Senator Charles E. Grassley Questions for the Record
United States Senate Committee on the Judiciary
Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes
June 12, 2024

Questions for Tony Abboud
Executive Director, Vapor Technology Association

1. Do any of your association's members sell vapor products that are not authorized for sale by the FDA, and if so, does your organization condone this practice?

Vapor Technology Association Response to
Question for the Record from Senator Charles E. Grassley
July 5, 2024

Virtually every company in this country, save one, is presently selling vaping products that are not authorized by the FDA. This includes the biggest companies in the tobacco industry as well as the smaller companies in the independent vaping industry. This fact is not because companies have not sought authorization, but because the FDA for its own political reasons has simply refused to authorize vaping products, has drug its heels for years on product application reviews, has rejected an untold number of applications for both hyper-technical and substantive reasons (only to later withdraw those rejections but still not authorize products), has misled companies as to what is required to obtain market approval, has changed the requirements for the applications *after* the applications were filed, and has not fairly or transparently performed its duties under the Tobacco Control Act and the Administrative Procedures Act. In short, FDA created the situation in which we are in by breaking its own regulatory process and rules.

The FDA's serial malfeasance, which, for example, led to the *en masse* rejection of millions of flavored products, has naturally resulted in 80 appeals to the federal courts (of which FDA has only won 12, per the testimony of the Department of Justice at the hearing). These appeals, many of which are still being adjudicated, cover an untold number of products. In January of this year, the United States Court of Appeals for the Fifth Circuit, in an *en banc* decision, excoriated the FDA's e-cigarette process. The Fifth Circuit opened its opinion with the striking statement, "Over several years, the U.S. Food and Drug Administration sent manufacturers of flavored e-cigarettes on a wild goose chase."[1] The Court later went on to explain, "FDA unquestionably failed to follow § 387g's notice-and-comment obligations before imposing its *de facto* ban on flavored e-cigarettes."[2] In its holding, the Fifth Circuit made clear:

> In sum, FDA's denials of petitioners' PMTAs were arbitrary and capricious. The agency did not give manufacturers fair notice of the rules; the agency did not acknowledge or explain its change in position; the agency ignored reasonable and serious reliance interests that manufacturers had in the pre-MDO guidance; and the agency tried to cover up its mistakes with post hoc justifications at oral argument. The contrary views

[1] *Wages & White Lion, et al v. FDA,* No. 28-60800 (5th Cir. 2024) (*en banc*), p.1.
[2] *Id.* at 41.

> expressed by some of our sister circuits do not address our principal concerns with FDA's decision-making.[3] We therefore hold the agency acted unlawfully. [4]

The Fifth Circuit's decision, and its admonishment to the FDA to provide a "full and fair regulatory proceeding on remand, notwithstanding its prior promises to reject their applications no matter what"[5] was so problematic that FDA was forced to seek review from the Supreme Court. On July 2, 2024, the U.S. Supreme Court granted cert in that case, which means that it will now have the opportunity to review FDA's unlawful conduct as laid bare by the Fifth Circuit's *en banc* ruling.

While VTA does not condone the sale of vapor products not authorized for sale by the FDA, we also do not condone a PMTA process that is so flawed, unfair, and arbitrary and capricious, and we do not condone the FDA's refusal to even review the applications filed by hundreds of companies covering hundreds of thousands of products. We believe FDA's failures have left products, which are appropriate for the protection of the public health, in this bizarre state of regulatory limbo. As a category, vaping products are dramatically less harmful than combustible cigarettes such that leading tobacco control scientists in the U.S. have demanded that the FDA and U.S regulators change their cautious views on e-cigarettes. Dr. Nancy Rigotti of Harvard University, and a member of the National Academies of Science, Engineering and Medicine, in an editorial that she published in the New England Journal of Medicine declared:

> "It is now time for the medical community to acknowledge this progress and add e-cigarettes to the smoking-cessation toolkit…. U.S. public health agencies and professional medical societies should reconsider their cautious positions on e-cigarettes for smoking cessation. The evidence has brought e-cigarettes to a tipping point. The burden of tobacco-related disease is too big for potential solutions such as e-cigarettes to be ignored."[6]

For this reason, urgent calls to remove all but a handful of vaping products from the market, because they are not "authorized" by an FDA that is failing both legally and morally in its obligation to protect public health, offers little relief or benefit to the 30 million Americans who remain addicted to smoking combustible cigarettes and the 13-15 million adult Americans who are vaping and do not want to return to smoking. Concern about Americans who smoke must remain at the forefront of the discussion since 480,000 Americans die every year from smoking and another 16 million suffer from smoking related illnesses, costing the U.S. hundreds of billions of dollars in lost GDP and healthcare costs. Therefore, repeated calls to enforce "unauthorized" but less harmful products out of the market simply gives the FDA a pass for its

---

[3] Importantly, those sister-circuits –which upheld the same FDA process about which the Fifth Circuit was so critical – gave the FDA complete deference in how it was interpreting and applying its PMTA rule. In light of the Supreme Court's recent *Loper v. Raimondo* decision, it is possible that the Supreme Court skeptically views the FDA's arbitrary and capricious actions and declares unlawful what the Fifth Circuit called FDA's "de facto ban on flavored e-cigarettes."

[4] *Wages & White Lion, et al v. FDA,* No. 28-60800 (5th Cir. 2024) (*en banc*), p. 49.

[5] *Id.* at 4.

[6] Rigotti, Nancy, M.D., Electronic Cigarettes for Smoking Cessation – Have We Reached a Tipping Point?, New England Journal of Medicine, 390:7, February 15, 2024, at https://vaportechnology.org/wp-content/uploads/2024/03/Rigotti-Editorial-on-ECIG-RCT-2_14_2024.pdf.

prior malfeasance that has put us, the U.S. market, and Americans who smoke cigarettes in this current predicament.

VTA believes that all vapor products sold in the U.S. should be subject to a fair and transparent FDA regulatory review and authorization process, and has lodged its criticisms with the FDA, with Congress, and with the Reagan-Udall Foundation for the FDA. In addition to the Fifth Circuit's dismantling of the FDA process, it is important to note that the FDA has been criticized for failing to properly implement its core regulatory function by an independent review group. In 2022, shortly after FDA Commissioner Califf took over at FDA, he asked the Reagan-Udall Foundation to conduct an independent review of the Center for Tobacco Products (CTP) regulatory program. In what the Associated Press called a "blistering report" in December 2022, the Independent Tobacco Expert Panel convened by Reagan-Udall made clear that CTP had failed on the most essential aspect of its job: assessing which products are "appropriate for the protection of the public health" (APPH) – which is the standard set forth in the Tobacco Control Act. Reagan-Udall made clear:

> *Applicants, however, will struggle to address the issues necessary to meet the APPH standard unless FDA clearly articulates its expectations*. A lack of clarity results in extraneous work on both sides--for applicants and for the Agency. *CTP has a responsibility to clearly identify application requirements*, if for no other reason than to reduce the burden on the Agency itself and improve efficiency."[7]

In addition, the report called on FDA "to explain how FDA is interpreting the APPH standard." FDA took one year to respond to the Reagan-Udall report when it issued a thin and highly bureaucratic "five year strategic plan" that stunningly offered no response on what is required to meet the APPH standard or how FDA is interpreting and applying it. Hence, to this day, FDA continues to operate with impunity and continues to deprive American consumers of authorized less harmful flavored vaping products.

While pending and new legal actions might ultimately hold FDA accountable, FDA has yet to answer for the scathing criticisms levelled by its own employees during the Reagan-Udall review. The submissions to the Reagan-Udall Stakeholder Portal by FDA staff articulated VTA's worst fears of what was going on inside FDA: namely, that the process had in fact been subverted to accomplish political objectives not based on science. Some of the most alarming FDA staff comments are quoted here:

- "In cases where reviews are finished and scientific decisions are made they are also overruled by political agendas and *pushed to change* decisions."
- "Politics are being permitted to drive the science and even limit or *alter science-based decisions*."
- "Reviewers in the…Office of Science…lack autonomy to exercise best scientific practices in their application reviews or express differing scientific opinions."

[7] Reagan-Udall Foundation for the FDA, Operational Evaluation Of Certain Components Of FDA's Tobacco Program, December 2022, p. 20.

- "Scientific disagreement is frowned upon, if not entirely suppressed and punished…"
- "In some divisions … a 'gotta get em' mentality …, which is unsupportive of a reviewer's fundamental duty to provide an unbiased review…"
- Need "extra barrier of isolation to prevent such *influence* with the scientists..."
- Need "a culture shift to promote that the scientists follow the science and not be *influenced by non-scientists* especially in terms of application review."

The full text of these FDA employee submissions are available for your review.[8] The words from the mouths of FDA employees speak volumes as to the level of political dysfunction in FDA's tobacco regulatory regime and easily explain why today we only have a handful of vaping products authorized.

VTA is not aware of any member companies that are selling vapor products which are not authorized for sale by the FDA but that have pending PMTAs under review by the FDA. This information is kept strictly confidential by the companies and by the FDA. For example, despite requests made by VTA and other stakeholders, the FDA refuses to publish a list of products that currently have a pending PMTA. Thus, there is no way for any company in the distribution chain to know the precise current or potential future status of any particular product.

Notwithstanding the foregoing, the FDA's recent prioritization of enforcement of the sale of non-PMTA products is a red herring because if the FDA was following the law and approving products such that there was a diverse marketplace of various ENDS flavored products, retailers would not take the risk of selling non-PMTA products and consumers would not feel the need to purchase same. If and when the FDA approves a diverse, flavored product category, we believe the influx of non-PMTA products would largely abate. Until such time as FDA reverses course and lawfully fulfills its statutory obligation, we believe non-PMTA products will find a way to remain on the market due to the incredible demand for these products, a demand created by more than 13 million adult vaping consumers who have demonstrated their preference for these non-authorized products over the FDA's authorized products. This means that FDA and DOJ resources are being expended on a problem that could best be resolved by FDA instead applying scientific methods to review and approve a diverse, flavored product category.

We do not believe that outright prohibition of flavored vaping products will work, and we also strongly believe flavored ENDS products are appropriate for the protection of public health and will save lives. The dangers of removing flavored vaping products from the market have been demonstrated scientifically and empirically. Leading tobacco control scientists at Yale, Georgetown and Missouri have demonstrated that in every state and municipality that has restricted flavored vaping products, there was a direct subsequent increase in cigarette sales. They explained, "cigarette sales increase even among brands *disproportionately used by underage youth*. Thus, any public health benefits of reducing ENDS [e-cigarette] use via flavor

[8] Reagan-Udall Foundation Stakeholder Portal, Comments by CTP Employees to Reagan-Udall, October 2022, captured while publicly available, at https://vaportechnology.org/wp-content/uploads/2024/03/FDA-Staff-Comments-to-Reagan-Udall.pdf.

restrictions may be offset by public health costs from increased cigarette sales."[9] To be sure, another recent study reported in Newsweek found that flavored e-cigarette bans have led to an increase in youth cigarette smoking.[10] That study concluded that "we also find that ENDS [e-cigarette] flavor restrictions may also have an unintended tobacco-related public health cost. We demonstrate that adoption of a restriction is associated with a one to three percentage-point increase in the probability of combustible cigarette smoking."[11]

And, as important as was the discussion about youth vaping at the hearing, it is critical to know that the youth vaping rate in the U.S. plunged a massive 61% since it peaked in 2019, and now only 7.7% of youth report having tried an e-cigarette in the last 30 days, and only 2.5% of youth use them regularly.[12] This was because, instead of banning all flavored vaping products, Congress raised the age to purchase all tobacco products to 21, something VTA championed with Congress and the White House. The result is that today the youth vaping rate now sits at a decade-low, a level not seen since 2013, before e-cigarette products were even regulated by the FDA and before the flavored disposable vaping products came to the market.

Flavored disposable vaping products have received intense focus recently, including at the hearing. But, as VTA shared with the Committee, the dramatic 61% decline in the youth vaping rate since 2019 coincided directly with the dramatic rise in flavored disposable vaping products. This tells us two things: (1) if anything, there is an inverse correlation between flavored disposable vaping products and youth usage; and (2) the dramatic rise in sales of flavored disposable vaping products cannot possibly be attributed to youth, and must be attributed to widespread adult usage. There is no credible argument that increasing sales of flavored disposable vaping products leads to increasing youth use, while youth use is plummeting at the same time.

As important, the National Youth Tobacco Survey year after year confirms that youth are not attracted to vaping on account of flavored products. Youth have consistently reported that flavors are not the reason they first tried an e-cigarette (14.5%) or the reason they currently use e-cigarettes (6.4%).[13]

To further demonstrate that the FDA has lost its way on its mission to end smoking, and has instead created an untenable marketplace, one need only look to its track record since passage of the Tobacco Control Act. Rather than filling the market with a wide variety of less harmful nicotine alternatives to smoking cigarettes under the PMTA process, which was the intent of the Tobacco Control Act, the FDA has done the opposite. FDA has authorized over 16,000

---

[9] Friedman, et al., E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales, 2023, at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4586701.
[10] Mesa, Jesus, Flavored Vape Bans Led to Increase in Teen Smoking: Study, Newsweek, June 10, 2024, https://www.newsweek.com/flavored-vape-bans-teen-smoking-1910815.
[11] Cotti, Chad, et al., The Effect of E-Cigarette Flavor Bans on Tobacco Use, National Bureau of Economic Research working paper, DOI: 10.3386/w32535, June 2024, https://www.nber.org/papers/w32535.
[12] Birdsey, Jan, et al., Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023, MMWR Weekly / November 3, 2023 / 71(44); 1173-1182.
[13] Park-Lee, Eunice, Ph.D, et al., E-Cigarette Use Among Middle and High School Students, United States, 2022, MMWR Weekly / October 7, 2022 / 71(40);1283–1284.

combustible tobacco products, including more than 3,700 deadly cigarettes.[14] Even more striking is that in the past two years under the current FDA leadership, FDA has accelerated its pace, authorizing 2,000 new combustible products, including 821 new cigarettes, and, only four vaping devices. All told, despite FDA receiving in excess of 20 million PMTAs for vaping products, FDA has only seen fit to authorize a handful (27 in total officially, but only around 10 when one considers what is available on the market) of vaping products, all owned by the three largest cigarette companies. These decisions clearly demonstrate that the current regulatory process in the hands of the FDA is broken.

The FDA is not acting in accordance with the law, not acting based on science – as it repeatedly professes – and is certainly not acting to protect the public health of Americans. Companies deserve a new, transparent, streamlined regulatory process that does not tilt to the whims of political or special interests. Americans deserve access to a wide variety of less harmful vaping products, particularly flavored vaping products that have been shown to help adults quit smoking. To reiterate Dr. Rigotti's warning, "The burden of tobacco-related disease is too big for potential solutions such as e-cigarettes to be ignored."

[14] VTA Report, FDA is on Fire, May 2024, at https://vaportechnology.org/wp-content/uploads/2024/05/VTA-Report-%E2%80%93-FDAs-Tawdry-Record-With-Cigarettes-Final-1.pdf.