Proposal 5: Stop using the public health test to protect the cigarette trade

Recommendation 5. The public health test in the Tobacco Control Act does not protect the public health, but it does protect the cigarette trade from competition. It should not be applied to non-combustible tobacco or nicotine products. These should be evaluated according to their product characteristics and risk to individual users, not unknowable post-market population effects.

One of the main failings of U.S. tobacco policy is the so-called public health test built into the Tobacco Control Act that guides the FDA's regulatory determinations. For a new tobacco or consumer nicotine product to be brought onto the market, the vendor is required to show that its release onto the market is appropriate for the protection of public health. The test uses the following formulation[1].

> ***Basis for Finding.*** *For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account:*
>
> *A. the increased or decreased likelihood that existing users of tobacco products will stop using such products; and*
>
> *B. the increased or decreased likelihood that those who do not use tobacco products will start using such products.*

It may sound reasonable, but this test does not serve public health. Its main effect is to create near-insurmountable market barriers-to-entry to much safer products than cigarettes, though it does not apply to thousands of cigarette products already on the market. The test is problematic not because new products really are inappropriate for public health, but because the burden of proof to meet this test is so great, especially in advance of the product being placed on the market. Consider the following:

- The public health impact of a product is *not a characteristic of the product itself* but an emergent property of the complex web of behavioral influences on the use of the product. Many of these are unknowable in advance or extremely difficult to predict and beyond the control of the manufacturer.
- There is no experience with a new product until it has been placed on the market, so the applicant has no relevant concrete data to offer from real-world use to support an application – a Catch-22. If there is data, it applies to older products, past market conditions, different regulatory environment, a different communications environment and different consumer preferences.
- It is hard enough to find consensus about entire categories, let alone specific products. Consider the disputed evidence and ideologically-based arguments about e-cigarettes regarding relative risk, gateway effects, renormalizing smoking and reducing quitting. If there is no consensus at the level of the entire category, then how can an individual manufacturer make a case for a specific product?
- It is impossible to set up meaningful trials because there are so many uncontrollable variables in real world use.
- The impact of one product depends on other products (competitors) or rival strategies (cessation or different harm reduction approaches)
- The public health impact of a product cannot be known until all consumer behavioral transitions have worked through – that may take decades.

These problems are not merely technical; they have a bureaucratic, legal and political dimension.

- **Bureaucratic**. If a harmful product is incorrectly approved there is a risk that the regulator will be shown to be wrong. However, if a beneficial product is not approved, there is no way to check if the decision was wrong and there has been avoidable harm. This asymmetry in accountability and reputational risk is an incentive to reject applications.
- **Legal**. A legal challenge from a manufacturer to a rejection will be easier to fight in court than a legal challenge from an interest group to an approval, given the inherent uncertainties and that the burden of proof rests with the manufacturer.
- **Political**. Where there is inherent difficulty in establishing a cast-iron case to approve a product, there is scope for decisions to be made for reasons other than relevant evidence – for example, reasons of ideology, to pacify or impress interest groups or simply to look and feel 'tough'.

These forms of bias can emerge because manufacturers face the daunting task of predicting the future use of a new product in changing market conditions, in a changing product landscape and with constantly evolving behavioral influences. They are little to do with inherent product characteristics.

Further, there are *ethical concerns* with relying on *population* health assessments, even if these could be done reliably, which they cannot. It can mean denying market access to products that are much safer to use as an individual than cigarettes. It means that one person may be denied access to a product that would be highly beneficial for them because of concerns about how *someone else* may use the product.

The public health test was included in the Tobacco Control Act because at the time it was thought the regulatory challenge would arise from re-engineered *combustible* products or 'safer cigarettes'[2]. The concern would be that changes in behavior or false reassurance could easily overwhelm the benefits of reduced individual risk. This becomes much less of a concern if the reduced risk product is orders of magnitude lower risk than smoking[3], as with non-combustibles. The test is applied elsewhere in the Act[4], thus creating barriers to setting reasonable product standards (recommendation 3) and to making truthful non-misleading claims to consumers (see recommendation 4)

The appropriate approach. For non-combustible products, regulators should focus determinations, standard-setting and risk communication on the actual product characteristics and risk to individuals, not on the unknown (and unknowable) way in which the product may be used in the marketplace. If populations effects are a concern, they should be a matter for post-market surveillance. If harmful effects emerge, then a regulator or manufacturer may be able to take corrective action.

References

1 Federal Food, Drug, and Cosmetic Act - Application for Review of Certain Tobacco Products Section 910(c)4. 2009 [link]

2 Stratton K, Shetty P, Wallace R, Bondurant S. Committee to assess the science base for tobacco harm reduction, Institute of Medicine. Clearing the smoke: Assessing the science base for tobacco harm reduction. National Academy Press. 2001. [link]

3 Kozlowski LT, Strasser AA, Giovino GA, Erickson PA, Terza J V. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. Tob Control. BMJ Publishing Group Ltd; 2001 Sep;10(3):201–3. [link]

4 See Tobacco Control Act Section 907(a)3 on Tobacco Product Standards [link] and Section 911((g)4 on Modified Risk Tobacco Applications [link]