September 25, 2023

Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dr. Brian King
Director
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf and Director King:

We are a coalition of regulated retailers, wholesalers, and manufacturers writing to express our urgent desire for FDA to bring regulatory order to the U.S. e-vapor marketplace, and to affirm our commitment to working constructively with the Agency on this vitally important issue. Today the legal market is being overrun by illegal and unregulated e-vapor products made and distributed by companies flagrantly violating virtually every rule and guidance FDA has issued since 2016.[1] That is not behavior we want in the marketplace – it's not good for any regulated market, and it is simply not sustainable.

We support the Agency in its desire to address illegal conduct in the marketplace, and we believe we can help make progress toward a compliance and enforcement program implemented at the scale needed for success. We ask that you join us in a two-way dialogue on this topic, starting with a compliance and enforcement workshop to be scheduled at the earliest possible time – we are ready immediately.

**Background**

At the outset, we want to clearly affirm our strong, unified support for a well-functioning federal regulatory system in which FDA oversight leads to accelerated reductions in underage use and in tobacco-related harm. We are invested in that system, and in those goals. The tobacco category is undergoing transformational change. Smoking is at all-time lows for adults and for kids.[2] And smoke-free technologies like e-vapor offer enormous potential for moving more adult smokers to less harmful alternatives. All the progress made in recent years has occurred within a legal, regulated system in which tobacco products are made, distributed, and sold by trade

[1] https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f
[2] https://apnews.com/article/how-many-people-smoke-us-64987fe2b7bf764c64d4594e5b02e6ea; truthinitiative.org/research-resources/traditional-tobacco-products/smoking-rates-decline-steeply-teens-2021.

partners like us committed to FDA oversight. But central to the long-term efficacy of any regulated market is the rule of law – good behavior being encouraged, bad behavior being punished. Without it, illicit markets arise that endanger the public, undermine the purpose of regulation, and reward those unwilling to respect the regulator's authority.

We have been committed to helping FDA bring e-vapor into the regulatory system in an orderly way since 2016, when the Agency first asserted authority over this category. In that Rule, the Agency made some important policy choices. First, it decided to allow e-vapor products to remain on the market, despite the fact that they lacked pre-market authorization and hence, as a technical matter, were in violation of the FDA Act. This policy choice was sensible – it allowed products with significant reduced harm potential to continue to be legally sold, avoided the risk of large illicit markets arising in response to any effort to sweep the legal market of these products, and it gave the Agency an opportunity to make product-by-product determinations on which products met the standard for authorization.

But the Agency also placed clear *conditions* on these products to remain on the market – conditions it expected everyone to obey. Among other things, the Agency ordered a stop to new e-vapor products entering the market without premarket authorization, and set a deadline for manufacturers to file PMTA applications.[3] In 2020, FDA issued guidance that set September 9, 2020 as the final deadline for PMTA applications.[4] This guidance also sought to address a significant spike in underage use by requiring the immediate removal of cartridge and pod-based flavored e-vapor products, other than tobacco and menthol, but exempted disposable e-vapor products from that restriction.[5] We followed all these rules. Responsible retailers stopped selling products no longer allowed to be sold. Responsible wholesalers stopped distributing them. And responsible manufacturers complied too – stopping the production of pod-based products affected by the flavor restriction, and preparing and timely submitting the PMTA applications laying out the extensive scientific case for why FDA should authorize these products for continued sale to adult consumers 21 and older.

But while we were busy following the law, other players rapidly emerged and took a completely different path. They flooded the market with thousands of new disposable e-vapor products with every flavor imaginable, with no science submitted to FDA by the prescribed deadline, and long after FDA had told everyone to stop bringing new products to market. Seeking to evade federal law altogether, many of the manufacturers claimed their products were made with synthetic nicotine.[6] Congress acted in 2022, ordering the removal of synthetic e-vapor products from the marketplace until they received FDA marketing granted authorization.[7]

Unfortunately, since 2020 the entire e-vapor category has been shifting rapidly to these flagrantly illegal products that violate virtually every rule FDA has established since 2016. We estimate

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[3] *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*. (81 Fed. Reg. 28974, May 10, 2016).
[4] Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization. April, 2020.
[5] Id., at p. 9, fn. 21.
[6] https://www.nytimes.com/2022/03/08/health/vaping-fda-nicotine.html
[7] https://www.cnn.com/2022/04/15/health/ecigarettes-vaping-loophole-synthetic-nicotine/index.html

that between one-third to fully half of all e-vapor products sold in the U.S. are flavored disposable products introduced after 2016, with no pending PMTA, all in violation of FDA's rules and guidance. They are reaching consumers through sellers willing to skirt the system, undaunted by the risks they face today of being caught and punished.
This activity isn't slowing down – it's speeding up. Last quarter alone, 500 new e-vapor SKUs entered the U.S. market, in gross violation of the 2016 Final Rule.[8] Even major celebrities are getting into the act. New illegal disposable vapor products have been launched recently with Hulk Hogan, Mike Tyson, and Snoop Dogg endorsing them, and with provocative flavor descriptors like "Apple Gummies," "Melonhead," "Cotton Candy," "Peach Rings," and "Candy."[9] And now we are seeing reports that these same companies are diversifying into other segments, including nicotine pouches, all in total disregard for the 2016 Final Rule, among other things. Clearly, something has to change.

**Our Perspective on the Path Forward**

We strongly support a regulatory future in which adult smokers are moving to less harmful products within FDA oversight. But rampant illegal conduct is a serious threat to everyone invested in this regulation-driven harm reduction future. To begin with, these illegal e-vapor products rank at the top of reported underage use, which last year ticked upward after two consecutive years of decline[10] and may, we fear, contribute to further incremental increases going forward. And while some of these manufacturers claim their products offer harm reduction benefits for adult smokers, none of them submitted the science as FDA required in 2020. The illicit sale of these unlawful products is intolerable while responsible wholesalers and retailers follow the law and have limited their product lines in compliance with FDA's rules and guidance.

We are grateful that the Agency has acknowledged this is a problem. And we see that the Agency has announced enforcement actions in the form of warning letters, civil monetary penalties, and an import alert addressing a handful of products.[11] But given the nature and scale of the problem, we believe the situation calls for a much more robust and coordinated compliance and enforcement program. What is needed in our view is a compliance and enforcement framework built for the marketplace as it exists today – where companies flagrantly defying Agency direction have rushed the marketplace, are gaining more dominance by the day, and now pose a threat to the regulatory system as a whole.

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[8] Databricks POS SCAN Data Model week ending 07/31/2023 as of 08/01/2023.
[9] https://vapetyson.com/; https://alternativepods.com/products/hulk-hogan; https://www.deathrowvapes.com/
[10] CDC, MMWR and Morbidity and Mortality Weekly Report, *E-cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020–2022* http://dx.doi.org/10.15585/mmwr.mm7225a1. Indeed, FDA was aware of concerning youth-use of flavored disposable vapor products a few months after it issued the 2020 guidance directing removal of non-tobacco, non-menthol pod-based products but exempting disposables. *See* FDA, *National Survey Shows Encouraging Decline in Overall Youth E-Cigarette Use, Concerning Uptick in Use of Disposable Products* (Sept. 9, 2020), https://tinyurl.com/4sxcb8js.
[11] https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products; *FDA Puts Firms Responsible for Esco Bars and Breeze — Two Popular Disposable E-cigarette Brands — on Notice* (May 25, 2023), https://tinyurl.com/yaascmas.

We are eager to share our views on how to reset the compliance and enforcement strategy and ask for an opportunity to exchange ideas in a forum where we can go into more detail. But in short, we believe the market requires at least three categories of regulatory intervention:

## 1. Compliance

Well-functioning regulatory systems have clear and coherent compliance frameworks in place to maximize good behavior and minimize the need for large-scale enforcement. Today, there is widespread confusion about what FDA's enforcement priorities are with e-vapor products. The Agency is correct that as a technical matter the Act required products to have a marketing order in place to remain on the market once FDA asserted authority over them. But the Agency made sound decisions in both 2016 and 2020 to allow the continued marketing of e-vapor products *as long as* companies making and distributing them obeyed FDA's conditions for staying on the market.

Responsible companies obeyed these rules. Irresponsible companies flouted them. All we ask of the Agency today is to clearly and unambiguously communicate that it is prioritizing enforcement against the latter, not the former.

More specifically, the Agency can and should communicate that it is prioritizing enforcement against products that entered the market after 2016 (in violation of the 2016 Final Rule), that failed to file PMTA applications (in violation of the 2020 Guidance), or that disregarded any other of the rules FDA has established for this category since 2016. And in order to help the trade align their conduct with these priorities, FDA can and should provide a complete list of product SKUs with properly pending PMTA applications under review since 2020,[12] a request we know others have made.[13] With that information clarified, FDA can direct its extensive state inspection infrastructure to focus on the presence of non-compliant products in a comprehensive way and begin to drive unlawful products out of the market.

## 2. Enforcement

Companies in open defiance of the Agency must be held accountable – and we believe that means FDA employing its most powerful enforcement tools on the worst offenders, immediately. These illegal actors are not hard to find. They are engaged in illegal conduct in broad daylight. We believe FDA could, and should, take direct action against them, including:

- Issuing cease and desist letters immediately to all, not just some, of the offending entities
- Imposing maximum and ongoing civil monetary penalties on all, not just some, of the offending entities

[12]Contrary to what we have heard the Agency say, there is no legitimate confidentiality interest any manufacturer has in this situation, since every e-vapor product on the market is required to have a PMTA pending.
[13] Energy Marketers of America (EMA) citizen petition to FDA, "[to] help to eliminate confusion and uncertainty in the marketplace." https://www.regulations.gov/document/FDA-2023-P-2225-0001

- Broadening FDA's import alert to cover all, not just some, of the illegal products made by the manufacturers covered so far

- Broadening FDA's import alert to cover all other manufacturers and all their illegal products as well

- Bringing injunction lawsuits against the major offending manufacturers and major distributors

- Commencing criminal investigations focused on the most egregious actors

**3. Authorization**

While these actions are necessary, we believe they will be insufficient in the long run without the Agency meeting adult consumer demand for authorized products within the legal system. There are over thirteen million adult e-vapor consumers in the U.S., millions of whom are former smokers. Since 2016, FDA has authorized just 23 e-vapor products and devices to meet adult consumer demand – just 3% of adult consumer demand today is being met by these products the FDA has authorized. The economic incentives for bad actors to cheat the system to supply unmet demand are simply too powerful to pass up.

We urge the Agency to take these realities into account as it reviews the thousands of e-vapor and other smoke-free product PMTAs still pending before it – including for e-vapor products with flavors appropriate for adults. Given the compelling evidence demonstrating beyond any reasonable scientific doubt that these products are substantially less harmful than cigarettes, FDA can establish a marketplace of authorized e-vapor products – distributed and sold through the responsible entities we represent – that can draw adult e-vapor consumers away from the illegal market and back into the legal one. And with authorization, the Agency can leverage its powerful post-authorization tools to closely monitor and regulate those products within the safety of the regulated system, to mitigate any risks of adverse impact, including underage use.

**Conclusion**

Our interest in this issue is clear. We support the long-term viability of a well-regulated tobacco product market that reduces underage use and delivers on harm reduction for adult smokers, all within the legal system we are a part of. We, the regulated participants in this industry, are where responsibility happens. We are the ones who distribute and sell only those products that comply with FDA rules. And we are the ones who make sure legal products are sold only to age-verified adults 21 and older.

As the industry participants most committed to following the law and playing our part in the right way, we hope the Agency is willing to work with us to identify solutions and build a more sustainable path forward. Two-way, transparent dialogue is, in fact, one of the areas of opportunity the Reagan-Udall Foundation identified in its report last year.[14]

[14] Operational Evaluation of FDA's Tobacco Program RUF Report, December 2022. Available at https://reaganudall.org/operational-evaluation-fdas-tobacco-program

With all this in mind, we ask that the Agency join us in a workshop with representatives of regulated industry to help correct the course forward for this category.

As we said at the outset, we are ready to meet immediately.

Sincerely,

**Altria Client Services**

**Convenience Distribution Association (CDA)**

**Energy Marketers of America (EMA)**

**ITG Brands, LLC**

**JT International U.S.A., Inc.**

**National Association of Tobacco Outlets (NATO)**

**New England Convenience Store & Energy Marketers Association, Inc. (NECSEMA)**

**RAI Services Company**