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Reagan-Udall Foundation
1333 New Hampshire Ave, NW
Suite 420
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Re: Stakeholder input on certain components of FDA's Tobacco Program

To whoever it may concern:

Americans for Tax Reform (ATR) thanks the Reagan-Udall Foundation for the opportunity to provide input into the operational review of FDA's (Food and Drug Administration) tobacco operations. ATR is a non-profit organization which advocates in the interests of taxpayers and consumers across the United States. ATR particularly appreciates the recognition of significant and substantial failures by FDA in the implementation of their mission to execute their congressional mandate to act on behalf of the protection of public health. These comments seek to assist the foundation in highlighting the failures of FDA to execute their congressional mandate to act, and it is submitted that the failures are due to structural issues that exist within FDA's Tobacco Program, and not merely a result of factors such as insufficient funding. As a direct result, FDA's Tobacco Program is placing millions of American in potential jeopardy by inappropriately regulating reduced-risk nicotine products.

ATR wishes to preface these comments by noting that while the scope of this review is on operational matters, and not policy, any review must be done in the context of the statutory requirements of the Family Smoking Prevention and Tobacco Control Act. As such, all operational activities of the FDA must be viewed in the context of public health overall. Therefore, no review can be comprehensive without noting the undisputed scientific consensus, repeatedly acknowledged by FDA, that reduced risk tobacco alternatives such as e-cigarettes represent significantly less risk than combustible tobacco, and are a vital component of the quit-smoking toolkit for regulators. ATR also wishes to draw the Foundation's attention to the fact that while FDA itself has not quantified the specific degree to which these products are safer, meta-analysis conducted by the UK Government through Public Health England, and replicated by the Royal College of Physicians and independent bodies such as Kings College London, have consistently concluded that vaping is approximately 95% less harmful than traditional combustible cigarettes.

Furthermore, the Cochrane Review, considered the gold standard of meta-analysis in the medical field, expanded numerous studies, all of which showed these products are two to six times more effective at getting smokers to quit, and stay off cigarettes, than traditional nicotine replacement therapies like gums, patches, or oral spray. Current evidence also shows they e-cigarettes are more effective, and no more harmful, than routinely offered NRT like patches and gum. In addition, other research has demonstrated that the use of flavors, a key question in the present debate, are more than twice as effective for smoking cessation than unflavored vapes. Due to this overwhelming scientific consensus, over 100 of the world's leading medical bodies have endorsed vaping products as a valuable tool to help adults quit smoking.

In the context of the overwhelming scientific consensus, FDA must provide an easy and accessible pathway for such products to be authorized in order to follow its statutory requirements to approve products that are appropriate for the protection of public health. providing adult smokers with an easily accessible pathway to purchased reduced risk products, FDA is failing in its mission. At a fundamental level, FDA must act with transparency and predictability as it relates to these reduced-risk products. This submission will detail how FDA's Tobacco Program has failed to fulfill their statutory requirement of protecting public health by changing guidelines, applying different standards without warning or notice, and bending to political pressure.

Firstly, rather than provide a streamlined, efficient, and cost-effective pathway through the PMTA (Premarket Tobacco Product Application) process, the current compliance burden for applicants is so immense as to price almost all manufacturers and retailers out of the market. By requiring small businesses to conduct longitudinal studies so complex that it would be difficult for top tier academic institutions to complete them, FDA has essentially placed an insurmountable barrier to entry. This barrier has had the effect of barring almost all participants from the process, clearly contrary to the goals of the protection of public health.

In addition to the insurmountably-high cost burden, FDA's lack of transparency has further eroded public trust and confidence in the agency, and hindered their ability to execute their mandate, by creating impossible administrative burdens on PMTA applicants. One example of how the PMTA process has unfairly burdened small vape manufacturers is the failure to provide notice of important changes to the process and requirements. According to documents obtained by *Filter,* an internal FDA memorandum altered standards for PMTAs after many such applications had already been submitted. In what was described by one federal judge as a "surprise switcheroo", the FDA clearly changed the guidelines it was operating under after applications had been filed, setting applicants up to fail. Any situation whereby if applicants followed the proposed rule and adhered to the advice FDA provided in public statements, only to have their application denied due to internal changes which occurred after deadline, is clearly contrary to sound principles of administrative law. Consumers and businesses are best suited to thrive when government agencies act predictably, making interactions between the agency the public accessible and productive.

Further, regarding the application process, FDA is alleged to have applied a "new and different standard" to data submitted by certain companies as part of their PMTA. Even more troubling, a number of Marketing Denial Order's (MDO) sent from FDA to companies was found to be inconsistent with the data submitted by said companies, indicating that FDA's review of such material was flawed. This demonstrates a failure of FDA at the most fundamental level, and ironically suggests that the overly complex and overly-burdensome standards they created became too burdensome for the agency to adequately enforce them, leading to blanket mass rejections.

As a result of this lack of transparency, and the implementation of administrative barriers, FDA has denied a staggering 99% of all applications received. The result of this is the very people FDA is tasked with serving have been harmed by FDA's failure to uphold their

statutory requirement of protecting public health that Congress has set for them. FDA's structural problems have left American adults who rely on reduced-risk nicotine products to stay off cigarettes without the knowledge that those products will remain on shelves. Make no mistake, restricting access to reduced-risk products is a proven way to increase smoking, thereby increasing smoking-related illness and death.

Additionally, the arbitrary actions taken by FDA's Tobacco Program has created an incredibly poor environment for innovation. Instead of dedicating resources to creating safer nicotine products that are more effective at helping adult smokers quit, vape manufacturers have been forced to spend excessive sums of money to submit their PMTA application, while being discouraged from innovation due to fear of future bans. The only companies that benefit from the actions of FDA's Tobacco Program are those with considerable resources. Small businesses are the backbone of the vapor industry and have been unfairly marginalized by FDA's Tobacco Program.

FDA's Tobacco Program can begin to remedy these problems by reversing course on their public education campaigns, and acting in line with what FDA has recognized is significant public misinformation regarding reduced risk tobacco alternatives. We note that CTP. Director Brian King in October stated *"I'm fully aware of the misperceptions that are out there and aren't consistent with the known science… We do know that e-cigarettes — as a general class — have markedly less risk than a combustible cigarette product"*

Despite FDAs clear recognition of the science, 63% of American adults are unaware vaping is healthier than combustible cigarettes, an increase from 47% in 2016. Even more these incorrect risk perceptions are extremely prevalent among doctors as well. A Rutgers University study from 2020 found that more than 80% of doctors think that nicotine causes cancer, for which there is no factual basis whatsoever. As such, it is vital for the protection of public health that FDA act to correct these misconceptions.

Rather than correcting this public misinformation, which has led to fewer people quitting smoking and numerous vapers returning to smoking, campaigns such as the FDA's "The Real Cost Campaign" which demonized nicotine users by portraying them as zombies and other scary creatures have exacerbated the problem. While FDA claims these advertisements are not meant for adults, the messaging is inevitably is seen by adults and can have extremely serious consequences for their mental health. The stigmatization of nicotine results in exclusion, rejection, and devaluation of nicotine users. There is evidence that stigmatization of smokers reduces self-efficacy and makes it less likely that a smoker will seek treatment for smoking-associated illnesses.

Particularly, research has shown that members of stigmatized minority groups experience a more acute form of smoking stigma that more detrimentally affects their mental health and wellbeing. Research has also shown that nicotine-containing vapes dramatically help people with mental health issues, who smoke at rates three to four times the national average, quit smoking, even when they have no desire to quit. For people suffering from schizophrenia, vaping has a demonstrated ability to make them feel more awake, less irritable, and have improved concentration.

It should be noted that those who will be helped most by an FDA committed to fulfilling the protection of public health standard will be minority groups, particularly members of the LGBTQ+ community as well as American Indian and Alaska Native people. 40% of

LGBTQ+ young adults are occasional cigarette smokers and 25% of all LGBTQ+ adults are tobacco users, compared to 19% of heterosexual adults. 22.6% of American Indian and Alaska Native adults are current smokers, compared to 13.7% of adults overall, which makes them the highest smoking ethnic group in the United States.

These people are in dire need of access to reduced-risk nicotine products that can profoundly change their lives. FDA's arbitrary actions that lack transparency and violate their statutory requirement make it harder for them to quit, or to stay off of cigarettes if they have already made the switch.

Vape manufacturers and retailers are forbidden by law from sharing scientific studies about their products with consumers. The responsibility for correcting the public's impression of reduced-risk products lies at the feet of FDA's Tobacco Program. There is a desperate need for widespread public messaging that vaping is safer than smoking and can save lives. FDA should be the agency that educates the public about the safer nicotine products that exist to help adults who smoke quit the deadly habit of cigarettes.

It must be made clear that FDA's problems are not caused by a lack of funding, but rather a result of significant and fundamental structural problems at the agency. Increasing the budget of FDA's Tobacco Program through new users fees on vaping products. The burden placed upon small manufacturers is already extreme and user fees would exacerbate this issue.

It must also be added that, as the Foundation is aware, numerous staff have also revealed that FDA's Tobacco Program has a toxic internal culture, rife with racism, sexism, and unconscious bias. FDA employees have shared concerns that FDA allows political pressure to influence scientific decisions and that scientific staff feel intimidated in the workplace.

To address these problems, both cultural and structural reform must be enacted. A culture hostile to reduced risk products must be transitioned to one more willing to accept the science and embrace a culture of transparency. This can be enhanced through the following seven reforms:

1. FDA should introduce cross-disciplinary expert analysis factoring input from fields like psychology and behavioral economics, to increase public awareness and engagement in the decision-making process.
2. FDA must provide an easy, streamlined, PMTA pathway, as initially promised.
3. FDA's PMTA process should focus on product safety and individual risk, not behavioral and population assessments that are better gathered by a singular post-market surveillance team.
4. FDA should be in regular, proactive contact with all PMTA applicants, as opposed to merely issuing MDO's after year long periods of silence.
5. FDA should consider implementing product standards, to assist in the streamlining process, and look also to countries such as the United Kingdom as a model for a regulatory system that works.
6. FDA must urgently act to combat significant public misinformation that it admits exists in the community and is a barrier to smoking cessation.
7. FDA must reform its approach to youth risk behavior. FDA should accept that youth can benefit from harm reduction and properly evaluate the consequences of reduced vape access for both adults and youth.

An analysis from Georgetown University Medical Center found vaping has the potential to save up to 6.6 million lives over a ten-year period. FDA's operational activities that provide unnecessarily impede the sale of reduced risk tobacco alternatives, evidenced by their denial of 99% of PMTAs, are the result of problems within FDA's Tobacco Program that are structural in nature and require significant reform. Americans for Tax Reform would like to thank the Reagan-Udall Foundation once again for the opportunity to offer comments during this critical review. We, and the millions of Americans across the country who use vaping to quit smoking, sincerely look forward to your report.

Sincerely,

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