

March 23, 2020

By Electronic Submission

Jeffrey M. Zirger Information Collection Review Office Centers for Disease Control and Prevention 1600 Clifton Road NE, MS-D74 Atlanta, Georgia 30329

Re: Docket No. CDC-2019-0117; Comment on Proposed Data Collections Submitted for Public Comment and Recommendations, National Youth Tobacco Surveys (NYTS) 2021—2023

Dear Mr. Zirger,

JUUL Labs, Inc. (JLI or Company) appreciates the opportunity to comment on the proposed data collection submitted for public comment and recommendations by the Centers for Disease Control and Prevention (CDC) for the 2021–2023 National Youth Tobacco Surveys (NYTS).¹

Surveys such as NYTS are imperative to understanding underage tobacco-use behaviors and in developing effective, data-driven tobacco-control strategies. In particular, NYTS can help identify trends in tobacco use among those underage, how they are accessing these products, and why they are using them. From that, regulators, public health, and other stakeholders not only have a better understanding of tobacco-use patterns among minors, but also how to develop targeted measures to address core drivers of underage use like product access and product appeal.

The results from annual NYTS surveys not only inform tobacco-control measures implemented by regulators but also efforts adopted by manufacturers and others within industry to help prevent underage access and use of their products. The intent of this comment is to provide recommendations for CDC's consideration to continue to ensure the quality and utility of the data, so that we can collectively continue to take informed actions to reduce, and hopefully eliminate, the use of tobacco products, including JUUL products, among those who are underage.

¹ 85 Fed. Reg. 3916 (Jan. 23, 2020).

I. Introduction

CDC intends to request approval from the Office of Management and Budget (OMB), pursuant to the Paperwork Reduction Act of 1995 (PRA), to conduct "cycles of the NYTS in 2021, 2022, and 2023," during which "changes will be incorporated that reflect CDC's ongoing collaboration with [the U.S. Food and Drug Administration (FDA)] and the need to measure progress toward meeting strategic goals established by the Family Smoking Prevention and Tobacco Control Act" (Tobacco Control Act). Currently, CDC and FDA collaborate to administer NYTS "to monitor a variety of aspects of tobacco use, including trends in current tobacco use, exposure to tobacco marketing, susceptibility to use, use of flavored tobacco products," and to "learn whether there are differences in tobacco product use by different characteristics."

In addition, NYTS results "will continue to be used to inform and evaluate the National Comprehensive Tobacco Control Program; provide data to inform the Department of Health and Human Service's [sic] Tobacco Control Strategic Action Plan, and provide national benchmark data for state-level Youth Tobacco surveys," and are "expected to provide multiple measures and data for monitoring progress on seven tobacco-related objectives for Healthy People 2030."⁴

Accordingly, NYTS bears a necessary and critical role in efforts to identify and track tobacco-use patterns and other trends among high- and middle-school students. And data collected from NYTS have and will continue to inform and shape regulatory policy across multiple public health programs that aim to reduce and prevent underage use of tobacco products, including ENDS and other relatively new alternative tobacco products. As such, it is imperative that the study be designed to accurately and timely capture use patterns and specific use causes among minors, particularly in a rapidly evolving marketplace of tobacco and other nicotine products.

Pursuant to the PRA, CDC requests comments to help evaluate whether the proposed collection of information under NYTS "will have practical utility;" and "[e]nhance the quality, utility, and clarity of the information to be collected." 5

JLI offers the following comments and specific recommendations relating to NYTS. The information that follows is intended to respond to CDC's specific request for comment and more generally support CDC in the design, execution, and reporting of NYTS to

² *Id.* at 3917.

³ FDA, "Questions and Answers on the National Youth Tobacco Survey: How We Collect and Analyze Data to Understand Youth Tobacco Use," available at http://bit.ly/2PR4ael.

⁴ 85 Fed. Reg. at 3917.

⁵ *Id*.

continue to inform tobacco-control measures that address underage use of tobacco products, including ENDS like JUUL products.

I. OPPORTUNITIES TO ENHANCE THE QUALITY AND UTILITY OF NYTS DATA

A. Refining NYTS to better track the rapidly evolving marketplace for tobacco products and changes in use patterns

1. CDC should consider updating the survey instrument and frequency of administration

Over the last few years, the tobacco and nicotine product marketplace has evolved rapidly, coinciding with rapidly changing trends in underage use and behavior. Given this evolving landscape, research intended to monitor underage use and behavior, including NYTS, should be designed and administered to account for and respond to these changes. Otherwise, study results would not provide an accurate picture of underage tobacco use, minimizing the utility of the findings.

Against this backdrop, and as outlined further below, we encourage CDC to consider approaches that enable NYTS data to be collected more frequently and for the survey findings to reflect product-specific data that account for the various products in the marketplace, including both legally- and illegally-marketed products, and the various channels through which underage users access them.

For example, the questions and responses, as well as the overall format for NYTS, are developed one to three years before the surveys are administered in the field. Recently, however, products and brands have been coming on and off the market every few months. Moreover, the manner in which newer tobacco products are being accessed and used by minors, including through shared, social use, has changed dramatically. Future policy actions, such as the new federal minimum-purchasing age for tobacco products, will also impact these trends. As a result, the current survey and reporting regime may not be designed to provide stakeholders with timely and fully accurate data on underage-use patterns.

Furthermore, implementation of FDA's Final Guidance on *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* and the upcoming May 12, 2020 deadline for premarket submissions for deemed products will have a substantial effect on the marketplace.⁷

⁶ See, e.g., FDA, Final Guidance, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization 11–17 (Jan. 2020) [hereinafter Enforcement Priorities Guidance].

⁷ See, e.g., id. at 11.

Jeffrey M. Zirger March 23, 2020 Page 4

Although these measures along with robust FDA enforcement should limit the availability of unauthorized tobacco products, there also could be an increase in "black market" or otherwise illegal products entering the market.⁸ Consequently, by the time NYTS is administered in the field in 2021, 2022, and 2023, the survey itself might not accurately or fully reflect the marketplace for tobacco products and corresponding changes or trends in underage access, appeal, and use.

A different but related issue is the frequency with which NYTS is conducted and the duration of time taken to release the study results. Because NYTS is administered once per year, the results of each cycle provide a perspective that reflects the marketplace and underage response (i.e., access, appeal, and use) at a set point. In other words, NYTS results for a particular year provide only a snapshot in time in an otherwise rapidly shifting marketplace. Moreover, because study results generally are collected from February to May, and initial findings more recently have been released the following fall, by the time that snapshot is provided it might not be reflective of the most current trends, particularly with respect to underage use.⁹

In the long term, the marketplace should become more stable, with manufacturers submitting premarket applications for deemed products to FDA by May 12, 2020, coupled with robust enforcement against illegally marketed products. ¹⁰ In the meantime, studies like NYTS which monitor underage use and behavior may need to be more agile and capable of capturing trends as they evolve.

2. CDC should consider refining questions on product type and brand, frequency of use, and access to and appeal of tobacco products

Another issue that affects the quality and utility of NYTS data relates to product type and brand identifiers used in the survey. The current NYTS includes questions and answers

⁸ Id. at 28.

⁹ See, e.g., Office on Smoking and Health, Methodology Report of the 2019 National Youth Tobacco Survey (2019), available at

https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/zip_files/2019/2019-nyts-methodology-report.zip, at 1–2 (noting that the 2019 NYTS survey was administered from February 15 through May 24, 2019); Center for Tobacco Products, "Spotlight on Science – Winter 2020," available at http://bit.ly/39n56it (noting that initial 2019 NYTS results were published in a November 5, 2019 article and a December 6, 2019 Morbidity and Mortality Weekly Report (MMWR)).

¹⁰ See, e.g., Enforcement Priorities Guidance at 11 ("FDA intends to prioritize enforcement of any ENDS product that is offered for sale in the United States after May 12, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).").

listing specific types of tobacco products, as well as specific brands of tobacco products. There are clear benefits to asking respondents about specific classes or brands of tobacco products, including JUUL products, to monitor prevalence and use patterns. Doing so, without taking appropriate steps, however, could lead to underreporting of other tobacco product use behaviors, especially those involving product classes or brands not specifically listed. Such underreporting also could omit illegally-marketed products — including blackmarket products — that have evaded regulatory oversight and enforcement, thus making it even more critical to capture such responses.

In addition, questions on the number of days respondents use certain tobacco products could benefit from more granular follow-up questions on frequency of use within such periods and which products were specifically used (including by order). For example, information on how frequently respondents use tobacco products on the days that they reported using these products (e.g., daily), or the volume of product use, could provide additional — and potentially more relevant — information on underage exposure to and use of tobacco products. Analyses of NYTS data show that the majority of past 30-day underage ENDS product users report using these products on fewer than 10 days in the past month, and that most of these users have used other tobacco products as well, suggesting patterns of experimentation across types of tobacco products. Without more granular information, the survey may not capture a full picture of the true nature of underage use.

Importantly, NYTS questions also could be modified to better identify how underage users circumvent minimum-purchasing age laws and age-verification requirements to access tobacco products. 15 Research indicates that underage users

¹¹ See 2020 National Youth Tobacco Survey (NYTS), Questionnaire, Questions 12–13 (asking respondents which brand of ENDS product they used, and specifically listing the following brands: blu, JUUL, Logic, NJOY, SMOK, Suorin, and Vuse).

¹² See 2020 NYTS, Questionnaire, Questions 8-9, 25, 37, 46, 50, 57-58, 107-112.

¹³ See, e.g., Inter-University Consortium for Pol. and Soc. Res., "Population Assessment of Tobacco and Health (PATH) Study [United States] Restricted-Use Files, Wave 4: Youth / Parent Questionnaire (English Version)," https://www.icpsr.umich.edu/files/NAHDAP/pathstudy/36231-4002-Questionnaire-English.pdf, at 140, 316, 346 (questions about how many times a day a respondent refills e-liquids, uses smokeless tobacco, and uses snus).

¹⁴ See, e.g., R. West et al., "Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey reveal about high school e-cigarette use in the USA?" *Qeios* (Oct. 7, 2019), https://www.qeios.com/read/article/391.

¹⁵ See 21 U.S.C. § 387f(d)(1), (3)(A)(ii); 21 C.F.R. § 1140.14(a)(2), (b)(2). Under the Tobacco 21 legislation, Congress amended section 906(d) of the FDCA by raising the minimum age to purchase tobacco products from 18 to 21 years, and adding a provision stating that "It shall be unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age." See Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, Div. N, tit. I, § 603(a) (Dec. 20, 2019). The Tobacco 21 legislation also requires that

continue to obtain tobacco products not only through brick-and-mortar retailers with inadequate age-verification measures, but also through social sourcing and shared use, which lack age-verification safeguards altogether. ¹⁶

While NYTS currently asks respondents where they obtained tobacco products and lists potential sources, the survey does not ask questions designed to identify and track how respondents were able to circumvent the federal legal age of access and ageverification requirements. The For example, NYTS could include follow-up questions asking: (i) if the respondent purchased a tobacco product at a brick-and-mortar retailer, whether the respondent was required to provide identification verifying their age; (ii) if the respondent purchased a tobacco product through an online retailer, whether the respondent was required to pass age-verification measures, such as providing detailed personal information or uploading government-issued identification; (iii) if the respondent obtained a tobacco product from another commercial source, whether the respondent was requested to prove or otherwise demonstrate they were at least 21 years of age. The responses to such follow-up questions would provide more granular data that could help regulators and policymakers evaluate the progress of laws raising the minimum-purchasing age to 21 years and imposing new age-verification measures.

Finally, NYTS questions could be modified to better evaluate the impact of marketing exposure, channels and sources of promotion to those underage, and whether there are differences between marketing from product manufacturers versus third parties. In addition, the questions could be amended to better assess exposure to and the impact of other pro-tobacco influences, such as social-media posts by peers. These, too, are evolving areas, and the results could inform regulatory policy relating to marketing strategies that can impact underage appeal. ¹⁸ For example, although the 2020 NYTS asks questions about how often respondents see advertisements or promotions for ENDS products through

FDA publish a final rule within 180 days of enactment updating its age verification requirements under 21 C.F.R. Part 1140 to require age verifications for "individuals under the age of 30." *Id.*, Div. N., tit. I, § 603(b)(1).

¹⁶ See, e.g., Enforcement Priorities Guidance at 46 (in response to public comments that "[purchasing] from other adolescents is a major factor driving ENDS usage in youth populations," stating that "FDA agrees that social sources remain a concern for ENDS and other tobacco products."); Centers for Disease Prevention and Control (CDC), Youth Risk Behavioral Survey (YRBS) (2017); S. Liu et al., "Youth Access to Tobacco Products in the United States, 2016–2018," 5 Tobacco Reg. Sci. 491 (2019); D. Mantey et al., "Retail Access to E-cigarettes and Frequency of E-cigarette Use in High School Students," 5 Tobacco Reg. Sci. 280 (2019); "Some FDA Claims About Teen Vaping Confirmed, Others Evaporate," *Tobacco Truth* (Apr. 2, 2019), https://rodutobaccotruth.blogspot.com/2019/04/some-fda-claims-about-teen-vaping.html.

¹⁷ See 2020 NYTS, Questionnaire, Question 15 (asking respondents, "During the past 30 days, where did you get or buy the e-cigarettes that you have used?" and listing sources such as a "gas station or convenience store," "grocery store," "drugstore," "vape shop," "[o]n the Internet," or "[f]rom a family member," "friend," or "some other person that is not a family member or a friend").

¹⁸ See, e.g., Enforcement Priorities Guidance at 24–27.

various platforms (e.g., Internet, in print media, in retail outlets, on television and streaming services, social media), they do not specify the source or owner of the advertisement or social-media posts. 19

3. CDC should consider maintaining and refining questions on cannabisrelated use to differentiate among "vaping products"

In recent years, while there has been an increase in underage use of ENDS, there has been a similar trend in the use of cannabis-based vaping products. 20 In the 2019 MTF survey results, for example, "marijuana vaping" within the past year among 12th graders increased from 13.1% to 20.8% from 2018 to 2019, while past 30-day use increased from 7.5% to 14.0%. 21 For 10th graders, use within the past year increased from 12.4% to 19.4%, while past 30-day use increased from 7.0% to 12.6%. 22

Given the significant difference between ENDS products and cannabis-based vaping products yet contemporaneous increases in underage use, JLI believes NYTS should continue to distinguish vaping products between those that contain nicotine and those that contain other substances, including cannabis-based substances, to monitor and assess underage use.

From at least 2016 to 2018, NYTS asked "Have you ever used an e-cigarette device with a substance besides nicotine?" Potential responses included: "Yes, I have used an e-cigarette device with Marijuana, THC or hash oil, or THC wax." ²³ Yet the 2019 NYTS no longer included that question or any question asking whether the respondent was using a vaping product that include a substance other than nicotine. Rather, in describing what "e-cigarettes" are, the survey merely references that "E-cigarettes are battery powered devices that *usually contain* a nicotine-based liquid that is vaporized and inhaled." ²⁴ And in the current questionnaire for 2020, there is only one question on "vaping marijuana,"

¹⁹ 2020 NYTS, Questionnaire, Questions 102–106.

²⁰ See Monitoring the Future National Survey Results on Drug Use (1975–2019), "2019 Overview: Key Findings on Adolescent Drug Use" (2019) [hereinafter MTF 2019 Survey], available at http://www.monitoringthefuture.org//pubs/monographs/mtf-overview2019.pdf.

²¹ See id.; see also University of Michigan Institute for Social Research, "National Adolescent Drug Trends in 2019: Findings Released, Marijuana Vaping Surges" (Dec. 18, 2019), available at http://monitoringthefuture.org//pressreleases/19drugpr.pdf.

²² See 2019 MTF Survey.

²³ See, e.g., 2016 NYTS, Questionnaire, Question 37.

 $^{^{24}}$ See 2019 NYTS, Questionnaire, Instruction 5 (emphasis added). JLI notes that it appears NYTS has used this descriptor consistently to define "e-cigarettes" over the years.

which sits within the more detailed questions on e-cigarette use: "Have you ever vaped marijuana or cannabis (including concentrates, waxes, or hash oils)?" ²⁵

In retaining questions that account for and track use of vaping products that contain substances other than nicotine, including cannabis-based substances, NYTS also may consider further distinguishing the products to avoid potential confusion in responses and reasons for use. The term "e-cigarette" or "electronic cigarette" generally has been used to refer to products that contain nicotine and deliver the substance through aerosolization, as opposed to conventional cigarettes that deliver it through combustion. ²⁶ Cannabis-based vaping products, however, are an entirely different product type, which deliver substances that remain illegal under federal law in any form, including THC waxes and oils, and are used for presumably different purposes. To remedy the confusion and better assess use patterns across these very different product classes, JLI suggests breaking out vaping products that deliver nicotine from vaping products that deliver other substances, while adding specific questions on use patterns and reasons for use for the latter. ²⁷

By clearly distinguishing between, and asking separately about, product types that deliver nicotine and those that deliver other substances, CDC would elicit more accurate responses on precisely which products minors are using, how they are accessing them, and why they are being used. These data are even more critical in light of the alarming, recent spate of respiratory-related illnesses that have been associated with cannabis-based vaping products, specifically with the ingredient Vitamin E acetate. With such data in advance, CDC, public health officials, and other stakeholders can implement appropriate measures, including education and awareness, to address underage use of these products.

4. Specific recommendations for CDC's consideration

To address the issues described above and improve the quality and utility of the NYTS data in a rapidly evolving landscape, JLI recommends that CDC consider:

²⁵ See 2020 NYTS, Questionnaire, Question 21.

²⁶ See, e.g., U.S. Dep't of Health and Hum. Servs., E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General (2016), available at https://e-cigarettes.surgeongeneral.gov/documents/2016 SGR Full Report non-508.pdf, at 3; FDA, Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS), https://www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends (last visited Mar. 22, 2020).

 $^{^{27}}$ See, e.g., 2020 NYTS, Questionnaire, Questions 6–20; 2019 NYTS, Questionnaire, Questions 34–38 and 41–46.

²⁸ See generally CDC, "Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products," https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

- Updating the survey questions and response options annually and at a date closer to the actual fielding of the survey, at least for the next three years;²⁹
- In addition to the in-classroom annual survey, administering shorter online surveys that could be completed at home, and would supplement the data and monitor potential changes in prevalence of underage use of tobacco products more frequently or on a more rapid timeline;
- Updating questions that identify specific classes or brands of tobacco products annually or semi-annually to better respond to the marketplace;
- Adding follow-up questions on frequency and order of tobacco product use during report use periods (e.g., daily use);
- Adding follow-up questions on how respondents are able to purchase products at brick-and-mortar or online retail outlets, in light of federal age restriction and verification requirements;
- Incorporating questions with additional granularity on social sourcing, such as
 the relationship between the respondent and the social source; and, whether the
 tobacco products in question are being shared, purchased third-hand, or
 provided for free for individual use;
- Incorporating questions with additional granularity on whether product advertising and promotion are generating brand awareness and encouraging product use and why;
- Adding questions on whether respondents differentiate company-sponsored advertisements from unaffiliated, third-party promotion;

²⁹ Historically, CDC has submitted its proposed data collections for NYTS once every three years. *See, e.g.,* 85 Fed. Reg. at 3916; 82 Fed. Reg. 47740 (Oct. 13, 2017) (PRA notice for 2018-2020 NYTS); 79 Fed. Reg. 36067 (June 25, 2014) (PRA notice for 2015-2017 NYTS). However, agencies can request PRA review for proposed information collections covering shorter periods of time. *See* 44 U.S.C. § 3507(g) (allowing OMB to approve collections of information for up to three years). For example, CDC submitted a PRA notice for a computer-based pilot for the 2017 NYTS in between the PRA notice for the 2015–2017 NYTS and the PRA notice for the 2018-2020 NYTS. 81 Fed. Reg. 52868 (Aug. 10, 2016). And, CDC also has submitted PRA notices for additional information collections for another tobacco product study, YRBS, in between its general three-year PRA notices (note that YRBS is conducted every other year). *See* 72 Fed. Reg. 9949 (Mar. 6, 2007) (PRA notice for study examining web-based administration of YRBS, issued between the PRA notices for the 2005–2007 and 2009–2011 YRBS); 73 Fed. Reg. 8875 (Feb. 15, 2008) (PRA notice for 2009-2011 YRBS); 69 Fed. Reg. 17669 (Apr. 5, 2004) (PRA notice for 2005–2007 YRBS).

- Adding questions on whether respondents are exposed to non-commercial social media posts, such as those posted by peers, along with follow-up questions on the potential impact of such exposure; and
- Retaining and refining separate questions that assess use of vaping products
 with substances other than nicotine, including cannabis-based substances, and
 adding prompts that identify use patterns, access points, and reasons for use
 associated with non-nicotine vaping products.

B. Addressing potential methodological bias to improve the reliability of NYTS reporting

Under the current survey approach, there is some potential for methodological bias that could cause respondents to under-report or misreport product use behaviors, resulting in deficient or inaccurate responses to act upon. First, published literature has shown that the setting in which a survey is administered, particularly one asking underage respondents to report potentially risky behavior, could impact the accuracy of what they report. In particular, in-school surveys where students are surrounded by peers may result in exaggerated, less truthful responses, as opposed to in-home, online surveys. There also may be time constraints arising from having to complete surveys during class periods that limit respondent consideration of key questions, which are less likely to exist outside of the school setting. The setting is some potential by the setting is some potential by a setting in the setting is some potential by a setting in the setting in the setting is some potential by a setting in the setting in the setting is some potential by a setting in the setting in the setting is some potential by a setting in the setting in the setting is some potential by a setting in the setting in the setting is some potential by a setting in the setting in the setting is some potential by a setting in the setting in the setting is some potential by a setting in the setting in the setting in the setting in the setting is some potential by a setting in the setting in

Second, the published literature also demonstrates that the order of questions, as well as the order of response options, can impact responses. When asked to select which tobacco products they use from a list, underage respondents tend to select options presented first; and, when asked in a series of yes/no questions which tobacco products they use, they more frequently report use of tobacco products asked about first.³²

Third, users may report using certain ENDS product brands when prompted by name, but may not report those very same products if they are shown an image of the ENDS

³⁰ See, e.g., N. Brener et al., "The Association of Survey Setting and Mode with Self-Reported Health Risk Behaviors among High School Students, 70 Pub. Op. Quarterly 354, 370 (2006).

³¹ See, e.g., FDA, "Questions and Answers on the National Youth Tobacco Survey: How We Collect and Analyze Data to Understand Youth Tobacco Use," available at http://bit.ly/2PR4ael.

³² See, e.g., A. Johnson et al., "Impact of Question Type and Question Order on Tobacco Prevalence Estimates in US Young Adults: A Randomized Experiment," 21 Nicotine & Tobacco Res. 1144 (2019); C. Delnevo et al., "Importance of Survey Design for Studying the Epidemiology of Emerging Tobacco Product Use Among Youth," 186 Am. J. Epidemiology 405 (2017); A. O'Halloran et al., "Response order effects in the Youth Tobacco Survey: Results of a split-ballot experiment," 7 Survey Practice, no. 3, at 5 (2014).

product and asked about using it.³³ Consequently, without adequate product images, there is potential for respondents to misreport the types of products and brands they actually use, particularly for well-known products or products that generally appear similar in type and design.

Fourth, there is potential for respondents to inaccurately identify tobacco products obtained through social sourcing or shared use. Social sourcing — for example, when underage users obtain tobacco products through of-age purchasers, such as friends, family, or strangers — is a major pathway for underage access to ENDS products.³⁴ And as NYTS and other surveys have observed, it is not uncommon for underage users to share ENDS products in social settings.³⁵ Both of these avenues for underage use could present challenges for identifying specific products, particularly if they are not presented in manufacturer packaging and resemble other products in the market.

To address the issues described above and improve the quality and utility of the NYTS data, JLI recommends that CDC consider:

 Supplementing administration of NYTS with online or short/rapid response surveys in between annual iterations of the survey, over the course of the spring semester in classrooms;

³³ See, e.g., C. Russell et al., Abstract, "Variation in Self-Reported Use of the JUUL Vaping Device between Survey Measures of Respondents' Verbal Recognition and Visual Recognition of the JUUL Brand," in Soc'y for Res. on Nicotine and Tobacco, "SRNT 26th Annual Meeting, New Orleans, March 11–14, 2020; Rapid Response Abstracts" (Feb. 28, 2020), available at

https://cdn.ymaws.com/www.srnt.org/resource/resmgr/conferences/2020 annual meeting/SRNT20 Rapid Abstracts 02272.pdf. In light of travel restrictions and other measures taken as a result of COVID-19, the scientific poster for this abstract was not presented at SRNT. JLI expects additional findings and information from this survey to be published or otherwise made publicly available in the coming months.

³⁴ See, e.g., Enforcement Priorities Guidance at 46 (in response to public comments that "[purchasing] from other adolescents is a major factor driving ENDS usage in youth populations," stating that "FDA agrees that social sources remain a concern for ENDS and other tobacco products."); CDC, Youth Risk Behavioral Survey (YRBS) (2017).

³⁵ See, e.g., Enforcement Priorities Guidance at 46 (in response to public comments that "[purchasing] from other adolescents is a major factor driving ENDS usage in youth populations," stating that "FDA agrees that social sources remain a concern for ENDS and other tobacco products."); Centers for Disease Prevention and Control (CDC), Youth Risk Behavioral Survey (YRBS) (2017); S. Liu et al., "Youth Access to Tobacco Products in the United States, 2016-2018," 5 Tobacco Reg. Sci. 491 (2019); D. Mantey et al., "Retail Access to E-cigarettes and Frequency of E-cigarette Use in High School Students," 5 Tobacco Reg. Sci. 280 (2019); "Some FDA Claims About Teen Vaping Confirmed, Others Evaporate," *Tobacco Truth* (Apr. 2, 2019), https://rodutobaccotruth.blogspot.com/2019/04/some-fda-claims-about-teen-vaping.html.

- Rotating the presentations of questions and response order, particularly for brand-specific questions across respondents, to account for potential bias from the order of the presentation;
- Providing non-branded product images to better enable respondents to accurately identify products and brands, particularly those that may appear similar and which respondents may confuse with one another,³⁶ similar to that provided in the PATH study;³⁷ and
- Incorporating questions about potential social sourcing and shared use when asking respondents to identify specific products they have used.

JLI appreciates the opportunity to comment on CDC's proposed collection of information. The annual NYTS serves as a platform to capture and understand the evolving tobacco-use patterns among those underage. Underage use of traditional tobacco products, such as combustible cigarettes, has declined significantly over the last several years. But the recent increases in ENDS use highlight a rapidly evolving marketplace of alternative tobacco products and corresponding change in underage use patterns. Moreover, with the advent of new technologies — including online sellers and open-access, social-media platforms — and with continuing trends of social sourcing and shared use, minors have unprecedented, unrestricted access and exposure to these newer tobacco products.

We hope that NYTS can continue to provide valuable information in understanding underage use patterns as they continue to evolve and inform additional control strategies to address and ultimately prevent such use of tobacco products.

Sincerely,

Jose Luis Murillo

³⁶ See, e.g., Russell, supra note 33.

³⁷ See, e.g., Inter-University Consortium for Pol. and Soc. Res., "Population Assessment of Tobacco and Health (PATH) Study [United States] Restricted-Use Files, Wave 4: Youth / Parent Questionnaire (English Version)," https://www.icpsr.umich.edu/files/NAHDAP/pathstudy/36231-4002-Questionnaire-English.pdf, at 79.

³⁸ See generally Enforcement Priorities Guidance at 6–9.