

Letter to *Tobacco Control* on priorities for FDA reform

Clive D. Bates responding to Matthew L. Myers

Towards more effective FDA premarket review of new tobacco products

Matthew L Myers

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Missing the point: a response to Matthew L. Myers

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NOT PEER REVIEWED The author appears to believe that the main problem with the FDA is that it is not doing enough to prevent new niche cigarette products reaching the market. This focus of concern is misplaced, given several thousand cigarette products are readily available and smokers are spoilt for choice with or without these new products. I have no great desire to see new cigarette products coming on the market, but is this *really* the most pressing agenda?

There are important issues for FDA and Congress to address, but on which the author did not comment. Allow me to suggest five:

1. FDA's governing framework for tobacco, the Tobacco Control Act, is unfit for the purpose of managing reduced risk products. It is designed to raise a high regulatory barrier to entry to a market dominated by worst products and to suppress innovation in better products. At the same time, it has protected the existing cigarette trade by 'grandfathering' the thousands of products that were on the market at 15 Feb 2007 and offering them an easy ride for subsequent modifications. A new legislative framework for recreational nicotine products is required.

2. FDA regulation is unlikely to offer a feasible route to market for most vapour products. Its approach will cause chaos in the marketplace, even though these products are helping many to quit smoking. The vapour category would be largely wiped out and confined to the tobacco industry's high volume commodity products if FDA proceeds on its present course. That would provide further protection for the cigarette trade and stimulate a black market. Workarounds, a change in the predicate date or simply doing nothing would be an improvement.

3. FDA's approach does little that supports and a lot that suppresses innovation, regardless of whether particular innovations are desirable for consumers. For example, under the proposed framework for vapour products to access the market, a third generation

e-cigarette manufacturer would likely need to go through a new and hugely burdensome authorisation (PMTA) to introduce new safety features like temperature control or to improve nicotine delivery through better aerosol science. A notification regime with an FDA right to intervene if the evidence justifies it would be preferable to a cumbersome authorisation regime.

4. FDA applies a bizarre approach to communicating the far lower risk of products like snus to consumers. This starts with a default FDA-imposed warning that is technically correct but not truthful because it is highly misleading ("*this product is not a safe alternative to smoking*"). It then requires tobacco companies to calculate if they are rich enough, the data extensive enough and whether it is sufficiently in their commercial interest to go through an arduous process to convince the FDA to allow them to change the warning to something more truthful ("*No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes*") - and face hostile resistance from tobacco control campaigner such as the author. FDA and CDC should be assessing the relative risks of these products, and communicating them clearly - so that public risk perceptions become, as far as possible, aligned with scientific reality.

5. FDA suffers from mission creep - a regulator should not be involved in campaigning. FDA should function, and be seen to function, as a neutral technocratic regulatory agency, leaving the hype to public health bodies like the CDC. In this case, there is a further problem - the scientific foundations of the new smokeless campaign are very poor and undermine FDA's credibility more generally. FDA should stick to its core mission and do it better.

Matthew L. Myers and his campaign would do better to consider the important issues in nicotine regulation, not expend time, money and credibility on marginal issues with negligible public health value.

Conflict of Interest:

I am a long-standing advocate for tobacco harm reduction and run the Counterfactual blog. I have no competing interests with respect to any relevant industry.