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April 30, 2019

By Electronic Submission
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-D-0661; Modifications to Compliance Policy for Certain Deemed Tobacco Products; Draft Guidance for Industry

To whom it may concern,

JUUL Labs, Inc. (JLI or the Company) is the manufacturer of JUUL products, a closed-system vapor platform, with the mission of eliminating cigarettes among adult smokers. JLI submits this comment on FDA's draft guidance entitled "Modifications to Compliance Policy for Certain Deemed Tobacco Products" (Draft Guidance).[1]

The Company welcomes FDA's Draft Guidance as an initial step toward much needed category-wide action to reverse the trend in youth use of vapor products. Vapor products present a significant and unprecedented public-health opportunity for adult smokers, to drive them away from combustible cigarettes to a less harmful alternative. But the harm-reduction potential of these products will be undermined unless we collectively address the issue of youth use.

In November 2018, JLI announced its action plan to address youth access, appeal, and use of JUUL products. This resulted in the suspension of non-tobacco and non-menthol-based (NTM) flavored JUUL products to traditional retail outlets. To curb youth access, JLI established a 21+ Restricted Distribution System (21+ RDS) in which NTM flavored JUUL products would be sold only through point-of-sale (POS) systems that utilize automated 21+ age-verification regardless of jurisdiction and prevent bulk purchases. Currently, the Company restricts the sale of these products to its ecommerce platform, where it uses automated, multi-step technologies to ensure purchasers are 21+ and limits the amount of product that can be purchased.

While the Company believes these and other actions it has taken are significant, and will have an impact on youth use of JUUL products, category-wide measures are

[1] As highlighted in this comment, the need for category-wide action for vapor products remains immediate to address the reported increase in youth use. To facilitate the implementation of these measures quickly, JLI requests that FDA move forward finalizing the Draft Guidance for certain deemed vapor products, but address other flavored tobacco products (e.g., cigars) separately, as that may take more time and require additional input from industry and other stakeholders.

needed to reduce youth use of *all* vapor products. The policy proposals outlined in the Draft Guidance are a starting point and track what JLI already has done voluntarily. JLI will continue to advocate for similar measures at federal and state levels to curb youth use of vapor products, while preserving the potential of these products for the adult smoker.

I. EXECUTIVE SUMMARY

- The reported increase in youth use of vapor products cannot go unabated if we are to preserve the harm-reduction potential of these products for adult smokers. We have a generational opportunity to eliminate cigarette use among adults, but must narrow the on-ramp to nicotine use for youth.

- That is why JLI supports the Draft Guidance's proposals aimed to restrict youth access and appeal of vapor products. By implementing well-tailored category-wide actions, manufacturers, their retail partners, and other stakeholders can work together to ensure vapor products stay out of the hands of youth.

- Many of these proposals are aligned with the significant actions JLI already has taken voluntarily, dating back to November 2018. At that time, JLI implemented its action plan to address youth access, appeal, and use of JUUL products. For example, the Company established its 21+ RDS for the sale of NTM flavored JUUL products, suspending their distribution to over 90,000 traditional retail outlets. Currently, the Company sells those products only through its ecommerce platform, where it uses third-party 21+ age verification against publicly-available records and limits the amount of product that can be purchased within a given period of time. The Company does not have plans to reintroduce NTM flavored products to traditional retail at this time.

- But more can and must be done. Not all flavors are equal — in their impact for adult smokers versus their potential appeal to youth. Certain categories of flavors, such as kid-specific candies, foods, and drinks, should not be marketed at all unless authorized by FDA. For other responsibly marketed NTM flavors, JLI supports the proposed restrictions on their sale at retail and online and appreciates the call for technologically-based measures that could prevent youth access. As outlined below, JLI believes they can be effectively restricted with POS technological advancements to ensure purchasers are of legal age and quantity limits are in place to reduce social sourcing. Any retailer that can meet these stringent standards should be permitted to sell responsibly marketed NTM flavored products to adults.

- Vapor manufacturers must subject their products to a rigorous scientific review to demonstrate their potential public-health benefit. While regulation and final guidance are still needed so industry can develop appropriate data to support the Agency's marketing authorization, manufacturers should be prepared to submit robust premarket applications as part of the submission process.

- Collectively, we must act now, deliberately and driven by the data. Since the reported increase in youth use of vapor products in the fall of 2018, little to no category-wide actions have been established. The proposals outlined in the Draft Guidance are an initial step, but we cannot expect any significant effect on youth-use rates until widespread requirements are in place and enforced. JLI will continue to push for categorical changes, such as those reflected in its November action plan, to preserve this unprecedented opportunity for adult smokers.

II. JLI'S ACTION PLAN TO ADDRESS YOUTH ACCESS, APPEAL, AND USE OF JUUL PRODUCTS CAN SERVE AS A BLUEPRINT FOR CATEGORY-WIDE MEASURES

In November 2018, in response to FDA's call to action, JLI submitted a comprehensive action plan to address youth access, appeal, and use of JUUL products.[2] The Company, as the market leader, understood the need to take swift and significant actions to lead the category.

With 39 commitments in total, the Company reset its business to restrict the sale of NTM flavored products; enhanced its 21+ ecommerce platform by adding two-factor authentication and facial-recognition technology; strengthened retailer compliance through an expanded secret-shopper program and penalty system for FDA CMP violations; eliminated social-media engagement other than Twitter for non-promotional purposes; and committed to exploring additional technological solutions to prevent youth use. Specifically, two elements of JLI's action plan can help serve as a guide for industry-wide actions to restrict access of vapor products at retail and online.

A. Restricting the Sale and Distribution of Flavored Products

Youth access is driven by a lack of age verification and — more often — social sourcing in which a friend, family member, or peer of legal age purchases the product for an underage youth. To address these gaps, JLI established its 21+ RDS for the sale of NTM flavored products — a system premised on automated sales controls at POS to verify age (21+) and identity and to prevent bulk purchases. As a result, the Company suspended the distribution of its NTM flavored products to its 100+ distributors and 90,000+ retailers and would reintroduce such products only through 21+ RDS-compliant outlets.

Currently, the Company sells its NTM-flavored products only through JUUL.com, which incorporates automated, multi-step technologies to ensure purchasers are 21+ regardless of jurisdiction and limits the amount of product that can be purchased. For age verification, the Company uses a third party to cross reference the purchaser's personal information, including name, date of birth, and partial social-security number, against publicly available records. If that third-party check fails or returns inconclusive, the Company requires the purchaser to upload a government-issued ID for additional analysis

[2] *See* Letter from FDA Commissioner Scott Gottlieb, M.D., to JUUL Labs, Inc. (Sept. 12, 2018), available at https://bit.ly/2VI75uc.

and verification. For bulk purchasing, the Company limits purchasers to 2 devices and/or 15 pod packages per month and 10 devices per year.

The Company also has established technical requirements for traditional retailers to be certified against its 21+ RDS. Through advancements in POS systems, JLI has developed an automated technological solution to restrict youth access at retail. This requires automated POS integration over the entire transaction to: (i) identify NTM product as "restricted"; (ii) require barcode scanning technology to verify age (21+) and identification; (iii) limit bulk purchases to 2 devices and/or 5 pod packages per transaction; and (iv) automatically block, without manual override, any transaction that does not pass the above requirements. Although JLI has not decided to sell its NTM flavored products using this phase of 21+RDS at this time, these same technologies could be incorporated by traditional retailers to create a fully automated, well-controlled sales system for age-restricted products, including vapor.

While the Company does not have current plans to reintroduce NTM-flavored products to traditional retail through its 21+ RDS criteria, it has worked with retail partners to test technical feasibility. JLI believes this solution could be adopted across industry quickly and efficiently with standard POS upgrades. This technological approach — predicated on automated age-verification and bulk-purchasing controls and open to any retailer that can enhance its POS systems — would be the most effective sales control to restrict youth access at retail.

B. Limiting Online Accessibility

Online resellers, with a lack of adequate age verification and bulk-purchasing limits, continue to be a source of access for youth. Although JUUL.com is the only authorized ecommerce outlet for JUUL products, other online marketplaces have attempted to sell the Company's products or counterfeit versions of the Company's products often with lax compliance controls. The Company, with third-party support, reviews these marketplaces to identify bad actors and seeks to remove illicit JUUL product listings. For example, JLI's reseller policy prevents retailers from online resale; but where retailers are in violation, the Company has suspended their accounts. JLI also has amended its distributor contracts to prevent sales to online resellers and circulates monthly "no-sales lists" to its distributors for retail accounts that have been terminated for selling JUUL products online.

JLI's ecommerce platform — the only authorized online seller of JUUL products — utilizes industry-leading technology to ensure purchasers are 21+ and limit the quantity of product that can be purchased. While robust, the Company has continued to enhance JUUL.com with additional controls. Since November, JLI has adopted two-factor authentication that requires the purchaser to provide a mobile phone number to create an ecommerce account; the number then receives a code that requires input to verify the account. JLI also has incorporated facial-recognition technology for uploaded IDs to prevent fraud. To test its own system, the Company has initiated a third-party audit of its

age-verification and bulk-purchasing controls, utilizing adults (aged 18–20 years) who are tasked with attempting to purchase product from JUUL.com.

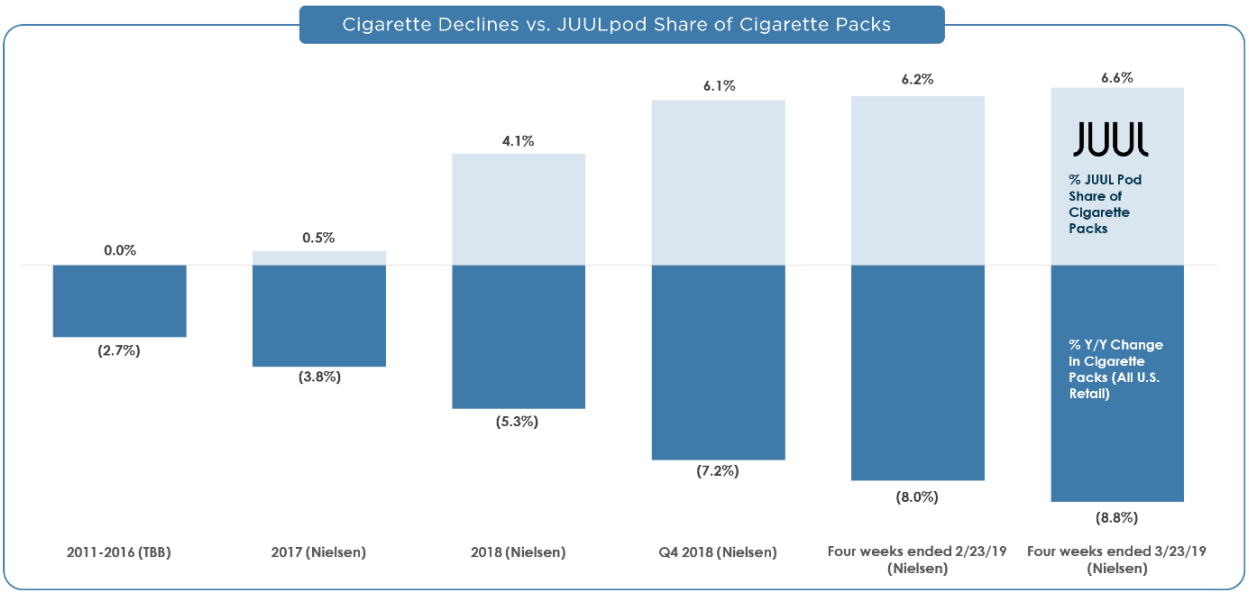
JLI will continue to evaluate other measures to address youth access, appeal, and use of its products. This has become a requirement to fulfill its mission of eliminating cigarettes and reducing the risk of nicotine delivery for adult smokers. The Company believes parts of its action plan can serve as a blueprint for broader, category-wide actions. FDA has embraced similar policies in its Draft Guidance — e.g., enhanced access restrictions for the sale of NTM flavored products at retail and online — and the Company supports the adoption of those concepts across industry.

III. A BALANCED REGULATORY FRAMEWORK TO RESTRICT YOUTH ACCESS AND APPEAL, BUT PRESERVE THE PUBLIC-HEALTH OPPORTUNITY FOR ADULT SMOKERS

A. The Need to Balance Reasonable Adult Access Versus Restrictions to Prevent Youth Use

Vapor products present an unprecedented opportunity to drive adult smokers from combustible cigarettes to a less harmful alternative. While containing nicotine, vapor products generally do not produce the thousands of harmful constituents linked to tobacco-related diseases, including cancer and cardiovascular and respiratory effects, that kill more than 480,000 Americans per year. Quitting nicotine consumption altogether may be the preferred public-health outcome. But quitting is hard, and adult smokers need a viable alternative that reduces consumption of the only legal consumer product that, when used as intended, will kill half of all long-term users.

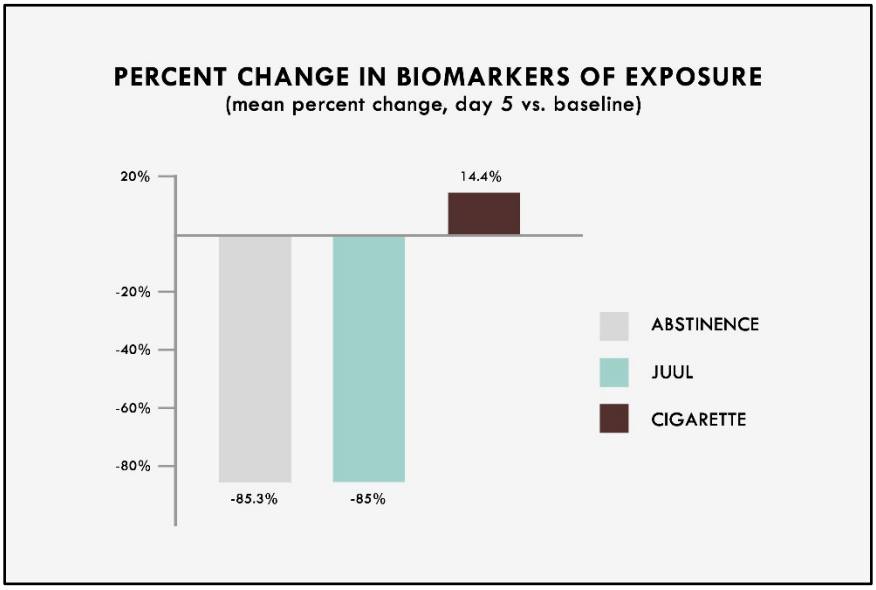
JLI believes its products, including its responsible flavor offerings, are leading the decline in cigarette consumption among adult smokers. While JUUL's sales volume, as measured as a percentage of the U.S. combustible cigarette market, has grown since 2018, cigarette-pack volumes continue to decline at accelerated rates. In the past two four-week reporting periods based on syndicated market data, cigarette volumes have faced year-to-year declines of 8% or more. For the period ending in late March 2019, year-over-year declines for cigarette-pack volumes steepened, falling to 8.8%. During the same four-week reporting period, JUUL product share of the combined cigarette and JUULpod market increased to 6.5%.



In markets where JUUL products have high market penetration, cigarette volume declines are even more pronounced. In our top five syndicated markets as measured by Nielsen — New York City, Portland, Oklahoma City and Tulsa, Seattle, and Denver — declines accelerated from 3.8% year-over-year one year ago to 9.9% year-over-year in the latest reporting period. More broadly, the data suggest a negative correlation between JUUL products and cigarette-pack volumes: In the top 25 U.S. cities measured by Nielsen, as sales of JUUL products increased, cigarettes plummeted.[3]

More critically, JLI is starting to see the potential positive health impact in its own data. In a recent clinical study of adult smokers which assessed biomarkers of exposure (BOEs) linked to tobacco-related cancers and heart and lung disease, the Company saw equivalent reductions between JUUL product users and smoking abstainers. The study — a randomized, open-label, parallel group, five-day inpatient assessment — examined changes, relative to baseline, in primary urine and blood BOEs in 90 adult smokers. The selected short-term biomarkers were carcinogens and toxicants observed in the use of combustible cigarettes. Study subjects were randomized into six groups and, over five days, used JUUL products, abstained from smoking, or continued use of their usual brand of cigarettes. Before the baseline reading, subjects abstained from smoking for twelve hours to assess BOE impact across the three groups.

[3] Market analyses provided herein were developed from syndicated market data provided by The Nielsen Company's "Answers on Demand Services for the Total Store/Tobacco Category."



The study found that all eight non-nicotine urine BOEs were reduced by an aggregate of 85.3% in the abstinence group compared to an 85% aggregate reduction in the JUUL product group. This represented a 99.6% relative reduction in aggregate BOEs for the JUUL product group. In the cigarette group, the same BOEs increased by an aggregate of 14.4% from baseline.[4]

Yet we cannot ignore the other side of this equation — the reported increase in youth use of vapor products. As has been well-documented, based on the Centers for Disease Control and Prevention (CDC) 2018 National Youth Tobacco Survey (NYTS), current use of vapor products (i.e., use within the past 30 days) among high-school students has increased to 20.8%.[5]

The data also suggest high levels of experimentation and social use driven by sharing among friends, family members, and peers, as opposed to sustained individual use over time. For example, the 2018 NYTS revealed that frequent use (use on 20+ days within the past 30 days) of all high-school students was at 5.76% compared to current use (use, at least one time, within the past 30 days) at 20.8%. Another study has shown that, of adolescent users of vapor products (aged 15–17 years), a third "vaped" alone and only 16% had never shared a vapor device, suggesting use was far more common in social-settings

[4] *See* Joanna Jay, et al., Changes in Biomarkers of Exposure Associated with Switching for 5 Days from Combusted Cigarettes to Nicotine Salt Pod System; Poster Presented at the 2019 Society for Research on Nicotine and Tobacco Annual Conference, available at https://bit.ly/2We4K7f.

[5] See CDC, 2018 NYTS; see also, CDC Morbidity and Mortality Weekly Report, Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018 (Feb. 11, 2019), available at https://bit.ly/2GS7Zf6. Comparatively, while current use rates of vapor products have increased among high-school students, "use within the past 30 days" of substances like alcohol (30.2%; 18.6%) and marijuana (22.2%; 16.7%) among 12th and 10th graders, respectively, remain higher and have been at stable levels for years. *See* Monitoring the Future, National Adolescent Drug Trends in 2018.

where vapor products were passed around or shared.[6] These types of data points are critical to understand the scope and impact of youth use and to develop effective measures to reverse the trend.

Thus, our goal: effectively address youth use, while preserving this generational public-health opportunity for the 34 million adult smokers in the U.S. These two objectives are not mutually exclusive. JLI believes a focused regulatory approach that accounts for youth access to and appeal of vapor products can ultimately address youth use. By tailoring category-wide actions to these factors, we can retain reasonable availability for adult smokers. But to achieve this outcome, we must be driven by the actual data (not personal sentiment and sensationalized anecdotes) and focus on the role flavored vapor products play and how and where youth are accessing these products.

B. The Critical Role of Flavors in Switching Adult Smokers from Cigarettes

Data continue to demonstrate the significant impact certain flavored vapor products have in initiating and maintaining adult smokers from combustible cigarettes, ultimately eliminating their consumption altogether. While flavors commonly available for combustible cigarettes (e.g., tobacco, menthol, and mint) are critical, we cannot discount the effects of other non-traditional flavors (e.g., fruits) for current adult smokers looking to switch or former smokers who already have. The debate around flavors, and balancing their appeal among youth to reduce use, must account for these facts.

JLI sees this impact in its own behavioral-research data. Just recently, the Company's third-party researchers published results from an expansive survey of adult smokers who initiated on JUUL products and completely switched from combustible cigarettes at unprecedented rates.[7] The study, published in the Harm Reduction Journal, included a non-probabilistic sample of 15,456 U.S. adult smokers (21+) who purchased JUUL products either at retail or online through JUUL.com. Survey participants were assessed at monthly intervals through three months to determine use rates, use patterns, and past 30-day smoking history. The last follow-up assessment was conducted after three months of JUUL use.

Based on the entire survey sample, 28.3% of JUUL users had completely abstained from smoking cigarettes in the 30 days prior to the final three-month follow-up assessment (ITT sample). Of those users who completed the three-month follow-up assessment, 47.1% of JUUL users had completely abstained from smoking cigarettes in the 30 days prior (efficacy sample). Smoking abstinence was higher among retail purchasers (55.1%) versus online purchasers (40.3%). The researchers estimated that, at the three-month follow-up

[6] Jessica K. Pepper, et al., How Do Adolescents Get Their E-cigarettes and Other Electronic Vaping Devices?, 33 Am. J. of Health Promotion 420 (2018).

[7] Christopher Russell, et al., Factors Associated with Past 30-day Abstinence from Cigarette Smoking in a Non-probabilistic sample of 15,456 Adult Established Current Smokers in the United States who Used JUUL Vapor Products for Three Months, 16 Harm Reduction Journal, no. 22 (2019).

assessment, "between 30.0% and 55.1% of new retail purchasers of a JUUL vaporizer and between 26.5% and 40.3% of new online purchasers of a JUUL vaporizer, all of whom were current smokers at the point of first purchase of a JUUL vaporizer, had not smoked a cigarette in the past 30 days."

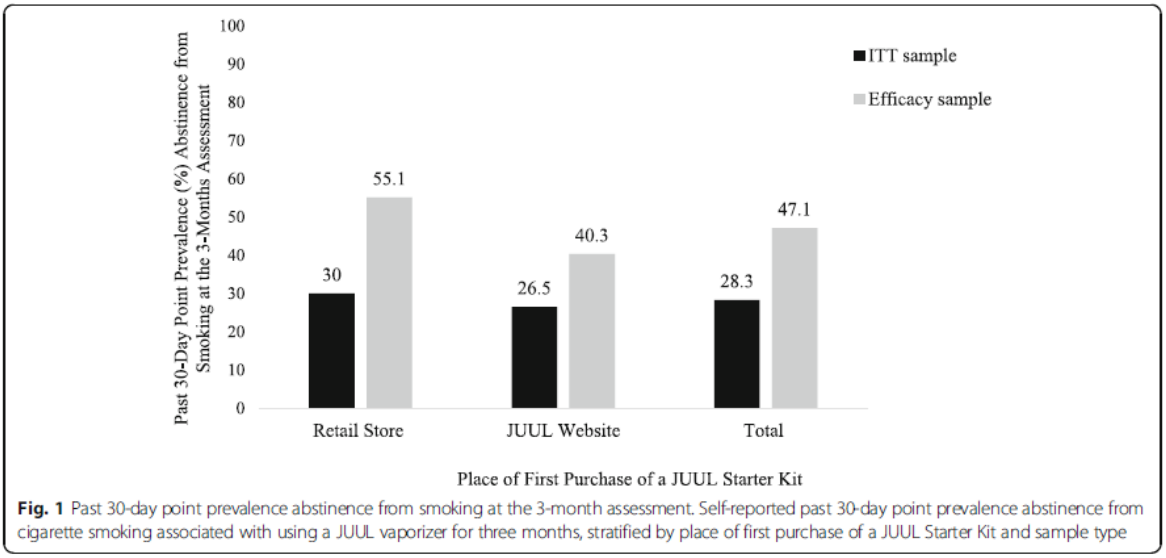
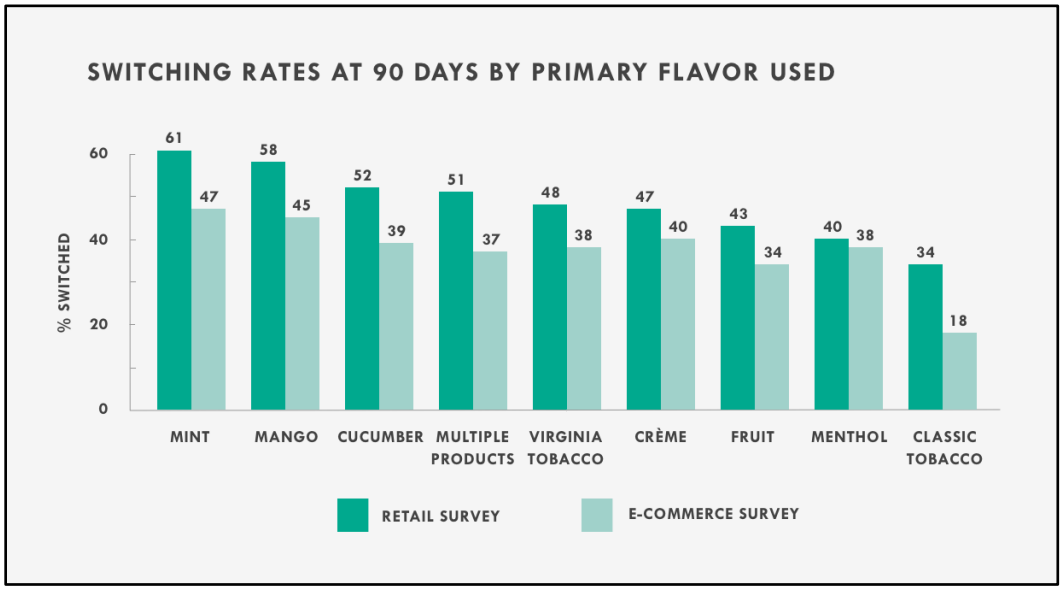


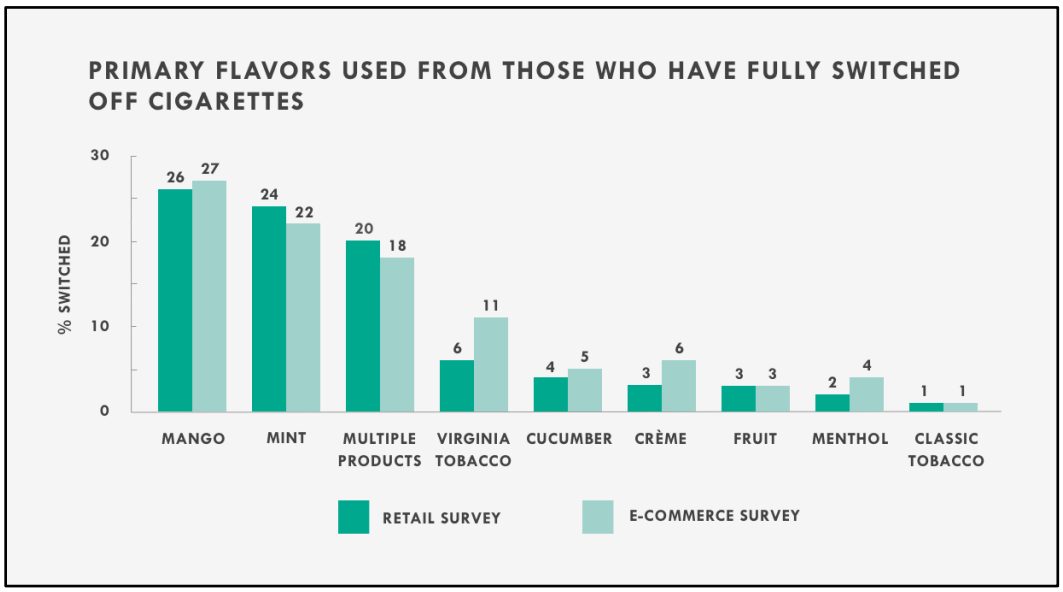
Fig. 1 Past 30-day point prevalence abstinence from smoking at the 3-month assessment. Self-reported past 30-day point prevalence abstinence from cigarette smoking associated with using a JUUL vaporizer for three months, stratified by place of first purchase of a JUUL Starter Kit and sample type

Among variables relating to use of JUUL products and smoking abstinence, including frequency of JUUL use and intent to quit smoking, the study assessed the role of flavors in transitioning adult smokers from cigarettes. Not only were non-tobacco flavors far more popular among JUUL users, but they also were significantly more impactful in switching adult smokers from combustible cigarettes completely.



Compared to those who primarily used Virginia Tobacco flavored JUULpods in the 30 days prior to the three-month assessment, those who primarily used Mint or Mango flavored JUULpods were 37% and 26% more likely, respectively, to have switched completely from combustibles. Mint and Mango were the most common primary flavors used, with primary users of Mint and Mango flavored JUULpods accounting for 44.7% of all participants who completed the three-month follow-up assessment and had not smoked a cigarette in the 30 days prior.

Compared to those who primarily used Virginia Tobacco flavored JUULpods, those who primarily used Classic Tobacco flavored JUULpods were 1.85 times less likely to have not smoked a cigarette in the 30 days prior to the three-month follow-up assessment. Adult smokers who *exclusively* used JUULpods in non-tobacco flavors (Mint, Menthol, Mango, Cucumber, Fruit, and/or Creme) in the 30 days prior to the three-month follow-up assessment were 30% more likely to have switched completely from cigarettes than those who exclusively used tobacco flavors (Virginia Tobacco and Classic Tobacco).



The Draft Guidance appropriately acknowledges the role even traditional flavors have in displacing cigarette consumption among adult smokers.[8] As highlighted above, Mint JUULpods not only are the most popular among adult smokers, but also the most effective at eliminating cigarette consumption. For JUUL users who purchased product at retail, 61% of respondents who primarily used Mint had not smoked any cigarettes in the 30 days prior to the three-month follow-up assessment. Forty percent of respondents who primarily used Menthol completely switched from cigarettes at the three-month follow-up assessment. Moreover, retail purchasers of JUUL products were 37% more likely to have

[8] *See* FDA, Draft Guidance at 19.

not smoked any cigarettes the 30 days prior to the three-month follow-up assessment compared to online purchasers.[9]

These data are just one example highlighting how flavored vapor products can move adult smokers down the risk continuum of tobacco use. Some level of flavor optionality is key and certain non-tobacco flavors can have a dramatic impact on engaging adult smokers who want to disassociate from the taste of cigarettes. There is no one-size fits all approach to flavor restriction, and much needed categorical actions to offset youth use must account for the critical role certain flavors play in eliminating cigarette consumption for adult smokers.

C. Understanding How Youth Are Accessing Vapor Products

To develop effective measures to address youth access, we first must understand how underage users are obtaining the product. Like other age-restricted items, youth access vapor products through a lack of age verification or social sourcing when a legal-age purchaser provides the product to an underage user. Data suggest the overwhelming point of access relates to the latter. Specifically, approximately 70–80% of youth use of vapor products comes from social sourcing.[10] Based on the 2017 YRBS, only 13.6% of high-school students (aged 17 years or younger) obtained a vapor product from a brick-and-mortar retail outlet, while 6.7% obtained a vapor product from online.

Recently released data from the 2018 NYTS tell a similar story: social sourcing is the predominant driver of youth access to vapor products.[11] Among underage e-cigarette users in high school, 58% obtained the product from a friend, 6.8% obtained the product from a family member, and 6.6% obtained the product from another person. Of commercial sources (less than 30%), specialty vape shops were the main contributors (12.9%), while gas and convenience stores were responsible for only 6.6% of underage access and use.

A separate study of adolescent users of vapor products (aged 15–17 years) found a similar outcome on the predominance of non-commercial sources.[12] Of the 1,729 adolescent users surveyed, 31.1% purchased the product from retail (e.g., convenience store, vape shop, or online), while 31.3% either bought the product from another person or gave money to someone else to purchase the product. The remainder obtained the vapor product from other non-traditional commercial sources, including as a gift, from a parent, or it was stolen.

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[9] *See* Russell, et al., *supra* note 7.

[10] *See* CDC, 2017 Youth Risk Behavior Survey (YRBS).

[11] *See* CDC, 2018 NYTS; *see also*, Tobacco Truth, Some FDA Claims About Teen Vaping Confirmed, Others Evaporate (April 2, 2018), available at https://bit.ly/2LsyeNR (last accessed April 5, 2019).

[12] *See* Pepper, et al., *supra note* 6.

For those that purchased the vapor product from a traditional commercial source:

- 32.2% obtained the product from online
- 22.3% obtained the product from a vapor shop or lounge
- 16.4% obtained the product from a tobacco specialty store
- 5.6% obtained the product from a convenience, gas, or liquor store
- 5.4% obtained the product from a mall kiosk
- 2.2% obtained the product from a grocery, drug, dollar, or mass market store.[13]

Another study, focused on access patterns among Californian high-school students who had used an e-cigarette within the last 30 days, further highlights the issue of social sourcing and where youth are obtaining vapor products illegally.[14] In this survey, of the 13,902 respondents from the California Student Tobacco Survey, 52.9% did not pay for the vapor product. Of those who did make a purchase, 35.9% bought the product from another individual (i.e., non-commercial retailer). Of those who purchased the product from a commercial retailer, the overwhelming majority accessed the product from a specialty vape shop or tobacco-only retailer.

The Draft Guidance proposes several considerations to reduce the risk for minors to access flavored vapor products.[15] We share that ultimate goal, but the Agency must account for how youth are actually accessing the product to develop effective measures to address it.

JLI believes that technological solutions that address both age verification and bulk purchases across *all retailers*, including brick-and-mortar and online, are the most effective measures to restrict youth access. The data confirm that simply limiting sales to one retail class (specialty vape) versus another (convenience stores) or imposing enhanced restrictions online (quantity limitations) while omitting them from traditional retail (no quantity limitations) will not solve the issue. Rather, social sourcing continues to be the main driver of youth access and, for commercial sales, specialty vape and tobacco-only outlets appear to be the leading sources of product leakage to youth.

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[13] *See id.* 15.9% obtained the product from "other location."

[14] *See* Julian Ong, et al., Where Do Californian Youth Get Their E-cigarettes?, as presented at the 2019 Annual Conference for the Society for Research on Nicotine & Tobacco (Feb. 2019).

[15] *See* FDA, Draft Guidance at 13.

D. A Tiered, Well-Tailored Approach to Restrict Youth Access and Appeal of Flavored Vapor Products

1. Categorical Ban of Kid-Appealing Flavors

Not all flavors are equal in their appeal to and impact on adult smokers, particularly given concerns around youth use. As the Draft Guidance recognizes, there is a difference between tobacco- and menthol-based (TM) and NTM flavors when assessing the importance for adults against their appeal to youth.[16] As discussed below, for certain responsibly marketed NTM flavors, enhanced access restrictions can ensure they stay out of the hands of youth, while preserving reasonable availability to adults.

But other NTM flavored products should not be commercially available at all. While the Draft Guidance contemplates increased enforcement against vapor products that are "targeted to minors or likely to promote use of ENDS by minors," JLI believes FDA should remove enforcement discretion for select categories of uniquely kid-appealing flavors until they go through premarket review and authorization. Vapor products that have characterizing flavors akin to, and are marketed as, kid-specific candies, foods, or drinks have no place in the market. Other categories to prohibit, as part of a model framework to restrict youth access and appeal, could include desserts, confectionary, soft drinks, energy drinks, and alcoholic drinks.

There are egregious actors in the marketplace, as evidenced in FDA's recent enforcement actions against manufacturers of flavored vapor products that were misleadingly labeled, packaged, and/or advertised to target youth.[17] JLI believes many manufacturers have taken advantage of FDA's current compliance policy for vapor products to remain on the market and have no intention of submitting premarket applications by the required deadline. By clearing the market of these kid-appealing products now, FDA can eliminate a significant portion of vapor products that may be contributing to youth use.

In addition, many manufacturers of kid-appealing flavors (and even those that market more traditional flavors) are selling their products in clear violation of FDA's current compliance policy for deemed products, including vapor. Only deemed products that were on the market as of August 8, 2016, may continue to be sold while a premarket application is submitted by the applicable deadline and reviewed by FDA.

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[16] *See id.* at 19.

[17] *See, e.g.*, Warning Letter to Electric Lotus, LLC (marketing products as "Cereal Treats Crunch," "Cereal Treats Loopz," "Cereal Treats Krispies," "Jammin Berries Blueberry Jam," "Jammin Berries Peanut Jamz Raspberry," "Dripflavors Strawberry Lemonade Salt," "Dripflavors Sour Apple Kiwi Gummy Salt," and "Heavy Custard Unicorn Cake"); *see also* FDA News Release, Companies Cease Sales of E-liquids with Labeling or Advertising That Resembled Kid-Friendly Foods Following FDA, FTC Warnings (Aug, 23, 2018), available at https://bit.ly/2GW1Qik.

JLI maintains that there is a meaningful number of illegally marketed products, including those sold as "JUUL compatible," that came to the market well after August 8, 2016, and have not obtained premarket authorization. Such products include flavors like: "Melon Bomb," "Pink Frosted Yellow Cake," Blue Razz Gummy," "Pink Lemonade," "Sour Rainbow," "Sour Gummy," "Rainbow Drops," "Taffy Burst," and "Cotton Candy."

FDA, itself, has flagged these potential bad actors in two rounds of letters requesting specific information on the legality of these products.[18] The Agency can, and should, take immediate action, including through an import alert, for any adulterated and misbranded products in violation of FDA's current compliance policy. Not only are these products in flagrant violation of FDA law and regulation, but they also target youth through kid-appealing flavors and are manufactured with unknown ingredients and under unknown quality standards that could present a significant public-health risk.

2. Enhanced Access Restrictions for Responsibly Marketed NTM Flavors

For other responsibly marketed NTM flavored vapor products at this time, there are tools to ensure they are restricted from youth but remain available to adults as less harmful alternatives to cigarettes. That is why JLI established its 21+ RDS for the sale of NTM flavored JUUL products, where they can be sold only through automated POS controls to ensure purchasers are 21+ and to prevent bulk purchases.

A similar set of technological solutions can be utilized across industry and enable any retailer (brick-and-mortar and online) to sell NTM flavored products under enhanced access restrictions. In its Draft Guidance, FDA specifically requested information about "whether there are any technologies or other measures that would also be well tailored to address youth access to vapor products."[19] With the Company' experience in developing its 21+ RDS, we offer some of these solutions below.

i. Enhanced Access Restrictions for Traditional Retail

Given advancements in POS technology, traditional retail outlets can incorporate new technologies and update existing sales systems to restrict youth access through automated sales controls. For example, retailers can now use barcode scanning technology to verify age and ID validity. Physical scanners or other software-based technologies can pull information from the barcode on government-issued IDs and determine whether the purchaser is of legal age and whether the ID has expired. The same technology also can extract information from the purchaser's ID and temporarily display that information on the POS screen, enabling the retail clerk to verify that it matches what is represented on the physical ID to reduce potential fraud. Moreover, the same POS systems can identify a

[18] *See* FDA, Letters to Manufacturers Regarding Tobacco Products That May Be Marketed Illegally (Oct. 12, 2018 and Feb. 28, 2019), available at https://bit.ly/2XUVy7Z.

[19] FDA, Draft Guidance at 13.

certain product as "restricted" and require that these added verification elements be met before the transaction can proceed.

Retailer POS systems also can set limits on the amount of product that can be purchased in a single transaction. For example, JLI requires its resellers to limit the sale of JUUL products to 2 devices and/or 5 pod packages per transaction. Retailers can upgrade their POS systems to automatically block any transaction that exceeds similar limits, thus addressing the potential for social sourcing.

With the availability of these technological capabilities, JLI proposes that the following requirements be adopted by traditional retailers to sell NTM flavored products:

Automated Sales Controls for Age Verification and Bulk Purchasing[20]
• Identify the product as "restricted" through the POS system; • Use scanning-technology for government-issued IDs to verify age and ID validity; and • Impose limits on the amount of product that can be purchased per transaction

We believe that the great majority of retailers do not want to contribute to youth use. They are our partners in promoting a culture of compliance to keep these products out of the hands of those underage. The adoption of automated sales controls and other technological solutions now available for POS systems can significantly limit the potential for youth access across all retailers.

ii. Enhanced Access Restrictions for Online Sales

Many ecommerce marketplaces lack effective age-verification and bulk-purchasing controls. Some age verifications are merely a self-attestation that the purchaser is of legal age; the "check-the-box" approach. Few major manufacturers or marketplaces limit the amount of product that can be purchased within a given period of time. Absent defined requirements for online retailers, youth will continue to flock to the internet to exploit these access deficiencies.

As a precondition to selling vapor products online, retailers should be required to implement the following controls:

[20] Although not an "automated feature," JLI proposes that retailers ensure vapor products are placed behind the counter or in a lock-box requiring vendor assistance to purchase the product.

Age-Verification Controls	Bulk-Purchasing Restrictions
• Require the consumer to create an online profile or account with personal information, including, but not limited to, name, address, and date of birth, and utilize a third party to verify that information against publicly-available records or databases	• Restrict the amount of product that can be purchased in a single transaction to a reasonable personal limit
or	*or*
• Require the consumer to upload a copy of his or her government-issued ID which is verified by a third party	• Restrict the amount of product that can be purchased during a defined period (e.g., month) to a reasonable personal limit

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Technological solutions premised on automated age-verification and bulk-purchasing controls can and should be adopted across industry. Such solutions will take the guessing game out of verifying a purchaser's age and could address the largest contributor to youth use — social sourcing. JLI will continue to support these initiatives, including partnering with responsible retailers to establish a 21+ RDS for traditional commercial outlets.

We cannot lose sight of the potential public-health impact vapor products may have, including their flavor offerings, for adult smokers. At this time, given the current reporting of youth use, the solution must be swift. But it also must be thoughtful and balanced. A tiered framework that reduces youth appeal and restricts youth access, placing enhanced restrictions on the sale of responsible NTM flavored products, can reduce underage use of vapor products yet still preserve their availability for adults.[21]

IV. SUPPORT FOR THE SCIENTIFIC REVIEW OF VAPOR PRODUCTS TO DEMONSTRATE THEIR POTENTIAL PUBLIC HEALTH BENEFIT

JLI agrees with FDA that vapor products, to demonstrate their public-health benefit, must go through the appropriate regulatory gates, including authorization of Premarket Tobacco Product Applications (PMTA) for new tobacco products. This will ensure a rigorous scientific assessment of the nonclinical, clinical, and behavioral research of these products for the protection of public health.

JLI continues to develop the research and data for JUUL products through its scientific program, as well as its next-generation product that could utilize user-level access

[21] Traditional flavors are part of the assessment, but without data suggesting a direct link between those flavors and increased youth use, they should be positioned to eliminate their cigarette counterparts. *See supra* Section III.B.

restrictions to prevent youth use. The Company also intends to comply with the current *or* proposed deadlines for premarket submissions as set forth in the draft guidance. But as FDA contemplates a modification of its current compliance policy, JLI believes it is imperative to recall why the deadlines for premarket submissions were extended in the first place.

A. Extension of the Compliance Deadline to Develop Robust Applications

In July 2017, FDA announced its comprehensive policy for the regulation of tobacco products, in an effort to shift adult smokers down the continuum of risk to less harmful products, including non-combustibles like vapor.[22] The Agency rightly noted that the "[t]he overwhelming amount of death and disease attributable to tobacco is caused by addiction to cigarettes — the only legal consumer product that, when used as intended, will kill half of all long-term users."[23] To facilitate innovation for products that could "have the potential to make a notable public health difference," FDA, in part, extended the deadline to submit premarket applications.[24] This would "provide manufacturers additional time to develop higher quality, more complete applications informed by additional guidance from the agency."[25]

In addition, FDA committed to issue rules and regulations to "make the product review process more efficient, predictable and transparent for manufacturers, while upholding the agency's public health mission."[26] For example, the Agency acknowledged the need to issue regulations outlining what information FDA expected to be submitted in an application. FDA also agreed to finalize guidance for PMTAs for vapor products. Over eighteen months later, while those actions have not been taken yet, FDA remains committed to issue the same rules and guidance for vapor products.[27]

B. Greater Clarity Still Needed for PMTAs for Vapor Products

JLI has previously commented on where additional information for the premarket review of new tobacco products is needed.[28] These areas include: (i) the standardization of nonclinical requirements; (ii) bridging studies across similar tobacco products; (iii)

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[22] FDA News Release, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-related Disease, Death (July 28, 2017), available at https://bit.ly/2GXBVa1.

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *See* FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., on Actions to Advance Our Comprehensive Plan to Reduce Tobacco-related Disease and Death, Through New Efforts to Improve the Tobacco Product Application Review Process, Including a Newly Proposed Rule (March 28, 2019), available at https://bit.ly/2GKFcrR.

[28] *See* JLI's Comment to Docket No. FDA-2018-N-3504, "Tobacco Product Application Review."

bundled submissions for multiple tobacco products; (iv) principles to assess nicotine effects among adult-smoker populations; (v) environmental assessments; and (vi) reliance on non-sponsor studies. The Company expects foundational rules and regulations, as well as final guidance, to cover these types of issues and looks forward to FDA initiating that process.

JLI believes industry participants that are focused on the harm-reduction potential of vapor products will comply with FDA's compliance deadlines. JLI also notes that preparing a PMTA requires substantial advance work, including the performance of rigorous scientific studies that by their nature demand significant time to complete. In developing its scientific program, JLI has relied on the current deadline (August 8, 2022, for vapor products), as well as the information that FDA has provided to-date through its existing draft guidance on PMTA submissions,[29] through the Agency's statements at public meetings, and in meetings that JLI requested to learn more about FDA's anticipated requirements and references for PMTAs.

JLI intends to submit a PMTA for JUUL products as soon as is feasible considering the need to develop data to support a robust review by FDA. Based on the information provided to date by FDA, JLI believes it will be able to make its PMTA submission by the proposed revised August 8, 2021 deadline for NTM flavored products. If the Agency does intend to move the deadline forward to August 2021, manufacturers would benefit from additional clarity from the Agency on what it expects to see in premarket applications and how it will review them. FDA's provision of additional final guidance will help ensure an efficient, predictable, and transparent review process to demonstrate the potential public-health benefit of these products and quicken the displacement of combustible use. And it will be necessary to ensure manufacturers can meet any revised deadline.

V. CLARIFICATION ON THE ENFORCEMENT OF FDA'S POLICY PROPOSALS

The Draft Guidance offers a series of policy proposals that, if adopted across industry, could have a significant impact on youth access, appeal, and ultimately use. For example, FDA outlines measures that could limit the risk of minors accessing certain vapor products at traditional retail and online — initiatives that align with JLI's actions from November 2018, including its adoption of 21+ RDS for NTM flavored products.[30] The Agency also states that it will increase enforcement against products that are "targeted to minors or likely to promote the use of ENDS by minors".[31] These proposals represent a thoughtful starting point to drive much needed categorical change.

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[29] *See* FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Draft Guidance for Industry (May 2016).

[30] *See* FDA, Draft Guidance at 12–13.

[31] *See id.* at 13.

As written however, the Draft Guidance's policy proposals read as general principles, without a clear and direct compliance mandate:

- How will FDA determine when NTM flavored vapor products are sold in a way that "pose a greater risk for minors to access such products" and what are the specific compliance requirements for manufacturers, distributors, and retailers?

- How will FDA determine which products are "targeted to or likely to promote use of ENDS by minors"?

- How are manufacturers obligated to comply with the requirement that their products not be sold in retail or online in a way that could contribute to youth access?

- How are manufacturers obligated to control the distribution of their products through, among other channels, wholesale distributors that legally own the product inventory upon receipt?

It also is unclear how these policies would be effectuated through legal enforcement and who the liable party would be:

- If a minor were to access an NTM flavored product online or at traditional retail because of inadequate sales controls, what are the legal consequences for the manufacturer?

- If one retail outlet is in violation for selling vapor products to youth, what are the implications for other outlets within the same national or regional chain and under common ownership?

- Does the failure to comply with one of FDA's proposals remove enforcement discretion for products that are legally marketed under FDA's current compliance policy for vapor products on the market as of August 8, 2016?

- Does the failure to comply with one of FDA's proposals render the product adulterated and/or misbranded within a single retail outlet or across interstate commerce?

JLI believes these policy proposals, to have their intended effect, should be adopted as legal requirements for the sale and distribution of vapor products. This will ensure actual behavioral change in the marketplace and drive industry to establish compliance programs aimed to reduce youth use. Without well-defined legal obligations and clear regulatory requirements, these proposals may fall short of driving category-wide action.

VI. CONCLUSION

In November 2018, JLI reset its business to lead the industry in combatting the reported increase in youth use of vapor products. JLI suspended the distribution of NTM flavored products to traditional retail and established a 21+ RDS to ensure purchasers are 21+ and to prevent bulk sales; enhanced its ecommerce platform already built on automated third-party age-verification and bulk-purchasing restrictions; expanded its retailer compliance program to ensure retail partners also work to prevent youth access; exited its social media to further limit product appeal; and initiated technologically-based solutions to address youth use through end-to-end product traceability and next-generation product with user-level access restrictions.

These actions are aligned with the Draft Guidance's policy proposals and are a step in the right direction to drive categorical change. JLI encourages the implementation of carefully tailored actions that will effectively address youth access and appeal of vapor products, but these measures will take time to reverse the trend in youth use. Critically, since FDA's call to action last year, little has been done across the category beyond JLI's actions — either through industry support or actual regulation and enforcement. That is why FDA should move quickly to effectuate the considerations outlined in its Draft Guidance for broader application across industry.

Currently, the NYTS and other nationally-representative surveys are being fielded across the country to assess prevalence of tobacco use, including vapor products, among high- and middle-school students. While JLI is optimistic that its actions may have an impact for youth use of JUUL products, we cannot expect a significant change in the data until the Agency has imposed category-wide actions.

JLI will continue to lead the category, if only because it cannot fulfil its mission to eliminate cigarettes among adult smokers so long as youth use goes unabated. We have acted and will continue to do so because it is the right thing to do and because we must preserve this generational opportunity to drive adult smokers from the very products that will kill them.

Regards,

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JUUL Labs, Inc.