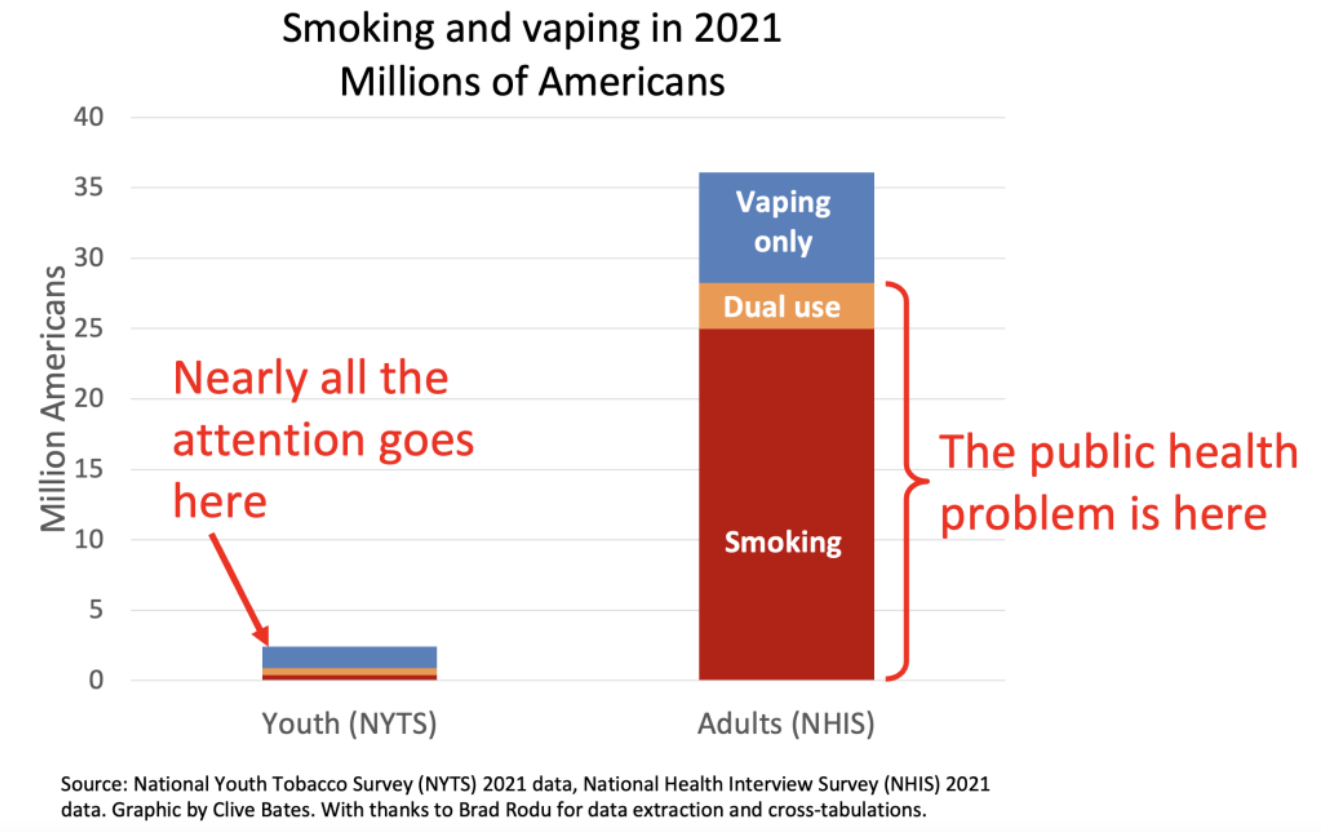
Rethinking U.S. tobacco and nicotine regulation (part 2)

written by Clive Bates | 16 May 2023



Source: National Youth Tobacco Survey (NYTS) 2021 data, National Health Interview Survey (NHIS) 2021 data. Graphic by Clive Bates. With thanks to Brad Rodu for data extraction and cross-tabulations.

Can the United States develop a federal regulatory approach to tobacco and nicotine that addresses the overwhelming public health problem, namely, *adult smoking, especially in disadvantaged populations?*

Can the US do this while providing a rational basis for regulating a much safer legal consumer nicotine market that will persist indefinitely?

Can it find a realistic approach to controlling youth nicotine use, taking all aspects of welfare into account and a realistic approach to youth risk behaviours?

Finally, can it create a regulatory regime that is fair, proportionate, transparent and duly mindful of trade-offs and unintended consequences?

We think it can.

Background

At last, the second part of a blog on how to do better tobacco policy in the United States. Part 1 looked back for inspiration at some pretty good recommendations made in 2001 by the Institute of Medicine.

In this (Part 2), we look forward and consider how FDA's Center for Tobacco Products should respond to the evaluation made by the Reagan Udall Foundation (RUF) in its polite but scathing *Operational Evaluation of FDA's Tobacco Program*. I submitted comments to the RUF evaluation and wrote a blog: Chaos, waste and failure: what is wrong with FDA tobacco regulation, and how could it improve? to expand.

> *The heart of the problem is the lack of a coherent regulatory strategy, grounded in real-world understanding.*

To its credit, FDA has seemed open to a substantive rethink in light of the RUF review. It did not (as I had feared) just brush it aside in the way that many bureaucracies would have. Instead, in February, it launched a deliberative process lasting through 2023 with a statement by CTP Director Brian King and an agenda for its formulating it response: *Actions to Address Recommendations from the Reagan-Udall Evaluation of CTP*.

How FDA should respond to the Reagan Udall critique

I have been fortunate to be part of a group that has come together to put views to the FDA on the appropriate strategic response to RUF. In a 3-page summary letter and 11-page briefing sent to Dr Robert Califf, FDA Commissioner, the group of twenty-three academics and experts have set out a proposed regulatory strategy. The documents have been posted on the website of the University of Michigan Tobacco Research Network – see the following links:

- Letter to Dr Califf (HTML format)
- Letter & Briefing (HTML format)
- Letter & Briefing (PDF as sent)

The letter functions as an executive summary of the longer briefing, which contains more specific proposals.

Four regulatory pillars

The response proposes an enhanced version of the FDA's 2017 "Comprehensive Plan" and rests on the following four pillars of regulatory strategy.

1. *To degrade the attractiveness and addictiveness of cigarettes and other combustible tobacco products. FDA should use its powers to control ingredients, addictive agents, emissions, exposures, packaging, warnings, marketing, and retailer behaviors.*
2. *To promote transition pathways to smoke-free status. FDA should authorize a wide range of low-risk nicotine products that will allow smokers low-risk alternatives and an off-ramp from smoking. Using its wider regulatory powers, FDA should promote smoking cessation with better evidence-based treatments.*
3. *To control risks arising from the ongoing use of smoke-free nicotine products. The FDA should use its powers to ensure that non-combustible tobacco products, while not risk-free, are safe enough and have an acceptable risk threshold. It should create a system of standards and soft standards ("comply or justify") that would expedite the pre-market application process.*
4. *To protect young people from tobacco-related health and welfare risks. FDA should take a holistic view of the interests of young people, especially those at the highest risk from tobacco or substance use, and recognize young people benefit in multiple ways when the adults in their lives quit smoking.*

Trade-offs and unintended consequences

As Reagan-Udall points out, FDA's approach to tobacco requires careful navigation of trade-offs and unintended consequences arising from its interventions – and that applies to the four-part strategy set out above. These trade-offs should be made explicit and grounded in minimizing disease risks to

the extent possible.

Four supportive actions

In addition to the four pillars proposed above, we identify four further supportive actions:

1. *Education. Undertake a concerted communications effort to better align public perceptions with scientific insight. There are widespread misperceptions about the significant differences in the risks of combustible and non-combustible products and public misunderstandings about the role of nicotine in behavior and disease. FDA is well positioned to correct misperceptions about nicotine to accelerate the decline of smoking.*
2. *Efficiency. Make immediate improvements in the efficiency, transparency, predictability, and proportionality of the PMTA process. Process re-engineering will reduce pressure on staff and litigation risks. It means, for example, relying more on standardization, post-market surveillance, and expediting authorization for product updates.*
3. *Enforcement. Build a rational regulatory regime and then enforce it. FDA should combine a more rational, transparent, and risk-proportionate system for authorizing smoke-free products with stricter enforcement action against unauthorized products, rogue marketing practices, and illegal sales to under-21s. A more orderly, well-regulated market will reduce, though not eliminate, the need for enforcement.*
4. *Engagement. Proactively engage stakeholders. FDA should be open to a wide range of perspectives on these issues and demonstrate a willingness to consult and engage widely, including through the Tobacco Products Scientific Advisory Committee (TPSAC). FDA could publish or sponsor objective scientific assessments and help build consensus towards a common base of knowledge.*

Don't forget to read the briefing for more on the reasoning and specifics behind these four pillars and four supporting actions.

Who signed the letter?

We have twenty-four signatures: David Abrams, Scott Ballin, Clive Bates, Neal Benowitz, Michael Cummings, Cliff Douglas, Jonathan Foulds, Tom Glynn, Martin Jarvis, Lynn Kozlowski, David Levy, David Mendez, Robin Mermelstein, Rafael Meza, Tom Miller, Ethan Nadelmann, Ray Niaura, Mike Pesko, Vaughn Rees, Steve Schroeder, David Sweanor, Jamie Tam, Kenneth Warner, and Daniel Wikler. Full titles and affiliations in the letter.

Some observations on the proposed four pillars

1. The first pillar (*To degrade the attractiveness and addictiveness of cigarettes and other combustible tobacco products*) is intended to incorporate a broader set of options than proposed in the 2017 plan. The 2017 plan focussed exclusively (and effectively bet the house) on FDA implementing a reduced nicotine rule. The problem is that such a rule may not happen quickly or at all and would consume a great deal of political capital. The idea here is to encourage FDA to pursue other options as well as, instead of, or in the interim before such a rule is agreed and implemented (if it ever is). As such, it represents a broader effort to take a proportional (i.e. harder) approach to the high-risk product, which includes but does not rely on the reduced nicotine rule. There has always been a danger of being reliant on one controversial and massive measure with multiple foreseeable and potential unintended consequences. So this pillar broadens the options for degrading the appeal of cigarettes. For this to work without chaotic backlash, illicit markets, and other unintended consequences, the second pillar below is essential – existing smokers must have multiple attractive pathways to smoke-free status.
2. The second pillar (*To promote transition pathways to smoke-free status*) recognises that smokers need all possible options to quit (or never start smoking), including and especially those who like smoking, don't want to quit, and/or are dependent. As far as possible, migration to smoke-free products needs to be consensual and embraced willingly by people who smoke. Excessive or exclusive reliance on coercive measures will cause a political and legal backlash, workarounds, product substitution and illicit

trade. This pillar essentially recognises the harm reduction approach and that any low-risk method (medical or consumer product) should be available to help people quit smoking or migrate to smoke-free status in the way that works for them. Going in more aggressively on harm reduction does not mean taking a laissez-faire approach. It means regulating primarily with consumer interest and consumer protection in mind rather than blocking as many products from the market as possible with insurmountable evidential hurdles – in the misplaced hope that people will respond by becoming nicotine-abstinent.

3. The third pillar (*To control risks arising from the ongoing use of smoke-free nicotine products*) recognises that it is very unlikely that the demand for nicotine will somehow disappear even if the demand for it in smoked form may (hopefully) dwindle to nearly nothing. Demand for nicotine will persist, but non-combustible products will steadily replace combustible forms of tobacco as the dominant consumer nicotine products. This means that standards need to be set without reference to cigarettes and reflect that use of nicotine in future may not start with smoking. This means regulating with the same sort of consumer protection mindset that is needed to govern the regulation of recreational drugs like alcohol or, in future, cannabis – making the products available to those who wish to use them with, but with broadly acceptable risks and the control of avoidable risks.
4. The fourth pillar (*To protect young people from tobacco-related health and welfare risks*) recommends a more nuanced approach to the interests of young people, including their interests in adult society through their family and their own development into adults. It is especially important to recognise the interests of those inclined to smoking, nicotine use, other substance use, or other risk behaviours on account of their individual characteristics or their circumstances – the common risk factors for youth smoking, nicotine or substance use. It is a mistake to try to control demand by placing restrictions on supply. It doesn’t work and has multiple unintended consequences because the demand just switches to something else – products not banned, illicit trade in banned products, workarounds, DIY or illicit manufacturing etc.

PMTA efficiency improvements

On the supporting actions, I will just pick out our proposals for improving regulatory efficiency: an essential and urgent priority, given the current mess.

The third of our supporting actions recommends improvements to the PMTA process. (*Efficiency. Make immediate improvements in the efficiency, transparency, predictability, and proportionality of the PMTA process*.) It may be helpful to list the suggested improvements here:

We recommend that the PMTA regime be simplified and made more proportionate by the following:

- *Develop and communicate a principled, transparent, proportionate, and legally defensible strategy for APPH determinations. If applicants are clear on what is expected and how their applications will be evaluated, there will likely be fewer applicants and better-quality applications. A robust regulatory strategy is the structural solution to the backlogs, litigation, and overwhelming demands on FDA staff and applicants.*
- *Aim to create routine and expedited pathways through evaluation for products that are broadly similar and already well-established in the market.[1] By avoiding unnecessary repetition, FDA could reserve its scientific and assessment resources for novel products that present either novel risks or new opportunities. FDA should be able to prioritize innovations that are likely to advance the public health agenda, for example, by reaching particular at-risk populations, highly dependent smokers, or nudging dual users into exclusive use of low-risk products.*
- *Improve the transparency of FDA's evaluation criteria and how the agency maintains consistency between products, assessors, and over time. Any guidance to assessors (e.g., internal reviewer guides, briefs on the state of the science) should be made public and readily available to applicants.*
- *Use guidance to provide advisory standards-based pathways through the PMTA assessment. Such 'soft standards' or 'heuristics' would not be mandatory tobacco product standards under the Tobacco Control Act. Applicants and evaluators would use them to expedite and simplify the technical evaluation process by capitalizing on commonly accepted*

scientific findings. The approach would be "comply or justify," meaning that additional evidence and scrutiny would be required for products that did not meet these soft standards.

- *Such 'soft standards' could also inform priorities for the exercise of enforcement discretion. For example, a soft standard that creates a presumption against using cartoons or childish branding would signal manufacturers not to include such imagery in pre-market applications (or be prepared to justify it) and to expect priority enforcement action in the absence of a PMTA.*
- *Develop a range of mandatory tobacco product standards under the Tobacco Control Act Section 907. This approach should help to standardize assessments and avoid the cost and waste of applications that will fail.*[2]
- *Pre-market assessment should focus on risks to the individual (toxicity, safety, abuse liability). Where individual risks are likely to be much lower, population and behavioral effects should be assessed post-market using real-world data. If adverse effects emerge, FDA retains the power to take corrective action, including removing products from the market.*
- *Use a single market-wide post-market surveillance system funded by user fees rather than imposing significant surveillance burdens on each applicant. A single surveillance system will provide a better insight into population effects, effects arising at category rather than product level, and capture products without authorization.*
- *Introduce a simplified system for evaluating incremental improvements to authorized products so American consumers can benefit sooner from product innovations. This should apply to both the PMTA process for authorizations and the MRTP pathway for modified risk claims. FDA's processes should encourage pro-health innovation, not obstruct innovation or deny Americans access to the best technologies available worldwide.*
- *Provide applicants with meaningful information on the progress of their applications with estimated decision dates. For many businesses, FDA's decisions are mission-critical and may be the difference between business viability and failure. They are entitled to timely assessments and realistic expectations about decision-making.*

- *Engage consistently with applicants to address reasonable application deficiencies so that these can be remedied with a view to FDA granting marketing orders rather than as a reason for abrupt denial. FDA should be aiming for a regulated competitive market with a diverse range of compliant products.*

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[1] The legal options for achieving this are beyond the scope of this briefing. It is possible this could be achieved through the expansion of existing pathways, like supplemental PMTAs, expanding bridging options, or through the creation of new pathways to illuminate a route forward for discrete categories of products. Our purpose here is to argue that this should be the *intent,* and that FDA should seek lawful means to deliver on it.

[2] Yagi, B., Lushniak, B., & Miller, B. (2023). Appropriate for the Protection of the Public Health: Why We Need Electronic Nicotine Delivery System Product Standards. *SSRN Electronic Journal*. https://doi.org/10.2139/SSRN.4383394

> *In addition, FDA should benchmark its processes against the requirements of good regulatory practice set out in relevant Executive Orders.[1] In doing so, FDA should revisit the Regulatory Impact Analysis for the 2016 deeming rule to reassess value for money and efficiency in the light of experience and outturns.[2]*

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[1] Office of Management and Budget, The White House. Regulatory Matters. https://bit.ly/3znTxGa Relevant Executive Orders on good regulatory practice include EO 12866 (Regulatory planing and review), 13563 (Improving Regulation and Regulatory Review), 13579 (Regulation and Independent Regulatory Agencies), 13610 (Identifying and Reducing Regulatory Burdens)

[2] DHHS/FDA (2016) Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco

Control Act; […] Docket No. FDA-2014-N-0189 Final Regulatory Impact Analysis May 2016 https://bit.ly/3HI3guG

Comments

Let us know what you think of this proposal in the comments – especially if you disagree or think it misses something important.