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Commissioner Scott Gottlieb, M.D.
Food and Drug Administration
10903 New Hampshire Avenue
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Commissioner Gottlieb,

On behalf of over 5.7 million FreedomWorks Foundation activists nationwide, I write to express our concern with the Food and Drug Administration's (FDA) current practice towards the tobacco and nicotine products industry. I say practice because the actions of FDA do not align with the policy by which the agency supposedly operates under both the law and your pronouncements as commissioner.

Since taking office, you have repeatedly made encouraging remarks regarding the regulation of tobacco and nicotine products. Your acknowledgement of the spectrum of risk for nicotine products, recognizing the fact that not all tobacco or nicotine products present anywhere near equal risk to public health, was seen as a long-overdue departure from prohibitionist and purist, quit-or-die policies that abandoned Americans who either could not quit smoking conventional cigarettes or exercised their freedom to not quit smoking cigarettes and using other nicotine products. However, the actions of FDA have not matched your words and do not align with the intent and text of the laws governing these products.

Last month, you announced that FDA would begin the process of implementing significant restrictions on the sale of flavored electronic nicotine delivery systems (ENDS) products. While this announcement was concerning on its own, we are further discouraged by the fact that premarket tobacco authorization (PMTA) has yet to be granted to Philip Morris International for its IQOS system. In fact, despite FDA's legal obligation under the 2009 Family Smoking Prevention and Tobacco Control Act (TCA) to review PMTA applications in 180 days, FDA has yet to decide on the IQOS application, one way or another, since its submission on March 31, 2017—some 628 days ago.

The IQOS system, while not technically an ENDS product, is undeniably similar to an ENDS device in that it uses electricity to create a nicotine-containing vapor and does not involve combustion of the tobacco it contains. Due to FDA's excessive delay, IQOS cannot be sold to Americans let alone marketed as a modified risk tobacco product (MRTP) as further outlined in the TCA. Of note is the fact that Philip Morris has not applied to sell IQOS flavors beyond those which you announced would not fall under the new ENDS flavor regulations.

These facts together suggest the full motive behind the proposed regulations vastly exceeds the one offered by FDA. You claim that the objective of proposed regulations on ENDS flavors is to reduce access to flavors that appeal to juveniles, who are already banned from purchasing these products. If this is truly the sole objective of FDA, then it stands to reason that, at the very least, the IQOS system would have received its PMTA approval by now.

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IQOS would be a critical tool in a policy arsenal that embraces the spectrum of risk and harm reduction strategy you claim to support, as indicated by the fact that it is approved for sale in over 40 countries including nations such as Canada, Germany, and the United Kingdom. Yet, today IQOS is unavailable in the United States without word from FDA on its fate while FDA is now openly planning to restrict access to other products critical in the fight to reduce combustible tobacco usage and its associated harms.

Your words on the spectrum of risk and harm reduction had given us hope that the federal government would finally make good on its promise to abandon the pie-in-the-sky goal of complete nicotine abstinence that has thus far made perfect the enemy of both better health outcomes and the freedom of adult Americans. The TCA makes clear as much that this is what Congress and the American people expected of FDA, given that it created the subcategory of MRTP.

If Congress did not intend for the tobacco and nicotine products industry to develop less-harmful products to address the gap between those who successfully quit smoking cigarettes and those who do not, then it seems highly unlikely it would have made the effort to devise this product category and outline a process by which FDA is to review these products in an explicitly expeditious manner. Of course, the previous administration did not adhere to this expectation, as currently zero of the 35 products to have begun the MRTP review process since 2009 have received FDA's approval.

Your words suggested that FDA would join the rest of the Trump administration in ending the regulatory obstruction and neglect of congressional intent routinely employed by the previous administration towards various industries to achieve outcomes beyond those outlined in statute. The fact pattern demonstrates otherwise. The move to introduce new regulations on the sale of flavored nicotine products which are already barred from sale to juveniles combined with the outrageous failure of FDA to comply with its 180-day obligation to review a nicotine product that would not be sold in the flavors FDA is targeting suggest that the proposed flavor regulations themselves are more about unilaterally smothering the nicotine product industry than protecting young Americans.

Actions speak louder than words. What Americans demanding less-harmful nicotine products are hearing is that the only thing that has changed at FDA is the rhetoric. Regulatory obstruction and quit-or-die unfortunately seem to be alive and well. We hope you will more closely consider FDA's ultimate obligation to execute the law, not ignore or circumnavigate it, as this process moves into the new year.

Sincerely,

Adam Brandon
President
FreedomWorks Foundation