Chairman Christopher A. Coons and Vice Chairman James Lankford
Senate Select Committee on Ethics
220 Hart Senate Office Building
Washington, DC 20510
mailbox_office@ethics.senate.gov

Subject: Ethics Complaint against Senator Richard Durbin

Dear Hon. Chairman Coons and Hon. Vice Chairman Lankford,

I am writing on behalf of my organization, the American Vapor Manufacturers (AVM), which represents independent vapor manufacturers across the United States. AVM is requesting that the Senate Select Committee on Ethics conduct an investigation into potential unethical misconduct by Illinois Senator Richard Durbin.

On September 15, 2022, in a speech on the floor of the Senate, Senator Durbin said the following:

> "But September 9, 2021, was the deadline and it was set by a federal judge for the U.S. Food and Drug Administration to finally, finally clear its enormous backlog of applications from e-cigarette companies seeking to sell their products in America. Companies that can prove their products were appropriate for protection of public health, they can go ahead and sell their products legally but e-cigarette products can't meet that standard. **They can't demonstrate a benefit to public health**. Vaping, as we know, is dangerous and addictive. These companies, like the tobacco companies of years gone by, are preying on our children.
>
> FDA had a **legal mandate to ban** these products from U.S. markets on September 9, 2021, but the Food and Drug Administration failed to meet the deadline not by one day, not by one week, not even by one month." **[Emphasis Ours]**

Combined with a litany of press releases, private meetings, and media interviews, the Senator is exerting pressure on FDA officials to ban all vaping products on the market. The Senator is insisting the agency act on his opinion and ignore the statutorily mandated scientific review process that the FDA is required to follow when reviewing product applications.

However, as you may be aware, the FDA is still undergoing its statutorily mandated scientific review of premarket tobacco product applications (PMTAs) for vaping devices and is in the midst of considering a wide swath of non-tobacco-derived nicotine products that have only recently submitted PMTAs.

We believe Senator Durbin is attempting to interfere with and influence the outcome of an ongoing executive branch agency review process in violation of Senate Ethics rules. Senator Durbin has not reviewed the evidence manufacturers have presented to the FDA as required by the agency's PMTA guidelines, but continues to pressure the FDA Center for Tobacco Products to abandon its duty to thoroughly review those applications in favor of his desired result – the total prohibition of all vaping devices.

It should be noted that the Senate Ethics Manual includes a discussion of case law that describes what happens when a Member of Congress attempts to exert influence beyond the scope of an agency's statutory duties:

> "[A]n agency determination will be voided only if the congressional contacts resulted in the decision-maker taking into consideration factors ''not made relevant by Congress in the applicable statute.''

Senator Durbin's Unethical Agency Influence

Senator Durbin has repeatedly issued public statements containing veiled threats to FDA officials, including calling for FDA Commissioner Robert Califf's resignation. On June 9, 2022, Senator Durbin was quoted in a press release as saying:

> "If Commissioner Califf feels no urgency to follow the law and a court order to protect our children from the dangers of nicotine addiction, then he should step aside and let someone else lead."

On June 22, 2022, another press release from Senator Durbin reads:

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

In his September 15 speech on the floor of the Senate, Senator Durbin called for the Secretary of Health and Human Services to "step in" and "take a more active role" if the FDA refuses to ban vaping:

> "Last week, I asked Health and Human Services Secretary Becerra to step in. If FDA cannot or will not do its job, it is time for the lead agency, Health and Human Services, to take a more active role."

Senator Durbin's speech also contains mention of the Congress's appropriations for the agency, no doubt to remind the FDA who holds the purse strings.

The Senate Ethics Manual explicitly addresses attempts by Members of Congress to interfere with the administrative process.

In a lengthy discussion on agency interference in Chapter 8, the manual advises Senate Members that they "have two moral obligations in this regard: (1) to pursue cases only on their merits, and (2) to ensure that they do not intervene in a manner and to a degree that damages the administrative process."

Senator Durbin's public posturing as the FDA conducts its ongoing review process for vapor products has the potential to bias the agency's decision-making.

The Manual goes on to say that "[t]he manner and degree of [Congressional] intervention also may become improper [. . .] when a legislator's conduct implies that a particular decision is not the administrator's to make, but has been mandated by the Member."

Finally, the Manual states that the Senate ethics guidelines were shaped and influenced by similar guidelines written for the House, which Senators were advised to use as guidance and which served as an influence for the final Senate rules:

> "The writings of Senator Douglas helped shape the guidelines applicable to Members of the House of Representatives in their dealings with administrators. Advisory Opinion No. 1 states that '**[d]irect or implied suggestion of either favoritism or reprisal in advance of, or subsequent to, action taken by the agency contacted is unwarranted abuse of the representational role.'** [. . . A]ll Senators are encouraged to use House Advisory Opinion No. 1 as a source of guidance for their actions." [Emphasis Ours.]

It is apparent that Senator Durbin is abusing his representational role by implying that there will be reprisals at the FDA should it not bend to his preferred outcome on vaping policy.

Political Pressure Creates Arbitrary Decision-Making

Political pressure from members of Congress like Senator Durbin has contributed to a dysfunctional and chaotic PMTA review process. It has become clear from judicial review of the agency's decision-making and internal documents made public by the press that the FDA has rushed and cut corners in its review of PMTA applications to the detriment of applicants.

On July 18, 2022, the Fifth Circuit Court of Appeals found that the FDA "pull[ed] a surprise switcheroo" on manufacturers when it changed without fair notice what types of studies it would accept as part of the PMTA process. On August 23, 2022, the Eleventh Circuit ruled that the FDA's review was "arbitrary and capricious" for failing to consider parts of PMTA applications the agency previously said would be "critical" and "necessary" to its analysis.

Investigative reporting uncovered internal agency memos that show how the FDA implemented a new "fatal flaw" box-checking strategy whereby filed applications for non-tobacco flavored vaping products would receive only a cursory review to determine whether they contained a particular type of study before being allowed to proceed to the full, statutorily mandated scientific review. This step was not mentioned in any of the FDA's rules or guidance for the PMTA process, yet it appears it was used as a short-hand approach to denying millions of applications without thoroughly considering the entirety of the evidence.

Nowhere was Senator Durbin's overreach more apparent than when he pressured the FDA to issue marketing denial orders for products made by Juul Labs, Inc. The agency's June 2022 decision to order Juul off the market came just one day after Senator Durbin's "step aside" remarks. This move was met with approval by Senator Durbin. But by the close of the week, the agency was forced to hastily reverse its decision and begin a new review of the products citing "scientific issues . . . that warrant additional review."

These events, coupled with the fact that FDA Commissioner Robert Califf has requested a Reagan-Udall Foundation review of the Center for Tobacco Products highlight the central fact that the agency has greatly mishandled the PMTA process. It is clear that intense political pressure from lawmakers like Senator Durbin has contributed to the FDA's dysfunction and inconsistent application of the law.

We hope that Senator Durbin's recent statements are as troubling to the Senate Select Committee on Ethics as they are to our members and their customers – the many millions of Americans who rely on vaping to stay off deadly cigarettes.

We request that the committee conduct a swift and thorough review of these potential ethics violations and take responsive action as necessary.

Sincerely,

Amanda Wheeler
President, American Vapor Manufacturers