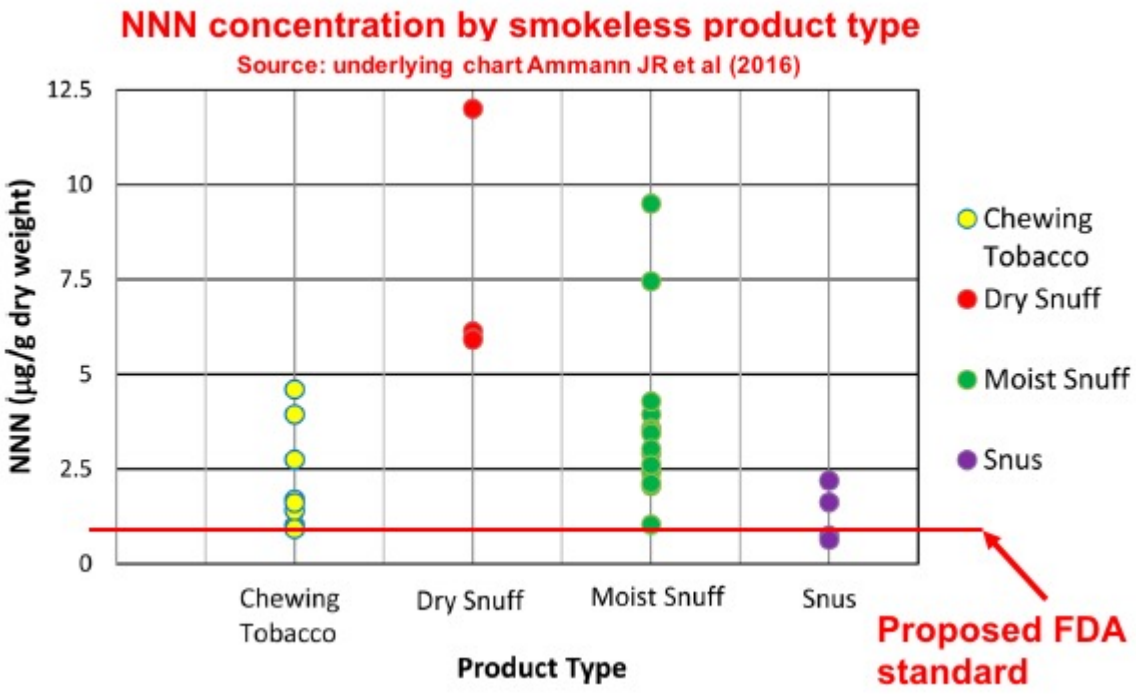
Reckless and pointless at the same time – FDA proposes NNN standard for smokeless tobacco

written by Clive Bates | 9 July 2017



Just looking for our submission to FDA's consultation? Here it is: Submission by Clive Bates & David Sweanor – PDF

But carry on below for some discussion and explanation of the chart.

Standards, good but… Normally, I'd be in favour of regulators setting standards for things they are regulating – standard-setting is a transparent approach that means everyone knows what they have to do, the supply chain can gear up, consumers know what they are getting, and there is no nonsense about changing the rules or not even disclosing what the rules are. *But…* three qualifiers to this cheery endorsement of standards:

1. a standard has to serve some purpose – to mitigate a material risk (e.g. by reducing a toxic exposure) or exploit and opportunity (e.g. facilitate trade)
2. it has to be set in way that is *achievable* – not set at some extreme level that is so difficult or impossible to achieve that it amounts to a *de facto*

prohibition.
3. the regulator has to be mindful of and avoid the dangers of harmful unintended consequences that might overwhelm any hoped-for benefits

This standard fails all of the above.

The chart above… is taken from Ammann et (2016). Researchers working for FDA examined NNN levels in 35 US smokeless products – I have added the parts in red. Two things to note.

1. FDA's proposed standard is set at the extremity. First, the standard is set at the lower extremity of what is on the market in this sample. This is a *ridiculous* thing for a regulator to do with an untried standard. NNN is not a completely controllable component of tobacco – it can depend on weather and humidity, for example, and there is bound to be natural variability in any plant product. The products with 94% of the market, that moist snuff (green blobs) are all over 2µg/g, with one exception, and with an average around 3.0µg/g. So these would need to make *deep, non-marginal* changes to meet the standard, if it was possible at all. Most of the larger companies in the market have already been trying to reduce NNN and may have exhausted the available technical options. So it is very far from clear that anyone can consistently meet this standard or even get close. A regulator concerned for its effect on the regulated market, should not act in this way – a standard would be designed initially to challenge outliers, then tighten over time. It's no good saying 'well, produce Swedish snus instead' – what happens to the people who choose American moist smokeless?

2. The inclusion of dry snuff in risk calculation. Second, look at 'dry snuff' and the high levels of NNN and these were probably much higher in the past. Dry snuff also shows up in surveys with elevated oral cancer risk. When FDA estimated the cancer risk for all smokeless tobacco it pooled in surveys that included dry snuff. These surveys had the effect of greatly increasing the *average* relative risk estimate for smokeless as a whole. Yet dry snuff market share is only 0.7%. So a hardly-used 'dirty product' was added to the mix to beef up the risk estimates, which were then applied to the widely-used but much lower risk products such as American moist snuff. Sleight of hand? *I couldn't possibly comment.*

Submission to FDA…. David Sweanor and I have just made a submission to FDA's consultation on a rule that would limit the concentration of a toxin NNN to 1

microgram per gram (1.0µg/g). The problem with this standard is that it fails the three tests above. It would cause a major disruption of the supply chain because that standard has been set at a level to the extreme of where most US smokeless tobacco sits (the trade-weighted average is over 3.0µg/g). In theory any product can change to meet the standard, but in many cases by becoming a completely different product. So our main argument is the rule:

1. Overstates benefits by using exaggerated estimates for risk by including dry snuff in estimates of average risk for smokeless. When you look at actual risks, they disappear. The whole thing is *pointless*.
2. Understates market disruption by assuming that much of the market is already or nearly compliant, which is false. In doing so it ducks deeper economic consequences, but also elevated risk of unintended consequences -e.g. people switching to smoking. Being willing to apply an extreme and disruptive standard while remaining indifferent to unintended consequences is *reckless*.
3. Ignores unintended consequences arising from disruption – the case is super sensitive to any additional smoking caused by changing product formulation, availability or price of smokeless. Only 7 in 1000 smokeless users would need to switch to smoking to completely offset even FDA's exaggerated benefits.
4. FDA does not apply the 'public health test' to itself with the same zeal that it applies to others – and so it just ignores the above.

The real story is that they shouldn't even be regulating here. FDA should spend its time undoing the damage it is about to do to the vaping industry and encouraging people to switch or quit.

Documents

- The proposed rule (Federal Register): *Tobacco Product Standard for N-nitrosonornicotine (NNN) Level in Finished Smokeless Tobacco Products*.
- Consultation (regulations.gov): Docket: FDA-2016-N-2527 (Our comment Tracking Number: 1k1-8xev-p31g)
- Our submission: Submission by Clive Bates & David Sweanor – PDF

Summary from our submission

Summary

Request. We respectfully suggest that the proposed rule is withdrawn as soon as possible after the closure of the comment process. Instead of pursuing damaging interventions on the lowest-risk tobacco products, FDA should redeploy its resources to encourage and facilitate smokers to switch to low-risk alternatives to cigarettes such as smokeless tobacco, heated tobacco products and vapor technologies.

The reasoning underpinning our suggestion is in four parts:

1. *Overstates benefits. The benefits of the rule are overstated because the risk, and hence risk reduction, are overstated. This arises as a result of inappropriate pooling of relative risk estimates for different types of smokeless tobacco, some of which are more harmful but rarely used.*
2. *Understates disruption. The FDA analysis is based on a completely unrealistic excessively optimistic assessment of the achievability of the standard for the products that dominate the US market. The analysis assumes unrealistically high compliance at baseline, though this conflicts with measurement data presented in the draft rule. The disruption of the smokeless market will therefore be much greater than FDA claims. That will make compliance more expensive, cause exit of firms and products, and affect the character of products with which smokeless tobacco users are familiar.*
3. *Ignores unintended consequences. If consumers' familiar products change in character, availability or price as a result of supply-chain disruption, it is not safe to assume that they will simply use these or other compliant smokeless products. The analysis is extremely sensitive to any additional smoking among the behavioral responses of smokeless tobacco users to supply chain disruption.*
4. *Fails tests for public health and good regulation. The proposed rule does not conform to the main principles of good regulation for federal agencies, and FDA has not shown that its rule would meet the public health test required for standard-setting under the Tobacco Control Act s907.*

Other writing and submissions of note

- Clive Bates & David Sweanor: comment & blog
- Brad Rodu, Tobacco Truth blog: Federal Studies: ZERO Mouth Cancer Deaths Among Men Who Dip or Chew Tobacco
- Brad Rodu: comment
- Brian Cater, CASAA (Consumers): comment and Julie Woessner: comment
- Carl V Phillips, Anti THR Lies: FDA's proposed smokeless tobacco nitrosamine regulation: innumeracy and junk science (part 1) – Part 2 – Part 3 – as a comment
- Brian Fojtik, Reason Foundation: The Proposed Tobacco Product Standard for NNN Level in Smokeless Tobacco Should Be Withdrawn – comment
- David Sweanor: initial comment
- Joel Nitzkin, R Street: initial comment; comment
- Zvi Herzig: comment
- Bill Godshall, Smokefree Pennsylvania: comment
- Peter Lee, PN Lee Statistics comment – detailed critique of the epidemiology
- Alex Brill, American Enterprise Institute: comment
- Scott Ballin: comment
- Patrick Hedger, FreedomWorks Foundation: comment
- Greg Conley, American Vaping Association: comment

Supply chain comments

- Altria (US Smokeless Tobacco): comment (devastating technical and legal take-down)
- Swedish Match (USA): comment – note a potential beneficiary of an extreme rule describes it as 'impractical'
- Reynolds America: comment
- National Tobacco Company: comment
- Eastern Dark-Fired Tobacco Growers Association: comment
- Dark Leaf Tobacco Dealers and Exporters Association: comment
- Virginia Tobacco Growers Association: comment

Government comments – a zinger from the Chief Economist at the US Department of Agriculture…

- US Department of Agriculture: comment

Comments in favour of the rule

- Society for Research on Nicotine and Tobacco (SRNT): comment
- Tobacco control coalition (29 organisations): comment
- University of California (Professor Glantz et al): comment