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Christi A. Grimm
Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
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Via Email

Dear Inspector General Grimm,

I am writing to request that the Office of Inspector General open an inquiry into improper political pressure that appears to have influenced senior leadership at the Food and Drug Administration (FDA) and the extent to which such interference has corrupted FDA's statutory obligation to properly implement its premarket tobacco product application (PMTA) review process based solely on scientific, empirically-based judgment.

This request comes on the heels of the agency's recent marketing denial order for Juul Labs, Inc. The FDA's order was so plagued with issues that a federal appellate court immediately issued an emergency stay, and the agency itself ultimately reversed course and administratively stated the denial, after admitting it had not reviewed all of Juul's data. In a message posted on Twitter, the FDA stated, "[t]he agency has determined that there are scientific issues unique to the JUUL application that warrant additional review." The FDA later clarified that it came to this decision after "reviewing litigation briefing materials."

What were in those litigation briefing materials? As the *Wall Street Journal* reported:

> *In court filings Tuesday, Juul said the agency overlooked more than 6,000 pages of data that the company had submitted to the FDA on the aerosols that users inhale. Juul also said the agency failed to consider the totality of Juul's evidence, which the company said established that the public-health benefits of Juul products significantly outweighed the potential risks.*

> *"FDA's order acknowledged that 'exposure to carcinogens and other toxicants present in cigarette smoke were greatly reduced with exclusive use' of Juul products compared with combustible cigarettes," Juul said in court documents.*

As members of the American Vapor Manufacturers (AVM) Association can attest, the FDA's performance in administering the PMTA process for vapor products has been an embarrassment. Despite applicants routinely submitting all of the necessary requirements and scientific research, the agency continues moving the PMTA goal posts, coming up with new requirements without any notice and comment, and issuing across the board denials with the exception of a handful of unpopular and outdated products.

Although Juul is the largest such company to receive a marketing denial order (MDO), members of AVM have been denied marketing approval for several million products for what seems to be similarly arbitrary and politically-influenced decision making. This is evidenced by the fact that advocacy groups and the members of Congress with whom they collaborate have all openly celebrated the agency's flawed and arbitrary decision-making process.

Political pressure from ideologically aligned Members of Congress, not the proper application of regulations, appears to be the actual driver of the agency's actions. Look no further than the not-so-subtle instructions to FDA Commissioner Robert Califf from Illinois Senator Dick Durbin, who has repeatedly called for the commissioner's resignation, saying on June 22:

> *"It's time for Commissioner Califf to do his job to protect our children or step aside."*

That very same day, an anonymously sourced report in the *Wall Street Journal* indicated that the FDA would deny a marketing approval for JUUL products in line with Senator Durbin's demand. Less than 36 hours later, the agency affirmed the *WSJ's* reporting until a federal judge intervened the next day to delay the decision.

To further emphasize the role political pressure appears to play in decision-making, several members of Congress and ideologically allied special interests publicly celebrated their interventions with Commissioner Califf as the impetus for the agency's decision to deny Juul marketing approval. Via a video conference, Congressman Raja Krishnamoorthi told Parents Against Vaping e-cigarettes (PAVe):

> *"After I and my office actually had a long conversation with the FDA Commissioner, [FDA] finally decided to…issue these MDOs."*

Without a transparent accounting of how these decisions were made, we are forced to speculate that political pressure, not science or facts, has driven FDA's conclusions. Frustratingly, the reasoning or justification behind Commissioner Califf's decisions is shielded from public view. If it complies at all, the agency claims to have a Freedom of Information Act request backlog of upwards of two years, which has thwarted or sidestepped numerous attempts to clarify concerns raised by the public.

At this stage, a thorough investigation from the Office of Inspector General is the only way the public can learn if the FDA is pursuing its political agenda or if it is in fulfilling its statutory duties to fully consider the scientific evidence on whether Electronic Nicotine Delivery Systems (ENDS) is providing a health benefit to adults by helping them quit smoking combustible cigarettes.

As part of this review, I encourage your office to focus on the following:

- Determine if Commissioner Califf was aware that his agency's JUUL decision was based on incomplete information as implied by the FDA's justification for its administrative stay.
- Make public all correspondence between Dr. Califf and his team and Members of Congress, including but not limited to Senator Dick Durbin and Representative Raja Krishnomorthi.
- Make public all correspondence, electronic communication, and phone call logs between any FDA official and *Wall Street Journal* reporter Jennifer Maloney, who received leaks about the denial order before it was officially announced.
- Make public all internal correspondence, emails, or memorandums between Dr. Callif, his immediate predecessor, and the Center for Tobacco Products.
- Make public all correspondence, electronic communication, and phone call logs between any FDA official and the Campaign for Tobacco-Free Kids and Parents Against Vaping e-cigarettes.

Thank you for considering my request for an inquiry. My organization represents thousands of small businesses being shuttered because of FDA decisions. Our businesses help adults access the most effective smoking cessation device ever devised. Yet the FDA - the very government agency charged with promoting public health - is actively undermining our efforts to end the cancerous scourge of combustible cigarettes.

Sincerely,

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CC:

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