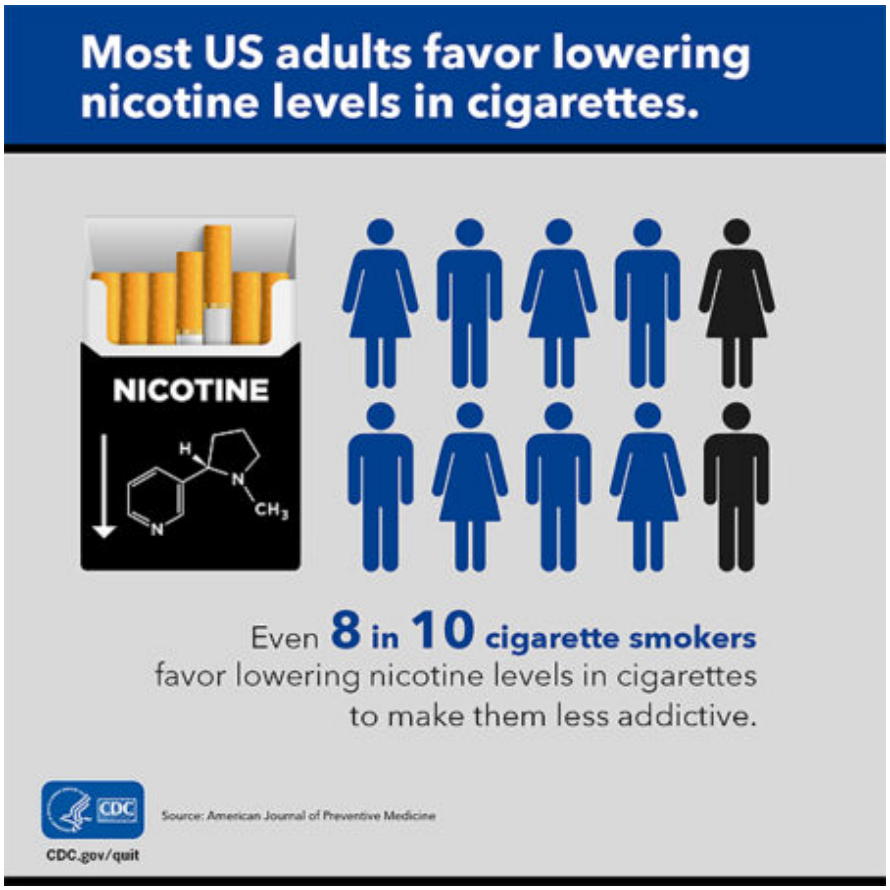
Twenty reasons to be sceptical about rules lowering nicotine levels in cigarettes – and what to do instead



Well, that rather depends on how you ask the question

To mark the annual US Food Drug and Law Institute Tobacco and Nicotine Products Regulation and Policy Conference (21-23 Oct), where FDA traditionally gives an update on its plans for nicotine regulation, I thought it worth noting that the centrepiece of its comprehensive strategy for nicotine seems to have disappeared. This would be a proposed rule lowering nicotine levels in cigarettes with a view to making them sub-addictive – persuading adults to quit and adolescents to never start. The trouble is that consumers, markets, producers, and criminal networks have a way of thwarting such bold measures.

Not in the work plan. The US Federal government periodically sets out its overall regulatory programme (the "Unified Agenda"). For Spring 2020, the Health and Human Services / FDA list (here) continues to show the absence of effort on rule-making that would reduce nicotine concentrations in cigarettes to sub-addictive levels. This disappeared from the list last year.

The centrepiece of a comprehensive strategy. In July 2017, this measure was announced as the centrepiece of FDA's strategy for tobacco/nicotine – a multi-year roadmap. It seems to have run out of road in less than three years, perhaps reaching a dead end with the departure of Scott Gottlieb – its most visible backer (speech, July 2017). It caused quite an earthquake at the time and precipitated a sell-off in tobacco stocks that they have not so far recovered from.

I have always been sceptical about this measure. Here are twenty reasons to be sceptical.

I. Political barriers

1. Huge illiberal intervention – it involves coercive personal behaviour change for millions of Americans. It is a *huge intervention* in the personal habits of a large number of ordinary law-abiding people. Even if some welcome it, many will resent it. There is a big difference between helping someone to quit smoking and *requiring them* to quit by regulatory fiat. Those who want to quit have multiple options to quit or switch already, on what basis should the state coerce those who do not want to quit?

2. Sensitive sub-populations – It is particularly challenging for vulnerable and other groups – psychiatric patients and people with mental health issues, veterans, homeless, seniors – etc. these will form a formidable and sympathetic opposition. People will vary in their intensity of opposition to this measure, but imagine just the last one per cent of most intense hold-out opponents: that's still two million people. Good policymaking might just leave the last few per cent in peace.

3. Identity politics – it will likely generate resentment against the Federal government and play into America's ongoing culture war. If COVID masks can generate such a strong response, I would expect the MAGA/2A/White-power crowd to add this as a further grievance. Maybe many will take up smoking to

stand up for their version of American values and "to own the libs".

4. The illusion of public support – policymakers are likely fooling themselves about the public popularity of the measure – see graphic at the top of this post, claiming 80% of the public favour the measure. But the problem with this is that the underlying survey is likely to be misleading. The survey presents what sounds like a moderate proposition: "*Do you favor or oppose requiring cigarette makers to lower the nicotine levels in cigarettes so that they are less addictive?*". There are several problems with this: (1) most Americans incorrectly think nicotine is the primary agent that causes cancer; (2) the extent of the reduction (>95%) and complexity of controlling 'addiction' by taking away the reason to smoke is not explained; (3) the respondent is asked whether they are for or against making the tobacco companies do something. Who could be against that?

5. The will of Congress – the intent of Congress was not to allow major changes like this without Congressional approval. Even if the letter of the law *might* allow it, the *intention* to disallow it is evident in S. 907d(3) of the TCA – see especially the chapeau. The proposed measure has many impacts beyond the FDA's jurisdiction, and these demand a broader assessment of the costs and benefits. A post-2020 Congress may have a different complexion, but the politics will always be difficult.

6. Taxation as an indicator of political will – in many ways, taxation functions as a graduated prohibition – an extremely high tax is functionally the same as a prohibition (with likely consequences for black market activity). But the United States has relatively low taxes on cigarettes, albeit with considerable variation between states. Why not try to get an increase in Federal cigarette tax passed as a first step and test the appetite for radical measures?

II. Policy design

7. Justification – the FDA has not made a compelling case for this measure. Neither has anyone else. The critical question is what happens, *in reality*, in response to a rule – how do suppliers (including illicit suppliers), consumers and markets respond? The least likely response is mass uptake of low-nicotine cigarettes by nicotine-seeking smokers, but what *will* they do and what are the consequences of their response? FDA's Advanced Notice of Proposed Rule-

Making (ANPRM) failed to assess the all-round impacts that the measure would have or to show that the detriments are worth the (claimed) benefits. While FDA is only supposed to look at the issue narrowly and concentrate on health impacts, that is the reason why Congress would (and should) expect to be the decision-maker.

8. Youth – though the measure is justified mainly in terms of ending youth addiction to nicotine, why would this work? Despite the outright prohibition of marijuana, past 30-day MJ prevalence at 12th grade has been reliably over 20% for at least twenty years (prohibitions don't work)

9. Science – most of the very substantial scientific effort to support the measure has not contributed much to underpinning its justification. It largely examines in detail the *least likely* behavioural response (use of VLN cigarettes). It, therefore, has little to contribute to showing the measure meets the "appropriate for the protection of public health" standard required for rulemaking. This requires evaluation of all changes in product use likely to be triggered by the measure.

10. Expanding scope – to be effective, a reduced-nicotine rule will need to be widened to *all combustibles*. Otherwise, people will switch to little cigars, hand-rolling tobacco, pipes or other devices, and there will be creative workarounds unless the measure covers every type of tobacco set on fire. This will widen the number of people affected by the ruling and, of course, increase the opposition to it.

11. Alternatives – any plausible attempt to introduce this strategy demands the availability of low-risk alternative nicotine products that most smokers can switch to if they can't or don't want to quit. The alternatives need to be good enough to make a switch possible and effortless for almost all smokers, but if they are good enough, there is no need for the coercion.

12. Contradictory strategies – the FDA/TCA approach to alternatives works against having credible low-risk alternatives available (and favours high risk or black market alternatives). This is combined with intense hostility from tobacco control activists and academics to low-risk alternatives, generating misleading fears about switching. In this environment, it won't be easy to create a credible switching proposition

13. Priority to pre-requisites – one approach to this is to identify pre-requisites or

parallel enabling measures and ensure there is a strategy to have them in place first. In my view, the measure is completely unviable without a wide range of alternative products that can displace smoking. This demands a more enlightened approach to regulation and a pro-innovation approach to reduced-risk products. FDA's cumbersome implementation of PMTA and MRTP processes are a huge barrier to innovation and product diversity. Fix that first!

14. Product-user interaction – if a regulator wants to tamper with product formulation to reduce appeal, why not remove toxins and leave the nicotine? The danger with the lowering nicotine is compensatory smoking (consuming more smoke to get the same nicotine). This is why advocates for the measure insist on deep reductions – so that compensatory smoking is not possible. But that makes it a form of prohibition if smoking is primarily a nicotine seeking behaviour and therefore triggers a wider set of behaviour changes. Tobacco companies have prototype products with reduced toxins, but these never made it to market, so we can be sure they are not appealing – presumably because the toxins contribute to the flavour experience of combusted tobacco. Why reduce the drug and increase the impurity of the delivery system?

III. Perverse consequences

15. Black market – a market for high nicotine cigarettes will arise (including counterfeit VLN with high nicotine but appearing to be low nicotine) – the only uncertainty is how large it will become and how quickly it will grow. What have supporters of this measure learnt from the very large black market that serves New York?

16. Gateway effects – black marketeers are a gateway to other black-market products and have no scruples about age restrictions or what is sold to whom.

17. Enforcement – a law like this will be difficult to enforce – either because it needs high penalties for people not to ignore it or because law-enforcement will be reluctant to enforce as it will seem unfair. Many officers may be smokers, former-smokers or know smokers. Who will do the enforcement, how will it be done, and what is their attitude to it? For some, a prohibition is an opportunity for corruption. Also, beware a racist application of the law. The war on drugs has filled American prisons with people of colour – new offences are easily created,

but expect inequality in the consequences.

18. Fiscal – Around $45 billion/year is raised in tax and MSA payments through the sale of cigarettes. What will happen to this revenue? If there are losers (for example, states' treasuries) will they oppose the measure? What is the proposal to address a transfer of this market to the illicit sector? What taxes will rise?

19. Economic collateral damage – while we may not like this business, the supply chain supports small and medium businesses from farm to corner store. Policymakers could mitigate the damage by introducing change over time. However, experts recommend rapid tapering from to low level over months rather than years – that purposefully creates an economic shock in the supply chain.

20. Political capital and opportunity cost – is this *really* the best way to spend political capital: to go to war with farmers in Kentucky and Tennessee, retailers everywhere, tobacco companies in court, libertarians etc.? The case for taking on these battles has to be weighed up carefully: how much effort id involved, with what chance of success in realising the hoped-for benefits and how quickly? Against that, there is the opportunity cost: what else could be achieved by the same effort and resources?

What should be done?

First, there needs to be clarity on the goal. The goal should be to *reduce harm* to the greatest extent possible as quickly as possible. It makes a huge difference to express the goal this way, rather than to aim to end nicotine use, "nicotine addiction", stop Big Tobacco or whatever other confused objectives are in play. The latter forecloses many effective and fast-acting options to reduce harm.

Any harm reduction approach should include harms created by the policies introduced to attain the goal – for example, arising from black markets, regressive taxation, stigma or negative welfare arising from coercion or punitive measures. These harms place limits on how a government can push conventional tobacco control policies.

In 2016, I suggested the following would be the primary drivers for change:

> *Objective. To radically reduce serious diseases caused as a byproduct of*

recreational nicotine use, without compromising welfare, and while respecting individual liberty and adopting an appropriate role for the state.

Strategy. Over the long term, the recreational nicotine market will evolve from smoking tobacco to nicotine delivery with dramatically reduced toxic exposure – as vapour, aerosol, smokeless tobacco, heat-not-burn tobacco products, nicotine lozenges etc. The market may be smaller or larger than it is today in terms of total numbers of users – it hardly matters as long as the harms are greatly reduced.

Elements of the endgame. These would be the main drivers for this transition:

1. *The market for recreational nicotine will evolve through producer innovation, consumer preferences and intense competition reshaping the $800 billion per year tobacco industry beyond recognition. The private sector will be the prime agent of this transition, in a market shaped by regulation and incentivised by the profit motive.*
2. *The accumulated pressures from conventional tobacco control measures (MPOWER) to stop smoking will drive users to seek alternatives and create a significant driver of transition, as now – but respecting boundaries between the state and the autonomy and agency of the citizen.*
3. *The availability of viable alternatives to smoking will greatly increase the responsiveness to pressures and incentives created by tobacco control measures, compared to having complete tobacco and nicotine cessation as the only or preferred option.*
4. *A light-touch and proportionate consumer-orientated regulatory framework will encourage innovation in and switching to very low-risk alternatives to smoking.*
5. *The public health community would need to change to adopt a responsible approach to risk communication and candour with nicotine users. It would approach the challenge with humility and empathy, and self-awareness about the limits of its intrusiveness in the lives of others.*
6. *The disruption and subsequent transformation of the tobacco industry into a recreational nicotine industry – with survival and prosperity for companies that adapt and lead transformation and failure and displacement through 'creative destruction' of those who do not. At the moment, most of the public health establishment is working to shield*

the industry from the disruptive pressures.

7. *Smoking evolves to an occasional pleasure for those who still retain a liking for it – but at levels unlikely to do much harm.*
8. *Those who wish to smoke can do so, much as now – they have good low-risk alternatives if and when they want to stop. The public health community focusses its concerns on people smoking in the decades after age 40.*

Beyond harm reduction. To call this 'harm reduction' is to belittle it. It is technological progress in the recreational nicotine market, solving problems in the way that human ingenuity has done for centuries. It brings about the obsolescence or marginalisation of a harmful and polluting way of using nicotine through emergence and uptake of superior technologies.

Before anyone says it… this is not 'lights' again. When the tobacco control community embarrassed itself by wrongly assuming a no less harmful product was safer, it cannot put that right by wrongly assuming a much safer product is no less harmful.

I believe these ingredients are in place, but the main obstacles to realising this are in the perverse attitudes of public health establishment and regulators trapped by ideology and extreme asymmetric risk-aversion.

As Sheikh Yamani might have said but didn't:

> *"the Stone Age didn't end because we banned stones".*

It's October 2020, I don't see much need to modify this approach – only to note (again) that it is the tobacco control establishment of activists, academics, media lackeys, compliant politicians and opinionated philanthropists that forms the primary defence of the cigarette trade against the tech-driven onslaught of this strategy.

Disclosure

In 2013, I made a bet with Joe Gitchell that a VLNC rule would not be in place by 28 June 2023 – see details here.

It looks unlikely to be in place by 2023, but politics can change – so who knows.