Fixing the broken and lawless American tobacco and nicotine market

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London

20 January 2025

Version 1.1

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Summary

This report provides analysis and a framework to support the reform of federal tobacco and nicotine market regulation, one of the most chaotic and conspicuous failures of the federal government and Food and Drug Administration. I will explain and summarise in four points:

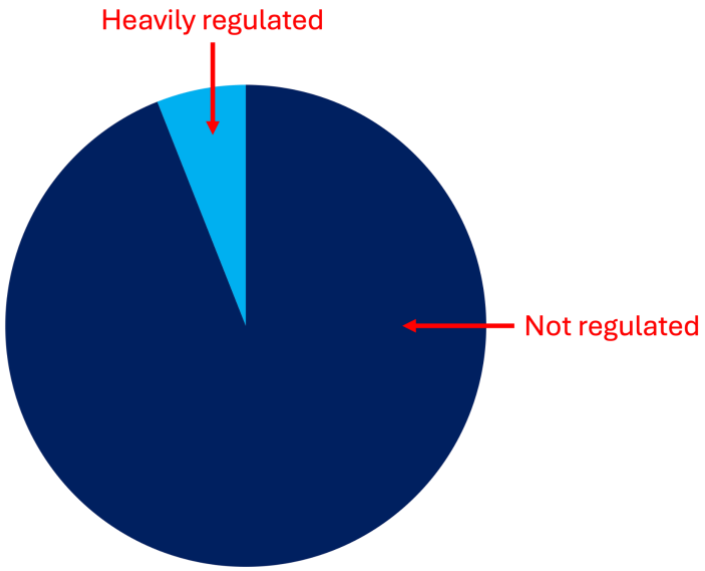
- **The problem**. The FDA has completely failed to regulate the tobacco and vape market, creating a chaotic, lawless mess harmful to people and legitimate businesses. It has approved only 34 vape products that users mostly do not want to buy, but over 3,800 cigarette varieties are available everywhere. As a result, well over 90% of vape sales in the US are unauthorised products, and the majority are illicit disposables, mainly from China.
- **What needs to change?** A successful application (PMTA) for a vape product to enter the market will likely cost $20-100 million and will take many years – these are near-insurmountable barriers to entry. Radical reform is urgently required to achieve three goals:
    1. To allow 4,000 or more vape product authorisations instead of a few dozen (currently 34)
    2. To bring successful application costs down below $500,000 (currently $20-100 million)
    3. To reduce the time to process an application to less than 180 days (currently many years)
- **How to achieve rapid change.** The barriers to market entry need to be radically lowered, and a vastly more efficient assessment regime must be established within the existing law. This would be based on four main actions:
    1. Split the assessment of the “appropriate for the protection of public health” standard between pre-market product-specific screening and post-market evaluation of population impacts, given the latter are impossible to know in advance.
    2. Apply efficient pre-market screening of vape products for safety relative to cigarettes and appropriate labelling, marketing and branding, then allow the products onto the market.
    3. Conduct extensive independent market surveillance for all products and populations.
    4. Assess and address any adverse behavioural or population effects once they emerge and take proportionate corrective or enforcement action, including product withdrawals.
- **Longer-term shift to a standards-based approach**. Regulation of nicotine needs to move to a risk management philosophy as the “appropriate for the protection of public health” standard will begin to make little sense as cigarette use declines further. We don’t use APPH to regulate beer or wine, but these industries are regulated by a wide range of standards and obligations for public health and consumer protection.

The benefits of this reform include improving health and providing positive choices for over 54 million citizens, protecting young people from unregulated products and unscrupulous vendors, supporting law-abiding American small and medium businesses, radically improving the efficiency and reducing the cost and intrusion of the federal bureaucracy, and fighting criminal networks that facilitate the flow of illicit Chinese goods into the United States.

Defining the problem

It's challenging to communicate just what a monumental mess the U.S. FDA has made of its responsibilities to regulate nicotine products under the Tobacco Control Act passed by Congress in 2009. Few would believe that a credible regulator could lose control of more than 90 percent of the market for safer nicotine products and favour market access for the most dangerous. Yet here we are.

One industry estimate suggests that sales of the 34 vape products (8 current systems) authorised by FDA's Center for Tobacco Products account for just **6 percent** of the vape market by value. No one knows for sure because the market is mainly illicit, and much of it is not tracked through shop scanner data. It should be treated as an informed estimate, not a measurement.

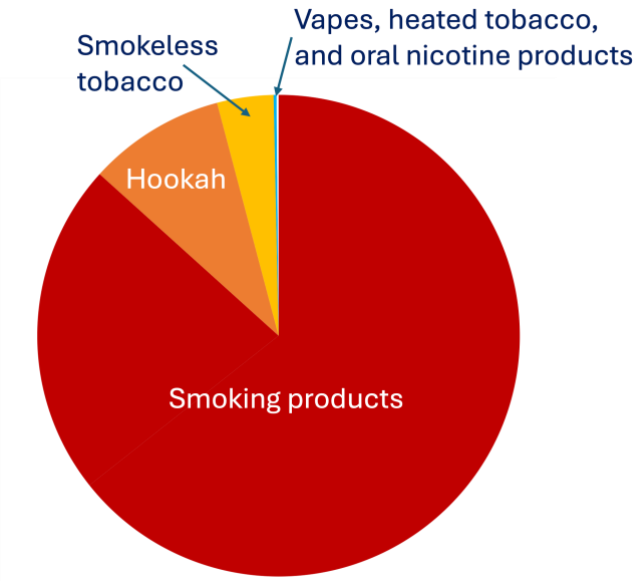


Tobacco and nicotine products authorised for sale in the United States

One nicotine pouch product (Zyn) with strength and flavour variants has been authorised after almost five years, even though products like Zyn, ON! and Velo have been widely available with rapidly growing use. One modern heated tobacco product, the iQOS from Philip Morris International, has been authorised, but this is a 2016 vintage product, and newer, better versions are available elsewhere in the world.

The market regulator (FDA) should know how much of the market is authorised or illegal, but it is either unwilling or unable to provide an estimate. Neither inspires much confidence.

On the other hand, the market is generously supplied with thousands of authorised and legal smoking and hookah products that can be bought anywhere.



Number of tobacco and nicotine products authorised for sale in the United States
Total 17,131 products on 17 January 2025

As long as a tobacco product is very harmful, there is no serious impediment to access to the market. For the safest products, however, the reverse is true. To compensate for this absurd distortion of the market, a gigantic unauthorised, illicit and informal economy in vapes and other safer products has emerged. How can that make sense? Nothing in the record suggests that is what Congress intended. Yet, with $8 billion in user fees collected by the FDA's Center for Tobacco Products, that is what has been delivered - *worse than nothing*.

A near-complete loss of regulatory control

If 6 percent of the vape market is authorised, the obvious implication is that the FDA has *not authorised* the other 94 percent of vaping products. 100 percent of pouches sold in the United States are unauthorised. FDA and the law consider these products as "**adulterated**" under section 902(6)(A) and "**misbranded**" under section 903(a)(6) of the Tobacco Control Act.

With a few exceptions, unauthorised products are subject to enforcement and potential removal from the market. Most of these products will be perfectly reasonable variants of established designs, and there is nothing at all wrong with them; they would be on sale in other jurisdictions without incident. Most, but not all.

There are around 19 million vapers in the United States (Altria tracker, Nov 2024), which means that approximately 18 million are using products officially classified as *adulterated* and *misbranded*. In practice, the regulator is missing in action - ineffectual for public health, and harmful to law-abiding businesses.

For all practical purposes, the regulator has no meaningful control over the market as it actually works. All the process, guidance, toxicology memos, behavioural science, thousands of pages

of applications, millions of dollars spent, years of delay and uncertainty serve no useful purpose. They are the barrier to entry that is the primary cause of the loss of control to illicit trade.

Characterising the regulatory failure

There are three different ways to look at this situation:

1. **Public health**. It is a regulatory failure because about 18 million American adults are using unregulated vaping products officially classified as adulterated or misbranded. If the law makes any sense, that must put millions at risk of *something*. Alternatively, these unauthorised products are mostly not adulterated or misbranded in any natural, not legalistic, meaning of these words. FDA may be doing harm by denying lawful access to beneficial products.

2. **Tobacco control activists**. It is a regulatory failure because the FDA has not "cleared the market" of unauthorised products, as 78 tobacco control organisations demanded in May 2024 (more on this below). But imagine if the FDA (somehow) did clear the market. There would be chaos and unpredictable behaviour change turmoil, which would likely include millions returning to smoking.

3. **Business**. It is a regulatory failure because most of these unauthorised products are perfectly good, far safer alternatives to smoking prevented from lawful access to the market by excessively high barriers to entry. The illicit market is caused by the regulation and hurts law-abiding business while making the public health situation worse.

Illicit markets may be keeping Americans supplied with life-saving alternative nicotine products, but they have the following problems:

1. The products are unregulated, and some may be dangerous, poor quality, and not what they say they are
2. Many law-abiding American firms with perfectly good products have been shut out or forced to trade in a legal twilight
3. Criminal agents and networks are involved and will supply any illicit products to anyone of any age
4. Criminal supply tends to engage young people in supply as well as consumption
5. A large share of the U.S. vape market has been gifted to remote Chinese manufacturers at the expense of American firms
6. Law-abiding businesses are undercut because illicit trade does not carry the FDA's vast compliance costs
7. Law-abiding businesses are uncompetitive because illicit trade can introduce innovative products, while compliant companies are stuck with long delays for new products and justifying products that are 10 years old and obsolete elsewhere

It is clear that a "do nothing" approach - the dominant strategy so far - is untenable. There are essentially two strategies available to address the problem:

- Option 1: more enforcement
- Option 2: more authorisations.

A mix of both is ultimately essential, but the question is where to place the emphasis.

Option 1: Solve the problem with more enforcement

Suppose enforcement worked

The usual response to an illicit market is to argue for more enforcement - to *ban harder*. As we should have learned from the war on drugs, this does not work very well and has multiple negative consequences. In this case, the challenge is far greater. Around 18 million adult Americans are already using these products, mostly as alternatives to smoking or as diversions from smoking if they started vaping younger.

If enforcement activity is at a small scale, then there is little risk as users will switch to other vaping products. If, however, the enforcement is at a large scale and makes vaping products significantly less available, less appealing, or less diverse, then there is a danger that current users will return to smoking. Given the relative risk of vaping and smoking, it would only need a small fraction of current vapers to return to smoking for the detriments following an enforcement drive to exceed any conceivable benefits. That would force the FDA to choose between enforcing its own ultra-pedantic interpretation of the law and harming millions of Americans. As it would be likely to choose the former, we should be very wary of this approach in public health.

The threat to public health would arise from enforcement actually working.

A brief aside: we should note the reckless and irresponsible posture of the 78 leading public health, medical, education, community and other organizations led by the Bloomberg-funded prohibitionists at the Campaign for Tobacco-Free Kids. It seems no one *ever* asks them what they expect would happen to millions of American vapers if they got their way. What do they think would happen if nearly all vape products were removed from the market? No one has put that simple, devastating question to them: not the supine media; not the politicians they have cultivated; no one at the FDA; not their leadership; not their staff; no one among the sleepwalkers on their boards; not the funders and foundations that keep them afloat; and not even the IRS, which allows them tax-exempt status for charitable and social welfare purposes.

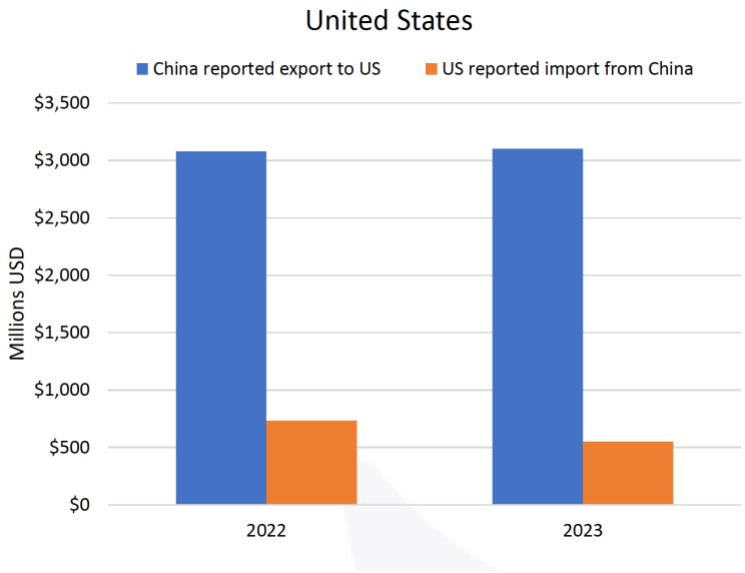
Enforcement probably won't work.

FDA undertakes enforcement activity at present, but it is never of sufficient scale to make material changes to the marketplace. If some products are removed from the market, users can find others would take their place.

Where there is unmet demand, illicit goods flow like water around rocks, with ever more inventive and threatening actors meeting the demand. Several factors combine to make large-scale enforcement in this marketplace exceedingly difficult. These include the huge volume of

container movements through U.S. ports (170,000 twenty-foot container equivalents per day in 2022) and inspection of about 3 per cent. Internet, social media, and encrypted comms (Signal etc) and global payments, possibly with crypto-currency make illicit commerce easier to do and harder to detect. FDA and CBP have no standing in China and no cooperation with the authorities in Shenzhen, the origin of most of the illicit disposable products. The “middlemen” in this trade are relatively small and elusive players - there are no headquarters to raid.

FDA and CBP are trying to do more at ports, but they will be chasing a moving target that can change company and product names. According to the analysis group, ECigIntelligence, there is already a large discrepancy between the Chinese reporting of vape exports to the U.S. and U.S. reported imports from China.



Source: ECigIntelligence analysis, UN Comtrade data (HS: 2404.12; HS: 8543.40) May 2024

Option 2: Solve the problem with more authorisation

Thousands of smoking products are authorised and widely available

If you wish to expose yourself to thousands of toxicants and well-proven risks of cancer, cardiovascular disease and debilitating respiratory conditions, you are in luck: FDA has authorised thousands of smoking products that are lawfully available almost anywhere you care to look.

The Tobacco Control Act as defined by Congress and as interpreted by the FDA has formed the recreational nicotine market to have the following shape: authorised products as of 17 January 2025 (see FDA’s database).

Product category	Number authorised	Share	Notes
Cigarettes	3,824	22.3%	2,765 authorisations since 2016 and 868 in the last three years (2022-24),
Other smoking products	10,991	64.2%	Cigars, hand-rolling tobacco, pipe products
Smokeless tobacco	645	3.8%	Wide range of long-established products
Hookah and waterpipe	1,594	9.3%	High-temperature heated tobacco usually using charcoal for heating
E-cigarettes	34	0.2%	Eight current systems with strength and flavour variants
Heated tobacco products	19	0.1%	One current system, the iQOS with heater and consumable variants
Nicotine pouches + oral tobacco	24	0.1%	Major products like Zyn, ON! and Velo have had to wait over 4 years. Zyn took 1,779 days.
Total	**17,131**	**100%**	

Vaping and other novel smoke-free products face extremely constricted access to the market

Vaping products account for 0.2% of the authorised products, yet 19 million vapers account for 35% of the total 54.8 million tobacco and nicotine users (Altria tracker, Nov 2024), a 175-fold misalignment.

The only way to fix the U.S. nicotine market from today's broken and dysfunctional mess is to authorise far more non-combustible products. I don't mean just a few more, but *thousands* more. This would provide vape users with a choice equivalent to smokers, form a good basis for a regulated market in the public interest, and work against illicit trade by crowding out unauthorised products with legal choices to meet adult demand.

This cannot be done with incremental adjustments, but a wholesale reform is needed (discussed below). There is minimal value in going from 34 to 74 or 104 authorised vape products using a more or less similar approach to the current PMTA. This is because the current approach is so expensive and unpredictable that only a small number of products and companies will *ever* be able to cross the barriers to entry imposed by the FDA. To authorise more products, these market-distorting barriers have to come down and transparency and predictability of the regulatory process must increase. *Radically*.

No one has a convincing explanation for why the asymmetry between vaping and smoking products is so pronounced. Many can explain how it got that way (FDA's exceedingly high barrier to entry to the vape market), but no one can explain why this outcome is *desirable*, especially given the illicit market "correcting" for this regulatory failure.

What about youth vaping?

FDA justifies its chokehold on the adult vape market as necessary to protect youth. It has also set a very high bar for any tobacco or nicotine product to have flavours other than tobacco, on the unproven basis that this will reduce youth vaping. There are three main fallacies at the heart of FDA's reasoning:

1. **Benefits to youth**. For some youth - those who would otherwise have smoked - adolescent vaping is a diversion from smoking and highly beneficial. FDA has resolutely determined never to consider these effects, even though the wording of the legislation requires they be considered.

2. **Youth uptake is not determined by product availability, diversity or flavours**. While the FDA controls 34 authorised products, thousands of unauthorised products are available and have increased in number and flavour diversity since 2020. Despite that, high school past-30-day vaping has fallen from a peak of 27.5 percent in 2019 to 7.8 percent in 2024.

3. **FDA has no control anyway**. If 94 per cent of the market is outside FDA control, it doesn't really matter what FDA does with the remaining 6 per cent. The only way it can do anything to control youth access is to recapture a much larger share of the adult market with authorised products.

The idea that the FDA's radical constriction on the market protects youth is false. More likely it harms them by exposing them to unregulated products and illicit suppliers.

No, the vape market is not targeted at youth

Given the volume of coverage and political heat generated by youth vaping, it would be easy to conclude that most vaping is by youth and most marketing and product design is targeted at youth. This is simply wrong.

Number of users United States, 2024	Youth (NYTS) million	Adult (Altria) million	Ratio adult:youth
Total nicotine/tobacco	2.25	54.3	24:1
Vaping	1.63	19.0	12:1
Smoking any combustible	0.76	36.9	49:1

The vast majority of users and potential users are adults - the total addressable adult market for vapes (i.e. all tobacco and nicotine users) is 24 times larger than youth.

The unauthorised market exists mainly to serve *adult consumers* for the reasons apparent in the table above. If adult demand was met by legal products, there would be little room for an illicit market to supply youth, and greater leverage over retailing and suppliers to conform to good age-related practice. The only way to make the enforcement challenge manageable is to dramatically reduce the policy dependence on enforcement - i.e. to shrink the illicit market - it does not make sense to have an enforcement challenge that amounts to 60-90% of the entire market.

How to authorise more products

The PMTA process barrier to entry needs to be lowered to achieve three big changes: (1) at least 4,000 authorised products; (2) an application cost of less than $500,000; (3) a start-to-finish application process lasting 180 days or less. These changes would dramatically expand the legal market and make the process within reach of far more law-abiding firms and product lines.

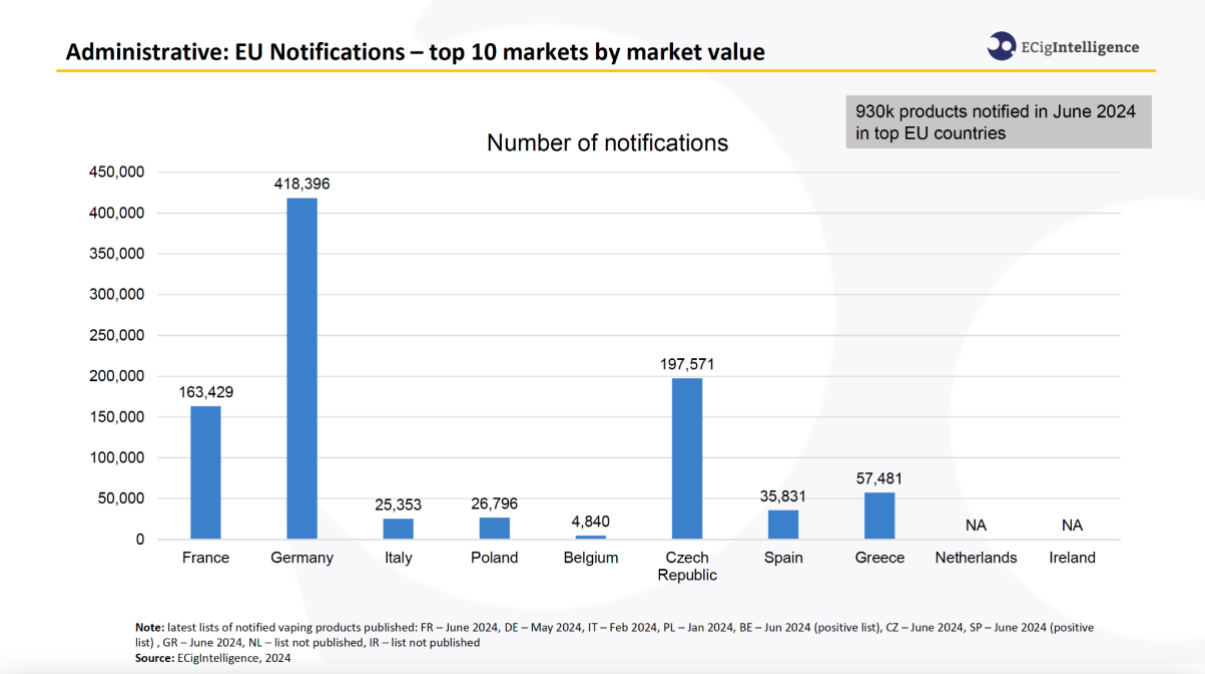
Let us consider these in turn.

1. Aim for at least 4,000 authorised nicotine vape and pouch products.

If there were 4,000 authorised vape products (about the same as cigarettes) that would amount to a radical change in the market capable of meeting adult demand. The reason to specify a number like this is a declaration of intent - to encourage applications from smaller firms or those who see the existing route market as impossible.

Is this reasonable? It is very reasonable. It would compare with 3,824 cigarettes and 14,813 combustible products in total. Internationally, it would be conservative: there are, for example, 47,422 vaping products registered in the database of the UK regulator (24 Dec 2024), the Medicines and Healthcare products Regulatory Agency (MHRA) - about 1,400 times as many as the United States. One manufacturer, SMOORE, has 1,314 products listed in the UK.

Why specify a rough target? It is necessary to set an expectation as this will help to calibrate the required reduction in barriers to entry. It is no good to have simplified standards so exacting that no one can meet them. In 2017, FDA proposed an NNN standard that would have wiped out >90 percent of the smokeless tobacco market, with unpredictable negative consequences. The use of the number gives a sense of a reasonable diversity of lawful approved products necessary to crowd out the illicit market, yet does not come close to the hundreds of thousands of notifications in the European Union - see graphic from EcigIntelligence below.



2. Reduce PMTA application costs to below $500,000

Industry estimates put the cost of a successful PMTA at $20-100 million for a vape product. We know from a Juul FTC filing from para 86-104) that Juul spent $100 million on its initial PMTA (and still wasn't successful). The PMTA process does not test for "appropriate for the protection of public health"; *it is primarily a size filter*. Only a few large firms and mass-market product lines will have the scale to finance these applications and recover the costs from sales. For everyone else, the compliance costs are too high, and success is so uncertain that it would be shovelling money onto a fire. A further problem is that the analytical requirements are so vague that no-one knows how much to spend and on what to increase their chance of success.

Is this cost reduction reasonable? It is very reasonable and should go further. The application cost levels envisaged in the FDA's Regulatory Impact Analysis for the deeming rule were below $500,000 (see table below) and with a redesigned PMTA process, it should be possible to match the expectations the FDA had in its 2016 estimates.

Estimated costs $	Initial application	Subsequent application
Device	$466,563	$192,654
Liquid	$131,643	$117,486

Overall average cost per PMTA, including Environmental Assessment
Regulatory Impact Analysis: extracted from Table 11(b) & 12(b)

Is this cost reduction enough? No, it should be far lower. These numbers should be seen as an upper limit and a first stage in cost-cutting efficiency, and they are something the FDA can work towards within its own paradigm. I have chosen these numbers because they are *FDA's estimates* from when it was trying to convince the White House it should have authority over vaping products.

Most of the products are variations on a few standard designs and most liquids contain similar ingredients. There is extensive worldwide experience with these products and very little sign of a problem. It should be easy to get the costs down. If there is a source of risk, it arises from FDA pricing legitimate manufacturers out of the market and leaving it to illicit trade.

3. Reduce the time to process a PMTA to no more than 180 days

Pre-Market Tobacco Applications (PMTAs) are now taking many years to reach a determination and the FDA is still dealing with applications for products that were on the market before 8 August 2016 and filed before 9 September 2020 (a court-imposed deadline). This process should be reduced to 180 days.

Is this reasonable? It doesn't matter whether it is reasonable; the law already requires it. 180 days is the maximum time between receipt of an application and the decision to deny or grant market access. This is required by law TCA §910(c)(1)(A). It is entirely reasonable for a regulator to consider an application for a fast-moving consumer product in under six months. Most of these products follow similar designs and have similar liquid ingredients, and have been extensively studied as a category (FDA has a a very large regulatory science programme). It would be far better if the FDA were spending its staff time evaluating *novel* products and *novel* risks, not repeating endless pedantry for thousands of broadly similar products.

It is also necessary to reduce FDA costs. If it takes assessors years to go through applications, then it suggests that the applications are too complex and, hence, too expensive. It also means that the FDA is evaluating products that are already obsolete by the time a decision is made. That is increasing the competitiveness of the illicit route to market, which can bring new products and features to market without delay.

The immediate and longer-term structural changes now needed

Two waves of reform are required:

1. **Immediate radical change** consistent with the current law, the Tobacco Control Act. This would greatly improve efficiency, transparency and predictability in the mandatory authorisation process for new tobacco and nicotine products (vapes, pouches etc). This means a major change to how the public health standard ("appropriate for the protection of public health" or APPH) is interpreted and assessed to be better grounded in the reality of the U.S. tobacco and nicotine market.

2. **Longer-term reform** of the regulatory, institutional and fiscal framework for recreational nicotine products requiring a change in the law. This would move away from APPH and towards a *risk management* regulatory philosophy based on standards. This is the approach used, for example, for alcoholic beverages such as beer and wine. No-one tries to justify these products on an APPH public health basis. Beer is never "appropriate for the protection of public health", but beer is subject to multiple controls on safety, quality, brewing, accuracy, warnings, tax etc. to ensure that it is managed with acceptable risk to the extent possible.

Immediate radical reform: a pragmatic interpretation of the Tobacco Control Act

Summary

An incoming administration should take four initiatives to improve the Pre-Market Tobacco Application (PMTA) pathway to market:

1. Reinterpret the public health standard to make it relevant to improving public health in the United States by splitting authorisation between pre-market and post-market phases
2. Reduce the pre-market compliance requirements to checks on product safety, packaging and marketing and release products to market with conditions and the right to recall rogue products even if authorised (as now).
3. Conduct in-depth and near-real-time market surveillance to understand market behaviours as a basis for corrective intervention.
4. Based on surveillance, use powers to act retrospectively to address adverse developments at population level - either acting retrospectively to withdraw authorised products or acting proactively to guide enforcement against illicit products

These are discussed in the sections below.

1. A new approach to assessing "appropriate for the protection of public health"

The public health standard or APPH is simply stated in the law at §910(c)(2)(A) and §910(c)(4).

> 2. **Denial of Application.** The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that
>
> A. here is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

> 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 applicant must submit evidence showing that its product meets this test. The challenge (for applicants and FDA) is that the effect of a newly released product on the use of tobacco and nicotine products by existing users and non-users is highly uncertain and impossible to foresee (more on this below). It also depends in part on a hidden counterfactual (what the users or non-users would do in the absence of the new product). In the case of young people who do not currently use tobacco, there is no basis for assuming that they will remain permanently abstinent as they grow older. In the case of adult smokers, there is no basis to assume they will smoke until they die. No one really knows what will happen once a product is on the market, and it cannot be treated in the same way as a medication because it is a consumer product and demand is a function of multiple contextual factors, rather than direction by a physician.

I believe the public health test can only be met in two stages:

1. **Pre-market**: showing that the product is significantly safer than cigarettes (one order of magnitude) and acceptably safe compared to a similar product that has not been authorised and therefore has unknown risks (i.e. illicit products).

2. **Post-market**: once introduced, there are no adverse emerging population trends developing with the product (or relevant category) that could be arrested by withdrawing the product or category or placing further restrictions on the supplier.

Between pre-market and post-market evaluation, the product would be made available on a kind of “probation” or conditional release, using enforcement discretion if necessary. This is already the case with PMTAs; a marketing-granted order can be rescinded or amended post-market.

Is that legal?

One might object that the law *requires* pre-market evaluation of all population effects and behavioural transitions, even if this is impossible. However, the law requires the Secretary to make a judgement in the population public health interest and behaviour change to be “taken into account”. The following criteria would allow the Secretary to split the application in this way:

- ***In a market where smoking still predominates***… The new products are much less risky than smoking and there is a general case that they are likely to displace smoking. In this case, the benefits of reduced smoking among adults and youth will almost certainly outweigh any detriments of nicotine uptake among non-users who would have

never otherwise have used nicotine. A much lower risk compared to smoking demands much less reliance on the balance of vaping uptake versus smoking cessation.

- ***In a market where illicit trade is significant***… Having quality assured products made by responsible law-abiding businesses is always better at a population level than the demand being met by illicit products supplied by criminal networks via an informal economy with no recourse or accountability. Not all unauthorised products are dangerous, far from it. But some may be. So, the population level imperative is to crowd out the illicit products with products with known and acceptable safety risks.

- ***In a market where many products are already on the market but still under review***… the PMTA process is supposed to be a *pre-market* pathway to market access. However, because of the process that has unfolded since 2016, many unauthorised products remained on the market and are awaiting evaluation. *Tthis is how it is currently working* - only without the suggested pre-market screening for safety and other product-related characteristics. Since 2016, there has been no pre-market authorisation system: no new vaping products have come to market via a PMTA without being on the market already. In practice, the system is already a post-market assessment system.

This represents a realistic and pragmatic approach to the population health standard in the r*eal-world conditions of the United States*, not an imagined ideal jurisdiction where there is no illicit trade, where the FDA hasn't authorised over 14,000 combustion products, and populated by a new type of teenager would never use nicotine if FDA did not allow nicotine products.

Why is the standard specified in this way?

Light and Mild failure. It is worth recalling the historical context when the TCA was drafted: concern was dominated by the misleading marketing of light and mild cigarettes - an apparent but faked reduction in risk, but potentially decreased quitting and increased uptake through false reassurance. These conditions do not apply to vapes and pouches etc - which are 1-3 orders of magnitude less risky than cigarettes. The difference allows for a qualitatively different approach.

Institute of Medicine Report on Tobacco Harm reduction. In 2001, the Institute of Medicine released the report Clearing the Smoke Assessing the Science Base for Tobacco Harm Reduction (2001). The IoM put forward a sensible and proportionate approach, discussed here: Rethinking U.S. tobacco and nicotine regulation (part 1). Note that IoM placed great emphasis on getting these products into the marketplace with a very limited single-stage barrier to entry.

> *In the absence of any claim of reduced exposure or reduced risk, manufacturers of tobacco products should be permitted to market new products or modify existing products without prior approval of the regulatory agency after informing the agency of the composition of the product and certifying that the product could not reasonably be expected to increase the risk of cancer, heart disease, pulmonary disease, adverse reproductive effects, or other adverse health effects, compared to similar conventional tobacco products, as judged on the basis of the most current toxicological and epidemiological information.* 7 Implementation of a Science-Based Policy of Harm Reduction

Why the population health standard makes little sense at the individual product level

It makes no sense to assess the impact of a single product on the marketplace before it is available. It is impossible. Let us consider four reasons why:

- **No system for trading off benefits and detriments**. FDA has no coherent framework that allows assessment of net public health impact of a new product and has not attempted to develop one. Such a framework would need to compare different types of harm (diseases, dependence, bystander risk) arising over different time periods (decades away, immediate) affecting different populations (youth, adults, deprived groups, youth smokers) caused by diverse products spanning a 2-3 orders of magnitude risk continuum (cigarettes, vapes, pouches). It would need a common currency of benefits and detriments (such as discounted QALYs) to allow comparison of different population effects emerging at different times. It would need some way to convert an authorised product launch into changed behaviours and then behaviours into public health benefits and detriments. It would need to consider a plausible counterfactual, including the benefit of vapes to young people who would otherwise smoke, and recognise that some youth risk behaviours have negligible long-term consequences.

- **Most single products have either negligible or unknowable population impact.** The PMTA process is specific to a single product and the applicant has to focus on that product. Yet the effect of adding (or not adding) a typical product (device or liquid) to the marketplace is negligible at the margin - users will just switch to or continue with the next available similar product (legal or illegal). The effect of denying one product, even one already on the market with significant market share (e.g. Juul), is unknown. It would depend on what the users of this product did instead. Would its users go back to smoking? Switch to illicit products, including counterfeits? Or would they become abstinent or never start? How could an applicant know that and how could FDA decide if they are right?

- **Population effects are driven by broader market trends**. At the population level (the basis of APPH), the market is shaped by broader category-wide trends - the emergence of successive generations of vaping product, improving pharmacokinetics (e.g. rise of nicotine salts), the rise of disposables (improving cost and convenience), the launch of nicotine pouches, and the growth illicit supply. But is also shaped by factors outside of the control of the manufacturer and FDA - state level regulation and taxation, statements of academics and activists, distorted risk perceptions, alarmist media coverage, teenage fads, and physician advice. For example, there is considerable evidence that state-wide flavour bans increase smoking, but there is no way for a manufacturer of flavoured products to bring that evidence into its PMTA because the applicant is applying for one product only.

- **FDA's actions only affect population health at the aggregate level but it is unaccountable for these effects**. The population effect of FDA's PMTA regime arises through the *aggregate effect of all FDA's decisions*, including its indecision (products that remain under review). For example, FDAs current practice has the effect of a *de*

facto ban on non-tobacco/menthol vape flavours, closing all vape shops, and stimulating illicit trade. This collateral damage has major public health consequences, but falls outside the scope of any single application and would not result from any single denial order - only the aggregate effect of all denials. None of this can be assessed in a single PMTA application for a single product and FDA cannot be held accountable for the totality of its decisions, only each decision in isolation.

No-one at FDA can explain their way through these challenges. Instead they have adopted a crude *de facto* standard: that a given flavoured product must have greater smoking cessation efficacy for adults (measured by an RCT or longitudinal study) than a tobacco flavoured product.

2. Pre-market screen for acceptable product characteristics

This part of the evaluation would focus on knowable product characteristics and the explicit non-negotiable requirements of the Tobacco Control Act at §910(b)(1)(A-G). These are as follows:

b. **Application**

1. **Contents.** An application under this section shall contain

A. full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

B. a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

C. a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

D. an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

E. such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

F. specimens of the labeling proposed to be used for such tobacco product; and

G. such other information relevant to the subject matter of the application as the Secretary may require.

These requirements (A-G) are not especially onerous unless the FDA chooses to make them onerous. They could be interpreted straightforwardly to bring application costs down to a much lower level and still meet the requirements of the Act. This is how FDA's Regulatory Impact

Analysis concluded that the costs would be lower than they have turned out. I set out reasonable expectations under A-G below.

A: These requirements would form the body of the pre-market assessment. Much of this could be generic findings related to entire product categories (vapes, pouches etc) backed up by specific product information on product emissions under particular usage conditions, with a focus on a range of target harmful or potentially harmful constituents (HPHCs) of the inhalable aerosol (vapes, HTPs) or constituents (pouches, smokeless). This information would aim to show the product is *much safer than smoking*. I see no reason to extend analysis of emissions to expensive human biomarker studies (there are enough of these already to draw general conclusions from based on emissions) or to pharmacokinetic studies, as nicotine delivery is largely under the control of the user within constraints set by the product design. There is no general need for non-targeted chemical analysis, it just adds costs. A different approach can be applied where there are novel products and risks - and this is where FDA's assessors should be spending their time, not on repetitive assessment of very similar products.

B: A listing of ingredients and design is a straightforward request and would be used to identify any novel features or ingredients or novel risks that might arise and demand additional scrutiny.

C: This would form the basis for compliance with a "good manufacturing practice" standard. Again it would highlight novel risks for closer scrutiny.

D: There are, at present, no applicable §907 tobacco product standards for vapes, pouches, heated tobacco products or snus so nothing is required. It may be advantageous to define such standards, but this lengthy and contested process would not meet the imperative for urgent action. In the meantime, FDA could consider "soft standards" in guidance. Under such a system, compliance with guideline thresholds for HPHC emissions or content would expedite authorisation. Non-compliance would either trigger denial, require a justification, or trigger a deeper evaluation.

E: There is no need to provide samples proactively unless FDA wishes to seek independent verification or auditing in a sample of applications. The FDA should be able to sample at any time on request or through test purchasing.

F: The labelling (including branding, imagery, descriptors etc) should form part of a pre-market assessment, with the FDA determining if the packaging has elements likely to appeal to youth or other irresponsible marketing (e.g. implying sporting or bedroom prowess). Again, principles could be established in guidance on a "comply or justify" basis, with compliance justifying expedited authorisation. Other aspects of labelling would also be addressed: statutory warnings, hazard information, contact for adverse effects, defective products etc.

G: This catch-all should be used sparingly. If Congress had intended it to be used to insist on multi-million-dollar RCTs or cohort studies, it could have specified that this was how it wished to see population impact specified. It could include the environmental assessment and mitigation measures. It is implicit in the FDA's 2016 cost estimates for the PMTA that this clause would not be used to greatly extend regulatory burdens.

By returning to the explicit text of the legislation and the intention of Congress to create a working system for authorisation of new products with proportionate costs, it is possible to radically reduce costs, greatly improve bureaucratic efficiency, and improve public health.

3. Conduct in-depth independent market surveillance

At present, the most insightful and up-to-date data on the market are coming from private sources, such as Altria's Adult Tobacco Market Tracker, E-cig Intelligence, and data providers like Nielson or IRI. Alternatively, the PMTA process requires successful applicants to track their own products. There is a strong case for the regulator having a much better real-time grip on the market it regulates. Not just the authorised products but all the unauthorised products still under review, and the various forms of illicit product. The aim should be to survey both adults and youth monthly or quarterly and consolidate this with sales data to develop a national picture of the main nicotine-use trends in the United States. Public sources are either too slow (PATH, NYTS, MTF) or too generic and lack resolution (NHIS, YRBS) to meet the needs of real-time regulation.

There is no reason why FDA should not be able to fund an extensive surveillance regime from the $712 million per year it already receives from user fees under §919 of the TCA. This large sum of money is poorly spent on non-core functions for a regulator, including deceptive youth anti-vaping campaigns and poor quality science that contributes to the public's misunderstanding of risk, while adding nothing to FDA's public health impact. A major rationalisation of the budget to concentrate on the core regulatory mission authorised by Congress in the 2009 Tobacco Control Act would reallocate sufficient funds for an extensive market surveillance regime. It would also reduce the wasteful duplication of surveys by companies with authorised products, removing another pointless burden.

4. Post-market corrective or enforcement action

Based on insights from post-market surveillance in (3) above, the FDA or relevant authorities would be able to take corrective action to remove or impose conditions on authorised products (or categories), and to guide enforcement actions against unauthorised or illicit products. It may be possible to define trigger metrics that would cause scrutiny or intervention - for example, when the youth prevalence of a product exceeds its adult prevalence by X%.

The only way to address population effects is once they have become evident - it will *never* be possible to reliably guess these in advance because they are the emergent characteristics of a complex adaptive system in a state of permanent flux. No applicant, regulator, activist, or analyst can know how this system will behave, let alone what will happen to a single product once released on the market. Trying to guess the unknowable in advance is misdirecting resources, generates asymmetric loss aversion, and leads to blocking products that could benefit public health.

Ten benefits of this reform

1. Supports and encourages more choice and better health options for 54 million American adult nicotine users
2. Protects young people by diverting adolescents who would otherwise smoke to safer options that are easier to quit
3. Protects young people by helping the adults in their life
4. Radically reduces unnecessary bureaucratic burdens saving pro-health American businesses millions of dollars
5. Radically improves the efficiency of a federal bureaucracy with significant potential for cost saving or reassignment
6. Lifts the FDA's bureaucratic boot from the neck of thousands of law-abiding American small and medium enterprises
7. Rewards, rather than penalises compliance and provides stronger incentive to seek authorisation
8. Pushes back an unlawful market dominated by illicit Chinese products avoiding regulation altogether
9. By squeezing the illegal market with legal products, it will be easier and cheaper to enforce against illegal products
10. Reduces criminality and stops nourishing criminal networks with new opportunities

Longer-term reform: rational regulation of a lawful recreational substance

Summary - towards a risk management framework

As cigarette usage falls, it will become increasingly difficult to apply the APPH public health standard, which is essentially a harm reduction justification for authorising low-risk nicotine products. Other than the situation where a high risk nicotine product is displaced by a low-risk product, there is not a compelling public health case for nicotine use. This is the same with alcohol, caffeine and cannabis. If there was a therapeutic case, then nicotine could be assessed as a therapeutic agent or treated like medical cannabis. But the dominant use will be *recreational* - people using it because they like it and believe they function better with it.

Instead of APPH as the governing principle, a new framework based on management of a relatively benign psychoactive substance with acceptable risks is required. This would require

authorities to acknowledge that nicotine is likely to be in use in society for the foreseeable future as a recreational substance. This is not an endorsement of nicotine use or a recommendation to take it up - it is a recognition of the likely reality. The regulator's role is to set standards that control the risks to acceptable and tolerable levels. This is a consumer protection role. It is not primarily a behaviour change role.

Alcohol is regulated in this way. For example, beer brewers have a range of standards to comply with:

- Approval of ingredients and additives
- Microbiological purity standards
- Chemical purity standards
- Testing for chemical and biological contaminants
- Water quality
- Mycotoxins
- Pesticide residues
- Packaging materials
- Labelling: ingredient disclosure, health warnings, alcohol content, and the identification of the producer.
- Good Manufacturing Practice
- Standards of identity
- Advertising controls

Several federal agencies are involved in regulating beer: the Food and Drug Administration, the Environmental Protection Agency, and the Alcohol and Tobacco Tax and Trade Bureau, and there are state-level controls too.

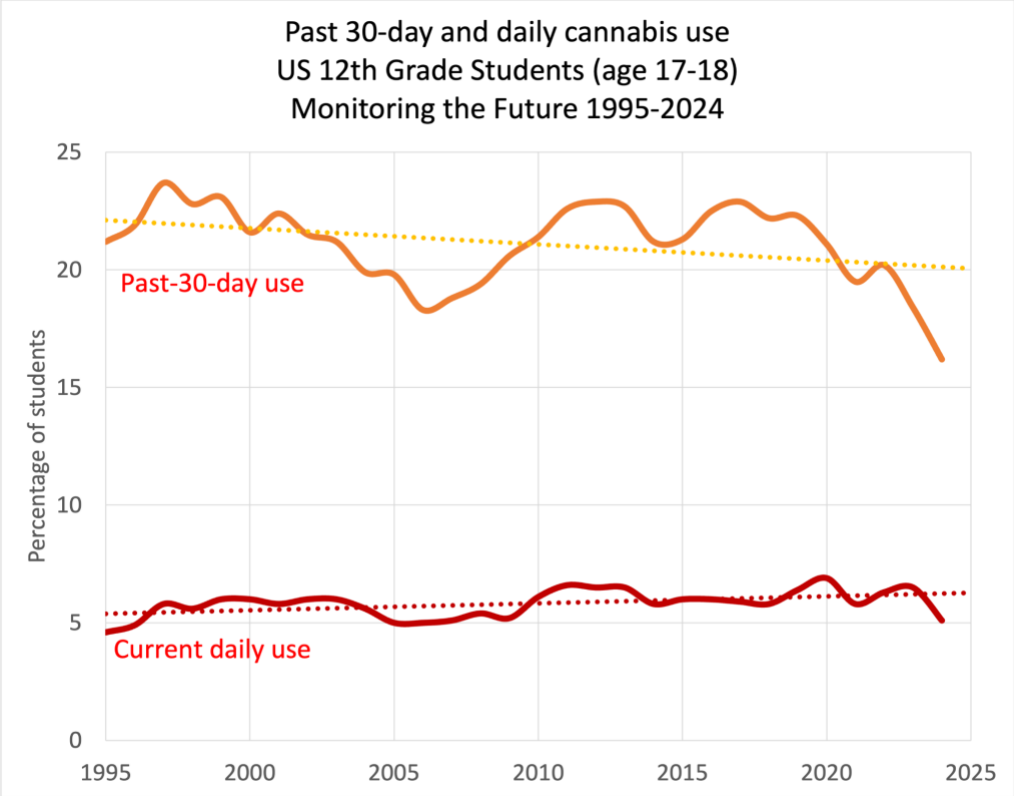
But does a microbrewery need to spend $20-80 million dollars to access the market? No, it does not.

Is alcohol used by teenagers? Yes it is - 21.7% of 12th graders used alcohol in the past-30 days.

Is alcohol harmful to young people? Yes, it is a contributory factor in road traffic accidents, DUI, injuries, violence, and vulnerability and loss of control.

Why not move to nicotine prohibition?

This requires a longer discussion. Prohibition of all nicotine may be seen by some as the clearest public health approach, advancing towards the nicotine-free society. Prohibitions can be explicit bans, or implicit through insurmountable regulatory barriers or excessive taxation, backed by a wall of alarmist misinformation. Prohibition is an option, but history is not encouraging. Ut is a fundamental error to assume that stopping lawful supply will somehow eliminate demand. Cannabis is subject to a broad federal prohibition, but cannabis use has persisted among young people at a steady and high level.



In my view, efforts to prohibit nicotine are indistinguishable from insisting that nicotine can only be supplied by criminal networks and in unregulated products with no controls on safety, quality, or youth access. Who wants that?

More on my views on FDA reform: Bringing the flamethrower of reform to FDA's Center for Tobacco Products (Nov 2024)