Huge FDA announcement on future tobacco and nicotine strategy

written by Clive Bates | 28 July 2017



FDA's Scott Gottlieb: "new comprehensive plan for tobacco and nicotine regulation"

It came as a surprise, but today's announcement from FDA on tobacco policy is *huge.* The video of Dr Gottlieb's speech and background is available here and speech text here.

The new Commissioner, Scott Gottlieb calls for FDA to develop a 'new comprehensive plan for tobacco and nicotine regulation' and announced 'bold and far-reaching measures' based on ' a firm foundation of rules and standards for newly-regulated products'. FDA announced it would "*begin a public dialogue about lowering nicotine levels in combustible cigarettes to non-addictive levels through achievable product standards*".

FDA Press announcement: FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death

Some highlights…

- **Breathing space**. Gives additional four years for submitting vapor product application (now PMTAs must be submitted by 8 Aug 2022 for e-cigarettes – it was previously 2018) to "*provide manufacturers additional time to develop higher quality, more complete applications informed by additional guidance from the agency*." I hope this will be enough to keep a diverse industry alive.
- **Product standards**. "*FDA intends to develop product standards for e-cigarettes to protect against known public health risks*" – standards provide certainty and transparency, and if sensibly defined, should lower the costs of participating in the market and provide meaningful benefits to consumers.
- **Process clarity**. "*FDA plans to issue foundational rules to make the product review process more efficient, predictable, and transparent for manufacturers, while upholding the agency's public health mission*". As well as the cost, the opaque assessment and approval procedure has been a major concern, so this is a really important advance.
- **Reduced nicotine cigarettes**. "*Begin a public dialogue about lowering nicotine levels in combustible cigarettes to non-addictive levels through achievable product standards*." Misguided in my view, but a public dialogue is a long way from a rule.
- **Flavors.** "*Will seek input from the public on a variety of significant topics, including approaches to regulating kid-appealing flavors in e-cigarettes and cigars*".
- **Medicinal nicotine**. "*Examine actions to increase access and use of FDA-approved medicinal nicotine products*". I suspect this means new 'indications' for harm reduction.
- **Redeploy resources**. Assess whether to abandon the backlog of substantial equivalence (i.e. trivial) applications. Sensible move, but another free ride for cigarettes.

Some quick reactions from me…

Grand strategy… The desire to have a rethink and introduce a comprehensive approach to nicotine is exactly right, necessary and urgent. The positive messages from Dr Gottlieb about harm reduction and his discussion of nicotine, addiction and harm from the delivery system show that he gets it. These statements are really important and show that FDA leadership is getting to grips with the

concept of exploiting differential risks in tobacco products for public health gain. And unlike the past, the warm words are backed by at least some deeds.

Saving the vapor category…? The easing of some of the regulatory stress from the vapor technologies is essential. The four-year delay of a requirement to submit PMTAs to 2022, the promise to simplify and clarify the application process, and the emphasis on standards and rules all mark the opening moves in a new regulatory philosophy, in my view. This is an important practical and concrete deliverable from the announcement.

Reducing nicotine in cigarettes… I was initially surprised to see FDA load itself up with the taking forward the reduced-nicotine concept when it has so much else to get right or wrong. Yet this was a headline part of the announcement. But on reflection, this has a number of merits. If FDA is going to have "*a new comprehensive plan for tobacco and nicotine regulation*" then it would have been strange to omit any consideration of this approach, especially as FDA has spent perhaps ~$100m on research in this area. Three useful things could come of the inclusion of the reduced nicotine strategy: first, we really do need a full-throated debate on the utility of this idea to stress test it; second, it is an end-game holy grail for some in tobacco control and their opposition would be inevitable without its inclusion; third, it serves as a warning to the tobacco companies – even as only a threat that never crystallizes into action – that the future needs to look different and that reduced-risk products are where this regulated market is heading.

It's no secret that I think the reduced nicotine idea is both misguided and unnecessary, but I am happy to see it debated and I am confident, in this case, that reason will prevail. Here's my presentation on why I think is a well-intentioned but misguided idea (clue: it's not a scientific issue, it's a question of political economy) complete with notes in the downloadable Powerpoint. Is nicotine reduction a viable strategy for tobacco control? No, definitely not. I also wrote about it in my critique of 'end-game' ideas.

Flavors… Dr Gottlieb referred to a need to crack down on "*obviously kid-attracting flavors*". Actually, very little is *obvious* about this issue. Are childish-sounding flavours actually attractive to at-risk adolescents or is it a retro thing for adults? Are these flavours attractive enough to change behaviour? If they do change behaviour, what is the nature of the change in vaping, in smoking? Is this

change of behaviour harmful or beneficial, taking account of smoking behaviour? Will it mean fewer adults switch or quit, or more relapse? All that is to be all be fought over in the rule-making process. If the scope of a ban on flavours is narrow (eg. to trademarked candy names) then it is not the end of the world, if it is a sweeping ban on whole sub-categories then it is very problematic. My views on the flavor issue here: Are e-liquid flavours really 'hooking another generation of kids'?

Overall very positive… Basically, I'm calling a big 'win' for the pro-harm reduction public health camp in the United States, consumer advocates as well as those who have been working tirelessly at every level of the industry from vape shop to multinational. On the public health side, please see AG Miller's letter (June) and the NTRI letter (July) to Dr. Gottlieb for read-overs to the announcement – full details of these initiatives here: American experts call for risk-based reform of FDA regulation of tobacco and nicotine.

My own paper on FDA policy reforms is here: Rethinking nicotine: implications for U.S. federal tobacco policy: a discussion paper (June 2017).

Update 9 August, 2017 AG Miller's response to FDA's 28 July 2017 announcement: Miller, Health Policy Experts Applaud FDA Tobacco Control Shift

Much good work done, much still to do!

Comments please. Am I being too nice about this…?