FDA wants to reduce nicotine in cigarettes – what could possibly go wrong (and right)?

written by Clive Bates | 25 October 2017



Some things don't have to be used to be useful

On 28th July, FDA announced that it wants to hold a "public dialogue" about regulating to reduce nicotine levels in cigarettes to "non-addictive levels". I've previously written about this idea in my critique of 'tobacco endgame' ideas, and I was pleased to present on the subject at SRNT 2017 conference. Generally, I've taken the view that the idea is crazy, unworkable, unethical and will never happen, and I have a hefty bet against it.

But now that FDA has announced it, everyone should ask: *might any good come of it?* That has prompted me to reconsider my previously entirely hostile approach. So here are some updated views in a report done in collaboration with Dr Carrie Wade, Director of Harm Reduction Policy at the R Street Institute, Washington DC.

- Counterfactual report: Reducing nicotine in cigarettes: Challenges and

opportunities

- R Street Institute Policy paper 115 and PDF

The three minute version…

- The reduced nicotine measure amounts to a prohibition of the dominant product in a market worth $94 billion, of which over $40 billion is federal and states tax revenue. Cigarettes without nicotine are no longer cigarettes, just as whiskey without alcohol is no longer whiskey.
- The reaction of the market – consumers, legal suppliers, criminal enterprise – to such a huge intervention is highly unpredictable and cannot be assessed by research into how people use reduced nicotine cigarettes, which they are willing to do in trials but will not in real life. The risks of unintended consequences are high and hard to dismiss in the absence of relevant evidence. The ethics of forced quitting of a personal behaviour are at best questionable and will generate political resistance in many of the 38 million Americans who smoke. The practical, fiscal, stakeholder, legal and political difficulties of introducing this measure will likely be overwhelming.
- There are more manageable options to reduce the appeal of smoking, if that is the FDA's policy intent. For example raising taxes, reducing selected toxins, control of additives and removal of branding. FDA will have to show that nicotine reduction will be superior to these approaches, but it has very little evidence with which to do this.
- However, the reduced nicotine measure is useful. It is an important signal of a direction of travel – the end of combustible tobacco products as nicotine delivery products. This could make it an 'agency threat' – a big stick that has influence in setting direction and pressing companies and their investors to respond.
- Furthermore, for such a proposal to work it has to be credible and FDA will have to work to overcome the many objections. The internal logic of FDA's approach calls for the availability of high quality low-risk alternatives to smoking that are acceptable to most smokers – otherwise the degree of forced quitting is excessive. FDA therefore needs to address the excessive regulatory burdens it has applied to vaping products, smokeless and heated tobacco products. It needs to apply its

technical-legal ingenuity to come up with a standards-based risk-proportionate regulatory framework. It also needs to make this pathway attractive to smokers by telling the truth about relative risk and allowing companies to do the same.

- These are good things to do in their own right, but they are *prerequisites* for a reduced nicotine rule. The final paradox is that if the market for alternatives is made to work, it will become unnecessary to actually introduce the reduced nicotine rule. The rule will have had its beneficial effect as a market signal and powerful agency threat.
- Rules, like nuclear weapons, don't have to be used to be useful. But they do have to be credible: and FDA has a lot of work to do to make the reduced nicotine proposal credible.

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About the authors

Enjoy! Please let us have your thoughts in the comments… I'm looking forward to discussing this at FDLI conference on 26 October. Here is my presentation:

Reduced nicotine rule: a terrible idea to be pursued relentlessly from **Clive Bates**