AMERICAN VAPOR MANUFACTURERS

Food and Drug Administration
Office of the Commissioner
10903 New Hampshire Ave
Silver Spring, MD 20993

February 17, 2023

Dr. Califf,

The same day the Reagan-Udall Foundation (RUF) released its critical analysis of the Center for Tobacco Products (CTP), December 19, you held the first of four separate meetings with outside groups to discuss RUF's conclusions. The stakeholders most impacted by the CTP's failings on tobacco and nicotine regulation–vaping-industry members and the millions of adults who have quit smoking with e-cigarettes–were not extended invites.

Instead, these were private discussions, scheduled at your request, with the executives of four activist groups, including Matt Myers of the Campaign for Tobacco-Free Kids (CTFK) and Harold Wimmer of the American Lung Association (ALA). These organizations share one thing in common; they have all demanded FDA and CTP follow a hardline prohibitionist approach to reduced-risk tobacco and nicotine products.

With the exception of an obscure notice buried deep in the FDA's website, the public was not informed that the agency had solicited input from these organizations. In response to our FOIA request, the agency said that no video, audio, nor notes of any kind were taken during the discussions.

In order to help address the "lack of clarity, transparency and communication" RUF found to be endemic at the FDA, we respectfully request the same opportunity to participate in future policy briefings that impact our industry. We believe these dialogues are necessary for two critical reasons.

First and most importantly, the FDA has been misled by a handful of wealthy, politically connected activist groups with a vested interest in seeing vaping products banned. This anti-vaping coalition, which includes the four groups you requested to meet with, has perpetuated egregious misinformation about the health effects and quit-smoking benefits of vaping. Since your agency frequently, but no doubt unintentionally, repeats the errors amplified by these groups, we would be glad to meet with you and correct the falsehoods that FDA has fallen victim to.

Second, your agency routinely meets with other industries it regulates. For example, following the release of RUF's recent report on FDA's food program, you held public meetings with advocacy groups *and* representatives of the regulated industry, most notably food and beverage maker Nestle. Undoubtedly, the Nestle corporation is not without past and present

controversies. Nonetheless, your willingness to speak with them directly made perfect sense, as it allowed you to hear directly from a stakeholder so you could begin to address RUF's myriad criticisms of FDA's food division. If the FDA intends to act as a neutral arbiter of the science on vaping and other harm reduction products, it should welcome the same balanced input from groups like ours.

At this point, though, FDA vaping and nicotine policy appears to be informed by a select few stakeholders with clear conflicts of interest and ideological commitments that are at odds with Congress' mandate that CTP decisions be based on population-level health outcomes. Their untoward political influence has brought your agency dangerously close to banning the most effective free-market intervention to combat smoking-related disease and death ever devised.

Your decision to meet solely with activist groups to discuss the RUF tobacco report calls into question your commitment to fairly assessing the failings of CTP laid out in that same report.

As a long-time partner of the pharmaceutical industry, you know the value of working with the private sector to improve the health and welfare of all Americans. We hope you will extend this collaborative mindset to nicotine policy and bring us and other appropriate stakeholders into future discussions about how FDA intends to regulate vaping products.

Sincerely,

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cc: Rep. James Comer, Ranking Member of the House Committee on Oversight and Reform