



IOWA DEPARTMENT OF JUSTICE
OFFICE OF THE ATTORNEY GENERAL

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Food and Drug Administration
21 CFR Part 1130
Docket No. FDA-2017-N-6189
Advance notice of proposed rulemaking
Tobacco Product Standard for Nicotine Level of Combusted Cigarettes

We are responding to the request for comment on the advanced notice of proposed rule-making (ANPRM) for a tobacco product standard for the nicotine level in combusted cigarettes¹. We welcome the opportunity to provide advice at this stage.

In the professional public health community, there is a wide range of views on the merits, practical viability, and likely consequences of introducing a rule to reduce nicotine levels in cigarettes, and possibly in other combustible tobacco products. Views range through a spectrum embracing:

1. Full endorsement for a rapid implementation of a tobacco product standard to reduce the nicotine level in cigarettes and in other combustible tobacco products²;
2. A sequential approach, in which the full potential of alternative nicotine delivery systems is realized to prepare the ground first, and then a nicotine standard follows³;
3. A nicotine standard should be held in reserve as an 'agency threat' to force the pace of reform in the tobacco/nicotine marketplace⁴;
4. A nicotine standard would be impractical and ultimately unnecessary, and a diversion from taking other more realistic measures⁵;
5. A nicotine standard would be excessively coercive and based on a poor legal and political mandate. It would cause an active black market and have other unintended consequences⁶.

It is not our purpose in this comment to resolve this debate over the appropriate strategy for a nicotine standard and we may individually take different positions on it. However, we all agree that there is one important requirement common to each of the perspectives above: that is the availability of low-risk non-combustible alternative tobacco or nicotine products that are sufficiently satisfying alternatives to cigarettes that smokers who choose to continue to use nicotine would be willing to switch to them.

The availability of alternative nicotine delivery systems (ANDS) is integral to a strategy of reducing nicotine levels in cigarettes by providing beneficial migration pathways for continuing nicotine users (1 & 2 above); necessary to maintain a credible threat to introduce such a rule (3 above); and required as an alternative strategy which renders a reduced nicotine rule for cigarettes unnecessary

because the alternatives themselves will drive the appropriate rate of switching and exit from smoking (4 & 5 above).

If a nicotine standard is introduced, it will create a significant impact on the personal behaviors of many millions of Americans. The key question is how will smokers respond to a change in the nicotine content in cigarettes? From a public health perspective, 'healthy' behavioral responses (becoming nicotine-abstinent or switching to low-risk, non-combustible nicotine products) will be in competition with 'harmful' behavioral responses (smoking reduced-nicotine cigarettes, smoking smuggled and/or counterfeit cigarettes, smoking other forms of tobacco, pursuing "do-it-yourself" modifications to products). Smokers will make their decisions based on the choices available to them, taking account of price, ease of access and legality, product appeal, and the relative ease of substituting an alternative product or behavior for tobacco smoking. It is important, therefore, that the low-risk and lawful options are highly competitive compared to the more harmful alternatives so as to maximize adoption of positive behavioral responses to a nicotine standard.

Without easy, low-risk pathways to exit from smoking that work for most smokers, there is a risk that a nicotine standard will trigger harmful behavioral responses as described above, or be seen as excessively coercive or punitive, causing a public and political backlash.

Both adult⁷ and youth⁸ smoking prevalence have fallen sharply over the period in which e-cigarettes have risen in popularity. The evidence as summarised by Abrams *et al*⁹ is positive about the potential for alternative nicotine delivery systems (ANDS) to displace smoking with a significant benefit to public health.

ANDS have the potential to disrupt the 120-year dominance of the cigarette and challenge the field on how the tobacco pandemic could be reversed if nicotine is decoupled from lethal inhaled smoke. ANDS may provide a means to compete with, and even replace, combusted cigarette use, saving more lives more rapidly than previously possible.

Scientists engaged in investigating the impacts of a nicotine standard have drawn attention to the need for alternative low-risk pathways to help smokers move away from cigarettes¹⁰.

The reduced nicotine content cigarette and the emergence of non-combusted nicotine products like e-cigarettes should be viewed not as alternatives but as complementary components of regulatory interventions that could virtually end combusted tobacco use.

Apelberg *et al* provided the modelling of public health impacts arising from a nicotine standard based on expert judgement referred to in the ANPRM¹¹. In the first year after the rule comes into effect, the median of eight experts' estimates is that 20 percent of adult smokers quit smoking as a result of the policy. The choice of alternatives to cigarette smoking is thus a key battleground for securing public health benefit from any rule. Apelberg *et al* recommend an approach to regulation that favors non-combustible products in a way that allows them to be viable alternatives to smoking.

To facilitate the transition from combusted to non-combusted forms of nicotine, we recommend that regulations regarding e-cigarettes and other ANDS focus on toxicity, safety and limiting youth uptake, but do not disrupt features that make them viable alternative to cigarette smoking.

In his commentary on FDA's comprehensive nicotine strategy, Neal Benowitz¹² expresses concern that FDA's regulation may, in fact, compromise the viability of e-cigarettes as an alternative to conventional cigarettes. The requirement for e-cigarette companies to submit Pre-Market Tobacco Applications (PMTAs) for each product is extremely burdensome:

This process could be expensive and putatively impossible for much of the independent e-cigarette industry. The move was seen as a potential threat to the viability of e-cigarettes as an alternative to conventional cigarettes.

We welcome FDA's announcements of 28 July 2017 delaying the requirement to submit PMTAs for e-cigarettes from 2018 to August 2022 and the possibility of developing safety standards for batteries and e-liquid ingredients¹³. However, the regulatory threat to the viability of e-cigarettes as an alternative to smoking has been *deferred* rather than eliminated by these announcements. It remains imperative that FDA creates an efficient, predictable and transparent regulatory regime and uses its leadership role to make the case for e-cigarettes as an alternative to smoking – and the pathway of choice for smokers who are reacting to the introduction of a nicotine standard for cigarettes or all combustible tobacco products.

There are several complementary reforms that should accompany and prepare the ground for the introduction of a nicotine standard. These are imperative and should have the aim of ensuring that a diverse range of high-quality alternatives to smoking is available; that the respective risks of combustible and non-combustible product are better understood by the public; that the regulatory regime encourages and does not hold back the innovation necessary for new products that can meet the needs of most smokers.

To meet these requirements, we recommend that the following complementary reforms be built into the comprehensive nicotine strategy:

- In regulating non-combustible alternative nicotine delivery systems, FDA should systematically apply the principles of good regulatory practice as it interprets its legal duties under the Tobacco Control Act. Principles of good regulatory practice are defined in long-standing Executive Orders¹⁴ that require each agency to:
 - design its regulations in the most cost-effective manner to achieve the regulatory objective;
 - base regulation on a reasoned determination that the benefits of the intended regulation justify its costs;
 - base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.
- In line with these principles, the PMTA process should be redesigned to make its costs and burdens more proportionate to risk while recognising the significant benefits that alternative nicotine delivery systems can provide when used as an alternative to smoking. It should not be a route to market that only works for a small number of products marketed by the largest companies. Excessive regulation of much safer alternatives should not be allowed to create *de facto* regulatory protection for the most harmful products.

- The PMTA process should as far as possible rely on standards and other transparent criteria that the applicants can understand in advance of an application. It should be clear to applicants which data are necessary and sufficient for a viable application and that all data collected has some relevance to consumer protection.
- FDA should focus standards on chemical, thermal, electrical and mechanical safety of the devices, liquids and aerosol; appropriate testing regimes; and on providing useful consumer information. The extent of evidence required for a successful PMTA should be limited to that necessary to provide reasonable assurance about safety and risk. Products with novel designs or likely to create novel risks, for example heated tobacco products, should require more complete testing, for example including human studies. But a lower bar should be set where a product does not raise novel issues and where data on the toxicity of aerosol emissions provides an adequate characterization of risk – implicitly applying the concept of ‘substantial equivalence’.
- In meeting the public health standard for non-combustible products, FDA should rely more on post-market surveillance and reactive intervention and less on expensive but unreliable pre-market estimates or modelling. No model would have predicted the rise of JUUL, for example, and the public health impact, positive or negative, of a product like JUUL can only be assessed with reference to its impact on smoking and on use of other e-cigarettes and tobacco products, which can only be known post-market.
- There remain extreme misperceptions about relative risks of combustible and non-combustible products¹⁵, and on the role that nicotine plays in causing harm¹⁶. FDA, CDC and the US Surgeon General should make clear, consumer-friendly, statements about alternatives to smoking, emphasizing that nicotine *per se*, while not harmless, causes much less harm than smoking, and emphasize that it is the hazardous agents in the smoke itself that cause by far the greatest burden of disease and death¹⁷.
- Information on risk provided by trusted agencies must change. The emphasis on there being “no safe” or “harmless” tobacco product, when given in isolation, under-informs consumers¹⁸ and can mislead them to think that non-combustible products are just as dangerous as cigarettes^{19 20}. FDA’s modelling (see Apelberg *et al*¹¹) assumes a substantial risk reduction when smokers switch to e-cigarettes, and it is important to share this insight with the public. This will prepare the ground for a nicotine standard by encouraging switching to non-combustibles both before and after the rule coming into effect.
- To make a nicotine standard work, FDA should use its influence and credibility to promote risk-proportionate policies that discourage smoking and encourage switching, for example, risk-proportionate taxation²¹. Although, FDA does not have jurisdiction over taxation, it will need other government agencies to adopt or even revise existing policies that support the switch away from smoking in response to a nicotine standard.

We hope these views are of value as FDA considers the wider aspects of its comprehensive strategy on nicotine – low-risk alternatives to cigarettes should play a significant role. For that to work, the appropriate regulatory, fiscal and information environment needs to be in place.

Yours sincerely,



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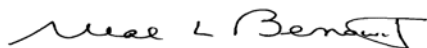


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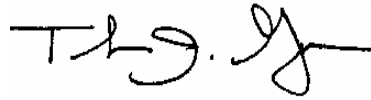


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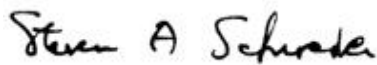
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