Bizarre FDA vaping retail restrictions more likely to do harm than good

written by Clive Bates | 17 April 2019



Caught in its auto-induced moral panic about the *teen vaping epidemic*, the FDA has decided that it would be better if certain vaping products were harder to get hold of than cigarettes, and the ones that were easiest to get hold of should be the ones most like cigarettes – tobacco and menthol flavour. This seems entirely mad to me and riddled with the potential for unintended consequences that would increase smoking in both adults and adolescents.

Needless to say, FDA has not acknowledged or assessed possible unintended consequences – yet these are likely to overwhelm any possible benefits.

So I decided to put in a comment on the measures on that theme. First, some background then my comment.

What is FDA proposing?

FDA intends to prioritize enforcement for lack of a marketing authorization against (in practice this means 'prohibit') flavoured ENDS products (other than tobacco-flavoured, mint-flavoured, and menthol-flavoured ENDS products) for:

- Products sold in locations that minors are able to enter at any time – so that would include all regular shops, convenience stores, gas stations etc;
- Products sold through retail establishments and online retail locations that have sold to minors after issuance of the guidance
- Products sold online with no limit on the quantity that a customer may purchase within a given period of time; or
- Products sold online without independent, third-party age- and identity-verification services that compare customer information against third-party data sources, such as public records.

By the way this will barely touch the sources that under-age vapers use. Brad Rodu just published an analysis showing that most (71.4%) of underage vapers are obtaining vapes from social source not covered by the new guidance: friends (56.%); family (6.8%); other people (6.6%). Another 12.9% from vape shops, meaning on 15.7% are obtaining vapes from regular retail outlets..

If it has any effect on adolescents, which I doubt, the new discriminatory retail restrictions will just shift more supply to social sources and better reward the enterprising young people who trade in this informal market.

The main effect will be on adults: it is the casual bureaucratic harassment of law-abiding adults while they try to obtain regular supplies of products they are using as alternatives to smoking. It won't take many to relapse to smoking to blow any conceivable case for these measure right out of the water.

Background documents

The draft guidance is available here – this implements the announcement FDA Commissioner Gottlieb made in November 2018.

Document ID: FDA-2019-D-0661-0001 – you can comment from here. The draft guidance is open for comment until 30 April 2019.

My response

There is so much wrong with this that I didn't go into, but here is what I did focus on.

Comment Tracking Number: 1k3-99b4-p98m

FDA should not proceed with the measures referred to section IV the draft guidance: "Modifications to Compliance Policy for Certain Deemed Tobacco Products".

Argument

1. FDA is using its enforcement discretion to create arbitrary and discriminatory regulatory policy as an alternative to regulation;

2. Section 906(d)(3)(A)(i) of the Tobacco Control Act prevents FDA regulating to "prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets", yet this is exactly what FDA is doing through the application of its enforcement discretion. It, therefore, goes against the intent of Congress.

3. FDA has shown no evidence that its proposed measures will work to reduce youth vaping. There are several leaps of logic from the observation that adolescents have preferences for certain flavors to asserting that these preferences cause the vaping and then the further assertion that reducing access to such flavors will reduce the uptake or prevalence of adolescent vaping. This chain of reasoning has not been established by the FDA.

4. FDA has provided no assessment of the risk that its proposed policy will increase youth smoking as fewer adolescent take up vaping instead of smoking or fewer adolescent smokers switch to vaping. Most regular adolescent vapers are also smokers or would-be smokers, yet FDA has not considered the interactions between smoking and vaping behaviors or the possible adverse impacts of its proposed intervention.

5. FDA has provided no assessment of the risk that its proposed policy will cause harm to adult smokers by making switching less attractive or by causing smokers committed to using flavored products to relapse back to smoking. Adult smokers are at significant risk and less switching, more dual-use or outright relapse back to smoking would represent high-harm outcomes of such a policy. These harms would be significantly greater and more immediate per user than any harms the changed compliance policy is designed to control.

6. FDA has not attempted to assess and then balance benefits and risks of the proposed compliance approach – it does not know, therefore, whether the proposed changes will do more harm than good.

7. Because they focus restrictions on the least harmful product while leaving the most harmful product untouched, it is at least plausible that more harm will arise.

The guiding principle of FDA action in this area should be whether its actions are appropriate for the protection of public health, taking account of changes in the patterns of all tobacco use that arise. This principle has not been applied here and the measure should not proceed.