strategies to fight smoking and ignite  
a public health revolution**

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## Eight federal strategies to fight smoking and ignite a public health revolution

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## Executive summary

36.5 million Americans (15% of adults) smoked 264 billion cigarettes in 2015. Cigarette smoking causes more than 480,000 deaths each year in the United States – more than HIV, illicit drugs, alcohol, motor vehicles and guns combined. Smoking-related illness in the United States costs more than \$300 billion each year, including nearly \$170 billion for direct medical care for adults and more than \$156 billion in lost economic productivity<sup>1</sup>. *Smoking creates a massive health and economic burden.*

Yet despite very large expenditures and sweeping federal powers, perverse tobacco policy is failing the American public and will soon destroy thousands of small and medium-sized businesses that are part of the solution, not part of the problem. The vast majority of harm to health is caused by cigarette smoking arising from burning tobacco and inhalation of smoke into the lungs, not from nicotine use. The 2014 Surgeon General's Report confirmed<sup>2</sup>:

*“Death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other burned tobacco products”.*

Where there is no combustion, as with smokeless tobacco, e-cigarettes or vaping products or heated tobacco products, the risks of nicotine use will *inevitably* be much lower (20-100 times lower) because the physical processes are so different. None of these products are perfectly safe – very little is. But they are very much *safer*.

These radically reduced risk products create an opportunity for major health and economic gains through technology substitution. However, U.S. policy has actively denied and stymied this opportunity:

- U.S. tobacco policy suffers from an ‘abstinence-only’ ideology. This intolerant approach rarely works well in any branch of public health. The opportunity is to move to a market-based ‘harm reduction’ approach whereby people who want to use nicotine or are not sufficiently motivated to quit nicotine can use products that are much less harmful than smoking.
- New regulation coming into effect over the period to August 2019 will have the effect of taking 90-99% of vaping products off the market for bureaucratic rather than safety reasons, and therefore dramatically limit options to switch from high-risk to low-risk products and obstruct innovation.
- The response to such rules will be to cause harm to people as they return to smoking and harm to American businesses as consumers seek black market supplies from international internet vendors.
- The American consumer has been systematically misled and denied truthful, non-misleading information about the relative risks of non-combustible products.
- The system of tobacco science funding in the United States is working to support expansion of federal bureaucracies and an abstinence-only ideology, rather than in the public interest.

**Concern about children.** Much of the rhetoric used by activists and regulators to justify poor or excessive regulation has been based on an emotive appeal to the protection of children. However, the data shows that coinciding with the rise of vapor products there has been a sharp decline in teenage

*smoking*: between 2011 and 2015, current use of cigarettes by high school students fell rapidly from 15.8% to 9.3%, and use of cigars and pipes also fell<sup>3</sup>. Non-smoking high school students are highly unlikely to use e-cigarettes; among those who do, most used them very infrequently<sup>4</sup>. Further, only a small minority of teenage vaping involves nicotine<sup>5</sup>, and much of the use is occasional and experimental rather than an entrenched habit<sup>6</sup>. Bans on sales of vapor products to minors were already in place (48 states) or in progress (2 states) prior to FDA asserting jurisdiction in 2016. It is unlikely that teenagers are harmed by the emergence of products much safer than cigarettes. However, it is likely that both teenagers and adults will be harmed by excessive regulation or *de facto* prohibition of low risk products that substitute for smoking.

**Proposed response.** To address this policy failure, we suggest eight proposals for discussion, summarized below and set out in more concise briefing form in the subsequent eight sections. The proposals are as follows:

- 1. Seize the huge opportunity presented by low-risk nicotine products** Revolutionize tobacco and nicotine policy, reduce healthcare spending and improve health by exploiting the very large difference in risk to human health caused by combustible and smoke-free products. Make appointments and provide direction and funding to embed this in federal agencies such as FDA, CDC, NIH and Office of the Surgeon General as well as the highest levels of the Department of Health and Human Services. It requires a concerted approach on many fronts.
- 2. Cancel the FDA deeming rule before it destroys the U.S. vaping market.** An *emergency response* is required to prevent the near complete and needless destruction of the US vapor industry by crudely designed and wholly inappropriate regulation. The following approaches are an urgent response:
  - a. Put the implementation process on hold and quickly pass legislation that changes the Tobacco Control Act predicate date to 8 August 2016 for nicotine products that do not contain tobacco.
  - b. Replace the costly, opaque and politicized product-by-product authorization regime with a standards-based regime where it is clear what is required of manufacturers (recommendation 3).
  - c. Add a range of interim safeguards concerning common ground issues such as battery and fluid safety if a standards regime will take time to agree. These should be applied by Congress in the instrument it uses to affect the changes above.
- 3. Establish a standards-based regime for low-risk nicotine products.** Regulate low risk tobacco and nicotine products by setting product standards (chemical, mechanical, thermal, electrical) that reduce individual risk to users while promoting innovation and ensuring the products are an attractive alternative to smoking. These standards would ensure average exposures were at least 90 percent lower than smoking and would make a further public health benefit test unnecessary.
- 4. Use new labels to inform consumers about relative risk.** Using its rulemaking powers, FDA should allow manufacturers to apply an accurate ‘harm reduction’ message to all non-combustible tobacco or nicotine products: *“This product presents substantially lower risks to health than cigarettes”* or other truthful, non-misleading communications

5. **Stop using the public health test to protect the cigarette trade.** The public health test in the Tobacco Control Act does not protect the public health, but it does protect the cigarette trade from competition. It should not be applied to non-combustible tobacco or nicotine products. These should be evaluated according to their product characteristics and risk to individual users, not unknowable post-market population effects.
6. **Restore honesty and candor to public health campaigns** Require FDA, CDC and other relevant federal agencies to act to bring public perceptions closer to reality, for example to set a goal that by 2020 at least 75% of Americans believe that e-cigarettes, smokeless tobacco and heated tobacco products are, correctly, each ‘very much less harmful’ than cigarettes. This could be realized through enabling language and funding included in the President’s Budget Proposal or by Executive Order.
7. **Refocus tobacco science on the public interest not bureaucratic expansion.** Overall, the imperative is to change the incentive structures in tobacco-related research to stress objectivity in the public interest, not to justify expanded bureaucratic intervention.
  - Congressional oversight hearings should examine the state of tobacco science
  - FDA/CTP should commission replications, counterfactuals, quality reviews and contrarian analysis to challenge its own thinking
  - CDC should commission tobacco use surveillance but outsource conduct and analysis to independent third parties and practice open data principles
  - NIH should produce guidelines on conduct and reporting of tobacco-related research (e.g. inclusion of comparisons with smoking, materiality of risk, not drawing policy conclusions)
  - Encourage establishment of a “Center for Nicotine and Tobacco Science in the Public Interest” to act as a defender of the public interest.
8. **Challenge vapor and smokeless prohibitions under WTO rules.** The United States should initiate complaints under World Trade Organization agreements about wholly unjustified prohibitions of low-risk nicotine products in jurisdictions outside the United States. This would give a win-win for public health and American exporters, while challenging the negligence of the World Health Organization and some of its member states.

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## 1 Seize the huge opportunity presented by low-risk nicotine products

**Recommendation 1.** Revolutionize tobacco and nicotine policy, reduce healthcare spending and improve health by exploiting the very large difference in risk to human health caused by combustible and smoke-free products. Make appointments and provide direction and funding to embed this in federal agencies such as FDA, CDC, NIH and Office of the Surgeon General as well as the highest levels of the Department of Health and Human Services

Current tobacco policy is mired in obsolete themes, confusion about goals and denial about highly positive developments in the marketplace<sup>1</sup>. The overwhelming majority of the risk associated with tobacco use comes from tobacco smoke and combustion, not from nicotine. Nicotine is a mildly psychoactive drug that can be addictive, but addictiveness depends on how fast, in what form, and how much is delivered. However, nicotine itself is not particularly harmful. It is the tobacco smoke that holds and transports the nicotine to the lungs where it is absorbed that is the cause of cancer, cardiovascular and respiratory illnesses. Combusted tobacco smoke is the most effective delivery system for nicotine, but there are products that deliver a nicotine experience that is nearly as satisfying *but without the smoke* – and therefore with greatly reduced health risks. These products have four main generic forms:



1. E-cigarettes and vaping products. These create much lower exposures to toxic agents<sup>2 3 4</sup> and are likely to be at least 95% lower risk than smoking<sup>5 6</sup>.
2. Heated tobacco products, in which a vapor is created by heating but not burning tobacco. These products are likely to be at least 90% lower risk than smoking<sup>7 8 9 10</sup>.
3. Unheated nicotine products, such as lozenges, films, inhalers and some forms of pharmaceutical nicotine replacement therapy (NRT). These are likely to approximate to NRT in their risk profile.
4. Smokeless tobacco such as well-established products like snus, which is likely to be at least 98% lower risk than smoking<sup>11</sup> and has been responsible for the lowest levels of smoking in the developed world in Sweden<sup>12</sup> and significant health gains<sup>13</sup>.

These smoke-free nicotine products have become viable consumer market competitors to smoking with a small fraction of the risk. They may not be completely safe - very little is - but the fundamental physical and chemical processes involved mean these products will be very much less harmful than smoking. Therein lies a vast untapped opportunity for both health and potentially reducing healthcare costs by “billions of dollars”<sup>14</sup>. As a study of the fiscal effects of tobacco harm reduction focused on the state of Indiana concluded<sup>15</sup>:

Making [e-cigarettes] more expensive for or unavailable to consumers is misguided because switching to [e-cigarettes] from combustible cigarettes leads to improved health outcomes for cigarette smokers. Over time, this will lower the substantial amount of state funds that are spent on public healthcare programs such as Medicaid.

The emergence of these products suggests a major rethink of nicotine policy is due and that it should be conducted based on new governing principles and civil dialogue – a process that is well advanced<sup>16</sup>.

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- <sup>2</sup> 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. [\[Link\]](#)
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- <sup>5</sup> Public Health England. E-cigarettes around 95% less harmful than tobacco estimates landmark review. [\[link\]](#) E-cigarettes: an evidence update 19 August 2015. [\[link\]](#)
- <sup>6</sup> Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [\[link\]](#)
- <sup>7</sup> Gilchrist M. Heat-not-Burn Products: Scientific Assessment of Risk Reduction. Presentation to Global Tobacco and Nicotine Forum, Phillip Morris International, September 2015. [\[link\]](#)
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- <sup>15</sup> Meyer J. The Fiscal Effects of Tobacco Harm Reduction: A Case Study of Indiana, *Economics* 21, 1 December 2016. [\[link\]](#)
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## 2 Cancel the FDA deeming rule before it destroys the U.S. vaping market

**Recommendation 2.** An *emergency response* is required to prevent the near complete and needless destruction of the US vapor industry by crudely designed and wholly inappropriate regulation. The following approaches are an urgent response:

- a. Put the implementation process on hold and quickly pass legislation that changes the Tobacco Control Act predicate date to 8 August 2016 for nicotine products that do not contain tobacco.
- b. Replace the costly, opaque and politicized product-by-product authorization regime with a standards-based regime where it is clear what is required of manufacturers (recommendation 3).
- c. Add a range of interim safeguards concerning common ground issues such as battery and fluid safety if a standards regime will take time to agree. These should be applied by Congress in the instrument it uses to affect the changes above.

In May 2016, the Food and Drug Administration published a 134-page regulation<sup>1</sup> deeming e-cigarettes and some tobacco products to fall under the Family Smoking Prevention and Tobacco Control Act. In doing so, the FDA has applied extremely burdensome regulatory burdens and an opaque authorization regime, the Pre-Market Tobacco Application (PMTA)<sup>2</sup> to many thousands of products made by thousands of businesses, the vast majority being small-scale American enterprises. The arguments against this rule are summarized in legal arguments in proceedings brought against the FDA by an American medium-scale advanced technology business<sup>3</sup>, and in a supportive *amici curiae* brief by public health experts<sup>4</sup>. The case against these regulations is broadly as follows:

- There is no problem to which the proposed rule provides a solution. In fact, the picture is one of public health success, with adult<sup>5</sup> and youth smoking<sup>6</sup> falling to record lows and at rapid rates.
- Despite alarmist claims about youth vaping, most teenage vaping does not involve nicotine<sup>7</sup>, is occasional or experimental<sup>8</sup> and frequent use is concentrated in young people who are already smokers<sup>9</sup>
- The claimed benefits of these regulations<sup>10</sup> are, in fact, nugatory or negative when examined<sup>11</sup>.
- The costs and burdens of the regulations are so large that they will destroy almost all the vaping market while leaving the cigarette market intact. All vaping products currently on the market and serving more than 8 million Americans<sup>12</sup> will be taken off the market by default and be required to regain access to the market via the PMTA authorization process, at a cost of at least \$182k-\$2.01m per application for liquids and \$286k-\$2.62m per application for devices<sup>13</sup>. (And some experts believe these costs are understated.)
- FDA will need to create a vast bureaucracy of scientists and evaluators to process the 6-7,000 PMTA applications it anticipates receiving. Yet even this volume assumes most of the industry is not a burden because it 'exits' the market. By 'exit' FDA means 'put out of business', not because there is anything wrong with their products, but because they cannot afford the costs and uncertainty of FDA's PMTA process and do not have the compliance experience that will be necessary.
- Vaping and use of other alternatives to cigarettes creates new pathways out of smoking for people



who do not wish to quit or find it difficult<sup>14</sup>. The FDA has failed to assess the likely impact of its own highly burdensome intervention on the resulting patterns of vaping and smoking. There are many scenarios in which its rules could *increase* smoking and cause harm by reducing the appeal of vaping products compared to cigarettes. FDA's regulation is reckless and amounts to an unjustified and harmful protection of the cigarette trade.

- FDA's intervention is certain to stimulate cross-border internet shopping as users try to source the products they currently use and take advantage of new innovations that FDA will obstruct from the US market. In doing so, it will be piling costs onto American businesses while subjecting them to cut-throat price competition from foreign internet vendors.
- Though regulation is supposed to be proportionate to risk, the most toxic products (cigarettes) were given a broad exemption to the authorization regime. The regulation of vaping products is not just disproportionate, but it is 'anti-proportionate', perverse and unfair compared to cigarettes.

Safeguards can be introduced rapidly pending the development of a full standards based regime, for example like those added to the Cole-Bishop amendment to the Agricultural Appropriations Bill<sup>15</sup>.

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- <sup>2</sup> Pre-market Tobacco Application. FDA information [\[link\]](#). FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry. May 2016 [\[link\]](#)
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- <sup>10</sup> FDA, Deeming Rule Docket No. FDA-2014-N-0189: Final Regulatory Impact Analysis, 10 May 2016, 5. *Willingness To Pay for Benefits of Rule*, page 67 [\[link\]](#)
- <sup>11</sup> Brief of *amici curiae* of Clive Bates and fifteen other in support of plaintiffs' motion for summary judgement, 5 August 2016 [\[link\]](#) see page 4-7 for short critique of each benefit claimed by FDA.
- <sup>12</sup> 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 [\[link\]](#)
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### 3 Establish a standards-based regime for low-risk nicotine products

**Recommendation 3.** Regulate low risk tobacco and nicotine products by setting product standards (chemical, mechanical, thermal, electrical) that reduce individual risk to users while promoting innovation and ensuring the products are an attractive alternative to smoking. These standards would ensure average exposures were at least 90 percent lower than smoking and would make a further public health benefit test unnecessary.

There are many problems with the authorization regime for vaping products introduced by FDA. This should be replaced with a regime that defines transparent industry-wide standards so that everyone involved can understand what is expected of them and how to comply – this is normal practice.

- The FDA’s process is extremely burdensome, with demanding evidential requirements and high costs of paperwork. This is compounded by evaluation costs and lengthy delays at the FDA.
- It is an opaque procedure in which the applicant does not know how the application will be evaluated or how pedantic or flexible the FDA’s evaluators will be. For example, how high evidential bars will be set, how trade-offs will be made, how inevitable uncertainties will be reconciled. Authorization decisions rest with the FDA and its staff, but like any agency it is vulnerable to politicization of its decision-making and the biases of its decision-makers.
- The authorization requires a ‘public health benefit test’ to be passed before the product is placed on the market<sup>1</sup> – taken literally or pedantically, this test involves proving a negative and can be almost impossible to meet<sup>2</sup>. Even for products that prove to be very beneficial, it is hard to prove this *before* the product is on sale. However, the public health benefit test may harm public health by erecting a bureaucratic hurdle that keeps beneficial products from the market - see section 5.
- Even an obviously beneficial improvement (e.g. hardware upgrade or adding temperature control) to a product must go through a new authorization. The regime acts as a barrier to innovation, yet innovation is necessary to attract more smokers away from cigarettes, and to make continuing improvements in e-cigarette safety.
- The most dangerous products, cigarettes, have escaped this regime completely<sup>3</sup>.

The alternative is to use the approach that is used for most products on the market in the United States – set industry-wide standards. Non-combustible products should comply with standards that govern chemical, thermal, electrical and mechanical risks. To achieve the optimum public health outcome, standards should be carefully set in a way that does not increase the likelihood that those who use low-risk products will relapse to smoking or that fewer smokers will switch.

- **Combustion products.** Combustible products (cigarettes, rolling tobacco, cigars etc) could continue to be regulated under the existing framework of the Tobacco Control Act.
- **Vaping products.** Set standards for testing methods and product characteristics that mitigate the main residual risks, and allow these standards to adapt to new knowledge and advancing technology. The French standards-setting body, AFNOR, has published a range of standards<sup>4</sup>, the

British Standards Institute has defined optional standards<sup>5</sup> and the European standardization body, CEN, has commenced work on a four-part standard<sup>6</sup>. Elements of a standards regime could include blacklisted ingredients where there are known health risks<sup>7</sup>, maximum concentrations for contaminants, limits to products of thermal decomposition measured in vapor, battery safety standards including covers on loose batteries and battery-charger compatibility<sup>8</sup>. Within the confines of the 1<sup>st</sup> amendment, limits could be placed on marketing that may appeal to or disproportionately reach under-18s could be imposed. For example, UK guidelines aim to strike a balance between protection of young people and commercial freedom to market an alternative to smoking to adults<sup>9</sup>.

- **Heated tobacco products.** The approach would be similar to that for vaping products, though with different standards to reflect the different ingredients and chemical processes involved.
- **Smokeless tobacco / nicotine products.** Set standards for residual toxins, such as tobacco-specific nitrosamines. This approach and an outline standard was recommended by WHO's expert group<sup>10</sup> and a company has established a standard to which it holds its own products<sup>11</sup>. Standards should be moderate to begin with aiming to remove outliers and then tighten up with experience.

FDA has powers to set such standards under Section 907 of the Tobacco Control Act<sup>12</sup>. In all cases, standard consumer protection legislation should be used to address concerns to the extent possible.

## References

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- <sup>5</sup> 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
- <sup>6</sup> European Centre for Standardisation, CEN/TC 437 - Electronic cigarettes and e-liquids [\[link\]](#)
- <sup>7</sup> A blacklist would target carcinogenic, mutagenic, reprotoxic substances and respiratory sensitizers. There are known ingredients of concern, for example: diacetyl (a buttery flavouring), cinnamaldehyde and benzaldehyde. The evidence does not so far support a material health risks at typical exposures, but there is a case for requiring alternatives to be used where these are available.
- <sup>8</sup> International electrical safety standards are available: IEC 60335-1 (safety of household appliances); IIEC 60335-2-29 (safety of battery chargers); IEC 62133 (safety of portable batteries); IEC 61558 (safety of AC adaptors); IEC 61000 series; and EN 55022 & EN 55024 (for USB chargers & cables)
- <sup>9</sup> 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 [\[link\]](#)
- <sup>10</sup> WHO Study Group on Tobacco Product Regulation Report on the Scientific Basis of Tobacco Product Regulation: WHO Technical Report Series, no. 951, 2008 [\[link\]](#)
- <sup>11</sup> Swedish Match, GOTHIA TEK® limits for undesired components [\[link\]](#)
- <sup>12</sup> Food and Drug Administration, Section 907 of the Federal Food, Drug, and Cosmetic Act - Tobacco Product Standards (2009) [\[link\]](#)

## 4 Use new labels to inform consumers about relative risk

**Recommendation 4.** Using its rulemaking powers, FDA should allow manufacturers to apply an accurate ‘harm reduction’ message to all non-combustible tobacco or nicotine products: *“This product presents substantially lower risks to health than cigarettes”* or other truthful, non-misleading communications.

Given there is 10-100 times difference in risk between cigarettes and non-combustible products (see section 1), how would consumers come to know this highly valuable health information? The statutory warnings that cover e-cigarettes, heated tobacco products and some novel products<sup>1</sup> and smokeless tobacco<sup>2</sup> are shown below.

**E-cigarettes etc.** **WARNING:** This product contains nicotine. Nicotine is an addictive chemical

**Smokeless tobacco** **WARNING:** This product can cause mouth cancer.  
**WARNING:** This product can cause gum disease and tooth loss.  
**WARNING:** This product is not a safe alternative to cigarettes.  
**WARNING:** Smokeless tobacco is addictive.

These warnings provide virtually no valuable, actionable or even truthful information to consumers.

- **Misleading about nicotine addiction.** Nicotine itself is not particularly dangerous to health. How addictive it is will depend on how rapidly and how high a peak exposure is reached in the brain as well as the interaction with other chemical agents in smoke – so addiction is strongly product and user-dependent. The term ‘addictive’ is vaguely understood and covers many forms of dependence – for example nicotine is not addictive in the same way as opioids even if it does meet almost all clinical definitions of an addictive substance for at least a portion of the population.
- **Misleading about health.** The evidence for smokeless tobacco causing mouth cancer, gum disease and tooth loss is very thin and may not apply to all forms of smokeless tobacco, for example snus<sup>3 4</sup>. The specific health warnings do not convey the *magnitude* of these risks either by comparison to smoking or to other risks such as those arising from dietary choices.
- **Misleading about safety.** The most damaging warning claims smokeless tobacco is ‘not a safe alternative to cigarettes’. Though technically true, this is profoundly misleading. It has been strongly criticized by experts for withholding the most crucial *differential* risk information<sup>5</sup>.

A 2011 citizen petition filed on behalf of Reynolds American<sup>6</sup> urged the FDA to initiate administrative rulemaking to replace the safety warning with the following text (and a further variation on this):

*“WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes”*

Though this contains truthful and non-misleading information, FDA determined it would not promote better understanding and rejected the petition in November 2015<sup>7</sup>. Despite this setback, the makers of these products do have a route by which they can make truthful health claims. This is the FDA’s Modified Risk Tobacco Product application process (MRTP)<sup>8</sup>, which is used to validate reduced-risk marketing claims. This process has been a total failure and, despite 33 applications, has yet to approve any modified risk claims<sup>9</sup>, despite the huge variation in real-world risk. In June 2014, the snus company Swedish Match applied<sup>10</sup> to have the same warning as proposed by Reynolds applied to 8 of its own products. Despite a 130,000-page submission and more than two years of deliberation FDA announced

further prevarication on 14 December 2016<sup>11</sup>. This explanation for this decision<sup>12</sup> has revealed FDA's willingness to make up the rules as the process unfolds, and in doing so to create new barriers to candid communication of risks in a way that consumer groups argue works against the consumer interest<sup>13</sup>:

- FDA cherry-picked studies showing adverse effects rather than looking at the science overall<sup>14</sup>.
- FDA insists that the company prove that its product *cannot* cause an adverse health effect before it can make a reduced risk claim.
- FDA insists that the company shows the product has lower risks for all possible health impacts, however trivial, not just the major causes of tobacco related disease

The FDA has a thoroughly flawed approach to risk communication:

- It relies on a tobacco company to find it commercially advantageous to apply in the first place. That is a bizarre and wholly inadequate basis for providing important risk information to the public.
- It relies on allowing tobacco companies to be the primary communicators of relative risk to the public, even though these companies are among the least trusted organizations in modern life.
- It applies only to that company's products, though near-identical products may be on the market and would be labelled differently.
- FDA does not have to justify its own warning regime or show it does not mislead consumers – the *status quo* is granted immunity from scrutiny or requirement to meet a public health benefit test.
- Messages should *inform* consumers, not aim to manipulate their behavior to achieve some desired outcome. For example, if the undisclosed purpose of these warnings is to deter all nicotine use, they may perversely mislead citizens into continued smoking where they might have switched to smokeless tobacco to reduce risks.

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## 5 Stop using the public health test to protect the cigarette trade

**Recommendation 5.** The public health test in the Tobacco Control Act does not protect the public health, but it does protect the cigarette trade from competition. It should not be applied to non-combustible tobacco or nicotine products. These should be evaluated according to their product characteristics and risk to individual users, not unknowable post-market population effects.

One of the main failings of U.S. tobacco policy is the so-called public health test built into the Tobacco Control Act that guides the FDA's regulatory determinations. For a new tobacco or consumer nicotine product to be brought onto the market, the vendor is required to show that its release onto the market is appropriate for the protection of public health. The test uses the following formulation<sup>1</sup>.

**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.*

It may sound reasonable, but this test does not serve public health. Its main effect is to create near-insurmountable market barriers-to-entry to much safer products than cigarettes, though it does not apply to thousands of cigarette products already on the market. The test is problematic not because new products really are inappropriate for public health, but because the burden of proof to meet this test is so great, especially in advance of the product being placed on the market. Consider the following:

- The public health impact of a product is *not a characteristic of the product itself* but an emergent property of the complex web of behavioral influences on the use of the product. Many of these are unknowable in advance or extremely difficult predict and beyond the control of the manufacturer.
- There is no experience with a new product until it has been placed on the market, so the applicant has no relevant concrete data to offer from real-world use to support an application – a Catch-22. If there is data, it applies to older products, past market conditions, different regulatory environment, a different communications environment and different consumer preferences.
- It is hard enough to find consensus about entire categories, let alone specific products. Consider the disputed evidence and ideologically-based arguments about e-cigarettes regarding relative risk, gateway effects, renormalizing smoking and reducing quitting. If there is no consensus at the level of the entire category, then how can an individual manufacturer make a case for a specific product?
- It is impossible to set up meaningful trials because there are so many uncontrollable variables in real world use.
- The impact of one product depends on other products (competitors) or rival strategies (cessation or different harm reduction approaches)
- The public health impact of a product cannot be known until all consumer behavioral transitions have worked through – that may take decades.

These problems are not merely technical; they have a bureaucratic, legal and political dimension.

- **Bureaucratic.** If a harmful product is incorrectly approved there is a risk that the regulator will be shown to be wrong. However, if a beneficial product is not approved, there is no way to check if the decision was wrong and there has been avoidable harm. This asymmetry in accountability and reputational risk is an incentive to reject applications.
- **Legal.** A legal challenge from a manufacturer to a rejection will be easier to fight in court than a legal challenge from an interest group to an approval, given the inherent uncertainties and that the burden of proof rests with the manufacturer.
- **Political.** Where there is inherent difficulty in establishing a cast-iron case to approve a product, there is scope for decisions to be made for reasons other than relevant evidence – for example, reasons of ideology, to pacify or impress interest groups or simply to look and feel ‘tough’.

These forms of bias can emerge because manufacturers face the daunting task of predicting the future use of a new product in changing market conditions, in a changing product landscape and with constantly evolving behavioral influences. They are little to do with inherent product characteristics.

Further, there are *ethical concerns* with relying on *population* health assessments, even if these could be done reliably, which they cannot. It can mean denying market access to products that are much safer to use as an individual than cigarettes. It means that one person may be denied access to a product that would be highly beneficial for them because of concerns about how *someone else* may use the product.

The public health test was included in the Tobacco Control Act because at the time it was thought the regulatory challenge would arise from re-engineered *combustible* products or ‘safer cigarettes’<sup>2</sup>. The concern would be that changes in behavior or false reassurance could easily overwhelm the benefits of reduced individual risk. This becomes much less of a concern if the reduced risk product is orders of magnitude lower risk than smoking<sup>3</sup>, as with non-combustibles. The test is applied elsewhere in the Act<sup>4</sup>, thus creating barriers to setting reasonable product standards (recommendation 3) and to making truthful non-misleading claims to consumers (see recommendation 4)

**The appropriate approach.** For non-combustible products, regulators should focus determinations, standard-setting and risk communication on the actual product characteristics and risk to individuals, not on the unknown (and unknowable) way in which the product may be used in the marketplace. If populations effects are a concern, they should be a matter for post-market surveillance. If harmful effects emerge, then a regulator or manufacturer may be able to take corrective action.

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## 6 Restore honesty and candor to public health campaigns

**Recommendation 6.** Require FDA, CDC and other relevant federal agencies to act to bring public perceptions closer to reality, for example to set a goal that by 2020 at least 75% of Americans believe that e-cigarettes, smokeless tobacco and heated tobacco products are, correctly, each ‘very much less harmful’ than cigarettes. This could be realized through enabling language and funding included in the President’s Budget Proposal or by Executive Order.

When asked how risky vaping or smokeless tobacco is compared to cigarettes, American adults gave the following answers in 2015 in a survey by the National Cancer Institute<sup>1</sup>.

<b>Compared to smoking cigarettes, would you say that electronic cigarettes are...</b>		<b>Do you believe that some smokeless tobacco products, such as chewing tobacco and snuff, are less harmful than cigarettes?</b>	
Much less harmful	5.3%	Yes	10.9%
Less harmful	20.6%	No	66.2%
Just as harmful	32.8%	Don’t know	22.0%
More harmful	2.7%	Other	0.9%
Much more harmful	2.0%		
I’ve never heard of e-cigarettes	1.2%		
I don’t know enough about these products	33.9%		

The only remotely correct answers are that e-cigarettes are “much less harmful” and “yes”, smokeless tobacco products are less harmful than cigarettes. So, these are shocking results, showing a dramatic misalignment of perception and reality in a way that implicitly favors continued smoking. There is also evidence that these misperceptions are worsening over time despite constantly improving specialist knowledge. A May 2016 survey<sup>2</sup> found that *“forty-seven percent of respondents said vaping was not healthier than smoking conventional cigarettes compared with 38 percent who felt that way a year ago”*.

If America’s 38 million smokers are basing their choices, at least in part, on these perceptions of risk, then many will be missing the opportunity to radically reduce their risk by switching to a non-combustible product. The question arises therefore: what is the cause of this misperception? The problem has its origins in misleading and misguided promotional activity by key federal agencies and their senior officials. These bodies strongly signal norms and expectations to the wider research, health and activist community. Three examples suffice, but the problem is replicated at state level.

**Centers for Disease Control and Prevention (CDC).** The lead public health agency has led highly negative ‘abstinence-only’ campaigns against vaping<sup>3 4</sup> and smokeless tobacco, denying or ignoring possible benefits to smokers<sup>5</sup> and exaggerating risks<sup>6 7</sup> while falsely claiming there are gateway effects<sup>8 9</sup>.

**Food and Drug Administration.** The main federal regulator has undertaken a sustained campaign to extend its bureaucratic reach to include e-cigarettes. It has, therefore, a bias to justifying an expanded role by finding problems to which its involvement could be proffered as a solution<sup>10 11</sup>. It has joined in the largely unfounded panic about youth vaping, ignored or underplayed the benefits to adults. FDA relentlessly conflates and confuses smoking, tobacco-use and nicotine use, creating the impression these are all essentially the same<sup>12 13</sup>. Though calling for a debate on nicotine<sup>14</sup>, it has used newspaper



articles to make alarmist statements about vaping<sup>15</sup>, which are easily shown to be baseless or misleading<sup>16</sup>. Its extremely burdensome deeming rule has pre-empted any 'debate' and it has done little to sponsor a genuine open-minded discussion about the role of nicotine in society. While calling for debate, FDA is running a campaign, *The Real Cost*, that fails to discriminate between nicotine products with radically different risk<sup>17</sup>. It is not even clear why FDA, a regulator, is running youth campaigns at all.

**Office of the Surgeon General.** The recent report of the Surgeon General on youth vaping avoided drawing obvious conclusions or plausible hypotheses from the data<sup>18</sup> and misrepresented the available science to create unjustified alarm<sup>19</sup>. The Surgeon General drew policy conclusions that were flawed for youth protection, but failed even to consider harmful unintended consequences for adults<sup>20</sup>. Although, more of the established media followed the Surgeon General's contrived narrative, it has started to attract much more critical analysis subsequently<sup>21</sup>.

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## 7 Refocus tobacco science on the public interest not bureaucratic expansion

**Recommendation 7.** Overall, the imperative is to change the incentive structures in tobacco-related research to stress objectivity in the public interest, not to justify expanded bureaucratic intervention.

- Congressional oversight hearings should examine the state of tobacco science
- FDA/CTP should commission replications, counterfactuals, quality reviews and contrarian analysis to challenge its own thinking
- CDC should commission tobacco use surveillance but outsource conduct and analysis to independent third parties and practice open data principles
- NIH should produce guidelines on conduct and reporting of tobacco-related research (e.g. inclusion of comparisons with smoking, materiality of risk, not drawing policy conclusions)
- Encourage establishment of a “Center for Nicotine and Tobacco Science in the Public Interest” to act as a defender of the public interest.

**A dysfunctional science system.** The science system for tobacco policy in the United States is failing the American people. Over years of conflict with Big Tobacco, tobacco control science has developed a culture with strong cognitive biases towards problem-finding and alarm-sounding, justifying ‘abstinence-only’ approaches, and a tendency to rally to support policy proposals that go far beyond what a science paper can support. This culture was never right or justifiable, even if it felt necessary to those involved. When it comes to reduced risk products, such activist bias is a scientific and public health disaster. Several skilled experts now monitor the literature and a tour of their work<sup>1</sup> or PubMed Commons<sup>2</sup> will reveal how bad the situation has become. The types of error widely propagated in the literature have been summarized in a guide to bad vaping science (see box)<sup>3</sup>. A devastating critique<sup>4</sup> of a recent WHO paper drew heavily on poor science that originated in the United States. Overall, the problem is an obsessive focus on minor or hypothetical risks combined with indifference to or denial of opportunities.

**A wall of money in favor of regulation.** The system of funding starts with deep biases. For example, a NIH request for applications for grant funding<sup>5</sup> stated: “*The overall goal is to develop an evidence base to inform smokeless tobacco control efforts, and to develop effective ways to limit the spread and promote cessation of smokeless tobacco use.*” The idea that smokeless tobacco might be a valuable low-risk substitute for smoking is excluded and the research subordinated to supporting control efforts. FDA’s Center for Tobacco Products funds a major tobacco regulatory research program and 14 Tobacco Centers of Regulatory Science<sup>6</sup>. These research centers will receive more than \$273 million in grants from 2013-2018. It should be obvious that so much science funded by a regulator will be biased towards finding reasons to regulate. Further, it will create supposedly independent advocates for FDA regulation. This establishes giant conflicts of interest that are never acknowledged by those involved. Professor Brad Rodu has analyzed overall NIH spending on tobacco-related research: he comments<sup>7</sup>

*In 2014, the NIH (mainly the National Cancer, Heart Blood Lung, Drug Abuse and Mental Health Institutes) dispensed \$623 million (total costs) in 1,300 grants to over 1,000 PIs at almost 300 universities, medical centers and other institutions. That works out to about \$600,000 for each investigator. Few researchers will jeopardize grants of that size by doing or saying anything that conflicts with NIH dogma.*

Even the most basic data on youth tobacco/nicotine use is controlled and interpreted by CDC and has been routinely misrepresented to create a moral panic<sup>8</sup>. But when full data is eventually released, the results appear much more positive, suggesting any gateways might be ‘exits’ from smoking<sup>9</sup>. The Truth Initiative’s Schroeder Institute has been one bright spot in a dismal U.S. landscape with recent in-depth and credible reviews on e-cigarette science<sup>10</sup> and nicotine<sup>11</sup>. This sort of impartial and robust analysis that should be informing U.S. tobacco policy – not that designed to support activism or more regulation.

**Amplification of bias.** The initial bias and perverse incentives are then amplified through various mechanisms, including: grant-seeking behavior by researchers; publicity-seeking by university press offices; impact-seeking by journals and editors; group-think and common cause by peer-reviewers; sensation-seeking by news outlets; the rise of ‘click-bait’ as a driver of news values.

**The case of “hidden formaldehyde”.** One example will suffice: a letter published in the New England Journal of Medicine claimed e-cigarettes could produce 5-15 times greater formaldehyde-related cancer risk than smoking<sup>12</sup>. This created huge global media coverage<sup>13</sup>. However, the experiment was deeply flawed (it operated e-cigarettes at temperatures no human would ever use)<sup>14</sup>, yet the journal published only a 125-word response three months later<sup>15</sup>, and declined to correct or withdraw the original letter even though it has no relevance to human health and despite the damage that such false information causes<sup>16</sup>. Nine months later, the team at Portland State were awarded a \$3.5m grant from NIH/FDA<sup>17</sup>.

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## Box 1: Challenging common sources of error in scientific papers on vaping

### 1 Toxic chemicals have been identified in e-cigarette vapor or e-liquids

- 1.1 Did they show potentially harmful *exposure* not just the *presence* of a chemical? “The dose makes the poison”.
- 1.2 How risky is the exposure compared to smoking?
- 1.3 How risky is the exposure compared to other risks such as those accepted under occupational health limits?
- 1.4 Were measurements made in realistic human operating conditions or overheated or at very high concentrations?
- 1.5 Are inappropriate proxies being used for risk – for example effects that are also seen with coffee or exercise?
- 1.6 Are flawed analogies being used – for example assuming all ultrafine particles are equally toxic?

### 2 Adverse health effects from e-cigarettes are reported

- 2.1 Was vaping the real cause?
- 2.2 Was the person suffering from adverse impacts of being a smoker before using e-cigarettes?
- 2.3 Is the study just observing the effect of nicotine on the body (though no serious disease is caused by nicotine)?
- 2.4 Is there evidence of actual harm or is it just a *change* in the body or brain?
- 2.5 Is it based on a cell culture study and are the limitations recognized and was exposure realistic proxy for human use?
- 2.6 Is it based on an animal study and are the limitations recognized?

### 3 Claims second-hand vapor is toxic and indoor vaping should be banned

- 3.1 Are vapor exposures to bystanders potentially harmful given they pose little risk to direct users?
- 3.2 Is the difference between risk or harm and nuisance or personal preference recognized?
- 3.3 Have false choices been proposed? – e.g. between a ban and *laissez faire*, when it could be left to owners to decide?

### 4 Nicotine damages the adolescent brain

- 4.1 What is the specific nature of the detriment to human health?
- 4.2 Where is the evidence for the brain damage from nicotine in the longstanding human population of smokers?
- 4.3 How does this compare to damage from alcohol, cannabis or caffeine?

### 5 More children using e-cigarettes and gateway effects

- 5.1 Did they characterize use properly? For example, ‘ever use’ of an e-cigarette is really a marker of experimentation.
- 5.2 Could the rising use of e-cigarettes be a good thing if it is displacing smoking?
- 5.3 High level of smoking associated with vaping – but is this due to independent common factors (confounding)?
- 5.4 Have they defined a gateway effect?
- 5.5 Are they assuming prior behavior caused the later behavior?

### 6 E-cigarettes keep people smoking and reduce quit rates

- 6.1 Has vaping been wrongly conceptualized as though it is a medical intervention?
- 6.2 Has the importance of product’s consumer appeal been recognized?
- 6.3 Was “dual use” described as problematic – any cutting down is beneficial and may be part of a longer transition?
- 6.4 Did they claim there are no benefits to cutting down?
- 6.5 Not enough randomized controlled trials (RCTs)? RCTs are a poor way to measure impact of diffusion of technology.

### 7 Flavors and e-cigarette marketing aimed at children

- 7.1 Do they assume it is just obvious that childish names appeal to kids?
- 7.2 Why would adolescents try to emphasize their childishness?
- 7.3 Have *preferences* for particular flavors been misrepresented as a *cause* of vaping?
- 7.4 Could it be a benefit that some flavors are attractive to adolescents if it means they don’t smoke?
- 7.5 Is an e-cig advertising in effect an anti-smoking ad?

### 8 Citing uncertainty and appeal to the ‘precautionary approach’

- 8.1 Have they understood what is known and recognized the physical processes in vaping are different to smoking?
- 8.2 Are they asking the impossible? For example, by saying we will only know the risks when we have 40 years of data?
- 8.3 Do they realize that ‘precautionary approach can do harm to health if it stops people accessing beneficial technology?

### 9 Tobacco industry involvement implies inevitable harm

- 9.1 Is the malign influence of tobacco companies assumed or demonstrated?
- 9.2 Is there over-reliance on decades old industry statements, documents or behaviors?
- 9.3 Is there a proper understanding of how the nicotine and tobacco market works?
- 9.4 Are the authors concerned about the right things? For example, are they fighting ill-health or capitalism?

### 10 Policy recommendations in a scientific paper

- 10.1 Do policy recommendations go beyond what their research justifies?
- 10.2 Have policy-making disciplines been followed – options generation, impact assessment, consultation etc.?
- 10.3 Are the authors’ policy positions revealing their biases and priors?
- 10.4 Have unintended consequences been ignored? Many e-cigarette policy proposals could lead to more smoking.

## 8 Challenge vapor and smokeless prohibitions under WTO rules

**Recommendation 8.** The United States should initiate complaints under World Trade Organization agreements about wholly unjustified prohibitions of low-risk nicotine products in jurisdictions outside the United States. This would give a win-win for public health and American exporters, while challenging the negligence of the World Health Organization and some of its member states.

There are many countries that have taken a highly counter-productive and harmful approach to low-risk nicotine products, especially vapor products, and that is to ban the manufacturing, sale or import of these products – either explicitly or by default through excessive regulation. In the European Union, snus is banned other than in Sweden<sup>1</sup> even though the product has had very significant health benefits<sup>2</sup> and even though chewing tobacco or nasal snuff is allowed on the market. A 2016 survey reports the prohibitions of e-cigarettes in the following jurisdictions<sup>3</sup>:

*Sale of all types of e-cigarettes is banned in 26 countries: Argentina, Bahrain, Brazil, Brunei Darussalam, Cambodia, Colombia, Greece, Jordan, Kuwait, Lebanon, Lithuania, Mauritius, Mexico, Nicaragua, Oman, Panama, Qatar, Saudi Arabia, Seychelles, Singapore, Suriname, Thailand, Turkey, United Arab Emirates, Uruguay and Venezuela.*

In these countries, the much more harmful combustible tobacco products (cigarettes etc.) are freely available. Incredibly, the World Health Organization has encouraged these prohibitions via its submission to parties to the Framework Convention on Tobacco Control<sup>4</sup>. WHO's Director General, Dr. Margaret Chan even called for e-cigarettes to be prohibited in China<sup>5</sup>. This represents unethical<sup>6</sup> and, at best, confused approach to health of over one billion existing smokers worldwide<sup>7</sup>.

There is no basis for snus or e-cigarette prohibition on public health, scientific or ethical grounds. Such bans may also be unlawful under trade law. This is the basis of the legal argument:

- **Trade law prohibits discriminatory treatment of 'like products' depending on their origin.** From a trade law perspective e-cigarettes and cigarettes may be considered "like products" based on four criteria (i) the physical properties of the products; (ii) their end-uses; (iii) consumer preferences and (iv) the international classification of the products for customs purposes<sup>8</sup>.
- If products are recognized as "like products" in the meaning of trade law, two key anti-discriminatory principles apply under the WTO General Agreement on Tariffs and Trade (GATT)<sup>9</sup>:
  1. **Most-favored-nation (MFN) principle** ("treating different foreigners equally"). Where a country allows market access to imported cigarettes from one trading partner, it must extend this "advantage" to the "like products" of other trading partners, including low risk nicotine products. Failure to do so would constitute a violation of Article I:1 of the GATT<sup>10</sup>.
  2. **National treatment principle** ("treating foreigners and locals equally"). If regulatory prohibitions prevent low-risk nicotine products from entering the market, while cigarettes can be produced, distributed and sold domestically, the conditions of competition discriminate against the imported product thereby constituting less favorable treatment under Article III:4 of GATT<sup>11</sup>

- **Public health exception will not apply.** It is possible to override these anti-discriminatory measures on public health grounds under the General Exception provisions of Article XX of GATT<sup>12</sup>. However, the country imposing the prohibition on the low risk product would need to justify the use of this exception, and it is hard to see how they could make this case – certainly not by relying on the WHO’s scientific assessment, which has been comprehensively discredited<sup>13</sup>.
- **Prohibition through excessive regulation.** Where technical regulations create discrimination via a *de facto* prohibition (for example in Australia), they may violate Articles 2.1 and 2.2 of the WTO’s Technical Barriers to Trade (TBT) agreement<sup>14</sup>, which respectively prohibit technical regulations that favor like products of national origin over like products from a foreign country, and require that “*technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective [including...] protection of human health*”.
- **WHO Framework Convention on Tobacco Control (FCTC).** The WHO’s tobacco control treaty does allow parties to take tobacco control measures that go beyond the terms of the FCTC, but only if these “*are in accordance with international law*” (Article 2)<sup>15</sup>, including WTO commitments.

The Office of the United States Trade Representative (USTR) monitors and secures U.S. trade interests<sup>16</sup>. The issue could come to the newly established White House National Trade Council for consideration. The Doggett Amendment<sup>17</sup> should not apply or be disapplied for vapor products.

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