

Exhibit 7

Title: 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 six months.

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ABSTRACT

Background: JUUL is the fastest growing and highest selling brand of e-cigarette/vapor products in the United States. Assessing the effect of JUUL vapor products on adult smokers' use of conventional tobacco cigarettes can help inform the potential population health impact of these products.

Methods: A non-probabilistic sample of 15,456 U.S. adults (21+ years), all of whom were established current smokers of conventional cigarettes, were recruited at their first purchase of a JUUL Starter Kit from a retail store or JUUL's website. Online surveys assessed past 30-day use of conventional cigarettes, JUUL vapor products, and other e-cigarettes/vapor products at three and six months. Logistic regression models examined factors associated with smokers' odds of self-reporting past 30-day abstinence from cigarette smoking at six months.

Results: Past 30-day smoking abstinence at six months was 31.6% in the intent-to-treat (ITT) sample ($n = 15,456$) and 54.0% among those who responded at six months ($n = 9,040$; 58.5% of ITT). Covariate-adjusted odds for reporting past 30-day smoking abstinence at six months were significantly higher among those who had primarily used Mint or Mango flavored JUULpods (versus Virginia Tobacco flavor) in the past 30 days; had exclusively used JUULpods in characterizing flavors (versus tobacco flavors) in the past 30 days; used a JUUL vaporizer on all 30 of the past 30 days; purchased their first JUUL vaporizer in a retail store (versus online) ; and first purchased a JUUL Starter Kit to help quit smoking completely. Adjusted odds for reporting past 30-day smoking abstinence were significantly lower among those who, at study enrolment, had smoked regularly for ≥ 20 years, smoked ≥ 20 cigarettes per day, and smoked on all 30 of the previous 30 days.

Conclusions: Around one-third of enrolled smokers and one-half of smokers who completed the study were past 30-day abstinent from cigarette smoking after using a JUUL vaporizer for six months. More frequent use of a JUUL vaporizer and primary use of JUULpods in characterizing flavors, particularly Mint and Mango, appear to be important to new JUUL users' chances of quitting smoking. The impact of suspending retail sales of flavored JUULpods on adult smokers' likelihood of quitting should be closely assessed.

Background

Tobacco harm reduction (THR) products and policies aim to prevent or reduce harm by promoting substitution of combustible tobacco with less hazardous non-combustible sources of nicotine to smokers who are unable or unwilling to quit smoking in response to conventional tobacco control measures.¹ Tobacco and nicotine products that present a reduced risk of ill health to an individual relative to smoking cigarettes have potential to benefit the health of the whole population to the extent that (I) they are used in place of more harmful tobacco products (e.g. cigarettes) by individuals who currently use such products *and* were unlikely to have quit or reduced their use of such products in the absence of the reduced-risk product, *and* to the extent that (ii) they are not used by individuals who are not current users of more harmful tobacco products *and* would likely have not initiated or re-initiated use of such products in the absence of the reduced-risk product.

Electronic cigarettes (e-cigarettes) – hand-held devices that use battery power to heat a solution of propylene glycol, glycerol and often flavorings and nicotine, to produce an aerosol that the user inhales – have emerged in the past decade with the greatest potential for meeting criteria for definition as tobacco harm reduction products. Since their introduction to U.S. market in 2007, e-cigarettes have rapidly grown in popularity among adults in several countries as an alternative to smoking conventional cigarettes,^{2, 3, 4, 5, 6} and the increasing use of e-cigarettes has been associated with significant increases in rates of smoking cessation at the population level.^{7 8 9 10} E-cigarettes are now the most popular assisted method of quitting smoking in the United States, used in 35% of smokers' most recent quit attempts.¹¹ By comparison, nicotine patches or gums were used in 25% of most recent quit attempts. Though data on the safety of long-term use of nicotine by inhalation will not be available until e-cigarettes have been in widespread use for several decades, several U.S. and global health authorities agree that currently available evidence suggests e-cigarette use is likely to be less harmful than smoking cigarettes. The magnitude of potential reduced harm to the individual user and the potential impact of e-cigarettes on the health of whole populations, however, continues to be debated.¹²

JUUL Labs Inc. is a San Francisco-based company that manufactures pre-filled e-liquid cartridges known as 'JUULpods' for use in an Electronic Nicotine Delivery System (ENDS) known as 'JUUL vaporizer'. JUUL is the fastest growing and highest selling e-cigarette/vapor product in the U.S. market, which is sized at approximately \$5.5 billion for 2018.¹³ According

to Nielsen data, past 52-week retail sales of JUUL products in the U.S. increased from \$150.0 million in July 2017 (+652.9% versus July 2016)¹⁴ to \$1.3 billion in August 2018 (+761.4% versus August 2017)¹⁵, making JUUL the first e-cigarette brand to record over \$1 billion in sales in a 52-week period through tracked channels. With a past 52-week sales total more than three times higher than its nearest competitor (an e-cigarette called VUSE, \$404.0 million), JUUL now has a greater past 52-week share of the U.S. e-cigarette market than all other e-cigarette brands combined, having increased its market share from 17.7% in July 2017 to 55.7% in August 2018.^{5, Foot 1} Assessing the potential population health impact associated with the rapid and substantial increase in sales of JUUL vapor products in the United States has become vitally important.

According JUUL's website, JUUL vapor products are intended for adult smokers who want to switch from combustible cigarettes. Under the Modified Risk Tobacco Product (M RTP) provision and the drug provisions in section 911 and section 201(g) of the Federal Food, Drug & Cosmetic Act (FD&C) respectively, manufacturers are prohibited from marketing a new tobacco product, including JUUL vapor products, as a safer, healthier, or less risky alternative to smoking tobacco, or effective as an aid to smoking cessation. Yet, anecdotal user testimonies, many of which are shared daily on social media platforms and internet discussion forums dedicated to vaping (e.g. E-Cigarette Forum), suggests many adult smokers in the United States are using or have used JUUL vapor products to help them to quit smoking completely or to cut down the number of cigarettes they smoke. There are no published data, however, on the likelihood that adult tobacco smokers who begin using a JUUL vaporizer then switch completely to use of a JUUL vaporizer, or the likelihood that adult tobacco smokers who begin using a JUUL vaporizer then continue to use a JUUL vaporizer in addition to continuing to smoke conventional cigarettes. Additionally, no data are available on the user characteristics and product use factors that are positively and negatively associated with smokers' likelihood of quitting smoking through use of a JUUL vaporizer. Previous research has, for example, identified the frequency with which smokers use e-cigarettes and the use of e-cigarettes containing non-tobacco flavors as important determinants of a smokers' likelihood of completely substituting e-cigarettes for conventional cigarettes.^{16 17 18 19 20 21}

¹ Nielsen notes these are likely to be underestimates of JUUL's true sales and market share, as Nielsen does not track sales through several channels where JUUL products are sold, such as online and vape shops.

Understanding the role that flavors play in the population's use of e-cigarettes, and the impact that flavored e-cigarette products have on the population's use of more harmful tobacco products, like conventional cigarettes, has been identified by the U.S. Food and Drug Administration (FDA) as a public health research priority. The ability to inhale e-cigarette vapor aerosol in a vast and growing variety of characterizing flavors – a distinguishable taste or aroma, other than the taste or aroma of tobacco – is thought to be a major feature accounting for the appeal of e-cigarettes to adult smokers as an alternative to continuing to smoke cigarettes. However, the same concerns that led the U.S. Congress to ban the sale of cigarettes with characterizing flavors in 2009 now exist for e-cigarettes. In particular, concerns have been raised, and some evidence has been reported, that non-tobacco flavored ENDS products, particularly fruit and sweet e-liquid flavors, are driving the appeal of e-cigarettes to youth, and that youth who initiate nicotine use through ENDS products will be more likely to subsequently try using more harmful tobacco products that deliver nicotine more efficiently, such as cigarettes.^{22 23 24 25 26 27 28} FDA Commissioner, Scott Gottlieb, has summarised the need to weigh the potential risks and benefits of flavored ENDS products to the whole population: "it possible for flavors to do both harm and good... On this issue, we see two sides – on the one hand, we need to know the role that flavors, including menthol, play in attracting youth to initiate tobacco use. But on the other hand, we also need to know whether...certain flavors may help adult cigarette smokers switch to potentially less harmful forms of nicotine delivery" such as e-cigarettes."²⁹ Collecting data that characterize the association between adults' use of flavored JUUL vapor products – the most widely used brand of vapor products in the United States – and their likelihood of quitting smoking in the short and long-term is therefore vitally important to estimating the potential population health impact of these products.

Through online surveys of a cohort of U.S. adult established current smokers, this study examined demographic, smoking-related and JUUL-related factors associated with self-reported past 30-day abstinence from cigarette smoking at six months after their naturalistic first purchase of a JUUL vaporizer in a retail store or at JUUL's e-commerce store. Of specific interest was the extent to which smokers' odds for reporting past 30-day smoking abstinence varied as a function of their frequency of use of JUUL refill pods in six non-tobacco flavors (versus two tobacco flavors).

Methods

Sample and recruitment

Eligible individuals were U.S. adults aged 21 years and older who had smoked at least 100 cigarettes in their lifetime, now smoke cigarettes ‘every day’ or on ‘some days’, and had purchased their first JUUL vaporizer Starter Kit from a U.S. retail store or through JUUL Labs Inc.’s e-commerce store at www.juulvapor.com within the past seven days. *Veratad Technologies*’ age verification software, *AgeMatchSM*, was employed by JUUL Labs Inc. to verify, at the point of an attempted online purchase, that individuals were of aged 21 years or older. A JUUL vaporizer Starter Kit contains a JUUL vaping device, a USB charging dock and one refill pod in each of four flavors (1x Virginia Tobacco, 1x Cool Mint, 1x Mango and 1x Crème Brûlée). Each JUUL vaporizer refill pod contains 5% nicotine by weight, and each refill pod contains 0.7ml, equivalent to 59mg/ml nicotine per refill pod.

Individuals were invited to participate in this study in two ways. First, JUUL Labs Inc. sent email invitations to 37,536 age-verified adults who had purchased a JUUL vaporizer Starter Kit through JUUL’s e-commerce store between 4 April 2018 and 25 June 2018. The email invited individuals to participate in a six-month online survey study about their use of combustible cigarettes, JUUL vaporizer products, and other e-cigarettes and vapor products. Invitations were sent to the email address associated with a customer’s age-verified verified account. Email invitations containing a web-link to the survey were scheduled to be sent to these individuals approximately four days after completing their online purchase of a JUUL vaporizer Starter Kit so as to be received by the individual within 1-2 days after the scheduled delivery of their purchased product(s).

Second, individuals who purchased a JUUL vaporizer Starter Kit in a retail store were invited to participate via 3” x 2.5” cards that were manually inserted into the packaging of 500,000 JUUL vaporizer Starter Kits, which were then distributed at random to approximately 10,000 licensed store retailers of JUUL vaporizer products across the United States. Starter Kits containing invitation cards were distributed across April 2018. Printed on each invitation card insert was the invitation text, the survey web address, and a unique six-digit alphanumeric code. Individuals who purchased a JUUL vaporizer Starter Kit that contained an invitation card insert were invited to type the survey web address – survey.juul.com – into their web browser, and

then, when prompted, type the six-digit code displayed on their invitation card insert. Entry of a valid code routed the individual to an Account Creation webpage, and then to the study Informed Consent Form. Each six-digit code was valid for one entry; attempts to re-use the code were blocked. Requiring the entry of a unique, one-time access code ensured that only individuals who had purchased a JUUL vaporizer Starter Kit in a retail store could proceed to the Account Creation webpage, and requiring individuals to create a user account ensured that only one survey could be completed per account.

Procedure

The first page of the survey displayed an Informed Consent Form (available upon request), which described the purpose of the survey, the names and contact details of the study investigators, information about who is eligible to take part and how survey data will be used, assurances of participant anonymity and confidentiality, and the source of funding for this study. Participants were informed that they were being invited to take part in six monthly online surveys about their use of combustible cigarettes, JUUL vaporizer products and other e-cigarettes and vapor products. Individuals who satisfied eligibility criteria and gave informed consent to participate began the survey. Participants were routed to questions that were applicable to them on the basis of a response or combination of responses to a previous question or questions. The survey instrument was designed with the assumption that all respondents to a question would be asked the next question, unless there were specific instructions routing a subgroup of respondents to a different question. Participants answered survey questions at their own pace. If a participant did not complete the survey, all data provided up to the point of exit from the survey was excluded from analysis.

The baseline survey took around 15-20 minutes to complete. Participants who completed the baseline survey received an automated email invitation to complete a follow-up survey every 30 ± 5 days for the next six months. An email invitation to participate in a follow-up survey was configured to be sent automatically to participants 25 days after the date of completion of the previous survey, with reminder emails sent 28 days and 31 days after the date of completion of the previous survey. Web-link access each follow-up survey expired 10 days after the first email invitation was sent. Participants received a USD\$30 virtual Visa Reward Card by email for each survey they completed.

Measures

Cigarette smoking in the past 30 days

The primary outcome measure in this study was self-reported past 30-day abstinence from cigarette smoking, which was determined at each assessment by a “No” response to the question, “In the past 30 days, have you smoked a cigarette, even one or two puffs?” Participants who indicated they have smoked a cigarette in the past 30 days were asked two further questions about their frequency of smoking in the past 30 days – “Do you now smoke cigarettes...” (every day; some days; not at all), and “On how many of the past 30 days did you smoke cigarettes?” (numeric response, 1-30), and one question about their intensity of smoking in the past 30 days – “On those days that you did smoke, how many cigarettes did you usually smoke each day? A pack usually has 20 cigarettes in it”. Participants who did not provide answers to these four questions at the baseline assessment were excluded from the analytic sample.

Cigarette smoking history

Questions assessed the age at which participants first smoked a cigarette, first started smoking regularly, the number of months/years for which participants had been smoking cigarettes regularly, and the number of cigarettes participants had smoked in their lifetime.

Use of a JUUL vaporizer and JUULpods flavors in the past 30 days

Questions assessed the number of days in the past 30 days on which participants had used a JUUL vaporizer and the total number of JUUL vaporizer refill pods they had consumed in each of eight commercially available flavors (Virginia Tobacco, Mint, Mango, Crème, Fruit, Cucumber, Classic Tobacco and Menthol) in the past 30 days. Participants were coded as a ‘primary user’ of a specific flavor of JUULpods when they reported having consumed more pods in that flavor than in any other flavor. For example, a participant who reported having consumed 10 Mango flavored JUULpods and 5 Mint flavored JUULpods in the past 30 days would be coded as a primary user of Mango flavored JUULpods.

Participants were coded as ‘past 30-day exclusive users to tobacco flavors’ if they reported use of only Virginia Tobacco and/or Classic Tobacco flavored JUULpods in the past 30days. Participants were coded as ‘past 30-day exclusive users to characterizing flavors’ if they reported use of only Mint, Mango, Crème, Fruit, Cucumber and/or Menthol flavored JUULpods in the past 30 days. Participants were coded as ‘past 30-day users of both tobacco and characterizing flavors’ if they reported consumption of at least one pod in Virginia Tobacco or Classic Tobacco flavor and at least one pod in Mint, Mango, Crème, Fruit, Cucumber or Menthol flavor.

Use of e-cigarettes other than a JUUL vaporizer in the past 30 days

Participants were asked if they had used any brand of e-cigarette or vaping device other than a JUUL vaporizer in the 30 days prior to each assessment.

Reasons for purchasing and using a JUUL vaporizer Starter Kit

At the baseline assessment, participants were asked to identify which, if any, of a list of health, social, financial, sensory and convenience reasons were reasons why they first decided to purchase a JUUL Starter Kit.

Demographics

Questions assessed sex, age, race-ethnicity, educational attainment, annual household income and census region of participants’ residence.

Data Analysis

Rates of past 30-day abstinence from smoking at the 3-months and 6-months follow-up assessments are reported for the intention-to-treat (ITT) sample (N = 15,456) that completed the baseline assessment. At each follow-up assessment, participants with a missing response to the question “In the past 30 days, have you smoked a cigarette, even one or two puffs?” were

recoded as ‘smoked in the past 30 days’ under the worst-case scenario assumption that these participants had returned to baseline patterns of cigarette smoking.

Rates of past 30-day abstinence from smoking at the 3-months and 6-months follow-up assessment are also reported for efficacy subsets of participants who provided smoking data at the 3-months assessment ($n = 9,272$, 60.0% of the ITT sample) and the 6-months assessment ($n = 9,040$; 58.5% of the ITT sample), respectively. A rate of past 30-day abstinence from smoking at *both* the 3-months assessment *and* the 6-months follow-up assessment is also reported for an efficacy subset of 7,726 participants comprising those who provided smoking data at *both* the 3-months assessment *and* at the 6-months assessment. Rates of past 30-day point prevalence abstinence from smoking observed in the ITT sample and in the efficacy subset samples were considered as lower and upper bound estimates of the rates of past 30-day point prevalence abstinence from smoking at each follow-up assessment.

Analyses of change in the past 30-day total number of cigarettes smoked between the baseline assessment and the 6-months assessment were restricted to participants ($n = 6,066$) who reported both (i) the number of days on which they had smoked any cigarettes in the 30 days prior to each assessment; and (ii) the number of cigarettes they typically smoked on each smoking day. The answers to these two questions were multiplied to give an estimate of the total number of cigarettes smoked by each participant in the 30 days prior to each assessment. Analyses compared estimates of the total sample number of cigarettes smoked in the 30 days prior to assessments at baseline, three months and six months.

Factors associated with past 30-day abstinence from smoking at the 6-months assessment were examined through two logistic regression models, with each model conducted in two steps. In Model 1 Step 1, six demographic variables (age, sex, race/ethnicity, annual household income, education level, and U.S. census region); four smoking history variables (age of first smoking, lifetime years of regular smoking, number of smoking days in the 30 days prior to the baseline assessment, number of cigarettes smoked per day in the 30 days prior to the baseline assessment); one e-cigarette use variable (past 30-day use of a secondary e-cigarette), and four JUUL use variables (place of first JUUL purchase, number of days of JUUL use in the past 30 days, primary JUULpods flavor used in the past 30 days, and having purchased a JUUL vaporizer to help quit smoking) were entered as predictor variables. To assess the extent to which the effect of participants’ primary use of JUUL pod flavors on past 30-day abstinence

from smoking at the 6-months assessment varied by place at which participants purchased their first JUUL Starter Kit, an interaction term for ‘primary JUUL pod flavor use’*‘place of first purchase of a JUUL Starter Kit’ was entered at Step 2.

Model 2 replicated Model 1 with the variable ‘primary JUULpods flavor used in the past 30 days’ replaced by the variable ‘JUUL pod flavors used regularly in the past 30 days’. Odds ratios are reported unadjusted and adjusted for the effects of other variables in the model. Odds ratios in these regression models indicate the proportionate change in a participant’s odds of self-reporting past 30-day abstinence from smoking associated with the indicator on the categorical predictor variable. Data analysis was conducted using SPSS, v. 25.0 and P values <0.05 were considered statistically significant.

Results

Sample characteristics

Demographic, cigarette smoking, e-cigarette use characteristics of new purchasers of a JUUL Starter Kit who completed the 6-months follow-up assessment ($n = 9,040$) are summarized in Table 1, stratified by smoking abstinence status at the 6-months assessment. New purchasers of a JUUL Starter Kit were more likely to be male (57.1%), aged 21-34 (67.0%), non-Hispanic White (67.9%), with a college and bachelor’s degree or higher (71.4%). With regard to cigarette smoking, most new purchasers of a JUUL Starter Kit first smoked a cigarette before age 18 (61.9%), had smoked regularly for fewer than 10 years in their lifetime (58.6%), smoked cigarettes on all 30 of the 30 days prior to purchasing a JUUL Starter Kit (50.5%), and smoked 1-9 cigarettes on each smoking day in the 30 days prior to purchasing a JUUL Starter Kit (52.7%).

With regard to use of a JUUL vaporizer in the 30 days prior to the 6-months follow-up assessment, most new purchasers reported having used a JUUL vaporizer on all 30 of the 30 days (54.8%) and had not used any e-cigarette other than JUUL vaporizer (88.4%). New purchasers were most likely to be primary users of Mango (25.1%) or Mint (22.4%) flavored JUULpods in the past 30 days, and least likely to be primary users of Classic Tobacco (1.9%) flavored JUULpods. At the 6-months assessment, 69.4% of new purchasers had exclusively

used JUULpods containing characterizing flavors in the past 30 days. By comparison, 8.6% had exclusively used JUULpods containing tobacco flavors, and 13.3% had used JUULpods containing both characterizing flavors and JUULpods containing tobacco flavors in the past 30 days. Most (83.4%) endorsed ‘to help to quit smoking cigarettes completely’ as a reason for purchasing a JUUL Starter Kit.

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Table 1. Demographic, smoking and e-cigarette use characteristics of participants who completed the 6-months follow-up assessment (n = 9,040; 58.5% of ITT sample), by smoking status at the 6-month follow-up assessment.

Variable	Smoking Status at 6-Months Follow-Up Assessment						
	Smoked in Past 30 Days (n = 4,154)		No Smoking in Past 30 Days (n = 4,886)				
	N	%	N	%	Total (n = 9,040)	N %	
Demographic Variables							
Sex							
Male	2,287	(55.1)	2,872	(58.8)	5,159	(57.1)	
Female	1,798	(43.3)	1,954	(40.0)	3,752	(41.5)	
Transgender	25	(0.6)	28	(0.6)	53	(0.6)	
Missing	44	(1.1)	32	(0.7)	76	(0.8)	
Age							
21-24	1,145	(27.6)	1,846	(37.8)	2,991	(33.1)	
25-34	1,444	(34.8)	1,623	(33.2)	3,067	(33.9)	
35-44	833	(20.1)	746	(15.3)	1,579	(17.5)	
45-54	443	(10.7)	381	(7.8)	824	(9.1)	
55-64	227	(5.5)	261	(5.3)	488	(5.4)	
≥ 65	62	(1.5)	29	(0.6)	91	(1.0)	
Race/Ethnicity							
Non-Hispanic, White	2,884	(69.4)	3,255	(66.6)	6,139	(67.9)	
Non-Hispanic, Black	117	(2.8)	168	(3.4)	285	(3.2)	
Non-Hispanic, American Indian/Alaskan	54	(1.3)	63	(1.3)	117	(1.3)	
Non-Hispanic, Asian, Hawaiian or PI§	441	(10.6)	485	(9.9)	926	(10.2)	
Non-Hispanic, 2 or More Races	1	(0.0)	1	(0.0)	2	(0.0)	
Hispanic†	332	(8.0)	480	(9.8)	812	(9.0)	
Missing	325	(7.8)	434	(8.9)	759	(8.4)	
Education							
Not HS graduate	111	(2.7)	122	(2.5)	233	(2.6)	
GED	151	(3.6)	204	(4.2)	355	(3.9)	
HS graduate	625	(15.0)	913	(18.7)	1,538	(17.0)	
Some college or associate's degree	1,618	(39.0)	1,789	(36.6)	3,407	(37.7)	
Bachelor's degree or higher	1,465	(35.3)	1,579	(32.3)	3,044	(33.7)	
Missing	184	(4.4)	279	(5.7)	463	(5.1)	

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Household Income			
< \$25,000	832 (20.0)	1,007 (20.6)	1,839 (20.3)
\$25,000 to \$74,999	1,692 (40.7)	2,027 (41.5)	3,719 (41.1)
≥ \$75,000	1,136 (27.3)	1,285 (26.3)	2,421 (26.8)
Missing	494 (11.9)	567 (11.6)	1,061 (11.7)
U.S. Census Region			
Northeast	957 (23.0)	1,016 (20.8)	1,973 (21.8)
South	1,502 (36.2)	1,812 (37.1)	3,314 (36.7)
Midwest	1,008 (24.3)	1,116 (22.8)	2,124 (23.5)
West	647 (15.6)	913 (18.7)	1,560 (17.3)
Missing	40 (1.0)	29 (0.6)	69 (0.8)
Smoking and E-cigarette Variables			
Age of first smoking			
≤ 11 years	144 (3.5)	155 (3.2)	299 (3.3)
12 to 14 years	1,025 (24.7)	888 (18.2)	1,913 (21.2)
15 to 17 years	1,612 (38.8)	1,773 (36.3)	3,385 (37.4)
18 to 24 years	1,283 (30.9)	1,958 (40.1)	3,241 (35.9)
≥ 25 years	77 (1.9)	99 (2.0)	176 (1.9)
Missing	13 (0.3)	13 (0.3)	26 (0.3)
Lifetime years of smoking			
≤1 year	271 (6.5)	554 (11.3)	825 (9.1)
1-5 years	980 (23.6)	1,599 (32.7)	2,579 (28.5)
6-10 years	897 (21.6)	1,000 (20.5)	1,897 (21.0)
11-20 years	1,067 (25.7)	925 (18.9)	1,992 (22.0)
≥ 20 years	863 (20.8)	698 (14.3)	1,561 (17.3)
Missing	76 (1.8)	110 (2.3)	186 (2.1)
Number of smoking days in 30 days prior to baseline			
1-9 days	413 (9.9)	847 (17.3)	1,260 (13.9)
10-19 days	381 (9.2)	754 (15.4)	1,135 (12.6)
20-29 days	863 (20.8)	1,213 (24.8)	2,076 (23.0)
30 days	2,497 (60.1)	2,072 (42.4)	4,569 (50.5)
Cigarettes smoked per day at baseline			
1-9 cigarettes per day	1,858 (44.7)	2,907 (59.5)	4,765 (52.7)
10-19 cigarettes per day	1,366 (32.9)	1,284 (26.3)	2,650 (29.3)
≥ 20 cigarettes per day	930 (22.4)	695 (14.2)	1,625 (18.0)
Days of JUUL vaporizer use in past 30 days at 6-months			
1-9 days	469 (11.3)	321 (6.6)	790 (8.7)

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Source: https://www.industrydocuments.ucsf.edu/docs/rkjj0303

10-19 days	636 (15.3)	431 (8.8)	1,067 (11.8)
20-29 days	748 (18.0)	677 (13.9)	1,425 (15.8)
30 days	1,960 (47.2)	2,994 (61.3)	4,954 (54.8)
Missing	341 (8.2)	463 (9.5)	804 (8.9)
Current use of an e-cigarette other than JUUL vaporizer			
Yes	553 (13.3)	483 (9.9)	1,036 (11.5)
No	3,596 (86.6)	4,396 (90.0)	7,992 (88.4)
Missing	5 (0.1)	7 (0.1)	12 (0.1)
Place of first JUUL vaporizer purchase			
Retail store	1,713 (41.2)	2,467 (50.5)	4,180 (46.2)
JUUL website	2,441 (58.8)	2,419 (49.5)	4,860 (53.8)
Bought JUUL vaporizer SK 'to help me quit smoking'			
Yes	3,433 (82.6)	4,103 (84.0)	7,536 (83.4)
No	719 (17.3)	783 (16.0)	1,502 (16.6)
Missing	2 (0.0)	-	2 (0.0)
Primary JUULpods flavor used in past 30 days (at 6-months)			
Virginia Tobacco	478 (11.5)	423 (8.7)	901 (10.0)
Mint	821 (19.8)	1,203 (24.6)	2,024 (22.4)
Mango	937 (22.6)	1,334 (27.3)	2,271 (25.1)
Crème	218 (5.2)	180 (3.7)	398 (4.4)
Fruit	134 (3.2)	127 (2.6)	261 (2.9)
Cucumber	173 (4.2)	169 (3.5)	342 (3.8)
Classic Tobacco	116 (2.8)	54 (1.1)	170 (1.9)
Menthol	193 (4.6)	171 (3.5)	364 (4.0)
Equal use of 2+ flavors, no primary	747 (18.0)	766 (15.7)	1,513 (16.7)
Missing	337 (8.1)	459 (9.4)	796 (8.8)
JUULpods flavors used in past 30 days (at 6-months)			
Only used JUUL vaporizer tobacco flavors*	443 (10.7)	335 (6.9)	778 (8.6)
Only used JUUL vaporizer characterizing flavors^	2,741 (66.0)	3,531 (72.3)	6,272 (69.4)
Used both tobacco and characterizing flavors	637 (15.3)	568 (11.6)	1,205 (13.3)
Missing	333 (8.0)	452 (9.3)	785 (8.7)

Abbreviations: SK = JUUL Starter Kit (JUUL vaporizer plus four JUULpods); HS = High School; GED = General Educational Development; PI = Pacific Islander.

§ Includes Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, Guamanian, Chamorro, and Samoan.

†Includes Mexican, Cuban, Puerto Rican and 'other Hispanic' ethnicity.

* JUUL vaporizer tobacco flavors include 'Virginia Tobacco' and 'Classic Tobacco'

^ JUUL vaporizer characterizing flavors include 'Mint', 'Mango', 'Crème', 'Fruit', 'Cucumber', and 'Menthol'.

Past 30-day point prevalence abstinence from cigarette smoking at 3-months and 6-months assessments

ITT sample

In the ITT sample (N = 15,456), past 30-day point prevalence abstinence from smoking at the 3-months assessment was 28.3%, with the abstinence rate higher among retail purchasers (30.0%; n = 2,346/7,823) than among online purchasers (26.5%; n = 2,021/7,633) (Figure 1). The past 30-day abstinence rate had slightly increased to 31.6% at the 6-months assessment, with extremely similar abstinence rates reported by retail purchasers (31.5%; n = 2,467/7,823) and online purchasers (31.7%; n = 2,419/7,633).

Approximately 20.3% of the ITT sample reported past 30-day smoking abstinence at *both* the 3-months assessment *and* the 6-months assessment (i.e. continuing quitters) (Figure 2). In contrast, 60.4% did not report past 30-day smoking abstinence at either the 3-months assessment or the 6-months assessments (i.e. continuing smokers). The rate at which participants became abstinent at the 6-months assessment having been smoking at the 3-months assessment (i.e. ‘new quitters’, 11.3%) was approximately 1.4 times higher than the rate at which participants returned to smoking at the 6-months assessment having been abstinent from smoking at the 3-months assessment (i.e. ‘relapsers’, 8.0%).

Efficacy subset samples

When the analysis was restricted to only participants who completed the 3-months assessment (n = 9,272), past 30-day point prevalence abstinence from smoking was 47.1%, with the abstinence rate higher among retail purchasers (55.1%; n = 2,346/4,260) than among online purchasers (40.3%; n = 2,021/5,012). When the analysis was restricted only those who completed the 6-months assessment (n = 9,040), past 30-day point prevalence abstinence from smoking was 54.0% (4,886/9,040), with the abstinence rate again higher among retail purchasers (59.0%; n = 2,467/4,180) than among online purchasers (49.8%; n = 2,419/4,860).

Lastly, when the analysis was restricted to only participants who completed *both* the 3-months assessment *and* the 6-months assessment ($n = 7,726$), past 30-day point prevalence abstinence from smoking at *both* the 3-months assessment *and* the 6-months assessment was 40.6%. In contrast, 38.7% did not report past 30-day smoking abstinence at either the 3-months assessment or the 6-months assessments (i.e. continuing smokers). The rate at which participants became abstinent at the 6-months assessment having been smoking at the 3-months assessment (i.e. ‘new quitters’, 13.9%) was approximately 2.0 times higher than the rate at which participants returned to smoking at the 6-months assessment having been abstinent from smoking at the 3-months assessment (i.e. ‘relapsers’, 6.8%).

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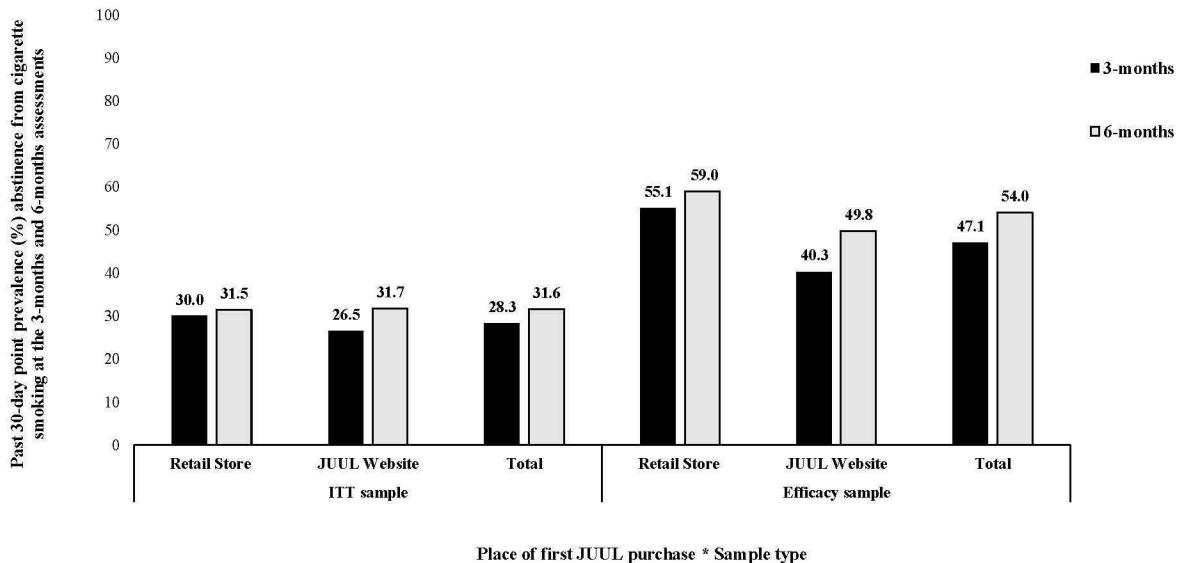


Figure 1. Self-reported past 30-day point prevalence abstinence from smoking assessed at three months and six months after first purchase of a JUUL Starter Kit, stratified by place of first purchase of a JUUL Starter Kit and sample type.

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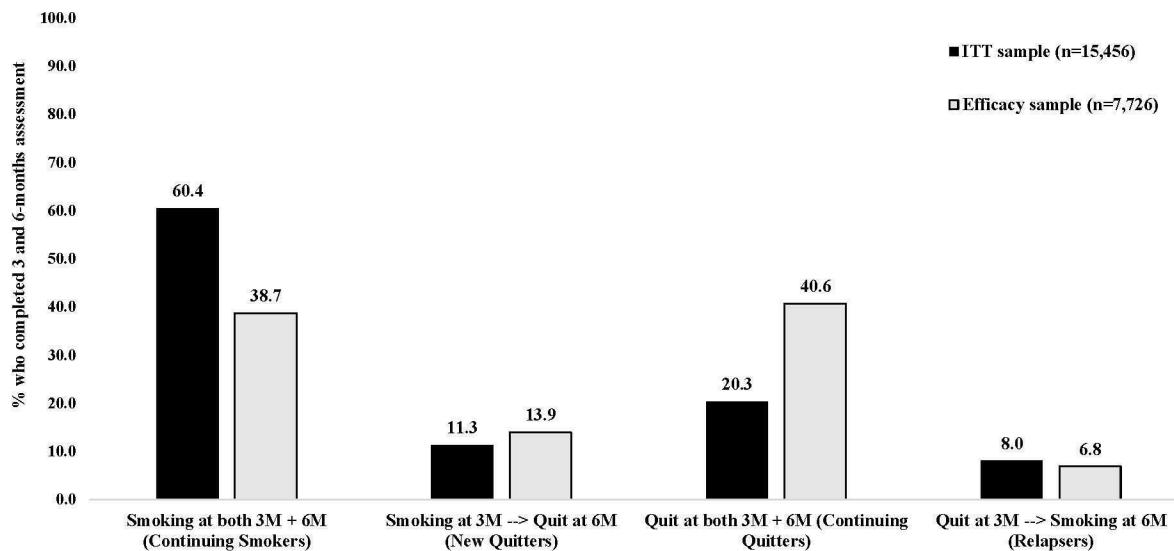


Figure 2. Transitions in cigarette smoking status between the 3-month assessment and the 6-month assessment among new users of a JUUL vaporizer who completed both assessments.

Total past 30-day cigarette consumption

Estimates of the total number of cigarettes smoked in the 30 days prior to the assessments at baseline, 3-months and 6-months by all enrolled participants ($N = 15,456$) and by participants who provided cigarette smoking data at all three assessments (efficacy sample $n = 6,066$; 39.2% of the ITT sample) are presented in Figure 3.

Intent-to-treat (ITT) sample

In the ITT sample, total past 30-day cigarette consumption reduced from 4,033,978 cigarettes smoked in the 30 days prior to the baseline assessment to 2,511,177 cigarettes smoked at three months (37.7% reduction from baseline), to 2,388,280 cigarettes smoked at six months (40.8% reduction from baseline). Among participants who reported or were imputed as smokers at six months ($n = 10,570$), total past 30-day cigarette consumption had reduced from 2,967,452 cigarettes in the 30 days prior to the baseline assessment to 2,221,278 cigarettes smoked at three months (25.2% reduction from baseline), to 2,388,280 cigarettes smoked at six months (19.5% reduction from baseline). Among participants who reported past 30-day abstinence from smoking at the 6-months assessment ($n = 4,886$), total past 30-day cigarette consumption had reduced from 1,066,526 cigarettes at baseline to 289,899 cigarettes at the 3-months assessment (72.8% reduction from baseline), to zero cigarettes smoked at the 6-months assessment.

Efficacy sample

In the efficacy sample, total past 30-day cigarette consumption reduced from 1,659,299 cigarettes smoked in the 30 days prior to the baseline assessment to 45,3561 cigarettes smoked at three months (72.7% reduction from baseline), to 40,1061 cigarettes smoked at six months (75.8% reduction from baseline). Among participants who reported past 30-day cigarette smoking at six months ($n = 2,414$), total past 30-day cigarette consumption had reduced from 840,554 cigarettes smoked at baseline to 411,443 cigarettes smoked at three months (51.1% reduction from baseline), to 401,061 cigarettes smoked at six months (52.3% reduction from baseline). Among participants who reported past 30-day abstinence from smoking at six months ($n = 2,414$), total past 30-day cigarette consumption had reduced from 818,745

cigarettes smoked at baseline to 42,118 cigarettes smoked at three months (94.9% reduction from baseline), to zero cigarettes smoked at six months.

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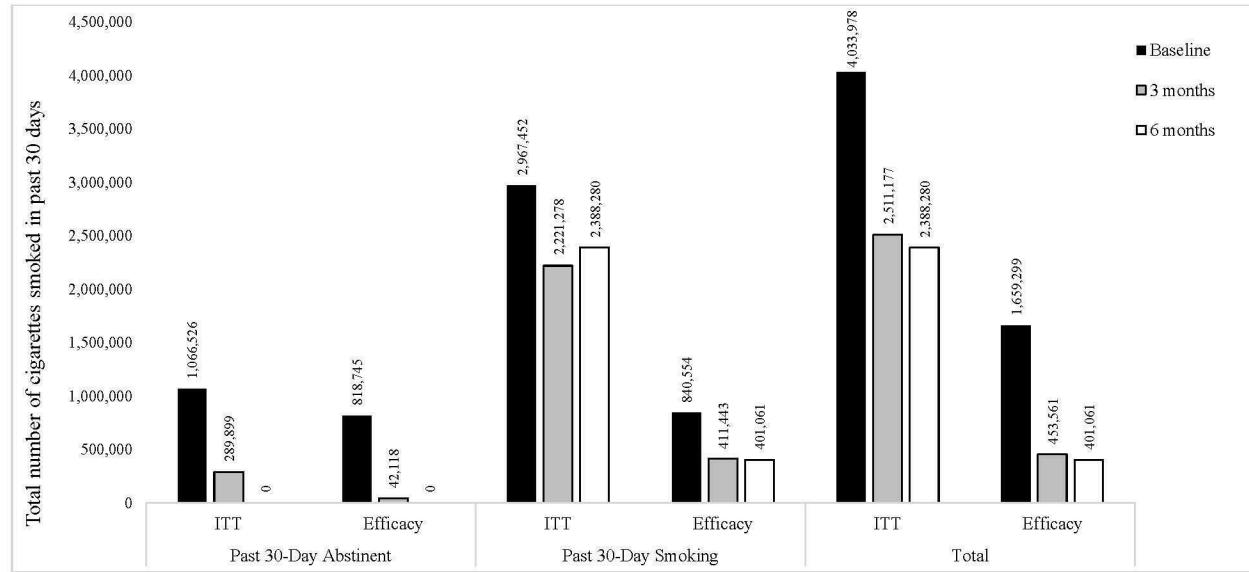


Figure 3. Total estimated number of cigarettes smoked in the 30 days prior to assessments at baseline, 3-months follow-up and 6-months follow-up, stratified by smoking status at six months and sample type (ITT N = 15,456; Efficacy n = 6,066).

Factors associated with past 30-day smoking abstinence at the 6-months assessment

Model 1

Participants' adjusted odds of reporting past 30-day abstinence from smoking at the 6-months assessments significantly varied by five JUUL-related variables – (i) primary JUUL pod flavor used in the 30 days prior to the 6-months assessment; (ii) number of days of use of a JUUL vaporizer in the 30 days prior to the 6-months assessment; (iii) place of first purchase of a JUUL Starter Kit; (iv) whether or not participants first purchased a JUUL vaporizer to help them quit smoking cigarettes; and (v) past 30-day use of any other e-cigarette other than JUUL vaporizer – three smoking-related variables – (i) number of smoking days in the 30 days prior to the baseline assessment; (ii) number of cigarettes smoked per smoking day at the baseline assessment; and (iii) number of lifetime years of regular smoking – and two demographic variables – (i) education level; and (ii) census region (Table 2).

JUUL-related factors

Mint and Mango were the most common primary flavors, with primary users of Mint and Mango flavored JUULpods in the 30 days prior to the 6-months assessment together accounting for 51.9% of all participants who had not smoked a cigarette in the 30 days prior to the 6-months assessment, and 47.5% of all participants who completed the 6-months assessment. Compared to those who primarily used Virginia Tobacco flavored JUULpods in the 30 days prior to the 6-months assessment, those who primarily used Mint flavored JUULpods ($aOR = 1.46; 1.21, 1.77$) or Mango flavored JUULpods ($aOR = 1.40; 1.16, 1.68$) were 46% and 40% more likely, respectively, to have not smoked a cigarette in the 30 days prior to the 6-months assessment. Compared to those who primarily used Virginia Tobacco flavored JUULpods, primary users of Crème, Fruit, Cucumber, Classic Tobacco or Menthol flavored JUULpods and those who did not have a primary JUULpod flavor in the 30 days prior to the 6-months assessment had statistically equivalent odds for reporting past 30-day smoking abstinence at the 6-months assessment.

The interaction term entered at Step 2 was not significant, indicating that the association between primary JUULpod flavor used in the 30 days prior to the 6-months assessment and past 30-day smoking abstinence at the 6-months assessment was not significantly moderated

by the place at which participants purchased their first JUUL Starter Kit. Rates of past 30-day smoking abstinence at the 6-months assessment stratified by past 30-day primary use of JUULpods in eight flavors and place of first purchase of a JUUL Starter Kit, unadjusted for the effects of other variables, summarised in Figure 4, show that, with the exception of Crème, higher rates of past 30-day smoking abstinence at the 6-months assessment were observed among initial retail purchasers than among initial e-commerce purchasers for all JUULpod flavors.

Compared to those who used a JUUL vaporizer on all 30 of the 30 days prior to the 6-months assessment, those who used a JUUL vaporizer on 20-29 days ($aOR = 0.45; 0.39, 0.52$), 10-19 days ($aOR = 0.39; 0.33, 0.46$), and 1-9 days ($aOR = 0.38; 0.31, 0.45$) in the past 30 days were 2.22 times, 2.56 times and 2.63 times less likely, respectively, to have not smoked a cigarette in the 30 days prior to the 6-months assessment. Compared to those who did not purchase their first JUUL Starter Kit ‘to help to quit smoking cigarettes completely’, those who reported having purchased their first JUUL Starter Kit ‘to help to quit smoking cigarettes completely’ were 45% more likely to have not smoked a cigarette in the 30 days prior to the 6-months assessment ($aOR = 1.45; 1.26, 1.68$).

Compared to those who purchased their first JUUL Starter Kit on JUUL’s e-commerce store, those who purchased their first JUUL Starter Kit in a retail store were 21% more likely to have not smoked a cigarette in the 30 days prior to the 6-months assessment ($aOR = 1.21; 1.08, 1.36$). Compared to those who had not used any e-cigarette other than a JUUL vaporizer in the 30 days prior to the 6-months assessment, those who reported past 30-day use of a secondary e-cigarette were 25% less likely to have not smoked a cigarette in the 30 days prior to the 6-months assessment ($aOR = 0.80; 0.67, 0.95$).

Cigarette smoking-related factors

Heaviness, frequency and lifetime duration of cigarette smoking at the time of first purchase of a JUUL Starter Kit were all negatively associated with participants’ odds of reporting past 30-smoking abstinence at the 6-months assessment. Compared to those who had smoked cigarettes on all 30 of the 30 days prior to the baseline assessment, those who had smoked cigarettes on 20-29 days ($aOR = 1.50; 1.30, 1.72$), 10-19 days ($aOR = 2.15; 1.80, 2.58$) and 1-9 days ($aOR = 2.38; 1.98, 2.86$) were approximately 1.5 times, 2.2 times and 2.4 times more

likely, respectively, to have not smoked a cigarette in the 30 days prior to the 6-months assessment.

Compared to those who were smoking 1-9 cigarettes per smoking day in the 30 days prior to the baseline assessment, those who were smoking 10-19 cigarettes per day ($aOR = 0.87; 0.76, 0.99$) and 20 or more cigarettes per day ($aOR = 0.78; 0.66, 0.92$) were 15% and 28% less likely, respectively, to have not smoked a cigarette in the 30 days prior to the 6-months assessment. Compared to those had smoked regularly for 20 or more years in their lifetime at the baseline assessment, those who had smoked regularly for 0-12 months ($aOR = 1.92; 1.38, 2.66$) and 1-5 years ($aOR = 1.57; 1.20, 2.07$) were 92% and 57% more likely, respectively, to have not smoked a cigarette in the 30 days prior to the 6-months assessment.

Demographic factors

Compared to those who had not graduated high school, those with a GED were 54% more likely to have not smoked a cigarette in the 30 days prior to the 6-months assessment ($aOR = 1.54; 1.02, 2.33$). Compared to those who lived in the West census region, those who lived in the Northeast ($aOR = 0.84; 0.71, 0.99$) and Midwest ($aOR = 0.83; 0.70, 0.98$) census regions were 19% and 20% less likely, respectively, to have not smoked a cigarette in the 30 days prior to the 6-months assessment.

Model 2

All variables that emerged in Model 1 as significant predictors of past 30-day smoking abstinence at the 6-months assessment remained significant in Model 2, with no non-significant predictors in Model 1 becoming significant in Model 2. The added predictor variable – use of JUULpod flavor categories in the 30 days prior to the 6-months assessment – was significantly associated with participants' odds of reporting past 30-day abstinence from smoking at the 6-months assessment. Compared to those who had exclusively used JUULpods in tobacco flavors in the 30 days prior to the 6-months assessment, those who had exclusively used JUULpods in characterizing flavors were 38% more likely to have not smoked a cigarette in the 30 days prior to the 6-months assessment ($aOR = 1.38; 1.15, 1.65$). The interaction term entered at Step 2

was non-significant, indicating that the association between past 30-day use of JUULpod flavor categories and past 30-day smoking abstinence at the 6-months assessment was not significantly moderated by the place at which participants purchased their first JUUL Starter Kit.

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Table 2. Per cent of participants reporting past 30-day point prevalence abstinence from smoking at the 6-month follow-up assessment and model information for two logistic regression analyses of factors associated with likelihood of reporting past 30-day abstinence from smoking at the 6-month follow-up assessment.

Predictor Variable	Unadjusted		Model 1 Adjusted		Model 2 Adjusted	
	% P30A	Unadjusted OR (95% CI)	Step 1	Step 2	Step 1	Step 2
			aOR (95% CI)	aOR (95% CI)	aOR (95% CI)	aOR (95% CI)
Sex						
Male	55.7	Ref.	Ref.	Ref.	Ref.	Ref.
Female	52.1	0.87 (0.80-0.94)**	0.97 (0.87-1.08)	0.97 (0.87-1.08)	0.95 (0.85-1.06)	0.95 (0.85-1.06)
Transgender	52.8	0.89 (0.52-1.53)	0.83 (0.43-1.60)	0.83 (0.43-1.60)	0.87 (0.46-1.68)	0.88 (0.46-1.68)
Age						
21-24	61.7	Ref.	Ref.	Ref.	Ref.	Ref.
25-34	52.9	0.70 (0.63-0.77)***	0.95 (0.81-1.11)	0.95 (0.81-1.12)	0.96 (0.82-1.12)	0.96 (0.82-1.12)
35-44	47.2	0.56 (0.49-0.63)***	0.98 (0.78-1.22)	0.98 (0.78-1.22)	0.98 (0.78-1.22)	0.98 (0.78-1.22)
45-54	46.2	0.53 (0.46-0.62)***	1.07 (0.80-1.42)	1.08 (0.81-1.43)	1.08 (0.81-1.43)	1.07 (0.81-1.43)
55-64	53.5	0.71 (0.59-0.87)**	0.88 (0.61-1.27)	0.88 (0.61-1.28)	0.88 (0.61-1.27)	0.88 (0.61-1.27)
≥ 65	31.9	0.29 (0.19-0.45)***	0.70 (0.37-1.32)	0.70 (0.37-1.32)	0.70 (0.37-1.31)	0.70 (0.37-1.30)
Race/Ethnicity						
Non-Hispanic, White	53.0	Ref.	Ref.	Ref.	Ref.	Ref.
Non-Hispanic, Black	58.9	1.27 (1.00-1.62)*	1.33 (0.99-1.78)	1.33 (0.99-1.79)	1.29 (0.97-1.74)	1.30 (0.97-1.74)
Non-Hispanic, American Indian/Alaskan	53.8	1.03 (0.72-1.49)	1.30 (0.83-2.05)	1.32 (0.84-2.07)	1.32 (0.84-2.08)	1.32 (0.84-2.07)
Non-Hispanic, Asian, Hawaiian or PI§	52.4	0.97 (0.85-1.12)	0.89 (0.75-1.05)	0.89 (0.75-1.05)	0.90 (0.76-1.07)	0.90 (0.76-1.07)
Non-Hispanic, 2 or More Races	50.0	0.89 (0.06-14.17)	1.07 (0.07-17.59)	1.08 (0.07-17.78)	1.13 (0.07-18.49)	1.14 (0.07-18.63)
Hispanic†	59.1	1.28 (1.10-1.49)***	1.07 (0.89-1.28)	1.07 (0.89-1.28)	1.06 (0.89-1.27)	1.06 (0.89-1.27)
Education						
Not HS graduate	52.4	Ref.	Ref.	Ref.	Ref.	Ref.
GED	57.5	1.23 (0.88-1.71)	1.54 (1.02-2.33)*	1.55 (1.03-2.34)*	1.57 (1.04-2.36)*	1.57 (1.04-2.37)*
HS graduate	59.4	1.33 (1.01-1.75)*	1.09 (0.78-1.52)	1.10 (0.78-1.53)	1.10 (0.79-1.53)	1.10 (0.79-1.54)

Some college or associate's degree	52.5	1.01 (0.77-1.31)	0.96 (0.70-1.32)	0.96 (0.70-1.33)	0.96 (0.70-1.32)	0.96 (0.70-1.32)
Bachelor's degree or higher	51.9	0.98 (0.75-1.28)	0.90 (0.65-1.25)	0.91 (0.65-1.26)	0.92 (0.66-1.27)	0.92 (0.66-1.28)
Household Income						
< \$25,000	54.8	Ref.	Ref.	Ref.	Ref.	Ref.
\$25,000 to \$74,999	54.5	0.99 (0.89-1.11)	1.07 (0.94-1.23)	1.08 (0.94-1.24)	1.08 (0.94-1.24)	1.08 (0.94-1.24)
≥ \$75,000	53.1	0.94 (0.83-1.06)	1.12 (0.95-1.31)	1.12 (0.95-1.31)	1.13 (0.96-1.32)	1.13 (0.96-1.32)
U.S. Census Region						
Northeast	51.5	0.75 (0.66-0.86)***	0.84 (0.71-0.99)*	0.83 (0.70-0.99)*	0.84 (0.71-1.00)	0.84 (0.71-1.00)
South	54.7	0.86 (0.76-0.97)**	0.96 (0.82-1.12)	0.96 (0.82-1.12)	0.97 (0.83-1.13)	0.97 (0.83-1.13)
Midwest	52.5	0.79 (0.69-0.90)***	0.83 (0.70-0.98)*	0.83 (0.70-0.98)*	0.84 (0.71-0.99)*	0.84 (0.71-1.00)*
West	58.5	Ref.	Ref.	Ref.	Ref.	Ref.
Age of first smoking						
≤ 11 years	51.8	Ref.	Ref.	Ref.	Ref.	Ref.
12 to 14 years	46.4	0.81 (0.63-1.03)	0.74 (0.55-1.01)	0.74 (0.55-1.00)	0.75 (0.55-1.02)	0.75 (0.55-1.02)
15 to 17 years	52.4	1.02 (0.81-1.30)	0.81 (0.60-1.09)	0.80 (0.60-1.08)	0.82 (0.61-1.10)	0.82 (0.61-1.10)
18 to 24 years	60.4	1.42 (1.12-1.80)**	0.93 (0.69-1.26)	0.92 (0.68-1.25)	0.94 (0.69-1.27)	0.94 (0.69-1.27)
≥ 25 years	56.3	1.19 (0.82-1.74)	0.92 (0.55-1.53)	0.93 (0.55-1.55)	0.89 (0.53-1.49)	0.89 (0.53-1.49)
Lifetime years of smoking						
≤ 1 year	67.2	2.53 (2.12-3.02)***	1.92 (1.38-2.66)***	1.92 (1.38-2.66)***	1.92 (1.39-2.67)***	1.92 (1.39-2.66)***
1-5 years	62.0	2.02 (1.78-2.29)***	1.57 (1.20-2.07)**	1.58 (1.20-2.08)**	1.58 (1.21-2.08)**	1.58 (1.21-2.08)**
6-10 years	52.7	1.38 (1.21-1.58)***	1.24 (0.97-1.59)	1.25 (0.97-1.60)	1.24 (0.97-1.59)	1.24 (0.97-1.59)
11-20 years	46.4	1.07 (0.94-1.22)	1.15 (0.93-1.42)	1.15 (0.93-1.42)	1.14 (0.93-1.41)	1.14 (0.93-1.41)
≥ 20 years	44.7	Ref.	Ref.	Ref.	Ref.	Ref.
Number of smoking days in 30 days prior to baseline						
1-9 days	67.2	2.47 (2.17-2.82)***	2.38 (1.98-2.86)***	2.39 (1.99-2.88)***	2.37 (1.97-2.84)***	1.50 (1.31-1.72)***
10-19 days	66.4	2.39 (2.08-2.73)***	2.15 (1.80-2.58)***	2.16 (1.80-2.59)***	2.16 (1.80-2.58)***	2.16 (1.80-2.58)***
20-29 days	58.4	1.69 (1.53-1.88)***	1.50 (1.30-1.72)***	1.50 (1.31-1.72)***	1.50 (1.31-1.72)***	2.37 (1.97-2.84)***
30 days	45.3	Ref.	Ref.	Ref.	Ref.	Ref.

Cigarettes smoked per day at baseline

1-9 cigarettes per day	61.0	Ref.	Ref.	Ref.	Ref.	Ref.
10-19 cigarettes per day	48.5	0.60 (0.55-0.66)***	0.87 (0.76-0.99)*	0.87 (0.77-1.00)	0.87 (0.77-1.00)	0.87 (0.77-1.00)
≥ 20 cigarettes per day	42.8	0.48 (0.43-0.54)***	0.78 (0.66-0.92)**	0.78 (0.66-0.92)**	0.79 (0.67-0.93)**	0.79 (0.67-0.93)**
Number of days of JUUL use in past 30 days (at 6-months)						
1-9 days	40.6	0.45 (0.39-0.52)***	0.38 (0.31-0.45)***	0.38 (0.31-0.45)***	0.36 (0.30-0.43)***	0.36 (0.30-0.43)***
10-19 days	40.4	0.44 (0.39-0.51)***	0.39 (0.33-0.46)***	0.39 (0.33-0.46)***	0.38 (0.32-0.44)***	0.38 (0.32-0.44)***
20-29 days	47.5	0.59 (0.53-0.67)***	0.45 (0.39-0.52)***	0.45 (0.39-0.52)***	0.44 (0.38-0.51)***	0.44 (0.38-0.51)***
30 days	60.4	Ref.	Ref.	Ref.	Ref.	Ref.
Current use of an e-cigarette other than JUUL						
Yes	46.6	0.71 (0.63-0.81)***	0.80 (0.67-0.95)*	0.80 (0.67-0.95)*	0.80 (0.67-0.95)*	0.80 (0.67-0.95)*
No	55.0	Ref.	Ref.	Ref.	Ref.	Ref.
Place of first JUUL purchase						
Retail store	59.0	1.45 (1.34-1.58)***	1.21 (1.08-1.36)**	1.24 (0.88-1.74)	1.23 (1.09-1.38)**	1.34 (0.93-1.95)
JUUL website	49.8	Ref.	Ref.	Ref.	Ref.	Ref.
Bought JUUL SK 'to help me quit smoking'						
Yes	54.4	1.10 (0.98-1.23)	1.45 (1.26-1.68)***	1.45 (1.26-1.68)***	1.46 (1.27-1.69)***	1.47 (1.27-1.69)***
No	52.1	Ref.	Ref.	Ref.	Ref.	Ref.
Primary JUULpod flavor used in past 30 days (at 6-months)						
Virginia Tobacco	46.9	Ref.	Ref.	Ref.	Ref.	Ref.
Mint	59.4	1.66 (1.41-1.94)***	1.46 (1.21-1.77)***	1.52 (1.20-1.92)**	NI	NI
Mango	58.7	1.61 (1.38-1.88)***	1.40 (1.16-1.68)***	1.46 (1.16-1.84)**	NI	NI
Crème	45.2	0.93 (0.74-1.18)	0.96 (0.73-1.27)	1.05 (0.74-1.49)	NI	NI
Fruit	48.7	1.07 (0.81-1.41)	1.31 (0.95-1.82)	1.34 (0.89-2.04)	NI	NI
Cucumber	49.4	1.10 (0.86-1.42)	0.91 (0.68-1.22)	0.80 (0.56-1.16)	NI	NI
Classic Tobacco	31.8	0.53 (0.37-0.75)***	0.82 (0.54-1.25)	0.80 (0.48-1.32)	NI	NI
Menthol	47.0	1.00 (0.79-1.28)	1.03 (0.77-1.38)	1.03 (0.71-1.49)	NI	NI
Equal use of 2+ flavors, no primary	50.6	1.16 (0.98-1.37)	1.06 (0.87-1.30)	1.00 (0.77-1.28)	NI	NI

JUULpod flavors used in the past 30 days (at 6-months)						
Only used JUUL tobacco flavors*	43.1	Ref.	NI	NI	Ref.	Ref.
Only used JUUL characterizing flavors [^]	56.3	1.70 (1.47-1.98)***	NI	NI	1.38 (1.15-1.65)**	1.42 (1.14-1.76)**
Used flavors from both tobacco and categories	47.1	1.18 (0.98-1.41)	NI	NI	0.99 (0.79-1.23)	1.03 (0.79-1.35)
Interaction Term: Primary JUULpod flavor used in past 30 days (at 3-months) * Place of first JUUL purchase						
Virginia Tobacco* Retail				Ref.	NI	NI
Mint* Retail	-	-	-	0.92 (0.62-1.36)	NI	NI
Mango* Retail	-	-	-	0.91 (0.61-1.34)	NI	NI
Crème* Retail	-	-	-	0.78 (0.44-1.40)	NI	NI
Fruit* Retail	-	-	-	0.94 (0.48-1.83)	NI	NI
Cucumber* Retail	-	-	-	1.42 (0.77-2.62)	NI	NI
Classic Tobacco* Retail	-	-	-	1.12 (0.45-2.78)	NI	NI
Menthol* Retail	-	-	-	0.99 (0.54-1.84)	NI	NI
Equal use of 2+ flavors, no primary* Retail	-	-	-	1.14 (0.76-1.72)	NI	NI
Interaction Term: JUUL pod flavors used in the past 30 days (at 3-months) * Place of first JUUL purchase						
Only JUUL tobacco flavors* Retail	-	-	NI	NI	-	Ref.
Only JUUL characterizing flavors* Retail	-	-	NI	NI	-	0.91 (0.62-1.35)
Both flavor categories and tobacco* Retail	-	-	NI	NI	-	0.87 (0.55-1.38)

Model 1: N =6,587, $\chi^2 = 745.676$, df =48, $p < 0.001$

Model 2: N =6,593, $\chi^2 = 728.296$, df =42, $p < 0.001$

*** p < 0.001, ** p < 0.010, * p < 0.050

Abbreviations: P30A = Past 30-day abstinence from smoking at the 6-months assessment; 3M = 6-months assessment; aOR = adjusted odds ratio; HS = High School; CPD = cigarettes smoked per day. PI = Pacific Islander; NI = Not included in the logistic regression model.

Unadjusted ORs were estimated using only the relevant variable as the predictor variable.

§ Includes Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, Guamanian, Chamorro, and Samoan.

†Includes Mexican, Cuban, Puerto Rican and ‘other Hispanic’ ethnicity.

* JUUL tobacco flavors include ‘Virginia Tobacco’ and ‘Classic Tobacco’

^ JUUL characterizing flavors include ‘Mint’, ‘Mango’, ‘Crème’, ‘Fruit’, ‘Cucumber’, and ‘Menthol’.

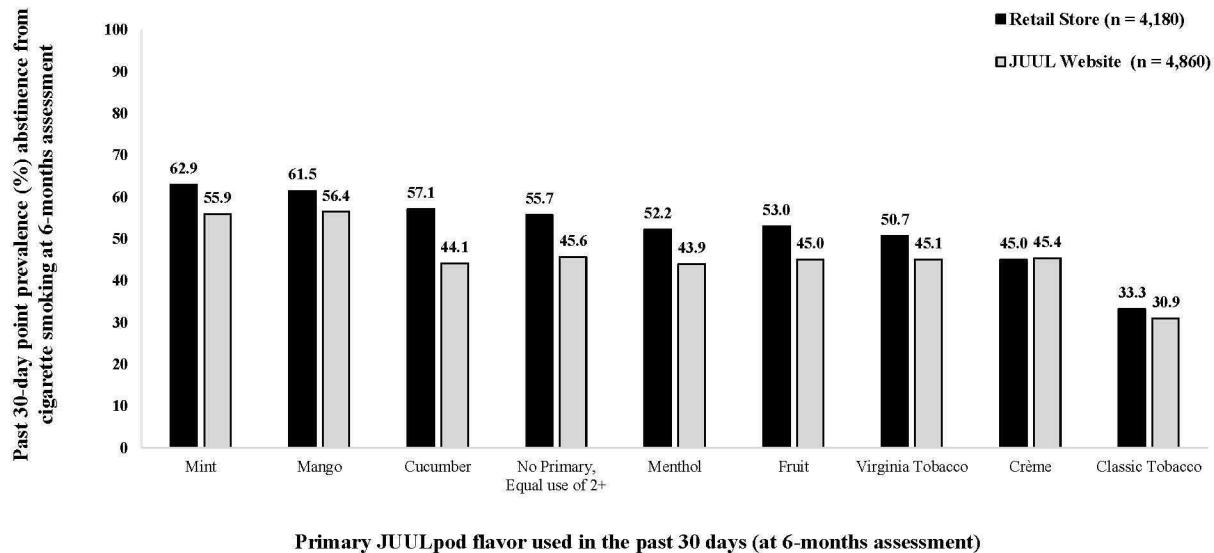


Figure 4. Past 30-day point prevalence self-reported abstinence from cigarette smoking at the 6-months assessment, by primary JUULpod flavor used in the past 30 days and place of first purchase of a JUUL Starter Kit, unadjusted for the effects of other variables (6-months sample n = 9,040).

Discussion

This study prospectively assessed rates of self-reported past 30-day abstinence from cigarette smoking in a large, non-probabilistic sample of U.S. adult established current smokers who purchased and used a JUUL vaporizer naturalistically for six months. Participants who were still using a JUUL vaporizer six months after their first purchase were typically male, aged 21-34 years, non-Hispanic White, college-educated, had initiated smoking before aged 18, had smoked cigarettes regularly for fewer than 10 years in their lifetime, and had been daily smokers of 1-9 cigarettes when they purchased their first JUUL Starter Kit. In a worst-case scenario in which non-respondents to survey assessments were assumed to be smoking cigarettes, 28.3% and 31.6% of new users of a JUUL vaporizer self-reported past 30-day abstinence from cigarette smoking at three and six months, respectively, and 20.3% self-reported consecutive past 30-day smoking abstinence outcomes at three and six months. Additionally, a higher rate of quitting smoking (11.3%) than relapsing to smoking (8.0%) was observed between the third and sixth month of using a JUUL vaporizer. Among participants in whom full past 30-day abstinence was not achieved at six months, past 30-day total cigarette consumption had reduced by more than 50% compared to total cigarette consumption in the 30 days prior to their first purchase of a JUUL Starter Kit. However, the rate at which a significant reduction in cigarette consumption at six months translates to later abstinence is unknown.

Smokers' likelihood of self-report past 30-day smoking abstinence at six months significantly varied by their patterns of cigarettes smoking prior to purchasing a JUUL vaporizer and by their patterns of use of their JUUL vaporizer and JUULpods. Daily use of a JUUL vaporizer, past 30-day primary use of Mint or Mango flavored JUUL pods, past 30-day exclusive use of JUUL pods in characterizing flavors, purchasing one's first JUUL Starter Kit in a retail store, and purchasing one's first JUUL vaporizer to help to quit smoking completely were all associated with significantly higher adjusted odds of not having smoked any cigarettes in the past 30 days at six months. Smoking regularly for more than 20 years, smoking more cigarettes per day and smoking on more days in the 30 days before one's first purchase of a JUUL Starter Kit, and past 30-day of a secondary e-cigarette (i.e. non-exclusive use of a JUUL vaporizer) were all associated with significantly lower adjusted odds of not having smoked any cigarettes in the past 30 days at six months.

JUULpod flavor choice was the strongest determinant of smoking abstinence at six months. JUULpods flavored to taste like Mint or Mango were both the most commonly used JUULpod flavors at six months and the flavors most strongly associated with quitting smoking after six months of using a JUUL vaporizer compared to the most popular tobacco-flavored JUULpod (Virginia Tobacco). Smokers who had primarily vaped JUULpods flavored to taste like Mint or Mango in the 30 days at six months were 46% and 40% more likely to have quit smoking, respectively, compared to those who had primarily vaped Virginia Tobacco flavored JUUL pods. For context, previously reported analyses of past 30-day smoking abstinence outcome data collected at three months found past 30-day primary users of Mint and Mango flavored JUULpods were 37% and 26% more likely than primary users of Virginia Tobacco flavored JUULpods. Present findings therefore indicate a strengthening of the associations between past 30-day primary use of Mint and Mango flavored JUULpods and past 30-day smoking abstinence between three and six months.

The question of whether flavored e-cigarettes are more likely to assist smokers to quit than they are to attract youth and non-smokers to use e-cigarettes, and then subsequently conventional cigarettes, has become increasingly controversial, particularly in light of data that show a 75% increase in past 30-day e-cigarette use among U.S. high school students between 2017 and 2018.³⁰ The FDA has statutory authority over the regulation of flavored e-cigarettes, but any action the agency decides to take must, in words of Commissioner Gottlieb, strike a careful public health balance between maintaining adult smokers' access to potentially less harmful sources of nicotine through e-cigarettes for adults who want to transition away from combustible cigarettes, and reducing youth appeal and access to e-cigarettes. A recent editorial in the *New England Journal of Medicine*³¹ suggested "the FDA should simply ban the sale of flavored nicotine products for use in e-cigarettes. The public health problem that e-cigarettes can help solve – by helping people who are users of combustible tobacco products stop smoking by switching to vaping – is adequately addressed by liquids that are not flavored to appeal to adolescents". On this basis, the authors urged the FDA "to use its statutory powers in regulating nicotine delivery devices to take the bold step of removing these flavored products from the market".

The premise for the authors' suggesting a complete ban on flavored e-cigarettes is their contention that e-cigarettes flavored to taste like tobacco should be sufficiently appealing and effective to assist adult smokers to transition away from smoking cigarettes. This contention is

potentially contradicted, however, by the present findings of significantly higher rates of past 30-day smoking abstinence among past 30-day primary users of Mint or Mango flavored JUULpods than among primary users of the most popular tobacco flavored JUULpod (Virginia Tobacco), and among past 30-day exclusive users or JUULpods in characterizing flavors (versus tobacco flavors). It should be stressed that the present findings neither support the argument that access to JUULpods containing non-tobacco flavors is *essential* for adult smokers to completely substitute a JUUL vaporizer for conventional cigarettes, nor do they rule out the possibility that adult smokers would simply switch to using available tobacco flavored e-cigarettes in the event that their preferred non-tobacco flavored products were banned. However, present findings do suggest that restricting adult smokers' access to JUULpods containing tobacco flavors alone may diminish adult smokers' interest in using a JUUL vaporizer as an alternative to continuing to smoke cigarettes, and may reduce the likelihood that adult smokers who do begin using a JUUL vaporizer will attempt to quit or cut down smoking, and succeed in those attempts.

Investigation of this potential negative effect has become more urgent since JUUL Labs Inc. announced, on 13 November 2018, the company would immediately stop selling its Mango, Crème, Fruit and Cucumber flavored refill pods to the over 90,000 retail stores in the United States that currently sell JUUL's flavored refill pods, including convenience stores and specialty vape stores. This action was taken in response to concern expressed by the FDA about the role of non-tobacco flavors in increasing the appeal of vaping to youth, JUUL Labs Inc. Present findings that smoking abstinence rates were significantly higher among users of characterizing flavors and among those who purchased their first JUUL vaporizer in a retail store suggest the impact of this voluntary action by JUUL Labs Inc. should be closely assessed for trends indicating a reduced rate of quitting smoking associated with this voluntary suspension of retail sales of flavored JUULpods. Data collected in the present study, which concluded on 3 January 2019, may therefore serve as bases for evaluating smoking abstinence rates among new users of the JUUL vaporizer post-removal of flavored JUULpods from retail stores.

If a statutory ban or voluntary suspension of flavored JUUL products from retail stores were to depress smoking cessation among adults, then such actions could only be justified from a public health perspective (i.e. yield a net positive impact) if the health benefits that would be lost through a reduction in smoking cessation were outweighed by the health benefits that

would be gained from a reduced rate of youth initiation of e-cigarette and other tobacco use attributable to the banning of flavored e-cigarettes. Estimating the impact of JUUL vapor products on the health of the whole population therefore requires collection of data on the use of JUULpods in non-tobacco flavors by youth and non-smokers, and the impact of use of these products on these individuals' use of other tobacco products that may carry more harm, such as conventional cigarettes, to give context to present data that show a significantly higher smoking cessation rate among adults who use JUULpods in characterizing flavors.

Smokers who used a JUUL vaporizer more frequently in the 30 days at six months had more than double the odds of not smoking any cigarettes in the past 30 days compared to those who used a JUUL vaporizer less-than-daily. This is consistent with findings from nationally representative surveys.^{32 33} For example, data from the 2014 and 2015 U.S. National Health Interview Survey (NHIS) showed that over half (52%) of daily e-cigarette users had quit smoking in the last five years. Daily e-cigarette users were 3.15 times more likely to have quit smoking compared to those who had never used an e-cigarette (28.2%). Those who used e-cigarettes on only some days were least likely to have quit (12.1%). The observation of similarly strong associations between daily use of a JUUL vaporizer and past 30-day cigarette abstinence outcomes in this study reinforce the notion that adults who are using a JUUL vaporizer to help them to quit smoking should be encouraged to use their JUUL vaporizer as needed each day.

Consistent with the literature on the negative association between severity of cigarette dependence and odds for quitting smoking, participants' likelihood of completely switching from combustible cigarettes to a JUUL vaporizer at six months decreased as their baseline frequency, heaviness and duration of cigarette smoking increased. These data have several important implications for the current and potential impact of JUUL vapor products on adult smoking cessation.

First, at present, new users of the JUUL vaporizer appear more likely to be lighter smokers who have been smoking for fewer years of their lifetime, and present data indicate that odds for quitting smoking at six months are highest among these smoker sub-groups. By appealing more to younger, lighter, shorter-term smokers who, by virtue of their reduced heaviness and duration of exposure to cigarette smoke are likely to be presently experiencing fewer health problems related to cigarette smoking, and by being more effective in helping these smokers

to quit within three months, the use of a JUUL vaporizer for even a short period of time may be highly effective in diverting younger, less dependent smokers away from smoking before they begin to experience serious smoking-related health problems and become increasingly dependent on cigarettes.

Second, there is a clear need to better understand why older, heavier, longer-term and female cigarette smokers are less likely to use JUUL vapor products, and why, beyond lifetime cigarette exposure, smokers who are at the greatest risk of developing smoking-related diseases – those smoking more cigarettes per day, smoking more days in the month, and have smoked for more years in their lifetime at the point of first purchase of a JUUL Starter Kit – have the greatest difficulty in completely substituting a JUUL vaporizer for combustible cigarettes within three months. Specifically, research should seek to understand the extent to which these smokers' lower likelihood of using a JUUL vaporizer and lower likelihood of completely switching to a JUUL vaporizer could be addressed by innovating the look, feel, taste, nicotine delivery and satisfaction of existing JUUL products to be increasingly socially acceptable and pharmacologically appealing to heavier, more frequent and longer-term cigarette smokers, and by increasing marketing of JUUL vapor products towards these smoking sub-groups. It should be acknowledged, however, that, for many smokers, there may be no level of innovation of a JUUL vaporizer or any other e-cigarette that will replicate or compete with the satisfaction of smoking a cigarette. Assisting these individuals to quit smoking sooner may require provision of adjunctive behavioural support, concurrent use of other products and methods that are empirically supported for smoking cessation, and/or education and practical skills training on how to use JUUL vapor products to maximise their chances of quitting smoking.

The conclusions of this study are limited in several ways. Smoking abstinence at three and six months was self-reported. Biochemical verification of self-reported abstinence was not possible due to the large sample size and remote collection of data. Carbon monoxide validation detects smoking only over the past 24 hours, and so would not have been a robust validation of the primary measure of any smoking in the past 30 days. Though participants were incentivised with \$30 to complete each survey, 41.5% of smokers were lost to follow-up at six months. Though the study invitation and informed consent procedure conveyed no expectation or requirement that smokers quit smoking in the next six months, some may have been unwilling to continue to respond to surveys if they felt embarrassed about not having quit smoking after six months. Others may have simply not wanted to continue to provide data after

they had quit smoking. Recoding missing respondents as smoking cigarettes therefore represents the most conservative estimate of the effect of using JUUL products, but may not represent a realistic estimate. Abstinence rates reported for all enrolled participants and for only those who responded to surveys at three and six months should therefore be interpreted as lower and upper bound estimates of the effect of using JUUL products on smoking abstinence.

Another possible reason for drop-out was that the survey web-link send to participants by email at the three and six months was only active for a 10-day window. The researchers received many emails from participants who had not completed their survey before the web-link expired and asked to be sent a new web-link. These requests were rejected in order to maintain a strict measure of smoking and JUUL use at each assessment.

The findings are likely to be valid for adult smokers in the United States who are motivated to use a JUUL vaporizer and purchase a JUUL Starter Kit of their own volition, but are not generalizable to the U.S. adult population of smokers or e-cigarette users, adult smokers who use others brands of e-cigarette, adult smokers who use a JUUL vaporizer for reasons other than to support an attempt to quit smoking, or adult smokers who are less motivated to use e-cigarettes, such as those randomized to receive e-cigarettes as part of a trial. By including only those who were adult established current smokers at the time of their first purchase of a JUUL Starter Kit, this study additionally does not yield data on the proportion of all new JUUL purchasers who are adults (versus adolescents) or current smokers (versus former smokers and never smokers). In turn, this study yields no data about the rate of smoking initiation and smoking relapse among those who were not actively smoking or had never smoked a cigarette, respectively, when they purchased their first JUUL Starter Kit. Estimating these rates are essential for modelling the impact of using JUUL vapor products on the health of the whole U.S. population, the majority of whom are non-users of tobacco products.

Lastly, data on the rates of smoking cessation and reduction associated with different patterns of use of a JUUL vaporizer for six months do not permit conclusions about the potential impact of JUUL products on the current or future health status of study participants. No data have been presented that would permit the conclusion that adults who switched completely from smoking cigarettes to using a JUUL are likely to have increased or reduced their exposure to harmful and potentially harmful toxicants, or their risk for developing serious health problems. The

present study collected no data that could adequately characterize the individual health impact of switching from smoking cigarettes to using a JUUL vaporizer. Studies that characterize the risk/safety profile of JUUL vapor products relative to combustible cigarettes, other ENDS products, and FDA-approved smoking cessation products and medications, and which characterize the patterns of use of JUUL vapor products that increase and decrease risks to users' health, are urgently needed.

Conclusions

This study provides the first evidence of the rate at which adult smokers in the United States who naturally purchased their first JUUL Starter Kit had completely substituted use of a JUUL vaporizer for smoking conventional cigarettes after six months. The study also identified patterns of use of JUUL products and conventional cigarettes that increased and decreased smokers' likelihood of having quit smoking at six months. As part of a broader collection of data on the human health impact of JUUL vapor products, these data can assist the FDA Center for Tobacco Products to determine whether issuing a marketing authorization order for JUUL vapor products would be appropriate for the protection of the public health under section 910 of the FD&C Act (21 U.S.C. 387j).

Declarations

Ethics Approval and consent to participate

Using the Department of Health and Human Services regulations found at 45 CFR 46.101(b)(2), Advarra Institutional Review Board (IRB) determined the component of this study involving collection of data from individuals who purchased a JUUL Starter Kit in a retail store to be exempt from IRB oversight (Exempt Determination received 5 April 2018; Protocol Number 00024906). Data are also reported by 7,633 age-verified adults who opted in to JUUL Labs Inc.'s internal market research surveys when purchasing JUUL products online. Informed consent to participate was obtained from all participants. The Informed Consent

Form used in the current study is available from the corresponding author on reasonable request.

Consent for publication

Not applicable

Availability of data and materials

The datasets analysed in the current study are available from the corresponding author on reasonable request.

Funding

Funding for this study was provided by JUUL Labs Inc. JUUL Labs Inc. had no input to or control over the study design, contents of the survey instrument, sample recruitment, data analysis, interpretation, or reporting of findings. The authors alone are responsible for the contents, production and decision to report this study.

Competing Interests

In the past 12 months, the employers of CR and NM, the Centre for Substance Use Research, has received funding from JUUL Labs Inc. to conduct research on the impact of JUUL vapor products on tobacco use behaviors, perceptions and intentions among adults and adolescents in the United States. In the past three years, the Centre for Substance Use Research has also received funding from several other e-cigarette manufacturers, including Fontem Ventures, Nicoventures and Philip Morris International, to conduct research on tobacco harm reduction, specifically, on factors that encourage and discourage smokers from trialling and completely switching to using e-cigarettes.

Authors' contributions

CR and NM conceived of the study. CR developed the survey instrument. CR and FH conducted the data analyses. CR, FH and NM wrote the manuscript. All authors read and approved the final manuscript.

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List of Figures

Figure 1. Past 30-day point prevalence abstinence from smoking at the 3-months assessment.

Figure 1 Legend: 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.