The tobacco control high command has lost its way – what we learn from its views on FDA priorities

written by Clive Bates | 21 April 2016

A recent editorial in the journal *Tobacco Control* discusses what's wrong with the FDA. In fact, the editorial is more telling about what's wrong with tobacco control.

Update: my e-letter in Tobacco Control – *Missing the point*

The President of the Campaign for Tobacco-Free Kids, Matthew L. Myers – arguably the *de facto* world leader in tobacco control advocacy – 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. See this *Tobacco Control* editorial by Myers: Towards more effective FDA premarket review of new tobacco products.

This singular focus of concern is absurd, given several thousand cigarette products are readily available and largely untroubled by any intrusive FDA intervention. I've no great desire to see new cigarette products coming on the market, but is this really the most pressing agenda?

Myers' approach was nicely satirised by Mike Siegel writing in 2015 in his

blog Campaign for Tobacco-Free Kids Touts Major Victory: Camel Crush Bold Taken Off the Market. Siegel points out that FDA blocking one Camel variant left *only 24 Camel variants* for smokers still to choose from. Also, this approach implicitly promotes the idea that there are good cigarettes (approved by FDA) and bad cigarettes (banned by FDA), which has the obvious potential to backfire.

But far worse is what Myers just ignores. No word in his editorial on any of the following, which really are important issues for FDA/Congress to address…

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 the recreational nicotine market and to suppress innovation in the tobacco and nicotine field. At the same time, it 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 Nicotine Act is needed in which the silly pretence that e-liquids are tobacco products can be abandoned, and meaningful, consumer-orientated, proportionate and non-discriminatory regulation introduced, recognising a spectrum of risks and the significant risk discontinuity between combustible and non-combustible products. I'm not even sure that FDA is culturally the appropriate agency to take this on.
2. FDA is unlikely to offer a sensible route to market for vapour products and will cause chaos. Despite the widespread beneficial effects these products are having, there are no scenarios in which FDA's involvement improves matters and many in which it creates more harmful unintended consequences [see my Bluffer's guide to FDA regulation]. 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, with CTFK's backing. That would provide further protection for the cigarette trade and stimulate a black market. I suspect the anticipated carnage is a *feature* rather than a *flaw* for most tobacco control activists. For example, CTFK vehemently opposes a shift of the 'predicate date' of 15 Feb 2007 that would postpone and partially ameliorate the forthcoming chaos FDA is likely to cause in the e-cigarette industry. The real priority is to find a reasonable workaround, or simply leave the deeming regulation on a shelf because there isn't actually a

problem that FDA is capable of solving under the existing legislation. "Do nothing" is actually the least-worst strategy available to FDA now – it would be good if CTFK could get behind "do nothing".

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-cig manufacturer would likely need to go through a new and massively burdensome authorisation (PMTA) to introduce new safety features like temperature control or to improve nicotine delivery through better aerosol science. Who benefits from barriers to them doing that? A better approach would be notification regime, with FDA having a right to intervene if it has evidence-based grounds for concern. This would be much better than an authorisation regime deliberately designed to be cumbersome.
4. FDA applies a completely ridiculous approach to communicating the far lower risk of products like snus to consumers. We can be pretty sure that snus is about 98-100% less risky than smoking, and one might expect that knowledge to be relevant to consumers. The approach to communicating this (MRTP) starts from a default FDA-imposed highly misleading and harmful warning ("*this product is not a safe alternative to smoking*"), and then requires tobacco companies to calculate if they are rich enough, the data expansive 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*"). They have to do this facing hostile opposition all the way from CTFK and its allies, a legal consortium and FDA's own scientific advisers, who display appalling bias and group-think. Why not have risk communication driven by consumer interests rather than tobacco company interests – and put the onus on the FDA to accurately gauge relative risk and ensure messaging from itself and CDC align public risk perceptions with reality?
5. FDA suffers from mission creep – a regulator should not get involved in campaigning. This week, FDA launched a highly misleading campaign on smokeless tobacco to add to its anti-scientific *Real Cost* campaign for adolescents – see Brad Rodu's devastating critique. FDA should function, and be seen to function, as a neutral technocratic regulatory agency,

leaving the hype to public health bodies like the CDC (at least there would then be only one of them). In this case, there is a further problem – the scientific foundations of the smokeless campaign are feeble and undermine FDA's credibility more generally. The @FDAtobacco twitter feed is habitually misleading and should be closed down or repurposed to focus on regulatory science.

I really despair: CTFK and Matt Myers could embrace the science, open their minds, show real leadership and get to work on this agenda. They could make a real difference. Instead, they are wasting their people's time, their funders' money and their organisation's credibility on things that barely matter to anyone but an insular circle of activists.

Further reading

Counterfactual: Bluffer's guide to the FDA regulation of tobacco and nicotine products – my crib sheet on how it all works, and why it doesn't.

Counterfactual: 10 ways to improve Matt Myers' letter to the New York Times – on Matt Myers' difficulties with the evidence and science of tobacco harm reduction.

Joel Nitzkin: What drives tobacco control policy? – a concise account of the strange belief system that appears to underpin the FDA's approach to tobacco and nicotine.