Smoke-Free Alternatives Trade Association
1629 K Street NW
Suite 300
Washington, DC 20006

General Assembly Raised Bill No.326
AN ACT PROHIBITING THE SALE OF FLAVORED CIGARETTES, TOBACCO PRODUCTS, ELECTRONIC NICOTINE DELIVERY SYSTEMS, AND VAPOR PRODUCTS.
(Hearing Date February 1, 2021)
Position: Oppose

Dear Honorable Chairs, Senator Abrams and Representative Steinberg, Honorable Ranking Members, Senator Hwang and Representative Petit, and members of the Committee.

Thank you for the opportunity to submit testimony regarding Senate Bill 326 (SB326), AN ACT PROHIBITING THE SALE OF FLAVORED CIGARETTES, TOBACCO PRODUCTS, ELECTRONIC NICOTINE DELIVERY SYSTEMS, AND VAPOR PRODUCTS.

My name is Mark Anton, and I am the Executive Director of the Smoke-Free Alternatives Trade Association (SFATA), based out of Washington, DC.

SFATA, a 501(c)(6) organization, is a national trade association of businesses that work in, or in service of, the vapor products industry, including manufacturers, distributors, and retailers. SFATA's mission is to advocate for a reasonably regulated U.S. marketplace, which allows its member companies to provide smoke-free products to adult consumers, while promoting a positive public image for vapor products, and educating businesses in our industry. All SFATA members must agree to adhere to the association's Member Code of Responsible Conduct, which includes, among other things, strict marketing and packaging guidelines. That document can be found here: https://www.sfata.org/content.aspx?page_id=22&club_id=89995&module_id=294336

SFATA also assists its members, which are small companies, with compliance of federal and state regulations. One of the ways we do this is by providing educational webinars regarding the development and building of Pre-Market Tobacco Applications with the Food and Drug Administration (FDA), and how to comply with new federally mandated shipping requirements, based on the PACT Act to prevent youth access to vapor products recently passed in the Omnibus spending bill.

Our members are law-abiding businesses and want to comply, but they are small and lack the resources of big tobacco firms to understand how to comply with federal and state laws, and SFATA helps them accomplish this. They are eager to work to help adult smokers with an alternative to smoking combustible cigarettes and prevent youth access, as they themselves are former smokers.

It is our assessment that SB326, if enacted, would significantly harm consumer welfare, lead to avoidable negative health outcomes, and cause unnecessary hardship on Connecticut small businesses. The bill to eliminate flavors in vapor products would put undue restrictions on vapor businesses in the

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state, as key findings in an industry study found the average vape store received 75-90% of its sales from flavored e-liquid other than tobacco in bottles.[1]

These restrictions would be particularly harmful to Connecticut's consumers, because it would prevent those trying to stop smoking from accessing vaping products that have been proven to help smokers quit, or switch from combustible cigarette use, the deadliest form of nicotine consumption.

In December 2019, the tobacco age was raised to 21 in Connecticut. In January 2020, the Food and Drug Administration (FDA) banned the sale of all fruit and sweet flavors in pod and cartridge-based e-cigarettes. The FDA took this action as they found, based on science, that cartridge-based e-cigarettes were the predominant vehicle of youth use of flavored vapor products. The FDA also noted that open-system flavored e-liquid did not play a substantial role in youth use.

SB326 does not distinguish between e-cigarettes and traditional tobacco products, placing both under the same category as "smoking" products, even though e-cigarettes are much safer than the combustible alternative. The scientific evidence from both the United States and European Union has proven beyond any reasonable doubt that e-cigarettes are safer than combustible cigarettes and are significantly more successful in helping smokers quit than traditional nicotine replacement therapies.[2][3][4]

Yale University School of Public Health performed a discreet choice study to determine the likely impacts of an FDA-proposed ban on flavors, on rates of smoking combustible cigarettes, and e-cigarette use. The conclusion found a ban on flavored e-cigarettes alone would likely increase the choice of cigarettes in smokers, arguably the more harmful way of obtaining nicotine.[5]

We must be reminded of the benefits of flavors in vaping products for the consumers of Connecticut and not impose such hardships on the businesses that provide such vital information and quality products to the consumer. Driving small vaping businesses out of the market will just put consumers in peril of not understanding the products and options that might remain. They will not get the support of

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[1] ECigIntelligence US Vape Store Survey 2019 Main Findings, September 2019, www.ecigintelligence.com
[2] Royal College of Physicians. "Nicotine without the smoke: Tobacco harm reduction." London RCP,2016. https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0
[3] Stephens WE. "Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke." Tobacco Control 2018;27:10-17. https://tobaccocontrol.bmj.com/content/27/1/10
[4] Hajek, Peter et al. "A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy." N Engl J Med 2019; 380:629-637 https://www.nejm.org/doi/full/10.1056/NEJMoa1808779
[5] Buckell J, Marti J, Sindelar JL. "Should flavours be banned in cigarettes and e-cigarettes? Evidence on adult smokers and recent quitters from a discrete choice experiment." Tobacco Control. 2019;28:168-175. https://tobaccocontrol.bmj.com/content/28/2/168.citation-tools

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knowledgeable staffers and previous smokers themselves. This will have a negative effect on the support these stores can provide in the future, therefore negatively impacting public health.

Reasonable regulation is paramount, but SB326 is not reasonable, as it places extreme requirements on law-abiding businesses and exerts significant burdens on an industry that has the effect of helping smokers transition or switch to lower risk products. The goal should be harm reduction and quitting smoking, or switching to vapor products, which accomplishes this objective.

Vape stores cannot survive on tobacco flavor alone, and this bill implies that will be the only flavor left to sell. Nor will tobacco-flavored vapor products be enough to keep consumers off of combustible cigarettes. So effectively, this bill would be a huge benefit to the large tobacco cigarette companies that manufacture and sell tobacco-flavored pods *and* analog cigarettes. This will continue to perpetuate the issue of dual use, which is vaping and smoking at the same time…again, negatively impacting public health.

This ban on flavors would effectively remove the most commonly used legal alternative (vaping) to smokers in Connecticut and would cause public harm. Forcing current users to seek other alternatives to acquiring the products they need, such as informal or underground markets or do-it-yourself kits—or worse yet—going back to combustible cigarettes.

San Francisco banned all flavored tobacco products in July 2018. A survey conducted by Addictive Behaviors Reports in June of 2020 concluded; that flavor bans may increase cigarette smoking; however, the data shows that cigarette use increased by 33% for the group of respondents aged 18-24, and concurrent vaping decreased 29% in this age group.

Massachusetts, a month after instituting a flavor vaping ban, showed cigarette sales increased. In June of 2020, a full tobacco flavor ban similar to SB326, went into effect. The ban on menthol cigarettes, lowered overall cigarettes sales by 24%, the state lost revenues of $32 million in excise taxes over the next 3 months, sending sales to neighboring states of New Hampshire and Rhode Island that saw increases in sales of cigarettes of 65% and 17% respectively. The vapor store industry closed down completely, effectively eliminating a $331 million a year industry.

In a Wall Street Journal article, a CDC employee made the following comment: “Adults using e-cigarettes as an alternative to cigarettes shouldn’t go back to smoking,” said Brian King, a deputy director of the CDC’s Office on Smoking and Health and a senior official involved in the agency’s vaping-related illness response.[6]

While we are in support of the noble goal of preventing youth use, we cannot support this bill with the inevitable outcome of hurting adults. Connecticut increased the age restriction to buying tobacco

[6] https://www.wsj.com/articles/during-covid-19-lockdowns-people-went-back-to-smoking-11611829803

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products to 21 in 2019, but we have not yet seen that data on the effectiveness on this action. However, if Connecticut follows US trends, then we should see the following: teen vaping dropped 29% between 2019 and March 2020 (when schools closed)[7], and another 32% by Nov. 2020[8]. We should build on this and make vapor products stronger as an alternative.

A study in the Harm Reduction Journal in 2018 concluded: "Judgements on whether authorizing marketing of flavored e-cigarettes would be appropriate for the benefit and protection of the public health should account for the possibility that adults who have switched completely from smoking cigarettes to using e-cigarettes in non-tobacco flavors may not have attempted to switch to e-cigarettes, or perceived themselves as able to switch, had e-cigarettes only been available in the flavors that are available through conventional cigarettes."[9]

We believe that the FDA is best suited for making this determination. The PMTA process is the most scientific and appropriate vehicle to make this determination. The applicants, of which many of our Connecticut members have initiated with the FDA, must show toxicology reports on harmful and potentially harmful constituents, as well as clinical reviews on the use of these products.

They also must demonstrate that they are appropriate for use by adult consumers and prove they are only marketing to adults who either vape or smoke currently. They must also show how they are going to prevent youth access and uptake of the products they are marketing.

This application and scientific review are very expensive, as well as exhaustive. Introducing and passing SB326 would effectively cause significant financial harm to our members, but it would also render the FDA process mute. This would not only be harmful to the businesses trying to comply, but would also put consumers in peril, especially if the FDA finds these products appropriate for the protection of public health.

Many health and public groups have made the false claim that vaping by youth leads to smoking. The following data puts that premise to rest. In 2008, the year vaping was introduced to the general market, the adult smoking rate was 20.6%, and the youth smoking rate in 2011 was 15.8%. However, the smoking rate among adults in 2018 was at 13.7% a 33.5% drop in adults, while the youth smoking rate in

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[7] https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf

[8] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2773494?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=120320

[9] Russell, C., McKeganey, N., Dickson, T. *et al.* Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J* **15,** 33 (2018). https://doi.org/10.1186/s12954-018-0238-6

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most recent data from National Youth Tobacco Survey shows the rate at 4.6%, a huge drop of 71%. The data does not indicate that vaping may lead to youth uptake of smoking. In fact, it is quite the opposite.

SFATA believes that we can accomplish the goal of both restricting youth access while also allowing adult access. This is the best strategy to keep reducing the overall smoking rates of adults. We have introduced our Responsible Industry Network (RIN) program to the Centers of Tobacco Products (CTP) at FDA. This program is designed to restrict flavors to adult-only vape stores, to products that have gone through the PMTA process. This will allow marketing to adults of products in the program, while at the same time putting strict conditions and compliance checks on the retailers selling these products.

You will find a summary of this program attached at the end of this testimony. We hope you will find it informative and proves that the vapor store retailers are responsible community members who take Tobacco Harm Reduction seriously.

It is our position to oppose this bill, as it would put many adults at risk of lapsing back to, or not initiating a switch away from, combustible cigarettes. It would put the youth at risk of illicit or underground markets of unknown manufacture and would cost the state of Connecticut considerable revenue.

SFATA opposes this legislation, and we urge the committee to vote NO on SB326.

Respectfully,

Mark W. Anton

Mark Anton
Executive Director

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Smoke-Free Alternatives Trade Association (SFATA) Responsible Industry Network (RIN): Proposal and Program Overview

I. Summary

- As a national trade association of businesses in the electronic nicotine delivery systems (ENDS) industry, the Smoke-Free Alternatives Trade Association ("SFATA" or "Organization") requires its members to uphold the highest standards of excellence and adhere to the Organization's Member Code of Responsible Conduct to offer less risky alternatives to combustible cigarettes for adult smokers that are appropriate for the protection of the public health. SFATA believes its members, including its retailer members, can further the U.S. Food and Drug Administration's (FDA) public health mission by self-regulating and complying with Organization's set standards, as well as all applicable health and safety requirements of state and local health authorities.
- SFATA advocates ENDS such as electronic cigarettes and e-liquids for adult use only. Accordingly, SFATA supports age restrictions on all tobacco products, including ENDS. We expect FDA to be supportive of innovative solutions to limit youth access. SFATA believes that controlled distribution would advance FDA's goals of restricting youth access to ENDS products, as described in FDA's Youth Tobacco Prevention Plan.[10]
- SFATA proposes its Responsible Industry Network ("RIN") program, which requires adherence to certain regulatory standards and SFATA's own, additional criteria for participation in a controlled network of eligible ENDS manufacturers, distributors, and retailers, implementation of robust age verification (including requirements for adult-only retail establishments) and product tracking measures, routine monitoring and data collection to further FDA's postmarket surveillance efforts and enhanced enforcement through program-related corrective actions and penalties and data sharing with law enforcement and regulatory authorities.

[10] *See* U.S. Food & Drug Admin., FDA's Youth Tobacco Prevention Plan (updated September 14, 2020) (available at https://www.fda.gov/tobacco-products/youth-and-tobacco/fdas-youth-tobacco-prevention-plan).

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II. SFATA Background and Mission Statement

- SFATA is a national trade association of businesses that work in, or in service of, the ENDS industry. Our members represent a wide cross-section of ENDS industry members, including distributors, manufacturers, and retailers. Firms must agree to uphold SFATA Principles as a condition of membership.
- SFATA believes in self-regulation and setting the standard for the vaping industry. As responsible business owners, our members understand that model corporate citizenship is vital to ensuring the continued availability of effective, innovative products that have the potential to eliminate the public health hazards caused by use of combusted cigarettes. Specifically, our members believe we have a responsibility to self-regulate the manufacturing, marketing, and sale of ENDS products based on compliance with regulatory requirements and commitment to SFATA's mission and adherence to the association's member Code of Conduct.
- We believe that a controlled distribution network that spans from the manufacturer, to the distributor, and on to the retailer, coupled with the robust age verification and data gathering measures described in this Proposal, would advance FDA's goals of restricting youth access to ENDS products and protecting the public health.

III. Program Objectives

SFATA's proposed RIN is intended to help FDA fulfill its public health mission by seeking to:

- Facilitate and monitor compliance of SFATA member ENDS products companies, including retailers, distributors, and manufacturers, to the Organization's mission and guiding principles, FDA regulatory requirements, and state and local laws.
- Control product marketing and sales and limit access via a controlled distribution buying network.
- Enable robust product tracking and tracing (and deter straw sales) via TraceVerify partnership or other measures that allow the product RFID tag/ QR Code (tracing lot number) to the purchaser ID at the point of sale.
- Direct accountability to manufacturers, distributors, and retailers with concrete, tangible corrective actions and consequences for non-compliance, including loss of the Organization's membership, program participation, and access to industry partners.
- Require retail participants in SFATA's RIN to sell products distributed by manufacturers also participating in the program, ensuring a closed loop system of control.
- Generate and compile comprehensive, broader postmarket surveillance data. By using a collaborative, joint approach to discover any new youth-attractive trends, industry can take a proactive approach in curbing youth uptake and assist in fulfilling FDA's public health mission.

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- Establish a robust reporting and records system that will help eliminate youth use of adult vapor products.
- Further enforcement efforts by regulatory and law enforcement authorities to deter bad actors and straw purchasers.

IV. Responsible Industry Network – Program Overview

- SFATA's RIN program requires adherence to FDA regulatory standards and SFATA's own, additional criteria for participation in a controlled network of eligible manufacturers, distributors, and retailers. Key components of the RIN program are:
    - Controlled Distribution Network - Retail participants in the RIN program are committed to selling ENDS products distributed by manufacturers also participating in the program, ensuring a closed-loop system of control. Membership criteria ensures the RIN program is limited to responsible, like-minded business members. RIN members will only sell products that submitted Pre-Market Tobacco Applications (PMTAs) to FDA.
    - Robust Age Verification – Includes requirements for adult-only[11] retail establishments and eCommerce platforms.
    - Upgraded Product Tracking Measures – Partnership with TraceVerify or other tools to link product manufacturing history (RFID tag/QR code) to Purchaser ID.
    - Routine Monitoring and Data Collection - To further FDA's postmarket surveillance efforts, a SFATA compliance officer will work with SFATA's Oversight Committee to ensure participating members operate within the parameters of the RIN Program.
    - Enhanced Enforcement - Through program-related corrective actions and penalties, and data sharing with law enforcement and regulatory authorities.
- This Proposal is intended to reduce the resource burden on both FDA and responsible industry members while furthering the public health, and establishes a more robust reporting and record system that will help minimize youth access to adult ENDS products.

V. Postmarket Surveillance

- Although postmarket surveillance typically requires well-designed monitoring of product safety for ***users***, given that FDA's mandate is to protect population health, SFATA believes that surveillance must be broader and must assess impact on users and non-users, transitions among tobacco-use states, and change over time.

[11] "Adult-only" is defined as requiring each person present to provide a government-issued identification showing a photograph and a date of birth indicating the holder is at least 21 years of age. Parents with minors present are allowed in when necessary to obtain supplies. *See* SFATA RIN "Program Requirements."

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- Postmarket data is needed to assess these parameters and how those data apply to real-world users. The challenge, however, is that new tobacco products may have small user bases. Thus, although surveillance mandates fall on each company, multiple, overlapping efforts may be wasteful, yielding fragmented and contradictory results. Rather, industry would benefit from collaboration on surveillance efforts, since collaborative joint effort would allow more robust, consistent results and perspective.
- Data will be submitted to FDA on an as-needed basis on behalf of all RIN program participants, streamlining the process for both industry and FDA.

VI. Enforcement

- SFATA believes members can work together to increase law enforcement and regulatory agencies' effectiveness, by means of deterring straw buyers and bad actors, to drastically reduce underage use of ENDS products by utilizing our controlled network to predict trends, to locate weaknesses, and build strengths.
- Through TraceVerify, the customer's age, driver's license number, and the state of issue will be permanently linked to the unique identifying number of the purchased ENDS product and be stored in a secure cloud database that law enforcement can access to cross-reference purchase data against DMV information. This will identify the offending straw buyer, or conversely, the employee who either did not scan the customer's ID or scanned the ID of an underage user, so authorities can levy the appropriate enforcement actions.