Response to Reagan-Udall review of FDA Center for Tobacco Products and FDA's tobacco and nicotine brief

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The text below is a formatted version of my submission to the Reagan-Udall Foundation operational review, as submitted via the Stakeholder Portal for the review. The review was initiated by FDA Commissioner Robert Califf. Stakeholder contributions were organized under the headings below, with responses of no more than 2,000 characters under each.

What recommendations do you have to improve FDA's tobacco program operations? Please specify for categories listed.

Regulations and guidance

Whatever the intent, FDA's regulation of tobacco and nicotine products functions in practice as a protection of the incumbent and highly damaging cigarette trade. There are about 3,000 cigarette variants on the US market, largely undisturbed by FDA.

The PMTA process for new products (vaping, heated tobacco, nicotine pouches etc.) is exceptionally burdensome, the rules are opaque, the process inefficient, and the outcomes unpredictable. The extreme compliance burdens, together with the unpredictability of the process, favor large companies. Tobacco companies are especially advantaged – first through the barriers to entry that protect the cigarette trade, second through the advantage to large companies in the vape market, and third through their ability to cross-subsidize vaping compliance costs from their cigarette business. Few vape companies have the balance sheet or patient investors to withstand the pressure FDA piles onto them.

Nicotine is sold in diverse products with a wide range of health risks, characterized mainly by whether they are smoked or smoke-free. Regulation should place the most severe burdens on the riskiest products (cigarettes) aimed at deterring use. Regulation of much safer smoke-free products should be proportionate and aimed at consumer protection.

These aims can be pursued through FDA's interpretation of its duties under the existing Act and how it meets its public health mandate. Revised legislation may be desirable, but it is not a prerequisite to achieving significant improvements in FDA's operational effectiveness.

FDA should not assume that nicotine use will or should disappear or that a nicotine-free world is its objective. FDA's long-term challenge is to regulate to create an acceptably safe, lawful consumer nicotine market. We would set this objective for caffeine, alcohol or, increasingly, cannabis. It should be no different for nicotine.

Application review

The review process is opaque, burdensome, grounded in false assumptions, subject to hidden rules, and open to political meddling. If the review process can deny Juul's application on a spurious pretext but grant a marketing order for a novel cigarette, ANY outcome can be contrived. Suggestions for improvement:

1. Before it can reform its review process, FDA needs to reset its fundamental assumptions. For example, FDA must take a broader view of its public health test to give due weight to harm reduction to adult smokers.

2. Youth vaping dominates FDA's approach, yet it acts as if it barely understands youth risk behaviors. Many young people engage in risky behaviors. Some adolescents will benefit from vaping as a diversion from smoking. Yet FDA explicitly denies this public health benefit. FDA assumes vaping flavors drive youth uptake. But that does not mean banning flavors will be beneficial. Adolescents may smoke instead, access a black market, or make their own.

3. The review process can be simplified using "soft standards". These are not mandatory standards as defined in S.907 of the TCA but optional faster routes through the review process. Compliance with such standards, set out in guidance, would expedite review, allowing FDA to concentrate on novel products or risks.

4. The behavioral and population assessments of the pre-market review are burdensome and pointless guesses at the future. They should be addressed through post-market surveillance with corrective action as required. The pre-market review should focus on individual risk and product safety.

5. There should be one post-market surveillance regime shared by all participants and for all products. Making each company do its own is wasteful and offers incomplete coverage.

6. FDA should rigorously apply the relevant Executive Orders on good regulatory practice (EO 12866, 13563, 13579, 13610). FDA should also revisit its regulatory impact analysis for the 2016 deeming rule.

Compliance and enforcement

It is no exaggeration to say the landscape of reduced risks products (e.g. vaping) available in the US market is a mess. It comprises products for which no pre-market review applications have ever been made, products that have had their applications rejected at various stages of review, products with marketing denial orders but subject to litigation in which FDA is likely to fail, and a small number of unattractive and similar tobacco-flavored vaping products that have marketing granted orders. These authorized products account for about

3% of the market. Such enforcement activity seems more theatrical and media-orientated, picking off small companies and marginal products.

However, it is only FDA's failure to enforce, together with its arbitrary use of enforcement discretion, that has prevented a full-scale crisis in the market for low-risk alternatives to cigarettes. Such a crisis would have stimulated a mass return to smoking by a significant fraction of the 12 million US vapers and increased pressure for black markets and home production. It follows that FDA's enforcement failure is advantageous in pure public health terms because it mitigates even more serious failures in regulation and review.

Yet, this is no way to run a regulator. It penalizes compliant businesses that spend heavily in staff time and dollars to comply and engage with the review process. It creates unpredictable market conditions and is costly and disruptive. It involves declaring over six million products to be illegal.

At present, the regulation is unenforceable. There are just too many legitimate products and producers without the scale to meet FDA's extravagant compliance demands. Changing that by introducing a far more proportionate regulatory regime is the way to address the enforcement problem. It is not by breaking in hundreds of doors or writing thousands of aggressive letters to companies helping ordinary people to stop smoking.

Communication with the public and other stakeholders

1. Professional communications

FDA's guidance to regulated businesses is verbose, convoluted, ambiguous, non-committal, often too late to be helpful, and prone to revision. Its communications should be written as though they are intended for small to medium enterprises, with greater depth in the background as needed.

2. Public communications

FDA spends ~$180 million annually on tobacco-related education and communication with the public. Yet public understanding of matters of critical importance to public health is extremely poor and deteriorating. It has failed, especially in terms of public perceptions of the risks of vaping or smokeless tobacco compared to smoking and the contribution of nicotine to disease. Its anti-vaping campaigns have been criticized as unscientific and alarmist, and there remains doubt about whether its campaigns raised awareness and interest in vaping among more rebellious youth. FDA should not be running emotive and unscientific messaging like its "Real Cost" campaigns.

What do you see as the strengths and challenges of the FDA Center for Tobacco Products?

Strengths and challenges

1. Strengths

The strength of FDA/CTP is its scientific capability and the commitment of its staff to ethical and lawful regulation in the name of public health. The sadness is that much of this institutional asset has been squandered on endlessly repetitive data processing that demonstrates the same findings about similar products within broad technology categories.

2. Challenges

The challenge is leadership and strategy. At the heart of FDA/CTP's problems is a lack of a viable regulatory philosophy for tobacco and nicotine products and a strategy that it can defend scientifically and ethically. Arbitrary, capricious, politically motivated, and possibly vindictive regulatory behaviors have filled the void, resulting in chaos. FDA needs a pragmatic, reality-based system to manage the broad range of nicotine products with three aims: (1) extracting the potential harm reduction benefits for both adults and adolescents, (2) taking a proportionate approach to managing risks to non-users, (3) permanently, managing risks to a level consistent with normal societal risk-appetites for people who will take up or continue to use nicotine for whatever reason.

Please share any additional comments

Additional comments

Under no circumstance should this process lead to FDA/CTP receiving even more money, especially through new user fees. Extending user fees to vaping products would add to already extreme and unnecessary compliance burdens. FDA's regulatory capacity problem is caused by its gross inefficiency. It should fix this by reform, not by pouring even more money into a failing regime.

FDA now collects $712 million annually in user fees from tobacco. From 2009-2022, FDA will have taken in $7.6 billion. I repeat a longstanding question: can anyone name any material benefit to public health from this money?

FDA reports its use of user fees to Congress. The totals below are from the 2021 report with my comments.

Research ($347m, 43.1% of which $220 (27.3%) is spent on research outside FDA). It makes no sense to fund genuine scientific inquiry via a regulator. Such research will be drawn towards making the case to regulate. This method of funding creates significant distortions

and unacknowledged conflicts. It tends to answer the questions asked, not look for the best questions. It suppresses critical academic appraisal of the agency.

Public education ($166m, 20.6%) and communications ($15m, 1.9%). FDA communication has been a conspicuous failure on any metric, including youth vaping and false and deteriorating risk perceptions relevant to its mission. A regulator should not be engaged in advocacy or campaigns that work through unscientific alarmism. FDA should also find more independent ways to evaluate its work.

Compliance and enforcement ($138m, 17.2%). The problem is the regulatory regime has created unmanageable compliance and enforcement burdens.

Management, leadership, admin ($30m, 4.7%). Overhead ($102m 12.6%).

Other regulatory systems appear far more efficient without creating additional problems or risks. For example, the UK regulator charges cost recovery for regulating vaping products: the cost is just £150 ($170) per registered product.