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How might FDA fix this e-cigarette PMTA mess?

Commentary on Glantz and Lempert and Meshnick *et al*

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In their articles critiquing the US Food and Drugs Administration's (FDA) first marketing order to allow the legal marketing of any e-cigarette, for Vuse Solo tobacco-flavoured e-cigarettes, Glantz and Lempert and Meshnick *et al* discuss a range of serious procedural, technical and substantive problems with FDA's publicly released explanation of how its evaluation of the Vuse application supports that order as appropriate for the protection of the public health.¹²

Those problems are too numerous to list here, but Glantz and Lempert and Meshnick *et al* reasonably conclude that FDA should withdraw its order allowing the marketing of the Vuse Solo e-cigarettes because the agency did not adequately evaluate the Vuse Solo application, did not establish that allowing its marketing was 'appropriate for the protection of the public health', and did not structure its final pre-market tobacco product application (PMTA) order to avoid increases in youth product use or unnecessary new health harms and risks.

It is now much more difficult to do such detailed critiques of FDA's decision-making relating to PMTAs because FDA no longer publicly discloses complete copies of its decision summaries for PMTA marketing orders but releases only the executive summaries. It appears, however, that all the problems Glantz and Lempert and Meshnick *et al* identify have continued in one form or another, supporting the withdrawal and reconsideration of all the subsequent orders FDA has issued allowing the marketing of other brands of tobacco-flavoured e-cigarettes.³

It is also clear that many of these problems have been identified and discussed before, with detailed critiques appearing after FDA had issued its first two orders allowing the marketing of PMTA products, for seven Swedish Match snus products in 2015 and for IQOS heated cigarettes in 2019, well before FDA began issuing PMTA orders for e-cigarettes in 2021.⁴⁻¹⁰

So why has FDA, with more than \$700 million in tobacco control funding each year and over 1000 employees in its Center for Tobacco Products, not done a better job evaluating applications, issuing PMTA orders and protecting the public health?

A fundamental problem, not explicitly discussed by Glantz and Lempert and Meshnick *et al*, is that FDA appears to have adopted a rather limited and dangerous interpretation of how new tobacco product marketing can qualify as appropriate for the protection of the public health. It seems to be enough for FDA if it determines (after a remarkably vague analysis) that allowing the marketing of the product

is likely to reduce overall health harms relating to tobacco use and not greatly increase overall youth or non-user adult use. While that approach might sound fine to some, it frees FDA from any responsibility to try to ensure that the marketing of the product will not create any unnecessary collateral damage that could readily be avoided, either without reducing the potential net harm reductions or while increasing those net benefits.

If FDA interpreted the appropriate-for-the-protection-of-the-public-health standard properly, it would not accept any new health harms or risks or increased youth use from the marketing of PMTA products that could readily be avoided. Accordingly, FDA would ensure that PMTA e-cigarettes were not only likely to be less harmful than smoking but also designed to be as minimally harmful as possible without interfering with their ability to serve as effective smoking substitutes. In addition, FDA would ensure that PMTA e-cigarettes, their design and appearance, and their packaging, labelling, instructions for use and marketing would work as effectively as possible to discourage youth use and discourage harm-increasing uses of the e-cigarettes—at least to the extent that could be done without disproportionately reducing potentially harm-reducing switching by smokers who would not otherwise quit or sharply reduce their smoking.

But FDA has done none of these things in its PMTA actions to date. As a result, the future marketing of the Vuse e-cigarettes and other products receiving PMTA marketing orders could cause considerably more new health harms and risks and increased youth use than were necessary to secure their potential harm reductions. And the risk that their marketing will actually cause a net *increase* in tobacco-related harms, instead of securing the harm reductions FDA expects, will be much higher than needed or appropriate.

Following an interpretation of 'appropriate for the protection of the public health' that requires taking readily available steps to minimise risks of new health harms and youth use (and maximising harm-reducing uses) of the permitted product would also require much more careful FDA analyses and modelling of possible future behavioural and health impacts, which would directly address many of the problems discussed by Glantz and Lempert and Meshnick *et al*.

Another problem outside the scope of the Vuse PMTA critiques of Glantz and Lempert and Meshnick *et al* is that FDA takes an enormous amount of



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time to review applications, make decisions and issue final PMTA orders, regularly missing statutory or court-ordered deadlines. That means many e-cigarettes have been left on the market, largely unregulated, despite clearly being inappropriate for the protection of the public health. Much of this problem comes from FDA largely failing to take action to remove entire categories of not-appropriate-for-the-protection-of-the-public-health e-cigarettes from the market but doing detailed, time-consuming case-by-case reviews of each pending application, instead.

For example, in September 2019—in the midst of a surge in youth e-cigarette use and the scary emergence of e-cigarette or vaping use-associated lung injury—President Trump and FDA leadership announced that FDA would be exercising its enforcement discretion to take off the market all e-cigarettes with any added flavours other than tobacco in order to better protect the public health—with all those e-cigarettes free to submit applications to receive PMTA orders to allow them to return to the market as legal products.¹¹ That was the right thing to do. But FDA scaled that back and ultimately took action against only capsule-based e-cigarettes without tobacco or menthol-added flavours, sharply reducing its protective impact.¹² Indeed, many youth and adults simply switched to menthol capsule-based e-cigarettes or to disposable e-cigarettes that still offered thousands of added flavours.^{13 14}

With its October 2021 order allowing the marketing of tobacco-flavoured Vuse Solo e-cigarettes, FDA also issued marketing denial orders for all Vuse Solo e-cigarettes with added flavours other than menthol. Accordingly, FDA could have immediately used its enforcement discretion to take off the market all other e-cigarettes still on the market with pending applications that also had added flavours other than tobacco or menthol—unless or until FDA made a decision on their pending application to allow their marketing. Instead, FDA left all those e-cigarettes on the market with those added flavours that FDA had formally found to strongly attract youth and increase youth use.

Similarly, FDA's PMTA marketing order for the Vuse Solo tobacco-flavoured e-cigarettes included some marketing restrictions, such as requiring strict age and ID verification for any digital advertising or sales to reduce youth exposure and access and prohibiting ads on TV or radio programmes with 15% or more of their audiences being under the age of 21 years. Accordingly, FDA could have immediately announced that it would pull off the market any e-cigarettes on the market with pending applications for PMTA orders if they did not immediately begin complying with those same marketing restrictions.

As FDA had formally found those marketing restrictions necessary to make the marketing of tobacco-flavoured e-cigarettes appropriate for the protection of the public health, they were certainly necessary to regulate the marketing of other flavoured e-cigarettes as well. Following that same logic, FDA could have also taken action to issue a new final rule to apply those same restrictions to all other tobacco-nicotine products, or at least all those are or might be as or more harmful than e-cigarettes.

But FDA did not do either of these things. Instead, it left on the market all those equally harmful and more harmful e-cigarettes (and other tobacco products) without any significant marketing restrictions to protect youth, and continued its slow case-by-case review of the many still-pending applications.

A new report by the Reagan-Udall Foundation identifies problems at FDA's Center for Tobacco Products and suggests some possible fixes, including some recommendations relating to FDA's review of PMTA applications and related disclosures.¹⁵ Unfortunately, it does not specifically mention many of the

problems mentioned here and by the Glantz and Lempert and Meshnick *et al* articles, nor does it make any recommendations that would address them. But perhaps the reforms instituted by FDA to address the Foundation's PMTA recommendations will expand to address these more fundamental and harmful shortcomings as well.

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