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Flavored E-cigarette Use and Progression of Vaping in Adolescents

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abstract

OBJECTIVES: Electronic cigarettes (e-cigarettes) are available in nontraditional flavors (eg, fruit and candy) that are banned in combustible cigarettes in the United States. Whether adolescent use of e-cigarettes in nontraditional flavors prospectively predicts continuation of vaping and progression to more frequent vaping is unknown.

METHODS: High school students in Los Angeles, California, completed 5 semiannual surveys (2014–2017 [10th grade to 12th grade]). Among past-6-month e-cigarette users at survey waves 1 to 4 (N = 478), e-cigarette flavor (or flavors) used was coded into 2 mutually exclusive categories at each wave (use of ≥1 nontraditional flavors [fruit, candy, sweet or dessert, buttery, blends or combinations, and other] versus exclusive use of tobacco, menthol or mint, or flavorless). Flavor used during waves 1 to 4 was modeled as a time-varying, time-lagged regressor of vaping status and frequency outcomes 6 months later at waves 2 to 5.

RESULTS: Across waves 1 to 4, there were 739 (93.8%) observations of nontraditional-flavor use and 49 (6.2%) observations of exclusive use of tobacco, mint or menthol, or flavorless e-cigarettes. Use of e-cigarettes in nontraditional flavors (versus only tobacco, mint or menthol, or flavorless) was positively associated with vaping continuation (64.3% vs 42.9%; adjusted odds ratio = 3.76 [95% confidence interval 1.20 to 10.31]) and past-30-day number of puffs per nicotine vaping episode (mean: 3.1 [SD 5.5] vs 1.5 [SD 3.8]; adjusted rate ratio = 2.41 [95% confidence interval 1.08 to 5.92]) 6 months later. Flavor used was not associated with the subsequent number of past-30-day vaping days or episodes per day.

CONCLUSIONS: Adolescents who vaped e-cigarettes in nontraditional flavors, compared with those who exclusively vaped tobacco-flavored, mint- or menthol-flavored, or flavorless e-cigarettes, were more likely to continue vaping and take more puffs per vaping occasion 6 months later.

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WHAT'S KNOWN ON THIS SUBJECT: Electronic cigarettes (e-cigarettes) in nontraditional flavors (eg, fruit and candy) are commonly used at e-cigarette use initiation by youth. Whether exposure to e-cigarettes in nontraditional flavors after youth start vaping prospectively predicts persistence and progression of vaping is unknown.

WHAT THIS STUDY ADDS: This study provides the first prospective longitudinal evidence indicating that among youth who vape e-cigarettes, use of e-cigarettes in nontraditional flavors is positively associated with subsequent persistence of vaping and puffs per vaping episode.

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The US Food and Drug Administration (FDA) prohibits the sale of combustible cigarettes in flavors other than menthol or tobacco.[1,2] These policies do not currently extend to electronic cigarettes (e-cigarettes), which are available in flavors not traditionally found in combustible cigarettes.[3]

E-cigarettes in nontraditional flavors (eg, fruit and candy) are commonly used at e-cigarette use initiation by youth.[4–8] Prospective longitudinal evidence of whether exposure to e-cigarettes in nontraditional flavors after youth start vaping predicts future continuation of e-cigarette use and progression to more frequent vaping patterns is lacking. Greater frequency and chronicity of vaping may be dose-dependently associated with increased risk of addiction, behavioral conditions resulting from nicotine neuroexposure, combustible tobacco use, and other adverse health effects.[9,10] Flavors may compound these risks; exposure to e-cigarettes in nontraditional (versus traditional) flavors is associated with increased combustible cigarette smoking susceptibility,[11] abuse liability,[9,10] and toxic emissions caused by aerosolization of flavoring compounds.[9]

The FDA was considering a policy to limit sales of e-cigarettes in nontraditional flavors to only specialty stores that sell tobacco products.[12,13] In September 2019, the FDA announced that it intends to finalize a compliance policy that would prioritize the agency's enforcement of the premarket authorization requirements for non-tobacco-flavored e-cigarettes, which would clear the market of flavored e-cigarette products until manufacturers obtained premarket authorization for their products or until a new policy is issued.[14] Ordinances prohibiting sales of e-cigarettes in nontraditional flavors within city or town boundaries have been introduced in several locations[15] and could be adopted elsewhere. Prospective data on the relation of adolescent use of flavored e-cigarettes with subsequent vaping patterns could help policy makers forecast whether future regulations that prevent youth exposure to flavored e-cigarettes would improve pediatric population health. This prospective cohort study tested whether adolescents who used e-cigarettes in nontraditional flavors, compared with those who only used traditional-flavored (tobacco and menthol or mint) or flavorless e-cigarettes, were more likely to continue vaping and progress to more frequent vaping patterns 6 months later.

METHODS

Participants and Study Design

Students from 10 Los Angeles County, California, high schools enrolled in a longitudinal cohort study of behavioral health beginning in fall 2013 (their ninth-grade year).[16] Of 4100 eligible students, 3396 (82.8%) provided assent and parental consent and enrolled in the cohort. Paper-and-pencil surveys were administered on-site at participating high schools every 6 months through 12th grade in spring 2017.

Flavored e-cigarette use was first assessed during the spring 2015 10th-grade assessment wave, the initial time point in the current study (wave 1; total surveyed = 3251 [96.0% of cohort enrollees]). Data from the fall 2015 11th-grade (wave 2; N = 3232 [95.6%]), spring 2016 11th-grade (wave 3; N = 3078 [91.0%]), fall 2016 12th-grade (wave 4; N = 3168 [93.8%]), and spring 2017 12th-grade (wave 5; N = 3140 [93.1%]) assessments were also included in this study. The analytic sample (N = 478 [14.1% of cohort enrollees]; Supplemental Fig 1) included students with ≥1 exposure wave–outcome wave pairings that met the following criteria: (1) across waves 1 to 4, students reported vaping e-cigarettes with or without nicotine in the past 6 months and at that same wave indicated which e-cigarette flavor they used (designated as exposure waves), and (2) vaping outcome data were available at the wave immediately after the exposure wave (waves 2–5; outcome waves). Individual students could contribute multiple exposure–outcome wave pairings to the analysis.

The University of Southern California Institutional Review Board approved this study. Written or verbal parental consent was obtained. All students assented to participation.

Measures

Flavored E-cigarette Use

At waves 1 to 4, participants were provided with a checklist of 9 different flavors identified in previous work[17,18] preceded by the headings "Vaping" or "Vaping in the Past 30 Days" and the instructional stem, "Which flavors did you usually use in your e-cigarette (select all that apply)?" Responses were coded to generate the study's exposure variable that had 2 mutually exclusive categories: (1) use of tobacco-flavored, menthol- or mint-flavored, or flavorless products only (unexposed to nontraditional flavors) and (2) use of ≥1 nontraditional flavors, which included fruit, candy, sweet or dessert, buttery, blends or combinations, or other flavors (exposed to nontraditional flavors; either with or without concomitant use of tobacco, menthol or mint, or flavorless products).[17,18]

Vaping Outcomes

Self-reported past-6-month use of e-cigarettes (with or without nicotine; yes or no) indicated whether youth continued vaping during the 6 months after the flavored e-cigarette exposure assessment.[19] At all waves, students completed vaping frequency items measuring

past-30-day number of days vaped nicotine (range: 0–30), number of nicotine vaping episodes (range: 0–20), and puffs per nicotine vaping episode (range: 0–20) per vaping day, as in previous work (see the Supplemental Information for detailed item descriptions, data coding, and preliminary psychometric data suggesting convergent validity across frequency measures).[20]

Covariates

On the basis of the literature,[20–28] we identified a priori covariates considered to be conceptually peripheral to the putative risk pathway, which could increase exposure to flavored e-cigarettes as well as alter vaping patterns and could therefore confound associations.

Time-Invariant Covariates

Demographics, including age (years; continuous variable), sex, and parental education (≥1 parent obtained a college degree [yes or no]), were assessed with self-report questionnaires. Forced choice of 1 of 8 race and/or ethnicity categories (American Indian and/or Alaskan native, Asian American, Black and/or African American, Hispanic and/or Latino, Native Hawaiian and/or Pacific Islander, white, multiethnic and/or multiracial, or other) was recoded into a 4-level variable (Hispanic, white, Asian American, and other race and/or ethnicity).[21,22] Because chronicity of vaping and device type may be associated with vaping patterns and e-cigarette flavors used,[26,27] additional covariates included age of vaping onset[25] (years; continuous variable) and e-cigarette device type[26,27] (forced choice: cigalike [appearance similar to combustible cigarette, nonrefillable, low power], midsize tank [appearance similar to a large pen, refillable, rechargeable, moderate to high power], or advanced personal vaporizer or modified electronic cigarette or "Mod" [similar in size to a smartphone, high power, modifiable, refillable]; assessed only at wave 2). Sensation seeking, assessed with the 12-item subscale of the urgency, perseverance, premeditation, and sensation seeking (UPPS) Impulsive Behavior Scale[28] (eg, "I generally seek new and exciting experiences and sensations"; Cronbach's $\alpha = 0.93$)[29] at wave 1, was included because it could influence the pursuit of flavors and vaping pattern.[30]

Time-Varying Covariates

All nicotine vaping frequency variables at each exposure wave were included as time-varying covariates to adjust for a propensity toward frequent vaping patterns that may precede use of flavors and subsequent vaping outcomes. To address confounding of vaping patterns and flavor choice with exposure to nicotine, other tobacco products, and social elements, we also included exposure wave self-report measures of past-month e-cigarette nicotine concentration typically used (0, 1–5, 6–17, or ≥18 mg/mL; recoded continuously [range: 0–3]),[20] number of smoking days (range: 0–30) and cigarettes smoked per smoking day (range: 0–20), past-6-month noncigarette tobacco product use (hookah, cigars, or smokeless tobacco [yes or no]) and peer vaping ([0 vs ≥1 friends who vaped in the past 30 days]).[24]

Statistical Analysis

Random-effect repeated-measures regression can increase statistical power in cases with low frequency exposures that are spread across multiple time points.[31] We used logistic random-effect repeated-measures regression models in which e-cigarette flavor used (any nontraditional versus only tobacco, menthol or mint, or flavorless) at the exposure waves (waves 1–4) was modeled as a time-varying and time-lagged regressor. Dependent variables were either any past-6-month vaping (yes or no; modeled with binary logit link distributions) or 1 of the past-30-day nicotine vaping frequency count variables (number of vaping days, episodes per day, and puffs per episode; negative binomial distributions) at the immediately subsequent outcome wave (waves 2–5).

Models were fit with and without adjustment for all time-invariant and time-varying covariates described above and included exposure wave time point (continuous variable: 1–4) random effects. Flavor–by–exposure-wave time point interactions were also tested. Analyses were conducted in Mplus version 7.[32] Because students could contribute multiple observations to the analysis (by providing ≥2 exposure–outcome wave pairings) and because of clustering of data within schools, 2-level random effects (time nested within students) and school-level random effects were included. Missing data were managed with full information maximum likelihood estimation. Regression coefficients were exponentiated to obtain odds ratios (ORs) or rate ratios (RRs) with 95% confidence intervals (CIs). Significance was set to 0.05 (2 tailed). For flavor regressor estimates, Benjamini-Hochberg multiple testing corrections were applied to control the study-wide false-discovery rate at 0.05.[33] For exploratory purposes, vaping outcome descriptive statistics for exclusive use of tobacco, menthol or mint, or flavorless products were compared with exposure to each of the 6 individual nontraditional flavors. Additional sensitivity analyses are summarized below and detailed in the Supplemental Information.

RESULTS

Sample

Cohort enrollees included versus excluded from analyses were more likely to be boys, reported higher

sensation-seeking scores, and differed in racial and/or ethnic distribution (Supplemental Table 4).

Descriptive Analyses

The analytic sample (N = 478; wave 1 mean age = 16.1 [SD 0.4]) was demographically heterogeneous (47.5% girls; 46.7% Hispanic; 47.5% had ≥1 parent with a college degree). The mean age of vaping initiation was 15.3 (SD = 0.9) years. Most students reported using advanced personal vaporizers or Mods (52.2%; Table 1).

Pooled across waves 1 to 4, there were 739 (93.8%) total exposure wave observations involving the use of e-cigarettes in nontraditional flavors constituted by 454 unique students. There were 49 (6.22%) exposure wave observations involving exclusive use of traditional flavors (tobacco and mint or menthol) or flavorless products constituted by 47 unique students. Of these 47 students, 23 also reported using a nontraditional flavor on ≥1 other exposure wave.

Illustrated in the left column of Table 2, fruit (total observations = 561 [71.2%]) and candy (N = 299 [37.9%]) were the most common nontraditional flavors used pooled across exposure waves. Supplemental Table 5 reports wave-by-wave frequencies of nontraditional-flavor use and exclusive traditional-flavor or flavorless use. Supplemental Table 6 reports detailed frequencies of the use of each e-cigarette flavor in the overall sample and shows that the use of menthol or mint (18.3%) was more common than flavorless (6.3%) and tobacco-flavored (3.0%) products.

TABLE 1 Descriptive Statistics for Study Covariates

Variable	Result	Available, No.[a]
Time-invariant covariates (total students: N = 478)		
Female sex, No. (%)	227 (47.5)	478
Age, y, mean (SD)	16.1 (0.4)	472
Race and/or ethnicity, No. (%)		465
Hispanic ethnicity	217 (46.7)	
White	102 (21.9)	
Asian American	92 (19.8)	
Other	54 (11.6)	
Parents graduated college, No. (%)	196 (47.5)	413
Age of vaping onset, y, mean (SD)	15.3 (0.9)	440
E-cigarette device type, No. (%)		205
Cigalike, mini e-cigarette, or slim model	19 (9.3)	
Midsize or vape pen	79 (38.5)	
Advanced personal vaporizer or Mod	107 (52.2)	
Sensation-seeking score,[b] mean (SD)	33.0 (9.7)	400
Time-varying covariates at exposure waves 1–4 (total observations: N = 788)		
No. d vaped nicotine in past 30 d, mean (SD)	6.4 (8.9)	780
No. d smoked cigarettes in past 30 d, mean (SD)	2.6 (6.7)	783
Cigarettes smoked per d, mean (SD)	0.9 (3.2)	784
No. nicotine vaping episodes per d, mean (SD)	4.9 (6.5)	784
No. puffs per nicotine vaping episode, mean (SD)	5.9 (6.4)	786
E-cigarette nicotine concentration, mg/mL, No. (%)		619
0	157 (25.4)	
1–5	245 (39.6)	
6–17	162 (26.2)	
≥18	55 (8.9)	
Past-6-mo other tobacco product use,[c] No. (%)	371 (47.9)	775
Past-30-d peer e-cigarette use,[d] No. (%)	570 (80.1)	712

[a] The number of students or observations with (nonmissing) data available for the respective variable and denominators for percentages reported for categorical variables.

[b] UPPS Impulsive Behavior Scale sensation-seeking score range: 0 to 48.

[c] Use of hookah, smokeless tobacco, cigars, and cigarillos (yes or no).

[d] One or more close friends vaped in past 30 days (yes or no).

Association of Flavored E-cigarette Use With Subsequent Vaping Outcomes

Table 2 reports descriptive results of study outcomes. Table 3 reports regression modeling results. With or without adjusting for the 15 covariates listed in Table 1, use of e-cigarettes in nontraditional flavors (versus exclusive use of tobacco, menthol or mint, or flavorless products) at waves 1 to 4 was associated with greater odds of continuing versus discontinuing vaping during the 6 months after exposure in waves 2 to 5 (64.3% vs 42.9%; adjusted OR = 3.76 [95% CI 1.20 to 10.31]). Use of e-cigarettes in nontraditional flavors (versus exclusive use of tobacco-flavored, mint- or menthol-flavored, or flavorless products) was also associated with a greater number of puffs per nicotine vaping episode 6 months later (mean: 3.1 [SD 5.5] vs 1.5 [SD 3.8]; adjusted RR = 2.41 [95% CI 1.08 to 5.92]). Use of nontraditional flavors (versus exclusively tobacco, mint or menthol, or flavorless products) was not significantly associated with the number of past-30-day nicotine vaping days (mean: 4.6 [SD 8.8] vs 2.9 [SD 7.3]) or episodes per day (mean: 3.5 [SD 6.3] vs 2.5 [SD 5.9]).

Flavor-by-time interactions were not significant in all models ($P > .15$), suggesting flavor–vaping outcome associations did not differ by study wave. Estimates of association for covariates in the adjusted model are reported in Supplemental Table 7 and show that peer vaping, use of an advanced personal vaporizer (versus a cigalike), vaping a higher nicotine concentration, cigarette smoking, use of other tobacco products, and exposure wave vaping frequency were positively associated with some vaping outcomes 6 months later.

TABLE 2 Descriptive Statistics of Vaping Outcomes in Combined Sample and Stratified by Flavor of E-cigarette Used

Flavor E-cigarette Used, Pooled Across Waves 1–4	Vaping Outcomes 6 mo After Flavor Assessment, Pooled Across Waves 2–5							
	Any Vaping		No. d Vaped Nicotine in Past 30 d		No. Nicotine Vaping Episodes Per d		No. Puffs per Nicotine Vaping Episode	
	% (SE)	Difference[a] (95% CI)	Mean (SD)	Difference[a] (95% CI)	Mean (SD)	Difference[a] (95% CI)	Mean (SD)	Difference[a] (95% CI)
Combined sample (*N* = 788)	62.9 (1.7)	—	4.5 (8.7)	—	3.5 (6.3)	—	3.0 (5.5)	—
Primary study exposure variable (mutually exclusive categories)								
Traditional flavor or flavorless only (*N* = 49)[b]	42.9 (7.1)	Reference	2.9 (7.3)	Reference	2.5 (5.9)	Reference	1.5 (3.8)	Reference
Any nontraditional flavor (*N* = 739)[c]	64.3 (1.8)	21.4 (7.5 to 35.3)	4.6 (8.8)	1.7 (−0.9 to 4.2)	3.5 (6.3)	1.0 (−0.9 to 2.8)	3.1 (5.5)	1.6 (0.04 to 3.2)
Individual nontraditional flavors (not mutually exclusive)								
Fruit (*N* = 561)[d]	62.5 (2.0)	19.6 (5.6 to 33.6)	4.2 (8.3)	1.3 (−1.0 to 3.7)	3.4 (6.1)	0.9 (−0.8 to 2.7)	2.8 (5.2)	1.3 (−0.2 to 2.8)
Candy (*N* = 299)[d]	63.0 (2.7)	20.1 (5.5 to 34.7)	3.8 (7.8)	0.9 (−1.4 to 3.2)	3.2 (6.0)	0.7 (−1.1 to 2.5)	2.8 (5.2)	1.3 (−0.2 to 2.8)
Blends or combinations (*N* = 260)[d]	70.4 (2.8)	27.5 (13.4 to 41.6)	4.9 (8.7)	2.0 (−0.4 to 4.6)	4.2 (6.9)	1.7 (0.05 to 3.5)	4.0 (6.2)	2.5 (0.7 to 4.3)
Sweets or desserts (*N* = 229)[d]	71.1 (2.9)	28.2 (14.0 to 42.4)	5.0 (8.8)	2.1 (−0.5 to 4.7)	4.3 (7.0)	1.8 (−0.04 to 3.7)	4.3 (6.4)	2.8 (0.9 to 4.7)
Other flavor (*N* = 73)[d]	72.7 (5.1)	29.8 (11.5 to 48.1)	6.5 (11.0)	3.6 (0.1 to 7.1)	4.9 (7.5)	2.4 (−0.1 to 4.9)	4.5 (6.8)	3.0 (0.9 to 5.1)
Buttery (*N* = 54)[d]	71.4 (6.1)	28.5 (10.0 to 47.0)	7.5 (11.2)	4.6 (0.9 to 8.3)	5.8 (7.8)	3.3 (0.6 to 6.0)	5.3 (7.1)	3.8 (1.6 to 6.1)

—, not applicable.
[a] Difference in vaping outcome between respective flavor category and traditional flavor or flavorless only category.
[b] Use of tobacco-flavored, mint- or menthol-flavored, or flavorless e-cigarettes only.
[c] Use of e-cigarettes in ≥1 nontraditional flavor (ie, fruit, candy, blends, sweets or desserts, other, or buttery).
[d] Subset of any nontraditional-flavor category that used respective individual flavor (not mutually exclusive with use of the 5 other individual nontraditional flavors).

Exploratory Analyses of Use of Individual Nontraditional Flavors

Relative to exclusive use of tobacco, menthol or mint, or flavorless products, the prevalence of vaping continuation was higher 6 months after use of each of the 6 individual nontraditional flavors (ie, fruit, candy, blends, sweets or desserts, other, or buttery; Table 2). The mean number of puffs per nicotine vaping episode was higher 6 months after use of 4 of the 6 individual nontraditional flavors than after exclusive use of tobacco, menthol or mint, or flavorless products. The number of past-30-day nicotine vaping days or episodes per vaping day did not uniformly differ by flavor used at exposure waves (Table 2).

Sensitivity Analyses

Sensitivity analyses found that the 3 vaping frequency items were moderately to strongly correlated with one another, providing preliminary evidence of their convergent validity (Supplemental Information, Supplemental Table 8). Sensitivity analyses suggested that the likelihood of unmeasured confounding was low and results were unchanged on the basis of past-30-day vaping at exposure (Supplemental Information). Analysis of alternative exposure variables suggested (1) possible graded (dose-responselike) associations between vaping a greater number of different nontraditional flavors and subsequent vaping patterns across most outcomes and (2) no differences in vaping outcomes between youth who used only nontraditional flavors and those who used both traditional and nontraditional flavors during concurrent or sequential waves (Supplemental Information, Supplemental Tables 9–12). To determine if graded associations were observed with traditionally flavored or flavorless products, models including the total number of traditionally flavored or flavorless

TABLE 3 Association of Flavored E-cigarette Use With Vaping Outcomes 6 Months Later

	Any Vaping in Past 6 mo, OR (95% CI)	Past-30-d Nicotine Vaping Frequency Outcomes		
		No. d Vaped, RR (95% CI)	No. Vaping Episodes per Vaping d, RR (95% CI)	No. Puffs per Vaping Episode, RR (95% CI)
Unadjusted models[a]				
Use of e-cigarettes in any nontraditional flavor[b]	4.86 (2.11 to 9.86)[c]	2.54 (0.94 to 6.77)	2.06 (0.98 to 4.31)	3.00 (1.46 to 6.17)[c]
Time[d]	1.14 (0.91 to 1.42)	1.15 (0.98 to 1.36)	1.14 (0.97 to 1.32)	1.09 (0.93 to 1.26)
Adjusted models[e]				
Use of e-cigarettes in any nontraditional flavor[b]	3.76 (1.20 to 10.31)[c]	1.47 (0.56 to 4.91)	1.65 (0.70 to 5.36)	2.41 (1.08 to 5.92)[c]
Time[d]	1.23 (0.96 to 1.56)	1.13 (0.93 to 1.38)	1.04 (0.87 to 1.25)	1.14 (0.98 to 1.34)

Estimates are of association of time-varying, time-lagged regressors at waves 1 to 4 and time-invariant covariates with vaping outcomes 6 mo postexposure assessment at waves 2 to 5 from logistic repeated-measures random-effect regression models including school random effects (total observations: range 768–788; totals for each outcome are presented in Supplemental Fig 1). Flavor-by-time interaction terms were tested in separate models and were not significant in all models ($P > .15$).

[a] Unadjusted models include use of e-cigarettes in nontraditional flavors and time as sole regressors.

[b] Time-varying variable assessed at each exposure wave at waves 1 to 4 involving use of ≥1 nontraditional flavor (fruit, candy, blends, sweets or desserts, other, or buttery [$N = 739$]) versus use of flavorless, tobacco-flavored, or mint- or menthol-flavored e-cigarettes only ($N = 49$).

[c] Statistically significant after Benjamini-Hochberg corrections for multiple testing to control the false-discovery rate at 0.05 for all estimates of e-cigarette flavor used (on the basis of 2-tailed corrected *P* value).

[d] Time is the continuous variable (scored: wave 1, 0; wave 2, 1; wave 3, 2; wave 4, 3).

[e] Adjusted models include use of e-cigarettes in nontraditional flavors, time, time-invariant covariates (age, sex, race and/or ethnicity, parental education, e-cigarette device type, age started vaping, and sensation-seeking score) and time-varying covariates (days smoked cigarettes in past 30 d, number of cigarettes smoked per day, e-cigarette nicotine concentration, days vaped nicotine in past 30 d, number of nicotine vaping episodes per day, no puffs per vaping episode, past-6-mo use of other tobacco products, and peer vaping) as simultaneous regressors. Association estimates for covariates are provided in Supplemental Table 7.

products used as regressors were tested and found no significant associations with any outcome (Supplemental Information, Supplemental Table 10).

DISCUSSION

This study provides new prospective evidence that adolescent use of e-cigarettes in nontraditional flavors may be associated with greater odds of continuing vaping and progression to more frequent vaping patterns. Previous research on this topic has predominately implicated nontraditional flavors in e-cigarette use initiation.[4–8] Existing youth studies linking e-cigarette flavor used with vaping persistence and progression have primarily been retrospective and cross-sectional,[4–8,34] leaving the temporal ordering of the association unclear. The present investigation addresses this gap by using a rigorous, prospective, longitudinal, 5-wave, time-varying, and time-lagged study design; comprehensive flavored e-cigarette use assessment; and sensitivity analyses that support the robustness and specificity of the identified associations. An additional study strength is the detailed vaping frequency outcome assessment, which permitted the identification of an association of flavored e-cigarette use with taking more puffs per vaping episode, which is notable given that frequent and consecutive puffing patterns can cause some e-cigarette devices to overheat and emit aerosol with greater toxicant concentrations.[35]

Common factors that increase exposure to flavored e-cigarettes and alter vaping trajectories could confound the observed associations. After adjusting for 15 potential confounders, estimates of association were reduced by 20% to 23% but remained statistically significant, suggesting that these factors only partially explained the results. Further increasing the plausibility of the associations was supplementary evidence of graded (dose-responselike) associations between exposure to more nontraditionally flavored e-cigarette products and subsequent vaping patterns, which has been previously reported in cross-sectional research.[34] It is unlikely that these graded associations reflect a nonspecific inclination toward using a greater diversity of e-cigarette products regardless of flavor. Sensitivity analyses found that the number of traditionally flavored or flavorless e-cigarette products used was not associated with vaping outcomes and observed no differences in vaping outcomes between youth using both nontraditional and traditional flavors versus those using nontraditional flavors only.

A conservative operationalization of nontraditional-flavor exposure was applied in this study, resulting in a modest prevalence of unexposed cases of e-cigarette use (ie, exclusive use of tobacco-flavored, menthol- or mint-flavored, or flavorless e-cigarettes; $n = 49$ [6.2%]). Youth who use traditionally flavored or flavorless e-cigarettes may represent a unique subgroup of the population that is inherently different from those who use nontraditional flavors, which may directly influence vaping behaviors and is not captured by covariate adjustment. However, the study's

time-varying design mitigates this concern. Approximately half of students who vaped only traditionally flavored or flavorless e-cigarettes during 1 survey wave used nontraditional flavors at another wave during the study and are represented in both exposure categories. Although unmeasured confounding is still possible, the likelihood that unmeasured confounders entirely explain associations was deemed to be low in supplemental analyses reported in the Supplemental Information.

It is possible that the sensory and pharmacologic effects of exposure to flavored e-cigarettes increases the persistence and frequency of vaping in youth. The adolescent brain is particularly sensitive to the pleasurable effects of palatable sweet tastes.[36] Laboratory experiments in young adults indicate that exposure to e-cigarettes in nontraditional flavors that produce sensory perceptions of sweetness (versus menthol and tobacco flavors) generate greater product appeal and willingness to use again.[37] A National Academies of Sciences, Engineering, and Medicine[9] consensus report concluded that that there was moderate evidence that product characteristics, such as nicotine and flavors, may increase the addiction potential of e-cigarettes. Nontraditionally flavored e-cigarette solutions could increase addiction potential because they can contain compounds that decrease product pH, which may increase the bioavailability of nicotine absorbed by the user at equivalent e-cigarette aerosol exposure doses.[38]

This study had limitations. First, exposure data in this study were collected in 2015 and 2016, before the emergence of pod-Mod e-cigarette products with high nicotine concentrations that are currently popular among youth.[39] Replication with more recent data would be useful to explore the generalizability of this study's results to the current milieu, in which youth use of pod-Mod e-cigarettes is ubiquitous. Second, tobacco, menthol or mint, and flavorless categories were collapsed, which is consistent with previous work[22] and past FDA regulatory proposals[12,13] but precluded analyses separating them from each other. Third, some students indicated past-30-day e-cigarette flavor use but did not report past-30-day vaping at certain exposure waves, raising the possibility of inconsistent reporting, although sensitivity analyses comparing these students to the remainder of the sample revealed no differences in flavor–outcome associations. Fourth, although previous work and supplementary analyses provide preliminary evidence of validity for the number of vaping episodes and puffs per episode measures (Supplemental Information),[20] these measures have not yet been extensively validated and may be subject to respondent recall error. Finally, covariate-adjusted association estimates may underestimate risk because certain covariates (eg, other tobacco product use, e-cigarette device, and nicotine concentration) could potentially be mediators along a putative causal pathway.

CONCLUSIONS

Although this study's observational design does not support causal inferences, the results highlight the possibility that regulations that reduce youth exposure to flavored e-cigarettes may aid in preventing young people who try e-cigarettes from becoming frequent and persistent users. Such regulations could also encourage existing adolescents who use flavored e-cigarettes to discontinue vaping. Over the past several years there had been no federal restrictions on the sale of flavored e-cigarettes in the United States. The FDA recently announced plans to enforce premarket authorization requirements for non-tobacco flavored products, and because no flavored products had gone through FDA premarket review, would result in removing flavored e-cigarette products from the market.[14] However, the timeline, parameters, and extent of enforcement of this policy remain unclear, and there are no product standards that would prohibit flavored e-cigarette products from returning to the market pending successful premarket authorization. Some have proposed that the FDA use its authority to set a product standard prohibiting e-cigarettes in nontraditional flavors to be sold anywhere in the United States.[40] Given the health risks associated with frequent and persistent youth use of e-cigarettes, particularly flavored products,[5,6] any regulatory policy that effectively limits youth exposure to flavored e-cigarettes is likely to improve pediatric population health.

ABBREVIATIONS

CI: confidence interval
e-cigarette: electronic cigarette
FDA: Food and Drug Administration
Mod: modified electronic cigarette
OR: odds ratio
RR: rate ratio
UPPS: urgency, perseverance, premeditation, and sensation seeking

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Supplemental Information

SUPPLEMENTAL RESULTS

Description of Nicotine Vaping Frequency Outcomes

Number of days participants reported vaping nicotine in the past 30 days was assessed at each wave ("In the last 30 days, how many days did you use e-cigarettes with nicotine?" Responses: 0, 1–2, 3–5, 6–9, 10–14, 15–19, 20–24, 25–29, or 30 days); responses were recoded into quantitative count variables by taking the mean integer within each response range (0, 2, 4, 8, 12, 17, 22, 27, or 30 days), as in previous work.[20] Participants also reported their usual number of nicotine vaping episodes per vaping day ("On the days you vaped nicotine, how many times did you usually pick up your e-cigarette device to vape?" Responses: 0, 1, 2, 3–5, 6–9, 10–14, 15–20, or >20 times per day) and puffs taken per nicotine vaping episode ("Each time you picked up your e-cigarette to vape nicotine, how many puffs did you usually take before putting it away?" Responses: 0, 1, 2, 3–5, 6–9, 10–14, 15–20, or >20 puffs) in the past 30 days in 2 separate items used previously.[20] Responses were recoded into quantitative count variables as the lowest value within the response option (0, 1, 2, 3, 6, 10, 15, or 20 puffs or episodes) per previous work.[20] Although the nicotine vaping episodes per day and puffs per episode have not undergone extensive validation study, previous research demonstrating a positive association between the nicotine concentration level vaped by youth and their subsequent number of vaping episodes per day and puffs per episode at follow-up[20] supports the criterion validity of these measures.

Initial Psychometric Evidence of Vaping Frequency Outcomes

To further probe the convergent validity of these items, we calculated associations between past-30-day nicotine vaping days vaped, vaping episodes per day, and puffs per episode at each time point in the current sample. If these items accurately assess vaping frequency, they would be expected to correlate with one another because youth who have a stronger motivation to vape would be expected to use on more days, report more vaping episodes per day, and take more puffs during each episode. As illustrated in Supplemental Table 8, there were moderate to strong correlations between the 3 frequency measures (Pearson correlations: mean = 61.4; range = 0.46–0.80; all $P < .001$), providing initial support for the convergent validity of these measures.

Assessment of Unmeasured Confounding

To estimate the extent of unmeasured confounding, we calculated the E value, a measure of the potential for bias arising from unmeasured confounders in observational studies,[41] for the primary models in Table 3. The E value provides an estimate of the minimum strength of association that an unmeasured confounder would need to account for to negate the observed association between nontraditional-flavored e-cigarette use and subsequent vaping patterns conditional on the included covariates.[42] Using the association estimates and CIs from the adjusted models in Table 3, we calculated E values for all significant odds and RRs. The E value for the observed adjusted OR of 3.76 (95% CI 1.20 to 10.31) for the association of use of any nontraditional flavors with past-6-month vaping status was 6.98. The E value for the adjusted RR of 2.41 (95% CI 1.08 to 5.92) for the association of use of nontraditional flavors with the number of puffs per vaping episode was 4.25. Thus, to negate the significant associations between nontraditional-flavored e-cigarette use and the 2 vaping outcomes observed in this study, fairly strong unmeasured confounding associations would need to remain over and above adjustment for the existing 16 covariates included in the analysis. This extent of unmeasured confounding is unlikely.

Influence of Students Who Did Not Report Vaping in the Past 30 Days at Exposure Waves

The survey packet was divided into separate sections based on sets of items addressing common constructs. Preceding the set of items of each section was a brief introductory label that described the ensuing survey items. The item for e-cigarette flavor used was imbedded within a section of the survey packet with several items about vaping patterns and products used. Across waves 1 to 4, the label for this section varied

between "Vaping," "Vaping in the Past 30 Days," and "In the last 30 days." Consequently, it is possible that findings may differ between students who provided e-cigarette flavor data but did not report vaping within the past 30 days at 1 or more exposure waves (N = 95) potentially because of inconsistent reporting versus the remainder of the sample (N = 383). To address whether this difference influenced the pattern of exposure to flavored e-cigarettes, we created a time-invariant binary variable distinguishing these 2 groups for several analyses. The prevalence of use of e-cigarettes in nontraditional flavors pooled across exposure waves did not differ between those who reported not vaping in the past 30 days at ≥1 exposure wave (93.3%) and the remainder of the sample (93.9%). To examine the potential influence of past-30-day e-cigarette use status on the association of flavor used and subsequent vaping, we retested all models in Table 3, adding the interaction term for the past-30-day use group by the nontraditional–versus–traditional-only flavor measure. The interactions were not significant in any of the models ($P > .37$), providing no evidence that the association between nontraditional flavors and subsequent vaping persistence and progression differed by past-30-day e-cigarette use status.

Association of Number of Nontraditional Flavors Used and Vaping Patterns

As a supplemental analysis of potential graded (dose-response) associations between flavored e-cigarette exposure and outcomes, total number of nontraditional flavors vaped was calculated as a 5-level exposure variable (0 [traditional flavors only] vs 1, 2, 3, or ≥4 nontraditional flavors), and models were retested by using this variable. Results revealed heterogeneity in associations of the number of nontraditional flavors used, with probability and frequency of e-cigarette use being based on how many flavors were used. Use of 1 vs 0 nontraditional flavors was not significantly associated with any vaping prevalence or frequency outcomes 6 months later (Supplemental Table 7). In contrast, after adjustment for covariates, use of ≥4 vs 0 nontraditional flavors was positively associated with past-6-month vaping prevalence (OR = 5.32 [95% CI 1.42 to 19.97]), vaping episodes per day (RR = 2.29 [95% CI 1.07 to 6.37]), and puffs per vaping episode (RR = 3.12 [95% CI 1.22 to 6.96]). The association of ≥4 vs 0 nontraditional flavors with number of days vaped was not significant (RR = 2.20 [95% CI 0.70 to 7.91]). The categories for 2 and 3 nontraditional flavors used generally exhibited association estimates that were between the 1 flavor and ≥4 flavor categories, suggesting a graded association between exposure to more nontraditional flavors and study outcomes.

Association of Number of Traditional-Flavored or Flavorless Products Used and Subsequent Vaping Outcomes

To determine if a similar graded association was observed with the traditional-flavored or flavorless products, we created a number of traditional-flavored or flavorless products 4-level variable (0, 1, 2, or 3; range: 0–3 products; coded as a continuous variable because of low frequency counts) and a parallel 4-level continuous variable for the total number of nontraditional-flavor products used (0, 1, 2, or ≥3, range: 0–3 products). We then tested 2 sets of univariable models: (1) those including time and the 4-level continuous total number of traditional-flavored or flavorless products as the only 2 regressors and (2) those including time and the 4-level continuous total number of nontraditional-flavored products used as the only 2 regressors. Illustrated in Supplemental Table 8, the total number of traditional-flavored or flavorless products used was not associated with past-6-month vaping (OR = 1.04 [95% CI 0.67 to 1.54]), the number of nicotine vaping days in the past 30 days (RR = 1.15 [95% CI 0.79 to 1.68]), the number of nicotine vaping episodes per day (RR = 1.17 [95% CI 0.88 to 1.60]), or the number of puffs per nicotine vaping episode (RR = 1.19 [95% CI 0.86 to 1.63]). In concordance with the primary results (Table 3), the total number of nontraditional flavors used continuous 4-level variable was significantly associated with past-6-month vaping (OR = 1.55 [95% CI 1.21 to 2.00]) and the number of puffs per nicotine vaping episode (RR = 1.40 [95% CI 1.16 to 1.68]) but not the number of vaping days in the past 30 days (RR = 1.22 [95% CI 0.98 to 1.51]) or the number of nicotine vaping episodes per day (RR = 1.26 [95% CI 0.98 to 1.56]). We then tested a multivariable model that included time, the number of traditionally flavored or flavorless products variable, and the number of nontraditionally flavored products variable as simultaneous regressors to parse the associations of the 2 flavor categories with vaping outcomes. The results of these models followed a similar pattern to the univariate models, with associations being slightly attenuated. In these multivariable models, total number of traditional-flavored or flavorless products used was not associated with past-6-month vaping (OR = 0.98 [95% CI 0.64 to 1.51]), the number of nicotine vaping days in the past 30 days (RR = 1.10 [95% CI 0.76 to 1.60]), the number of nicotine vaping episodes per day (RR = 1.14 [95% CI 0.84 to 1.54]), or the number of puffs per nicotine vaping episode (RR = 1.13 [95% CI 0.82 to 1.54]). In these multivariable models, the total number of nontraditional flavors used was significantly associated

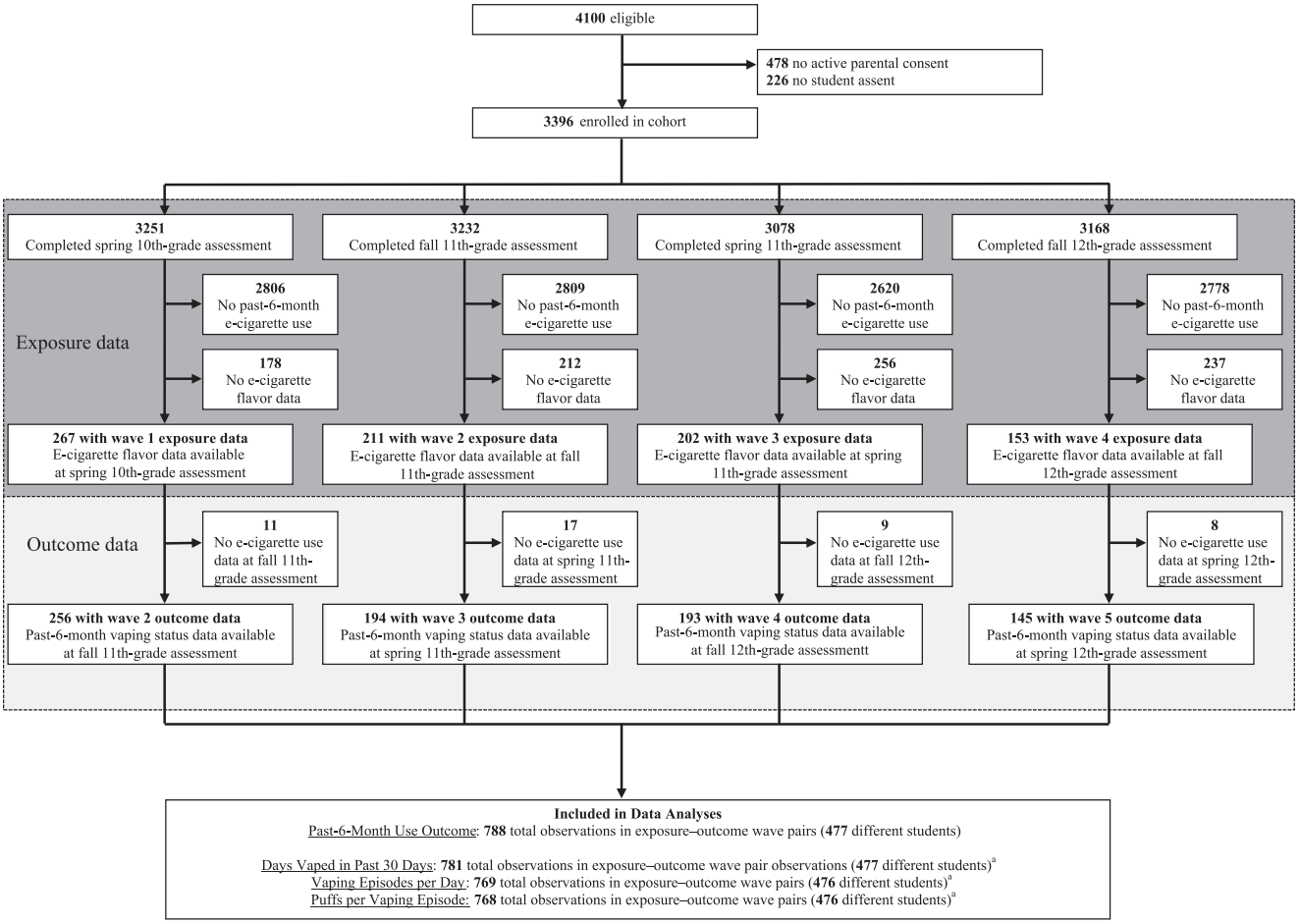
with past-6-month vaping (OR = 1.51 [95% CI 1.20 to 2.01]) and the number of puffs per nicotine vaping episode (RR = 1.39 [95% CI 1.15 to 1.68]) but not number of vaping days in the past 30 days (RR = 1.21 [95% CI 0.97 to 1.51]) or the number of nicotine vaping episodes per day (RR = 1.20 [95% CI 0.94 to 1.49]).

Test of Differences in Vaping Outcomes Between Youth Who Used Nontraditional Flavors Only and Those Who Used Both Traditional and Nontraditional Flavors in the Same Wave

The primary analysis aggregated youth who used nontraditional flavors only (observations = 140) and those who used both traditional and nontraditional flavors, including flavorless products (observations = 599) into the same category. To determine if these categories were associated with different vaping outcomes, we retested the primary unadjusted models using a regressor variable that split these classifications into separate categories to conduct head-to-head comparisons of vaping outcomes. Given the results above indicating that number of nontraditional flavors used predicted vaping outcomes and that cases in which youth use of e-cigarettes in both nontraditional and traditional (versus only nontraditional) flavors also involved use of significantly more nontraditional flavors (mean = 2.31 [SD 0.86] vs 1.64 [SD 0.85]; $P < .001$), we also included the number of nontraditional flavors as an additional covariate in the model to adjust for confounding with the bifurcation of youth who used nontraditional flavors only and those who used both traditional and nontraditional flavors. The results showed no significant differences between the 2 categories in vaping outcomes, and the number of nontraditional flavors variable significantly predicted greater odds of vaping continuation (OR = 1.53 [95% CI 1.20 to 2.02]) and higher number of puffs per vaping episode (RR = 1.37 [95% CI 1.10 to 1.67]) 6 months later (Supplemental Table 11).

Test of Differences in Vaping Outcomes Across Youth Who Did Versus Did Not Transition Between Use of Traditional Flavors Only and Use of Nontraditional Flavors Across Waves

There were 23 total students who transitioned between use of traditional flavors only and use of nontraditional flavors across different waves (13 students reported transitioning from use of traditional flavors only to use of nontraditional flavors at a subsequent wave, and 10 students transitioned from nontraditional-flavor use to traditional-flavor use only at a subsequent wave). To determine the influence of such transitions on the study results, we tested new models additionally including a time-invariant flavor-transition variable contrasting youth with (n = 23) versus without (n = 455) cross-wave transitions between use of traditional flavors only and use of nontraditional flavors. Model results showed no difference between youth with versus without cross-wave flavor transitions in vaping outcomes, and the association of the original use of nontraditional-flavored e-cigarette use and vaping continuation (OR = 3.78 [95% CI 1.23 to 10.42]) and a higher number of puffs per vaping episode (RR = 2.37 [95% CI 1.06 to 6.26]) 6 months later remained statistically significant (Supplemental Table 12).



SUPPLEMENTAL FIGURE 1

Participant flowchart. [a] Because of missing data for these outcomes, the number of observations and students are lower than for the past-6-month outcome.

SUPPLEMENTAL TABLE 4 Characteristics of Students Included in Versus Excluded From the Analytic Sample

Sample Characteristics	Students Included in the Primary Analytic Sample (N = 478)	Students Excluded From the Primary Analytic Sample (N = 2918)	Group Difference,[a] P
Male sex, *n* (%)	251 (52.5)	1330 (45.6)	.006
Age, y, mean (SD)	16.10 (0.44)	16.09 (0.41)	.39
Race and/or ethnicity, *n* (%)			.003
Hispanic ethnicity	217 (46.7)	1388 (48.5)	
White	102 (21.9)	442 (15.4)	
Asian American	92 (19.8)	607 (21.2)	
Other	54 (11.6)	424 (14.8)	
Parents graduated college (versus less education), *n* (%)	196 (47.5)	1286 (51.1)	.18
Sensation-seeking score, mean (SD)	33.02 (9.66)	31.38 (9.13)	.001

Denominators may be less than totals in column headings because of missing data. Age is a continuous variable; UPPS Impulsive Behavior Scale sensation-seeking score range: 0 to 48.
[a] Tests of differences in sample characteristics by inclusion in the analytic sample were conducted with χ^2 tests for categorical variables and 1-way analysis of variance for continuous variables.

SUPPLEMENTAL TABLE 5 Vaping Outcomes by E-cigarette Flavor Category Used for Each Exposure–Outcome Wave Pairings

Exposure	Past-6-mo Vaping Status, *N* (%)	No. d Vaped Nicotine in Past 30 d, Mean (SD)	No. Nicotine Vaping Episodes per d, Mean (SD)	No. Puffs per Nicotine Vaping Episode, Mean (SD)
Wave 1 (exposure) → wave 2 (outcomes)				
Only tobacco, menthol, mint, or flavorless (N = 16)	8 (50.0)	1.31 (3.79)	1.56 (4.97)	0.50 (1.10)
Any nontraditional flavor (N = 240)	146 (60.8)	3.03 (7.41)	2.46 (5.27)	3.03 (5.73)
Wave 2 (exposure) → wave 3 (outcomes)				
Only tobacco, menthol, mint, or flavorless (N = 10)	4 (40.0)	5.00 (10.61)	4.60 (8.33)	3.20 (6.41)
Any nontraditional flavor (N = 184)	112 (60.9)	3.32 (7.18)	3.31 (6.06)	2.78 (5.16)
Wave 3 (exposure) → wave 4 (outcomes)				
Only tobacco, menthol, mint, or flavorless (N = 11)	4 (36.4)	0.27 (0.90)	1.00 (1.95)	0.27 (0.65)
Any nontraditional flavor (N = 182)	120 (65.9)	3.97 (8.44)	3.54 (6.45)	3.01 (5.32)
Wave 4 (exposure) → wave 5 (outcomes)				
Only tobacco, menthol, mint, or flavorless (N = 12)	5 (41.7)	4.83 (9.31)	3.50 (6.84)	2.50 (4.40)
Any nontraditional flavor (N = 133)	97 (72.9)	7.06 (10.93)	5.79 (7.71)	4.05 (5.88)

The total was 478. Past-6-mo vaping status included vaping e-cigarettes with or without nicotine in the past 6 months (yes or no). Number of days vaped nicotine in past 30 days range: 0 to 30. Number of nicotine vaping episodes per day range: 0 to 20. Number of puffs per nicotine vaping episode range: 0 to 20.

SUPPLEMENTAL TABLE 6 Prevalence of Use of Each Individual E-cigarette Flavor at Each Exposure Wave

	Exposure Wave				Pooled Across Waves 1–4 (N = 788), No. Observations, %[a]
	Wave 1 (n = 256), No. Students, %[b]	Wave 2 (n = 194), No. Students, %[b]	Wave 3 (n = 193), No. Students, %[b]	Wave 4 (n = 145), No. Students, %[b]	
Flavorless	16 (6.3)	10 (5.2)	12 (6.2)	12 (8.3)	50 (6.3)
Tobacco	10 (3.9)	5 (2.6)	3 (1.6)	6 (4.1)	24 (3.0)
Menthol or mint	30 (11.7)	32 (16.5)	44 (22.8)	38 (26.2)	144 (18.3)
Fruit	183 (71.5)	136 (70.1)	140 (72.5)	102 (70.3)	561 (71.2)
Candy	85 (33.2)	65 (33.5)	81 (42.0)	68 (46.9)	299 (37.9)
Sweets or dessert	65 (25.4)	53 (27.3)	65 (33.7)	46 (31.7)	229 (29.1)
Buttery	10 (3.9)	14 (7.2)	18 (9.3)	12 (8.3)	54 (6.9)
Blends or combinations	76 (29.7)	63 (32.5)	67 (34.7)	54 (37.2)	260 (33.0)
Other	20 (7.8)	28 (14.4)	17 (8.8)	8 (5.5)	73 (9.3)

Students were instructed to select all flavors that apply. Each flavor (row) is not mutually exclusive.
[a] Denominator for percent values reflect the total number of exposure wave observations; because students used ≥2 flavors within a wave, percentages total >100% for the column.
[b] Denominators for percent values reflect the total number of students at a respective wave; because students used ≥2 flavors within a wave, percentages total >100% for the column.

SUPPLEMENTAL TABLE 7 Association of Covariates With Vaping Outcomes From the Adjusted Model

	Association With Study Outcomes			
	Past-6-mo Vaping Status, OR (95% CI)	No. d Vaped Nicotine in Past 30 d, RR (95% CI)	No. Nicotine Vaping Episodes per d, RR (95% CI)	No. Puffs per Nicotine Vaping Episode, RR (95% CI)
Time-invariant covariates				
Age[a]	1.25 (0.94 to 1.67)	1.09 (0.86 to 1.38)	1.05 (0.79 to 1.39)	1.06 (0.81 to 1.43)
Female sex	1.10 (0.65 to 1.84)	1.14 (0.74 to 1.74)	1.78 (1.03 to 3.08)	1.12 (0.75 to 1.65)
Race and/or ethnicity				
Hispanic	Reference	Reference	Reference	Reference
White	2.07 (0.93 to 4.60)	1.61 (1.40 to 1.87)	1.93 (0.96 to 3.27)	1.32 (0.74 to 2.34)
Asian American	1.79 (0.76 to 4.17)	1.32 (0.85 to 2.05)	1.81 (0.92 to 3.56)	1.46 (0.83 to 2.58)
Other	1.05 (0.41 to 2.69)	1.25 (0.94 to 1.66)	1.46 (0.87 to 2.49)	0.73 (0.39 to 1.36)
Parent(s) graduated college	1.11 (0.65 to 1.90)	1.14 (0.72 to 1.82)	1.22 (0.66 to 2.25)	1.25 (0.83 to 1.89)
E-cigarette device type				
Cigalike, mini e-cigarette, or slim model	Reference	Reference	Reference	Reference
Midsize e-cigarette or vape pen	0.75 (0.35 to 1.38)	1.49 (0.82 to 2.70)	1.62 (0.77 to 3.43)	0.99 (0.59 to 1.68)
Advanced personal vaporizer or Mod	1.46 (0.79 to 2.69)	2.38 (1.45 to 3.91)	2.22 (1.08 to 4.58)	2.45 (1.58 to 3.81)
Age started vaping[a]	0.67 (0.48 to 0.93)	0.89 (0.83 to 0.94)	0.87 (0.61 to 1.14)	0.93 (0.89 to 0.97)
Sensation-seeking score[a,b]	1.26 (0.98 to 1.64)	0.95 (0.76 to 1.19)	0.99 (0.75 to 1.31)	1.09 (0.98 to 1.18)
Time-varying covariates				
No. d smoked cigarettes in past 30 d	1.03 (0.96 to 1.12)	1.06 (0.99 to 1.13)	1.03 (0.96 to 1.12)	1.01 (0.95 to 1.05)
No. cigarettes smoked per d	1.11 (1.03 to 1.22)	1.06 (0.92 to 1.21)	1.02 (0.97 to 1.07)	1.08 (0.97 to 1.19)
E-cigarette nicotine concentration[c]	1.04 (0.77 to 1.40)	1.44 (1.07 to 1.93)	1.10 (0.80 to 1.52)	1.20 (1.04 to 1.51)
No. d vaped nicotine in past 30 d	1.06 (1.01 to 1.11)	1.06 (1.03 to 1.09)	1.06 (1.02 to 1.11)	1.01 (0.98 to 1.03)
No. nicotine vaping episodes per d	1.02 (0.97 to 1.07)	1.03 (0.99 to 1.07)	1.05 (1.01 to 1.11)	1.03 (0.99 to 1.06)
No. puffs per vaping episode	1.01 (0.96 to 1.06)	1.01 (0.98 to 1.05)	1.02 (0.97 to 1.08)	1.07 (1.04 to 1.11)
Past-6-mo use of other tobacco products[d]	1.67 (0.99 to 2.80)	1.60 (1.02 to 2.49)	1.80 (1.08 to 3.00)	1.83 (1.27 to 2.62)
Peer vaping	2.10 (1.12 to 3.96)	3.03 (1.72 to 5.37)	1.09 (0.65 to 1.83)	1.27 (0.78 to 2.05)

Estimates are of association of time-varying, time-lagged regressors at waves 1 to 4 and time-invariant covariates with vaping outcomes 6 mo postexposure assessment at waves 2 to 5 from logistic repeated-measures random-effect regression models including school random effects (total observations: range 768–788; totals for each outcome are presented in Supplemental Fig 1). Models include use of e-cigarettes in nontraditional flavors, time, and all time-invariant and time-varying covariates as simultaneous regressors.

[a] Continuous variables were rescaled (mean 0; SD 1) such that the estimates indicate the change in odds or rate in the outcome associated with 1 SD higher on the covariate.

[b] UPPS Impulsive Behavior Scale sensation-seeking score range: 0 to 48.

[c] E-cigarette nicotine concentration range: 0 to 3 (0 = 0 mg/mL, 1 = 1–5 mg/mL, 2 = 6–17 mg/mL, and 3 = ≥18 mg/mL).

[d] Past-6-month use of other tobacco products, hookah tobacco waterpipe, smokeless tobacco, cigars, little cigars, or cigarillos (yes or no).

SUPPLEMENTAL TABLE 8 Correlations Among Past-30-Day E-cigarette Use Frequency Outcomes at Each Assessment

Variable	Wave 1			Wave 2			Wave 3			Wave 4			Wave 5		
	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3
1. No. d vaped nicotine in past 30 d	—	0.59	0.46	—	0.65	0.53	—	0.70	0.54	—	0.67	0.59	—	0.80	0.54
2. No. nicotine vaping episodes per d	—	—	0.53	—	—	0.66	—	—	0.60	—	—	0.65	—	—	0.61
3. No. puffs per nicotine vaping episode	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—

Pearson *r* coefficients are reported. All $P < .001$. —, not applicable.

SUPPLEMENTAL TABLE 9 Association of Number of Nontraditional Flavors Used With Vaping Outcomes

	Past-6-mo Vaping Status, OR (95% CI)	No. d Vaped Nicotine in Past 30 d, RR (95% CI)	No. Nicotine Vaping Episodes per d, RR (95% CI)	No. Puffs per Nicotine Vaping Episode, RR (95% CI)
Unadjusted models[a]				
1 vs 0 nontraditional flavors	4.15 (1.52 to 9.59)	2.20 (0.99 to 6.48)	1.72 (0.81 to 3.63)	2.15 (0.99 to 5.31)
2 vs 0 nontraditional flavors	6.93 (2.17 to 13.51)	2.83 (1.14 to 6.35)	2.04 (0.89 to 4.66)	3.93 (1.75 to 8.86)
3 vs 0 nontraditional flavors	4.90 (1.81 to 12.82)	2.19 (0.92 to 5.13)	2.64 (1.18 to 6.13)	3.80 (1.66 to 7.62)
4+ vs 0 nontraditional flavors	7.22 (2.90 to 15.83)	3.72 (1.41 to 8.53)	2.81 (1.25 to 6.34)	4.27 (1.90 to 8.42)
Adjusted models[b]				
1 vs 0 nontraditional flavors	2.02 (0.66 to 6.20)	1.36 (0.63 to 4.32)	1.49 (0.67 to 4.10)	1.86 (0.81 to 4.29)
2 vs 0 nontraditional flavors	5.00 (1.39 to 17.96)	1.91 (0.89 to 7.50)	2.00 (0.74 to 5.42)	2.85 (1.17 to 6.46)
3 vs 0 nontraditional flavors	4.08 (1.14 to 14.60)	1.41 (0.65 to 5.44)	2.14 (0.91 to 6.83)	2.54 (1.01 to 6.49)
4+ vs 0 nontraditional flavors	5.32 (1.42 to 19.97)	2.20 (0.70 to 7.91)	2.29 (1.07 to 6.37)	3.12 (1.22 to 6.96)

The total number was 476 to 478 (768–788 observations). Displayed are the estimates of association of time-varying, time-lagged regressors at waves 1 to 4 and time-invariant covariates with vaping outcomes 6 month postexposure assessment at waves 2 to 5 from repeated-measures random-effect logistic regression models including school random effects (totals available for each outcome are presented in Supplemental Fig 1).

[a] Unadjusted models include time-varying flavored e-cigarette use and time of assessment as sole regressors with school-level random effects.

[b] Adjusted models include time-varying flavored e-cigarette use and time of assessment regressors as well as age (continuous), sex, race and/or ethnicity (Hispanic, white, Asian American, and other), highest level of parental education (college graduate versus less education), e-cigarette device type (cigalike, midsize, or Mod), age of vaping onset (continuous), and sensation seeking (range: 0–48) as time-invariant covariates and past-30-day frequency of nicotine vaping (range: 0–30 days), past-30-day frequency of cigarette smoking (range: 0–30 days), cigarettes smoked per day on each smoking day (range: 0–20 cigarettes), number of nicotine vaping episodes per day (range: 0–20 episodes), number of puffs per nicotine vaping episode (range: 0–20 puffs), e-cigarette nicotine concentration (coded continuously: 0 mg/mL = 0, 1–5 mg/mL = 1, 6–17 mg/mL = 2, and 18–24 mg/mL = 3), past-6-month noncigarette tobacco product use (yes or no), and past-30-day peer e-cigarette use (yes or no) as time-varying covariates.

SUPPLEMENTAL TABLE 10 Associations of Number of Nontraditionally Flavored Products Used and Number of Traditionally Flavored or Flavorless Products Used With Vaping Outcomes

	Past-6-mo Vaping Status, OR (95% CI)	No. d Vaped Nicotine in Past 30 d, RR (95% CI)	No. Nicotine Vaping Episodes per d, RR (95% CI)	No. Puffs per Nicotine Vaping Episode, RR (95% CI)
Univariable models[a]				
No. traditional flavors or flavorless products[b]	1.04 (0.67 to 1.54)	1.15 (0.79 to 1.68)	1.17 (0.88 to 1.60)	1.19 (0.86 to 1.63)
No. nontraditional-flavor products[c]	1.55 (1.21 to 2.00)	1.22 (0.98 to 1.51)	1.26 (0.98 to 1.56)	1.40 (1.16 to 1.68)
Mutivariable model[d]				
No. traditional flavors or flavorless products[b]	0.98 (0.64 to 1.51)	1.10 (0.76 to 1.60)	1.14 (0.84 to 1.54)	1.13 (0.82 to 1.54)
No. nontraditional-flavor products[c]	1.51 (1.20 to 2.01)	1.21 (0.97 to 1.51)	1.20 (0.94 to 1.49)	1.39 (1.15 to 1.68)

Displayed are the estimates of association of time-varying, time-lagged regressors at waves 1 to 4 and time-invariant covariates with vaping outcomes 6 month postexposure assessment at waves 2 to 5 from repeated-measures random-effect logistic regression models including school random effects (totals available for each outcome are presented in Supplemental Fig 1).

[a] Univariable models include only time and either the number of traditional flavors or flavorless products or the number of nontraditional-flavor products as only 2 regressors.

[b] Four-level continuous variable (scored: 0, 0 products [n = 599]; 1, 1 product [n = 169]; 2, 2 products [n = 11]; and 3, 3 products [n = 9]).

[c] Four-level continuous variable (scored: 0, 0 products [n = 49]; 1, 1 product [n = 386]; 2, 2 products [n = 118]; and 3, ≥3 products [n = 225]).

[d] Multivariable models include time, the number of traditional flavors or flavorless products variable, and the number of nontraditional-flavor products variable as simultaneous regressors.

SUPPLEMENTAL TABLE 11 Associations of Number of Nontraditionally Flavored Products Used and Number of Traditionally Flavored or Flavorless Products Used With Vaping Outcomes

	Past-6-mo Vaping Status, OR (95% CI)	No. d Vaped Nicotine in Past 30 d, RR (95% CI)	No. Nicotine Vaping Episodes per d, RR (95% CI)	No. Puffs per Nicotine Vaping Episode, RR (95% CI)
Use of e-cigarettes in both traditional and nontraditional flavors versus nontraditional flavors only	1.73 (0.95 to 3.79)	1.43 (0.90 to 2.28)	1.24 (0.91 to 2.08)	1.46 (0.94 to 2.41)
No. nontraditional flavors[a]	1.53 (1.20 to 2.02)	1.24 (0.99 to 1.56)	1.22 (0.95 to 1.51)	1.37 (1.10 to 1.67)
Time	1.11 (0.90 to 1.37)	1.14 (0.96 to 1.37)	1.10 (0.94 to 1.27)	1.07 (0.92 to 1.25)

Displayed are the estimates of association of time-varying, time-lagged regressors at waves 1 to 4 with vaping outcomes 6 month postexposure assessment at waves 2 to 5 from repeated-measures random-effect logistic regression models including school random effects. The model included time, the binary use of e-cigarettes in both traditional and nontraditional flavors (n = 140) versus nontraditional flavors only (n = 599) variable, and the number of nontraditional-flavor products used as simultaneous regressors.

[a] Four-level continuous variable (scored: 0, 0 products; 1, 1 product; 2, 2 products; and 3, ≥3 products).

SUPPLEMENTAL TABLE 12 Associations of Cross-Wave Transitions in Flavored E-cigarette Use With Vaping Outcomes

	Past-6-mo Vaping Status, OR (95% CI)	No. d Vaped Nicotine in Past 30 d, RR (95% CI)	No. Nicotine Vaping Episodes per d, RR (95% CI)	No. Puffs per Nicotine Vaping Episode, RR (95% CI)
Use of e-cigarettes in any nontraditional flavor[a]	3.78 (1.23 to 10.42)	1.42 (0.55 to 4.84)	1.66 (0.71 to 5.38)	2.37 (1.06 to 6.26)
Cross-wave flavor-transition status[b]	1.04 (0.37 to 2.54)	1.07 (0.41 to 2.66)	1.02 (0.52 to 2.35)	1.16 (0.88 to 2.71)

Displayed are the estimates of association of time-invariant and time-varying, time-lagged regressors at waves 1 to 4 with vaping outcomes 6 month postexposure assessment at waves 2 to 5 from repeated-measures random-effect logistic regression models including school random effects. The model included time, time-varying use of e-cigarettes in any nontraditional flavor, and cross-wave flavor-transition status as simultaneous regressors.

[a] Use of e-cigarettes in any nontraditional flavor, time-varying variable assessed at each exposure wave at waves 1 to 4 of ≥1 nontraditional flavor (fruit, candy, blends, sweets or desserts, other, or buttery [N = 739]) versus use of flavorless, tobacco-flavored, or mint- or menthol-flavored e-cigarettes only (N = 49).

[b] Cross-wave flavor-transition status, time-invariant variable contrasting students with (n = 23) versus without (n = 455) cross-wave transitions between use of traditional flavors only and use of nontraditional flavors.

SUPPLEMENTAL REFERENCES

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Communication from Public

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Comments for Public Posting:	Los Angeles Unified Files Class Action Lawsuit against JUUL for Targeting Youth, Creating Public Nuisance.

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COUNTY OF SAN BERNARDINO
SAN BERNARDINO DISTRICT

OCT 29 2019

BY _____
RAFAEL HERNANDEZ, DEPUTY

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN BERNARDINO, SAN BERNARDINO DISTRICT

LOS ANGELES UNIFIED SCHOOL DISTRICT, on behalf of itself and similarly situated school districts;

Plaintiff,

v.

JUUL LABS, INC., f/k/a PAX Labs, Inc., and PAX LABS INC., and DOES 1-100,

Defendants.

Case No. CIV DS 1932301

CLASS ACTION COMPLAINT FOR:

1. **Public Nuisance**
2. **Strict Liability – Design Defect**
3. **Strict Liability – Failure to Warn**
4. **Negligence**

DEMAND FOR A JURY TRIAL

Plaintiff, on behalf of itself and all others similarly situated, alleges the following based on information and belief:

INTRODUCTION

1. One of the great public health success stories over the past decade has been a reduction in youth tobacco use and in nicotine addiction. Youth smoking rates plummeted from 28% in 2000 to 7.6% in 2017.[1] This success has been the result of years of litigation and strict regulation. It is also due to a public health message that Big Tobacco can no longer dispute or contradict, and which is simple, stark, and effective: smoking kills.

2. This incredible progress towards eliminating youth tobacco use has now largely been reversed due to JUUL's e-cigarette products and vaping. Between 2011 and 2015, e-cigarette use among high school and middle school students increased 900%.[2] Between 2017 and 2018, e-cigarette use increased 78% among high school students, from 11.7% of high school students in 2017 to 20.8% of high schoolers in 2018.[3] Among middle school students, e-cigarette use increased 48% between 2017 and 2018.[4] In 2018, 4.9 million middle and high school students used tobacco products, with 3.6 million of those students using e-cigarettes.[5] Between 2017 and 2018, the number of youth e-cigarette users increased by 1.5 million.[6]

3. Consistent with this trend, students in the Los Angeles Unified School District ("Plaintiff," "LAUSD," or "District") are vaping at high rates, which continue to climb. On August 19, 2019, the Los Angeles County Department of Public Health announced that more than 30% of LA County high school students reported using e-cigarette products, and 10% of those students are regular users. This is up 6.4% from the previous year.

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[1] Meredith Berkman, Testimony of Meredith Berkman, Parents Against Vaping E-cigarettes, U.S. House Committee on Oversight & Reform (July 24, 2019), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2019.07.24%20BerkmanPAVe%20Testimony.pdf.
[2] Jerome Adams, Surgeon General's Advisory on E-cigarette Use Among Youth, Ctrs. for Disease Control & Prevention (Dec. 2018), https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-ecigarette-use-among-youth-2018.pdf.
[3] *Id*.
[4] 2018 NYTS Data: A startling rise in youth e-cigarette use, U.S. Food & Drug Admin. (Feb. 2, 2019), https://www.fda.gov/tobacco-products/youth-and-tobacco/2018-nyts-data-startling-rise-youth-e-cigarette-use.
[5] *Id*.
[6] *Id*.

4. According to the Centers for Disease Control and Prevention ("CDC") Director Robert Redfield, "The skyrocketing growth of young people's e-cigarette use over the past year threatens to erase progress made in reducing tobacco use. It's putting a new generation at risk for nicotine addiction."[7] The U.S. Food and Drug Administration ("FDA") Commissioner Scott Gottlieb described the statistics related to youth vaping as "astonishing" and both the FDA and the U.S. Surgeon General have appropriately characterized youth vaping as an "epidemic."[8] The National Institute on Drug Abuse found that the 2018 spike in nicotine vaping was the largest for any substance recorded in 44 years, and the Secretary of the U.S. Department of Health and Human Services declared that "[w]e have never seen use of any substance by America's young people rise as rapidly as e-cigarette use [is rising]."[9]

5. A major cause of this epidemic is JUUL Labs, Inc., the maker of the JUUL e-cigarette. JUUL entered the e-cigarette market in 2015 and now controls over 70% of it.[10] Over a million JUUL e-cigarettes were sold between 2015 and 2017.[11] In 2017, JUUL generated over $224 million in retail sales, a 621% year-over-year increase.[12] By June 2018, sales had skyrocketed another 783%, reaching $942.6 million.[13] The e-cigarette category as a whole grew 97% to $1.96 billion in the same period, largely based on JUUL's market success.[14] JUUL's dominance of the e-cigarette market has been so rapid, and so complete, that the act of vaping is now often referred to as "juuling."

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[7] Texas governor signs law increasing the age to buy tobacco products to 21, CNN (June 8, 2019), https://m.cnn.com/en/article/h_b4cf0b92fd821251a4ae48df9b717145.

[8] Angelica LaVito, FDA chief Gottlieb threatens to pull e-cigarettes off market if 'astonishing' surge in teen use doesn't slow, CNBC (Nov. 16, 2018), https://www.cnbc.com/2018/11/16/fda-chief-gottlieb-threatens-to-pull-e-cigarettes-off-market.html ; Jayne O'Donnell, FDA declares youth vaping an epidemic, announces investigation, new enforcement, USA Today (Sept. 12, 2018), https://www.usatoday.com/story/news/politics/2018/09/12/fdascott-gottlieb-youth-vaping-e-cigarettes-epidemic-enforcement/1266923002/.

[9] Jan Hoffman, Study Shows Big Rise in Teen Vaping This Year, N.Y. Times (Dec. 17, 2018), https://www.nytimes.com/2018/12/17/health/ecigarettes-teens-nicotine-.html ; Rajiv Bahl, Teen Use of Flavored Tobacco was Down, But E-Cigarettes Are Bringing It Back Up, Healthline (Jan. 9, 2019), https://www.healthline.com/health-news/flavored-tobacco-use-rising-again-among-teens.

[10] Richard Craver, Juul ends 2018 with 76 percent market share, Winston-Salem J. (Jan. 8, 2019), https://www.journalnow.com/business/juul-ends-with-percent-market-share/article_6f50f427-19ec-50be-8b0c-d3df18d08759.html.

[11] Melia Robinson, How a startup behind the 'iPhone of vaporizers' reinvented the e-cigarette and generated $224 million in sales in a year, Bus. Insider (Nov. 21, 2017), https://www.businessinsider.my/juul-e-cigarette-one-million-units-sold-2017-11/.

[12] *Id.*

[13] Angelica LaVito, Popular e-cigarette Juul's sales have surged almost 800 percent over the past year, CNBC Health & Sci. (Sept. 11, 2018), https://www.cnbc.com/2018/07/02/juul-e-cigarette-sales-have-surged-over-the-past-year.html.

[14] *Id.*

6. JUUL's market dominance has attracted the attention of government regulators, including the FDA. On February 24, 2018, the FDA sent a letter to JUUL expressing concern about the popularity of its products among youth and demanding that JUUL produce documents regarding its marketing practices.[15] On September 12, 2018, the FDA sent letters to JUUL and other e-cigarette manufacturers putting them on notice that their products were being used by youth at disturbing rates.[16] In October 2018, the FDA raided JUUL's headquarters and seized more than a thousand documents relating to JUUL's sales and marketing practices.[17] As of October 2019, the FDA, the Federal Trade Commission, multiple state attorneys general, and the U.S. House of Representatives Committee on Oversight and Reform have all commenced investigations into JUUL's role in the youth vaping epidemic and whether JUUL's marketing practices purposefully targeted youth.

7. JUUL now insists it never marketed to young people. This assertion is patently false. JUUL has compelled a generation of youth, who were never cigarette smokers, into nicotine addiction and put them at risk for severe lung injury and/or other health harms resulting from aerosol inhalation. JUUL is working to maintain JUUL's record-breaking sales and market dominance—which would not be possible if the customer base was truly only adults looking to quit smoking, or for a purported healthier alternative to smoking.

8. In fact, JUUL does not have a legitimate basis to claim that its product is healthier than cigarettes. On September 9, 2019, the FDA warned JUUL that it has violated federal law by making unauthorized representations that JUUL products are safer than cigarettes.[18]

9. Plaintiff has already taken actions to reduce tobacco use among its students—but now it must address the new epidemic of youth vaping. Plaintiff is the second largest school district in the nation, serving approximately 600,000 students across 710 square miles. On September 10, 2019, the

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[15] Matthew Holman, Letter from Director of Office of Science, Center for Tobacco Products, to Zaid Rouag, at JUUL Labs, Inc., U.S. Food & Drug Admin. (Apr. 14, 2018), https://www.fda.gov/media/112339/download.

[16] Letter From US FDA to Kevin Burns, U.S. Food & Drug Admin. (Sept. 12, 2018), https://www.fda.gov/media/119669/download.

[17] Laurie McGinley, FDA seizes Juul e-cigarette documents in surprise inspection of headquarters, Wash. Post (Oct. 2, 2018), https://www.washingtonpost.com/health/2018/10/02/fda-seizes-juul-e-cigarette-documentssurprise-inspection-headquarters/.

[18] Juul Labs, Inc. Warning Letter, U.S. Food and Drug Admin. (Sept. 9, 2019), https://www.fda.gov/inspectionscompliance-enforcement-and-criminal-investigations/warning-letters/juul-labs-inc-590950-09092019.

District's Superintendent Austin Beutner issued a statement emphasizing the danger of vaping: "The impact on the students and communities we serve, totaling nearly 5 million people, is very real. . . . Los Angeles Unified is taking action to inform students of the dangers, and is looking at other options to better protect them against this health crisis."[19]

PARTIES

10. Plaintiff Los Angeles Unified School District is a unified school district organized and operating pursuant to the laws of the State of California.

11. Defendant JUUL Labs, Inc., f/k/a PAX Labs, Inc. ("JUUL"), is a Delaware corporation. Its principal place of business is in San Francisco, California. JUUL manufacturers, designs, sells, markets, promotes, and distributes JUUL e-cigarettes, JUULpods and accessories.

12. PAX Labs, Inc., is a Delaware Corporation. Its principal place of business is in San Francisco, California. PAX Labs, Inc.'s current website says it was founded in 2007. For much of the relevant time period and until at least 2017, PAX Labs, Inc. and JUUL operated as the same company. During that time, JUUL manufactured, designed, sold, marketed, promoted, and distributed JUUL e-cigarettes, JUULpods, and accessories as a part of PAX Labs, Inc.

13. Plaintiff is ignorant of the names and capacities of Defendants Does 1 through 100, but upon information and belief, Does 1 through 100 are the servants, consultants, contractors, employees, or agents of the other defendants named herein and acted within the scope therein.

JURISDICTION AND VENUE

14. The Court has subject-matter jurisdiction over this action pursuant to California Constitution, Article VI, § 10, and California Civil Code section 382.

15. The Court has personal jurisdiction over JUUL under California Code of Civil Procedure section 410.10, as the principal places of business of both JUUL and PAX LABS, Inc. are in California.

16. Venue in San Bernardino County is proper under California Code of Civil Procedure section 394, as the action is brought by the District and the District is not situated in this County.

[19] https://achieve.lausd.net/site/default.aspx?PageType=3&DomainID=4&ModuleInstanceID=4466&ViewID=6446EE88-D30C-497E-9316-3F8874B3E108&RenderLoc=0&FlexDataID=82038&PageID=1

FACTUAL ALLEGATIONS

A. Following Big Tobacco's lead

17. JUUL was founded by Adam Bowen and James Monsees. The company's beginnings can be traced to the pair's collaboration on a product design master's thesis when they were graduate students at Stanford University in 2004—Monsees completing a Master of Fine Arts in Product Design, and Bowen a Master of Science in Mechanical Engineering in Product Design.[20] Their proposed product? A better cigarette.

18. Monsees has described the cigarette as "the most successful consumer product of all time . . . an amazing product."[21] But years of anti-smoking campaigns have successfully denormalized cigarette smoking. As part of their product design research, Monsees and Bowen interviewed smokers who talked about feeling self-conscious of the signs of smoking, for example, coming back into a room after a smoke break and smelling like smoke, or having their hands smell like cigarettes even after washing them multiple times.[22] They ended their presentation with a clip from an episode of South Park, a satirical cartoon, showing the characters assembled at the Museum of Tolerance and shaming a smoker.[23] Monsees and Bowen set out to "deliver[] solutions that refresh the magic and luxury of the tobacco category" and recreate the lost "ritual and elegance that smoking once exemplified."[24]

19. Essentially, Monsees and Bowen saw a market opportunity in a generation of consumers brought up on anti-smoking norms. In Monsees' words, they wanted to redesign the cigarette "to meet the needs of people who want to enjoy tobacco but don't self-identify with—or don't necessarily want to be associated with—cigarettes."[25] Monsees saw "a huge opportunity for products that speak directly to those consumers who aren't perfectly aligned with traditional tobacco products."[26]

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[20] Allison Keeley, Vice Made Nice?, Stanford Mag., (Aug. 2012), https://stanfordmag.org/contents/vice-made-nice.
[21] Gabriel Montoya, Pax Labs: Origins with James Monsees, Social Underground, https://socialunderground.com/2015/01/pax-ploom-origins-future-james-monsees/ (last visited Sept. 7, 2019).
[22] Jordan Crook, This is the Stanford thesis presentation that launched Juul, Tech Crunch (Feb. 27, 2019), https://techcrunch.com/2019/02/27/this-is-the-stanford-thesis-presentation-that-launched-juul/.
[23] *Id.*
[24] Onboardly Interview with Ploom Cofounder and CEO James Monsees, Pax.com (Apr. 30, 2014), https://www.pax.com/blogs/press/onboardly.
[25] *Id.*
[26] *Id.*

20. At one point during their thesis presentation, Monsees states, "The cigarette is actually a carefully engineered product for nicotine delivery and addiction."[27] This description applies just as well to the product he and Bowen would launch a decade later—JUUL.

21. The outcome of Monsees and Bowen's thesis project was a "heat-not-burn" e-cigarette, which uses loose-leaf tobacco. The device heated tobacco contained in pods to a constant temperature, vaporizing nicotine and flavor without burning the materials or producing smoke.

22. After graduation, Bowen and Monsees worked on bringing their thesis project to the market, incorporating under the name Ploom in 2007. In those early years, they spent a lot of time talking about what Bowen called "the kind of typical thoughts of evil Big Tobacco companies like coming down and squashing you."[28] But ultimately, that "was not really an issue."[29] In fact, not only did Big Tobacco not squash them, but the opposite. Although Bowen and Monsees characterized their products as aimed toward consumers not aligned with traditional tobacco products, they themselves have aligned with Big Tobacco on at least two occasions: first, with Japan Tobacco and then with JUUL.

23. In 2010, Ploom launched its e-cigarette as the ModelOne, using pods of loose-leaf tobacco heated by butane. It did not catch on. Ploom only sold a few thousand units. By then a company with a dozen employees, Ploom was faltering, in need of money, technological expertise, and marketing savvy.[30]

24. Help came from Japan Tobacco International ("JTI"), a division of Japan Tobacco Inc., the fourth-largest tobacco company in the world. In December 2011, JTI and Ploom entered into a strategic agreement, which gave JTI a minority stake in Ploom and made it a strategic partner. In a statement regarding the agreement, Monsees said, "We are very pleased to partner with JTI as their deep expertise, global distribution networks and capital resources will enable us to enter our next phase of

[27] *See supra* note 20
[28] Keeley, supra note 18.
[29] *Id*.
[30] David H. Freedman, How Do You Sell a Product When You Can't Really Say What It Does?, Inc.com, http://area51.thedct.net/project102-startupdhaka/business/how-do-you-sell-a-product-when-you-cant-really-say-what-it-does/ (accessed Oct. 22, 2019).

growth and capitalize on global expansion opportunities."[31] As Bowen explained in an interview, "We were still doing a lot of our own internal product development, but now we had access to floors of scientists at JTI."

25. In 2012, Ploom unveiled the PAX, a loose-leaf vaporizer that didn't use pods, but which was much more successful. The following year, Ploom combined elements of the PAX with the pod system as the ModelTwo. Although consumers were enthusiastic about both the PAX and the ModelTwo, the products were limited to a small, high-end market. The PAX, for example, retailed for $250 when it was first marketed. But, as one of Ploom's investors remarked in 2014, "The company is going to invade the bigger, lower-end market now dominated by e-cigarettes." He explained that Ploom had "lots of products in the works" and that "we know we need something cheaper than PAX to go after the mass market. There are still huge opportunities out there."[32]

26. In February 2015, Ploom and JTI ended their relationship, with Ploom buying back JTI's minority stake in the business. JTI acquired the ModelTwo and pods product line, as well as the Ploom name, while Ploom kept its open-system PAX vaporizer and changed its name to PAX Labs Inc. Monsees characterized the partnership as having "afforded both parties many mutual benefits," but said that the new arrangement would "fuel continued growth" and that PAX intended "rapid rollouts of new products."[33]

27. PAX made good on its promise of new products and invading the bigger, lower-end market. As discussed further below, PAX launched the JUUL in June 2015 with a well-publicized launch party in New York City and a viral social media marketing campaign.

28. The company renamed itself JUUL Labs, Inc. in 2017.

[31] Innovative Partnership for Ploom and Japan Tobacco International JTI to Take Minority Share in Ploom, Japan Tobacco Int'l, https://www.jti.com/our-views/newsroom/innovative-partnership-ploom-and-japan-tobacco-international-jti-take-minority (accessed Oct. 22, 2019).
[32] Freedman, supra note 28.
[33] JTI to Acquire Ploom Product Line, Convenient Store News (Feb. 16, 2015), https://csnews.com/jti-acquire-ploom-product-line.

29. By the close of 2017, according to Nielsen data, JUUL had surpassed its competitors in capturing 32.9 percent of the e-cigarette market. The total e-cigarette market itself expanded 40 percent to $1.16 billion. [34]

30. In 2018, JUUL's gross profit margins were 70%[35] and it represented 76.1% of the national e-cigarette market.[36] In a complaint it filed in November 2018 against 24 vape companies for alleged patent infringement, JUUL asserted that it was "now responsible for over 95% of the growth in the ENDS pod refill market in the United States" and included the following chart:[37]

Appendix 5: U.S. ENDS Pod Market Retail Unit Sales Growth 2018

4-Week Unit Sales by End Date

	Nielsen			IRI		
	Apr 21	Sep 8	Share of Growth	Apr 22	Sep 9	Share of Growth
Total Market	36,002,645	55,773,039	100%	29,546,883	50,793,955	100%
Juul	22,618,886	41,501,172	95.5%	14,964,158	35,166,120	95.1%
Vuse	6,385,922	6,172,595	-1.1%	7,204,900	7,409,312	1.0%
MarkTen	3,677,300	4,240,285	2.8%	2,904,168	3,230,237	1.5%
Logic	1,785,167	2,018,023	1.2%	1,928,841	1,876,006	-0.2%
Blu	1,062,360	1,461,127	2.0%	1,305,209	1,937,225	3.0%
Other	473,010	379,837	-0.5%	1,239,607	1,175,055	-0.3%

[34] Ari Levy, E-cigarette maker Juul is raising $150 million after spinning out of vaping company, CNBC (Dec. 19, 2017), https://www.cnbc.com/2017/12/19/juul-labs-raising-150-million-in-debt-after-spinning-out-of-pax.html.
[35] Dan Primack, Scoop: The Numbers Behind Juul's Investor Appeal, Axios (July 2, 2018), https://www.axios.com/numbers-juul-investor-appeal-vaping-22c0a2f9-beb1-4a48-acee-5da64e3e2f82.html.
[36] Robert K. Jackler et al., JUUL Advertising Over Its First Three Years on the Market 2, Stanford Res. into the Impact of Tobacco Advert. (2019), http://tobacco.stanford.edu/tobacco_main/publications/JUUL_Marketing_Stanford.pdf
[37] Verified Complaint Under Section 337 of the Tariff Act of 1930 at 6, In the Matter of Certain Cartridges for Elec. Nicotine Delivery Sys. & Components Thereof, Investigation No. 337-TA-1141 (USITC Nov. 19, 2018)

31. JUUL shattered previous records for reaching decacorn status, reaching valuation of over $10 billion in a matter of months—four times faster than Facebook.[38] This all came just three years after its product launch.

32. JUUL's staggering commercial success didn't come from a blank slate. Under the Master Settlement Agreement between Big Tobacco and the States, the public has access to hundreds of thousands of Big Tobacco's internal documents. In creating JUUL, Monsees and Bowen carefully studied the marketing strategies, advertisements, and product design of Big Tobacco. As Monsees candidly acknowledged, the internal tobacco documents "became a very intriguing space for us to investigate because we had so much information that you wouldn't normally be able to get in most industries. And we were able to catch-up, right, to a huge, huge industry in no time. And then we started building prototypes." [39]

33. Monsees and Bowen reviewed documents in the Big Tobacco archive that included information on how to manipulate nicotine pH to maximize nicotine delivery in a vapor while minimizing the "throat hit" that may potentially deter new smokers. Other records related to tobacco industry market strategies and advertisements designed to lure non-smoking youth. Monsees and Bowen were able to take advantage of an extensive online tobacco advertising research database maintained by the Stanford Research into the Impact of Tobacco Advertising ("SRITA"), an inter-disciplinary research group devoted to researching the promotional activities of the tobacco industry. SRITA's database contains approximately 50,000 original tobacco advertisements. According to Monsees, JUUL's advertising was informed by traditional tobacco advertisements, and SRITA in particular had been very useful to JUUL.[40]

34. It is no secret that a good portion of the Big Tobacco playbook involved targeting youth. Beginning in the 1950s, JUUL's now corporate affiliate, Philip Morris, intentionally marketed cigarettes to young people under the age of 21 to recruit "replacement smokers" to ensure the economic future of

[38] Zack Guzman, Juul Surpasses Facebook As Fastest Startup to Reach Decacorn Status, Yahoo! Fin. (Oct. 9, 2019), https://finance.yahoo.com/news/juul-surpasses-facebook-fastest-startup-reach-decacorn-status-153728892.html.
[39] Montoya, supra note 19.
[40] Jackler et al., supra note 34 at 27.

the tobacco industry.[41] Philip Morris knew that youth smoking was essential to the tobacco industry's success and longevity, as an internal Philip Morris document makes clear: "It is important to know as much as possible about teenage smoking patterns and attitudes. Today's teenager is tomorrow's potential regular customer, and the overwhelming majority of smokers first begin to smoke while still in their teens."[42] For this reason tobacco companies focused on the 14-24 year-old age group, because "young smokers have been the critical factor in the growth" of tobacco companies and the 14-18 year-old group is an increasing segment of the smoking population.[43] As the Vice-President of Marketing at R.J. Reynolds Tobacco Company ["RJR"] explained in 1974, the "young adult market . . . represent[s] tomorrow's cigarette business. As this 14-24 age group matures, they will account for a key share of the total cigarette volume—for at least the next 25 years."[44]

35. Big Tobacco is now prohibited from employing these tactics and strategies to market traditional cigarettes. Nothing prevented JUUL from doing so.

36. Restrained from its historical playbook, Big Tobacco has looked for opportunities for growth in the e-cigarette market. In December 2018, Altria, the maker of Marlboro cigarettes and a Tobacco giant, took a 35% stake in JUUL and invested billions into the company. Seeing JUUL as a proven gateway to other substances, including cigarettes, Altria saw an opportunity to expand JUUL's market share and grow the e-cigarette market in the hopes of ultimately driving more cigarette and tobacco use and nicotine addiction. Altria could use JUUL to circumvent the regulatory and legal restrictions on Big Tobacco's marketing tactics.

B. JUUL targeted kids

37. Because of Big Tobacco's demonstrated effectiveness at addicting youth to nicotine, cigarette manufacturers operate under tight restrictions regarding their advertising and marketing activities. By way of example, cigarette companies may not:

A. Use outdoor advertising such as billboards;

[41] Amended Final Opinion at 972, U.S. v. Philip Morris, No. 99-cv-2496 (D.D.C. Aug. 17, 2006), ECF 5750.
[42] Tobacco Company Quotes on Marketing to Kids, Campaign for Tobacco-Free Kids (May 14, 2001), https://www.tobaccofreekids.org/assets/factsheets/0114.pdf.
[43] *Id*.
[44] C.A. Tucker, Marketing Plans Presentation to RJRI B of D, Truth Tobacco Industry Documents, U. of S.F. (Sept. 30, 1974), https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=ypmw0091.

B. Sponsor events;

C. Give free samples;

D. Pay any person to use, display, make reference to or use as a prop any tobacco product, tobacco product package in any media;

E. Pay any third party to conduct any activity which the tobacco manufacturer is prohibited from doing; or

F. Sell "flavored" cigarettes.

38. All of these above activities were prohibited because of their effectiveness at appealing to youth. As described below, all of these activities figured prominently in JUUL's marketing campaign.

39. According to Dr. Robert Jackler, an otolaryngologist and professor at Stanford University School of Medicine and principal investigator for SRITA, JUUL's initial marketing was "patently youth oriented."[45] JUUL's 2015 ad campaign, called "Vaporized" was designed to create a "cult-like following."[46] Its imagery featured a vivid color scheme and models in their twenties in poses that researchers note are evocative of behaviors more characteristic of underage teens than mature adults.[47] Dr. Jackler and his colleagues found it "clear" that this imagery resonated with underage teens who aspire to emulate trendsetting young adults.[48]

[45] Robert K. Jackler, The Role of the Company in the Juul Teen Epidemic, Testimony of Robert Jackler before the House Subcommittee on Economic and Consumer Policy (July 24, 2019), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2019.07.24%20Jackler%20Testimony.pdf at 2 ["Jackler Testimony"]

[46] Id. at 4

[47] Jackler et al., supra note 34

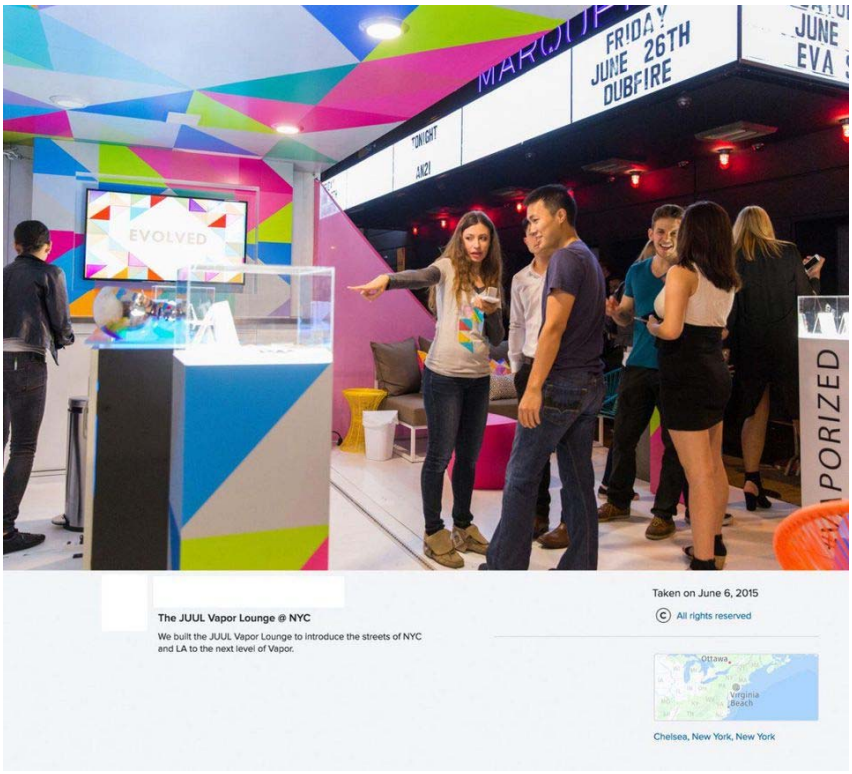
[48] Id. at 7

40. Tobacco advertisers have long understood that teens are attracted to such imagery. The Vaporized campaign was featured on the front page of VICE magazine, "the #1 youth media company in the world."[49] In the summer of 2015, an animated series of Vaporized billboards, with the campaign's youth-appealing imagery, were displayed in New York's Times Square.[50]

41. Over the first year after JUUL launched its ad campaign in June 2015, it held a series of at least 50 highly stylized parties, typically with music entertainment, in cities across the United States.[51] Thousands of young people were given free nicotine-filled JUULpods (appropriately named "JUUL starter kits"), and JUUL posted photos of various young people enthusiastically puffing on JUULs across their social media channels.[52] JUUL advertising also featured popular stars such as Katy

[49] Id. at 5
[50] Id. at 17-18
[51] Id. at 3.
[52] Id.

Perry holding a JUUL at the Golden Globes.[53]



(Source: Kathleen Chaykowski, The Disturbing Focus of Juul's Early Marketing Campaigns, Forbes (Nov. 16, 2018), https://www.forbes.com/sites/kathleenchaykowski/2018/11/16/the-disturbing-focus-of-juuls-early-marketingcampaigns/#3da1e11b14f9).

42. JUUL knew these images would be successful in achieving the intended result because it intentionally crafted them to mimic specific traditional tobacco advertisements that Big Tobacco had used to target teens. In fact, many of JUUL's ads are nearly identical to old cigarette ads that were designed to get teens to smoke. Like its Big Tobacco predecessors, the focus of JUUL's initial marketing was on colorful ad campaigns using eye-catching designs and youth-oriented imagery with themes of being cool, carefree, stylish, attractive, sexy and popular—unusual themes and images if one's objective is to promote an adult-only smoking cessation device.[54]

[53] Jackler Testimony at 8

[54] Virginia Slims vs Juul Advertisement, Stanford U. Res. into the Impact of Tobacco Advert. (2015), http://tobacco.stanford.edu/tobacco_main/imagescomp.php?token2=fm_tn_st328.php&token1=fm_tn_img10799.php&theme_file=fm_tn_mt035.php&theme_nam e=Cigs%20vs.%20eCigs&subtheme_name=Cigs%20vs%20eCigs%20JUUL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BE HER OWN
BOSS
BE
Marlboro
Die Menge an Teer, Nikotin und Kohlenmonoxid, die Sie
inhalieren, variiert, je nachdem, wie Sie Ihre Zigarette rauchen.

(Source: Julia Belluz, The Vape Company Juul Said It Doesn't Target Teens. Its Early Ads Tell a Different Story, Vox (Jan. 25, 2019), https://www.vox.com/2019/1/25/18194953/vape-juul-e-cigarette-marketing.)

43. JUUL used Big Tobacco's effective advertising imagery, but coupled it with a modern, state-of-the-art marketing campaign designed to target youth. It relied heavily on social media, crafting a powerful online presence, which persists even after JUUL deleted its accounts in the face of mounting public scrutiny. JUUL was particularly active on Instagram, which is the most popular social media site among teens.[55] JUUL cultivated hashtags, allowing it to blend its ads in with wide range of user content, increasing exposure while concealing the commercial nature of the content.[56] JUUL then used hashtags to reinforce the themes it crafted in its product design, like #style, #technology, #smart, and #gadget. JUUL's hashtags attracted an enormous community of youthful posts on a wide array of subjects. According to Dr. Jackler, #Juul contains literally thousands of juvenile postings, and numerous Instagram hashtags contain the JUUL brand name.[57]

44. Even after JUUL halted its own social media posts in November 2018, viral peer-to-peer promotion among teens insured continued corporate and product visibility among young people.[58] In fact, community posts about JUUL increased after JUUL itself quit social media in the Fall of 2018. Prior to November 2018, over a quarter of a million posts appeared. In the eight months after JUUL halted its promotional postings, the rate of community postings increased significantly, resulting in the number of posts doubling to over half a million.[59]

45. JUUL also paid social media influencers to post photos of themselves with JUUL devices and to use the hashtags that it was cultivating.[60] JUUL entered a contract with an advertising agency specifically to identify and recruit social media influencers that had at least 30,000 followers to, according to an internal JUUL email, "establish a network of creatives to leverage as loyalists" for the

[55] Jackler et al.
[56] Id. at 23
[57] Jackler Testimony at 10.
[58] Id. at 11.
[59] Id.
[60] Jackler et al.

JUUL brand.[61] One such influencer was Christina Zayas, whom JUUL paid $1,000 for just one blog post and one Instagram post in the Fall of 2017.

46. JUUL instituted an "affiliate program" to recruit those who authored favorable reviews of its products by providing such reviewers with a 20% discount of purchases of JUUL products.[62] It even recruited JUUL users to act as part of their marketing team by asking users to "refer a friend and get a discount."[63]

47. Such tactics masked JUUL advertisements as user content, further increasing exposure and ultimately solidifying the company in teen pop culture as a form of cultural currency. JUUL's strategy was so successful in embedding its products into pop culture that it entered the vernacular as a verb. The JUUL device and the term "juuling" are so pervasive that JUUL effectively eliminated not only competitors, but also any potentially alarming terms like "smoking" or "e-cigarette," which could alert users to the true nature of the device or activity. A recent study found that 63% of adolescent JUUL users did not know that JUULpods contain nicotine.[64] This has worked to JUUL's advantage and was a deliberate part of its strategy. In the first year after its launch, not one of JUUL's 171 promotional emails said anything about nicotine content,[65] and it did not include nicotine warnings on the JUUL packaging until August 2018, only after it was forced to do so.

48. The design of JUUL's product is also acutely attractive to youth. Unlike most of its predecessors, JUUL looks nothing like a cigarette. Instead, JUUL is sleek and linear and seems like the latest tech invention. This is not surprising, given the founders' Silicon Valley product design education and training. JUUL co-founder Adam Bowen drew on his experience as a design engineer at Apple to make JUUL's design mimic technology children were already familiar with, like Apple's iPhone.[66] This

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[61] Kenrick Cai, Juul Funded High Schools, Recruited Social Media Influencers To Reach Youth, House Panel Charges, Forbes (July 25, 2019), https://www.forbes.com/sites/kenrickcai/2019/07/25/juul-high-schools-influencers-reach-youth-house-investigation/#1ea8bcdf33e2.

[62] Jackler Testimony at 9-10

[63] Id. at 9.

[64] Juul e-Cigarettes Gain Popularity Among youth, But Awareness of Nicotine Presence Remains Low, Truth Initiative (Apr. 18, 2018), https://truthinitiative.org/sites/default/files/media/files/2019/03/JUUL-E-cigarettesGain-Popularity-Among-Youth-But-Awareness-of-Nicotine-Presence-Remains-Low.pdf.

[65] Jackler et al. at 25

[66] How JUUL made nicotine go viral, Vox (Aug. 10, 2018), https://www.youtube.com/watch?v=AFOpoKBUyok.

made JUULs look "more like a cool gadget and less like a drug delivery device. This wasn't smoking or vaping, this was JUULing."[67] The evocation of technology makes the JUUL device familiar and desirable to the younger, tech-savvy generation, particularly teenagers. According to 19-year-old Michelle Williams, "our Grandma's have iPhones now, normal kids have JUULs now. Because it looks so modern, we kind of trust modern stuff a little bit more so we're like, we can use it, we're not going to have any trouble with it because you can trust it." 15-year-old Sam Friedman agrees: "The tech aspect definitely helps people get introduced to it and then once they're introduced to it, they're staying, because they are conditioned to like all these different products. And then this is another product. And it's just another product. Until you're addicted to nicotine." [68]

49. The JUUL device even has features reminiscent of youth-oriented tech culture and gaming, like "secret" features users can unlock, such as making the indicator light flash rainbow colors in "party mode." JUUL has been so successful in emulating technology that the small, rectangular devices are often mistaken for—or passed off as—flash drives.

50. The ability to conceal a JUUL is also part of the appeal for adolescents. The devices are small and slim, so they fit easily in a closed hand or a pocket. The ease and simplicity of use—there is nothing to light or unwrap, or even an on-off switch—also make it possible to covertly use a JUUL behind a turned back, which has become a trend in many schools. Finding new ways to hide the ever-concealable JUUL has spawned products designed just for that purpose, such as apparel that allows the wearer to use the device while it is concealed in the drawstring of a hoodie or the strap of a backpack.[69]

51. JUUL also created special flavors that make its addictive, high-tech device even more attractive to adolescents. Tobacco companies have known for decades that flavored products are key to nicotine adoption by youth. A 1972 Brown & Williamson memorandum: "Youth Cigarette – New Concepts," specifically noted the "well known fact that teenagers like sweet products."[70] According to

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[67] Id.
[68] Id.
[69] Evie Blad, 'Juuling' and Teenagers: 3 Things Principals and Teachers Need to Know, Educ. Wk. (July 18, 2018), https://www.edweek.org/ew/articles/2018/07/18/juuling-and-teenagers-3-things-principals-and.html.
[70] Marketing Innovations, Inc., Brown & Williamson Tobacco Corp. Project Report: Youth Cigarette—New Concepts, U.C.S.F. Truth Tobacco Industry Documents (Sept. 1972), https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=hzpd0040.

2004 data, 17-year-old smokers were more than three times likely as those over 25 to smoke flavored cigarettes and viewed flavored cigarettes as safer.[71] For this reason, in 2009 the FDA banned flavored cigarettes pursuant to its new authority under the Family Smoking Prevention and Tobacco Control Act of 2009. In announcing the ban, FDA Commissioner Dr. Margaret Hamburg declared that "flavored cigarettes are a gateway for many children and young adults to become regular smokers."[72]

52. There is no reason to believe that flavors play any different role with respect to e-cigarettes and youth. In fact, a 2017 study of the cigarette flavor ban found that the ban was effective in lowering the number of smokers and the amount smoked by smokers, though it was associated with an increased use of menthol cigarettes (the only flavor still available).[73] According to the Surgeon General, 85% of adolescents who use e-cigarettes use flavored varieties.[74] Studies also show that flavors motivate e-cigarette initiation among youth,[75] and that youth are much more likely to use flavored tobacco products than adults are.[76] Despite JUUL's claims that its target market is adult smokers, JUUL sold its product in flavors like Cool Mint, Crème Brulee, Fruit Medley, Cucumber, and Mango. These flavors were the reason countless adolescents started using JUUL products.

53. The flavors pose dangers beyond luring young people into trying nicotine. Studies now show these sweet and fruity flavors present distinct additional health hazards. Researchers have found that some of the chemicals JUUL uses for flavor and perfume contain relatively high levels of acetals. Acetals are airway-irritating chemicals that may cause lung damage. Dr. Robert Jackler said that test

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[71] Gardiner Harris, Flavors Banned From Cigarettes to Deter Youth, N.Y. Times (Sept. 22, 2009) https://www.nytimes.com/2009/09/23/health/policy/23fda.html.

[72] Id.

[73] Charles J. Courtemanche et al., Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use, American Journal of Preventive Medicine 52(5):e139 - e146 (2017), https://tobacco.ucsf.edu/more-evidence-supporteliminating-flavors-reduce-youth-cigarette-and-e-cigarette-use; MB. Harrell, et al., Flavored e-cigarette use: Characterizing youth, young adult, and adult users, Prev Med Rep. 2017; 5: 33–40 (Nov. 11, 2016), doi: 10.1016/j.pmedr.2016.11.001 PMCID: PMC5121224.

[74] E-Cigarette Use Among Youth and Young Adults, U.S. Dept. of Health and Human Services (2016), https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf (accessed Oct. 22, 2019).

[75] Karl Paul, Flavored Vapes Lure Teens Into Smoking and Nicotine Addiction, Study Shows, MarketWatch (Feb. 26, 2019), https://www.marketwatch.com/story/flavored-vapes-lure-teens-into-smoking-and-nicotine-addictionstudy-shows-2019-02-25

[76] A.C. Villanti et al., Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study, 53 Am. J. of Preventative Med. 139 (2017), https://www.ncbi.nlm.nih.gov/pubmed/28318902.

results have shown that JUUL's sweet and fruity flavors "contribute[] to the increasing body of evidence documenting toxicological effects of e-cig vapor."[77]

54. It is clear that JUUL targeted youth as a key business demographic. A recent study showed that 15 through 17-year-olds are 16 times more likely to use JUUL than 25-34 year olds.[78]

55. JUUL was well aware from the beginning that its products would appeal to youth. A former JUUL manager, who spoke to The New York Times on the condition that his name not be used because he worried about facing retribution from the company, said that within months of JUUL's 2015 introduction, it became evident that teenagers were either buying JUULs online or finding others who made the purchases for them. Some people bought more JUUL kits on the company's website than they could individually use—sometimes 10 or more devices at a time. "First, they just knew it was being bought for resale," said the former senior manager, who was briefed on the company's business strategy. "Then, when they saw the social media, in fall and winter of 2015, they suspected it was teens."[79]

56. This "suspicion" has been confirmed by the U.S. Surgeon General, who found that JUUL's Twitter account was being followed by adolescents and that 25% of those retweeting official JUUL tweets were under 18 years old.[80]

57. By the fall of 2018, JUUL was under intense scrutiny. A group of eleven United States senators wrote JUUL's CEO, Kevin Burns, a letter in April 2018, declaring that the JUUL device and JUULpods "are undermining our nation's efforts to reduce tobacco use among youth and putting an entire new generation of children at risk of nicotine addiction and other health consequences."[81] Less than a week later, then FDA Commissioner Gottlieb announced a crackdown on retailers to limit youth access to e-cigarettes and enforcement actions against JUUL in particular.[82] At the same time, the FDA

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[77] Susie Neilson, Irritating Compounds Can Show Up in 'Vape Juice', NPR (July 30, 2019), https://www.npr.org/sections/health-shots/2019/07/30/746238009/irritating-compounds-discovered-in-vapejuice.

[78] D.M. Vallone et al., Prevalence and correlates of Juul use among a national sample of youth and young adults, Tobacco Control (Oct. 29, 2018), http://dx.doi.org/10.1136/tobaccocontrol-2018-054693.

[79] Matt Richtel & Sheila Kaplan, Did Juul Lure Teenagers and Get 'Customers for Life'? N.Y. Times (Aug. 27, 2019), https://www.nytimes.com/2018/08/27/science/juul-vaping-teen-marketing.html.

[80] Adams, supra note 2.

[81] Richard Durbin et al., Letter from 11 U.S. Senators, to Kevin Burns, CEO of JUUL Labs, Inc., United States Senate (April 18, 2018), https://www.durbin.senate.gov/imo/media/doc/JUUL%20Letter%20- %20S%20IGNED.pdf.

[82] Scott Gottlieb, Statement from FDA Commissioner Scott Gottlieb, M.D., on new enforcement actions and a Youth Tobacco Prevention Plan to stop youth use of, and access to, JUUL and other e-cigarettes, U.S. Food and Drug Admin.

sent JUUL a request for documents relating to marketing, product design, and public health impact.[83] In July 2018, Massachusetts Attorney General Maura Healey announced an investigation into JUUL regarding marketing and sale to minors.[84] In September 2018, FDA Commissioner Gottlieb called youth vaping an "epidemic" and sent letters to JUUL and other e-cigarette manufacturers demanding a plan to reduce youth use.[85] Then, in October 2018, as alleged above, the FDA raided JUUL's headquarters and seized more than a thousand documents relating to JUUL's sales and marketing practices.[86]

C. Addictive By Design

58. In addition to designing its devices to be particularly attractive to youth, JUUL designed its devices to be highly addictive. Unlike most other e-cigarettes, which use freebase nicotine, JUUL uses patented nicotine salts from which it makes liquid nicotine cartridges, or JUULpods.[87] Each JUULpod is, according to the Company, the equivalent of a pack of cigarettes. Each pod contains an alarming amount of nicotine, with up to 59 mg per ml—an amount that is roughly three times the amount of nicotine that can be sold to consumers in the European Union in a JUULpod. On top of ramping up the amount of nicotine, JUULpods enabled the Company to increase the rate and amount of nicotine delivery to the JUUL user, roughly doubling the concentration and tripling the delivery speed of nicotine of the average e-cigarette.[88]

59. Big Tobacco spent decades manipulating nicotine in order to foster and maintain addiction in their customers. RJR developed and patented nicotine salt additives, including nicotine benzoate, to increase nicotine delivery in cigarette smoke. The objective was to provide an additional

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(April 23, 2018), https://www.fda.gov/news-events/press-announcements/statement-fdacommissioner-scott-gottlieb-md-new-enforcement-actions-and-youth-tobaccoprevention?utm_campaign=04242018_Statement_Youth%20Tobacco%20Prevention&utm_medium=email&utm_source=Eloqua.

[83] Id.

[84] AG Healey Announces Investigation into JUUL, Other Online E-Cigarette Retailers Over Marketing and Sale to Minors, Mass.gov (July 24, 2018), https://www.mass.gov/news/ag-healey-announces-investigation-into-juulother-online-e-cigarette-retailers-over-marketing.

[85] Letters to Manufacturers Regarding Plans to Address Youth Access and Use, U.S. Food & Drug Admin. (Sept. 12, 2018), https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/ctp-letters-industry#youthaccess.

[86] McGinley, supra note 17

[87] Rachel Becker, Juul's Nicotine Salts Are Dominating the Market – And Other Companies Want In, The Verge (Nov. 21, 2018), https://www.theverge.com/2018/11/21/18105969/juul-vaping-nicotine-salts-electroniccigarettes-myblu-vuse-markten.

[88] How Much Nicotine is In Juul?, Truth Initiative (Feb. 26, 2019), https://truthinitiative.org/researchresources/emerging-tobacco-products/how-much-nicotine-juul.

"nicotine kick" based on increased nicotine absorption associated with lower pH. JUUL uses this very same concept for its market-dominating e-cigarettes. The Company's patent for its nicotine salts describes a process for combining benzoic acids with nicotine, a formulation that mimics the nicotine salt additive developed by RJR. JUUL's use of benzoic acid and manipulation of pH affect the palatability of nicotine inhalation by reducing the "throat hit" that users experience when vaping. Indeed, this was the objective behind using nicotine salts (as compared to "free base nicotine" which has a higher pH). According to Ari Atkins, one of the inventors of the JUUL device, "[i]n the tobacco plant, there are these organic acids that naturally occur. And they help stabilize the nicotine in such a way that makes it . . . I've got to choose my words carefully here: Appropriate for inhalation."[89]

60. Because smokers are already accustomed to a certain level of harshness and throat hit, developing a product with low levels of harshness and minimal "throat hit" is only a critical concern if your goal is to appeal to non-smokers, and specifically, young people. Minimizing the harshness of nicotine also allows one to vape more frequently and for longer periods of time and masks the amount of nicotine being delivered by eliminating the unpleasant throat hit normally associated with large doses of nicotine. The harshness of free base nicotine makes prolonged vaping difficult; the use of nicotine salts solves that problem. Put another way, the nicotine salt technology behind JUULpods makes JUUL "smoke" highly potent yet hardly perceptible.

61. The increased nicotine exposure facilitated by the JUUL device has serious health consequences. The ease of use and "smoothness" strip away external inhibitors and enable extreme levels of unfettered use. Using the JUUL's own calculations, consuming two JUULpods in a day is the equivalent of consuming two to four packs of cigarettes a day. In this way, JUUL has not only created a new generation of e-cigarette smokers, but has also pioneered a new style of smoking—vaping—that is more nicotine-saturated than ever before.

62. Increased rates and duration of smoking lead to greater overall exposure to nicotine. Nicotine is a neurotoxin. A highly addictive, psychoactive substance that targets brain areas involved in

[89] David Pierce, This Might Just Be the First Great E-Cig, Wired.com (Apr. 21, 2015), https://www.wired.com/2015/04/pax-juul-ecig/.

emotional and cognitive processing, nicotine poses a particularly potent threat to the adolescent brain, as it can "derange the normal course of brain maturation and have lasting consequences for cognitive ability, mental health, and even personality."[90] Animal researchers from the Yale University School of Medicine has found that vaping during adolescence can lead to long-term brain changes, like attention deficit hyperactivity disorder.[91]

63. Studies also show that exposure to nicotine as a teen—even minimal exposure—biologically primes the brain for addiction and greatly increases likelihood of dependence on nicotine as well as other substances later in life.[92] In a study done on mice, even "very brief, low-dose exposure to nicotine in early adolescence increases the rewarding properties of other drugs, including alcohol, cocaine, methamphetamine—and these are long-term changes."[93]

64. JUUL's use of flavors only amplifies its addictive qualities. Research done by Nii Addy, associate professor of psychiatry and cellular and molecular physiology at the Yale School of Medicine, found that "sweet flavors can make the nicotine more palatable . . . but also act in the brain to increase nicotine taking."[94] This effective is especially troubling for teenage brains, which are more sensitive than adult brains to rewards. According to University of Pennsylvania psychologist Janet Audrain-McGovern, research shows that "if the first e-cigarette you used was flavored, then you're more likely to go on and use an e-cigarette again."[95]

65. According to congressional testimony from Dr. Jonathan Winickoff, a professor of pediatrics at Harvard Medical School and the Director of Pediatric Research in the Tobacco Research and Treatment Center, "[n]icotine addiction can take hold in only a few days, especially in the developing adolescent brain that is particularly vulnerable to addiction to nicotine. . . Many of my

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[90] N.A. Goriounova & H.D. Mansvelder, Short- and Long-Term Consequences of Nicotine Exposure during Adolescence for Prefrontal Cortex Neuronal Network Function, Cold Spring Harbor Persp. in Med. 2(12) (Dec. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3543069/.

[91] Jon Hamilton, How Vaping Nicotine Can Affect A Teenage Brain, NPR (Oct. 10, 2019), https://www.npr.org/sections/health-shots/2019/10/10/768588170/how-vaping-nicotine-can-affect-a-teenage-brain.

[92] National Institute on Drug Abuse, Principles of Adolescent Substance Use Disorder: A Research Based Guide (2014), https://www.drugabuse.gov/publications/principles-adolescent-substance-use-disorder-treatmentresearch-based-guide/introduction.

[93] Hamilton, supra note 92

[94] Id.

[95] Id.

patients find Juul nearly impossible to stop. Nicotine withdrawal can cause headaches, insomnia, irritability, anxiety, and depression, and these withdrawal symptoms are one of the primary reasons a nicotine addiction is difficult to overcome." Moreover, there is a lack of effective tools to help adolescents overcome nicotine addiction: there is no good data on how to treat adolescents with e-cigarette dependence; there has not been enough research on youth tobacco cessation strategies; and most of the pharmacological therapies approved for adults have been shown to be ineffective or only marginally effective in adolescents. [96]

66. Research in Massachusetts indicates that daily JUUL and other e-cigarette use is much more likely to continue than daily cigarette smoking. Out of the surveyed students who reported ever using cigarettes, only 17% indicated that they remained daily smokers. Out of the surveyed students who reported ever using e-cigarettes daily, 58% remained daily users. This data demonstrates both that e-cigarette use in teens is very persistent, a result consistent with the addictiveness of JUUL and the difficulty teens have in trying to quit.[97]

67. E-cigarette use also puts adolescents at increased risk for cigarette smoking. Compared to adolescents who do not use e-cigarettes, those who do are 3.5 times more likely to begin smoking cigarettes

68. The dangerous and destructive nature of nicotine is not a recent discovery. As a key ingredient in tobacco products, the drug and its deleterious effects have been the subject of scientific research and public health warnings for decades. Nicotine causes cardiovascular, reproductive, and immunosuppressive problems with devastating effects. Part of the reason the national decline in cigarette use in recent years was such a victory for public health was because there was a corresponding decline

[96] Jonathan Winickoff, Testimony of Jonathan Winickoff before the U.S. House of Representatives Committee on Oversight and Reform Subcommittee on Economic and Consumer Policy, U.S. House Committee on Oversight & Reform (July 24, 2019), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2019.07.24%20Winickoff%20AAP%20Testimony.pdf at 2 [hereinafter "Winickoff Testimony"].

[97] Id.

in teen exposure to nicotine. From 2000 to 2017, the smoking rate among high school students fell by 73%.[98]

69. That trend has completely reversed. In 2018, more than one in four high school students in the United States reported using a tobacco product in the past thirty days, a dramatic increase from just one year before.[99] But there was no increase in the use of cigarettes, cigars, or hookahs during that same time period.[100] There was only increased use in a single tobacco product: e-cigarettes. While use of all other tobacco products continued to decrease as it had been for decades, e-cigarette use increased 78% in just one year.[101] This drastic reversal caused the CDC to describe youth vaping an "epidemic."[102]

70. The teen vaping epidemic, of which JUUL is the architect, has and will continue to have significant costs, both for individual users and for society. Nicotine addiction alone has significant health care costs, and these costs are exacerbated when adolescents are involved. Adolescent nicotine addiction leads to memory and attention problems, and increase chances of addiction later in life, all of which will continue to have long-lasting impacts on society.

71. Science is also beginning to show that e-cigarettes have the potential to cause even more, distinct health risks and costs. The very same liquids that enable e-cigarettes to deliver nicotine with such potency are proving to be increasingly dangerous. When heated, the vape liquid turns into aerosol, which may contain, in addition to nicotine, ultrafine toxic particles such as lead, additional chemicals, and volatile organic compounds.[103] These chemicals have the potential to be deadly. Vaping is now linked to conditions like chronic obstructive pulmonary disease and seizures, and there were 193

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[98] Matthew L. Myers, Press Release: On 20th Anniversary of State Tobacco Settlement (the MSA), It's Time for Bold Action to Finish the Fight Against Tobacco, Campaign for Tobacco-Free Kids (Nov. 26, 2018), https://www.tobaccofreekids.org/press-releases/2018_11_26_msa20.

[99] Progress Erased: Youth Tobacco Use Increased During 2017-2018, Ctrs. for Disease Control and Prevention (Feb. 11, 2019), https://www.cdc.gov/media/releases/2019/p0211-youth-tobacco-use-increased.html.

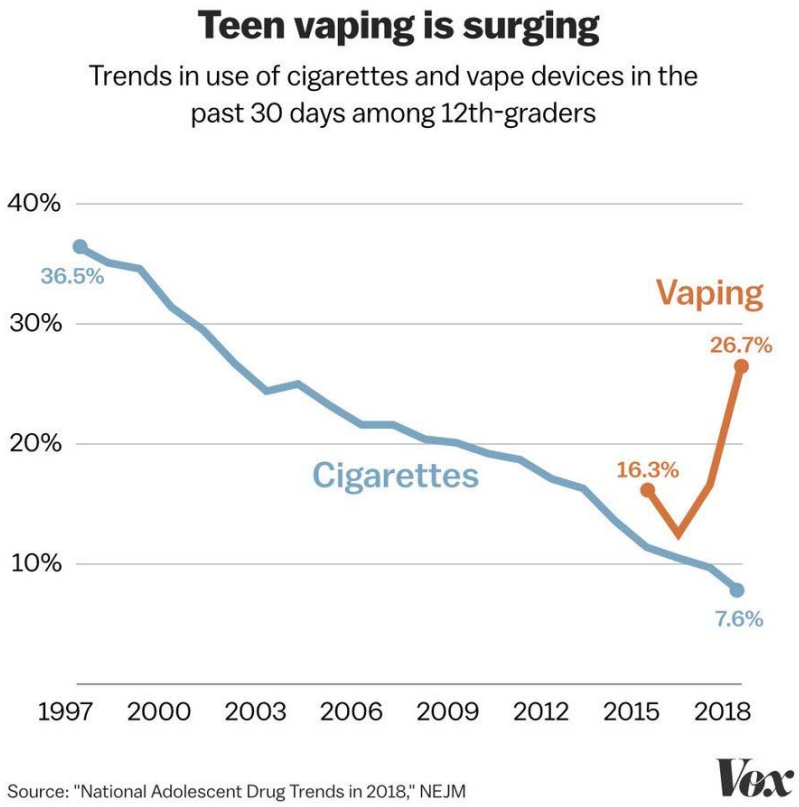
[100] Tobacco Use By Youth Is Rising: E-Cigarettes are the Main Reason, Ctrs. for Disease Control & Prevention (Feb. 2019), https://www.cdc.gov/vitalsigns/youth-tobacco-use/index.html.

[101] Scott Gottlieb, Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes, U.S. Food & Drug Admin. (Nov. 15, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scottgottlieb-md-proposed-new-steps-protect-youth-preventing-access.

[102] Adams, supra note 2.

[103] Lena H. Sun, He went from hiking enthusiast to 'on death's door' within days. Doctors blamed vaping, Wash. Post (Aug. 24, 2019), https://www.washingtonpost.com/health/one-mans-near-death-experience-with-vapingrelated-lung-failure/2019/08/24/ca8ce42c-c5b4-11e9-9986-1fb3e4397be4_story.html?arc404=true.

possible cases of severe lung illness associated with e-cigarette product use in 22 states in less than two months in the summer of 2019 alone.[104] Public health officials reported the first known death from a vaping-related illness on August 23, 2019.[105] On September 11, 2019, a teenager in King County became the first person in Washington State to be diagnosed with a severe lung disease associated with vaping.[106] By October 10, 2019, lung illness tied to vaping had killed 26 people, and there were over 1,300 possible cases of serious illness reported from 49 states.[107] Only Alaska has not yet seen a case. 16% of these patients have been under the age of 18.[108] In October 2019, a 17-year-old boy from the Bronx, New York, became the first child to die from vaping-related respiratory illness.[109]



[104] CDC, FDA, States Continue to Investigate Severe Pulmonary Disease Among People Who Use E-cigarettes, Ctrs. for Disease Control & Prevention (Aug. 21, 2019), https://www.cdc.gov/media/releases/2019/s0821-cdc-fdastates-e-cigarettes.html.

[105] Matt Richtel & Sheila Kaplan, First Death in a Spate of Vaping Sicknesses Reported by Health Officials, N.Y. Times (Aug. 23, 2019), https://www.nytimes.com/2019/08/23/health/vaping-death-cdc.html.

[106] Nicole Brodeur & Ryan Blethen, King County teen is first in state diagnosed with severe lung disease related to vaping, Seattle Times (Sept. 11, 2019), https://www.seattletimes.com/seattle-news/health/king-county-teen-isfirst-in-state-diagnosed-with-severe-lung-disease-related-to-vaping/.

[107] Nicole Brodeur & Ryan Blethen, King County teen is first in state diagnosed with severe lung disease related to vaping, Seattle Times (Sept. 11, 2019), https://www.seattletimes.com/seattle-news/health/king-county-teen-isfirst-in-state-diagnosed-with-severe-lung-disease-related-to-vaping/.

[108] Denise Grady, Vaping Illnesses Top 1,000, C.D.C., N.Y. Times (Oct. 3, 2019), https://www.nytimes.com/2019/10/03/health/vaping-illnesses-cdc.html.

[109] Ed Shanahan and Azi Paybarah, Bronx Teenager's Death Is the Youngest Vaping Fatality in U.S., N.Y. TIMES (Oct. 8, 2019), https://www.nytimes.com/2019/10/08/nyregion/vaping-death.html

72. Many teenagers are simply unaware of these risks, an ignorance that JUUL preys on. According to Dr. Winickoff, many of his patients believe JUULing is harmless:

> Counseling teens and preteens on e-cigarette use is challenging. Many of my patients have wildly incorrect beliefs about e-cigarettes. They know that cigarettes are dangerous, but assume that Juul—since it's ubiquitous, comes in childfriendly flavors, and is marketed as a healthier alternative to smoking—must be harmless. I have to explain to kids that e-cigarettes do not have the same positive health benefits as the fruits whose flavor they copy. Even the term vapor calls to mind harmless water vapor. There is no water in these products.

Winickoff Testimony at 1.

73. In a clear admission of responsibility, JUUL's former CEO Kevin Burns has apologized to all the parents for the vaping epidemic. Mr. Burns said, "I'd tell [the parents] that I'm sorry that their child's using the product." After this apology and in response to the growing number of vape-related health incidences and the threats of legal action, JUUL replaced Mr. Burns with K.C. Crosthwaite. Mr. Crosthwaite was the chief growth officer at Altria, the makers of Marlboro cigarettes. Replacing Mr. Burns with a "growth executive" from Big Tobacco is a clear sign that JUUL does not plan to stop its obsession with growth regardless of public health impacts.

D. <u>JUUL and School</u>

74. In addition to severe health consequences, widespread "JUULing" has placed severe burdens on society, and school districts in particular. It is not an overstatement to say that JUUL has changed the educational experience of students across California.

75. JUUL use has invaded school bathrooms—now known as "the Juul room."[110] As one high school student explained, "it's just a cloud."[111] The ubiquity of JUUL use in high school bathrooms has generated numerous online spoofs about "the juul room."[112]

76. Kids have also coined the term "nic sick"—which, as one high school student explained to CBS News, "kinda seems like a really bad flu, like, just out of nowhere. Your face goes pale, you start throwing up and stuff, and you just feel horrible."[113]

77. Such rampant JUUL use has effectively added another category to teachers' and school administrators' job descriptions; many now receive special training to respond to the various problems that JUUL use presents, both in and out of the classroom. A national survey of middle schools and high schools found that 43.3% of schools have had to implement not only an e-cigarette policy but a JUUL-specific policy. Participants in the survey reported multiple barriers to enforcing these policies, including the discreet appearance of the product, difficulty pinpointing the vapor or scent, and the addictive nature of the product. [114]

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[110] Moriah Balingit, In the 'Juul room': E-cigarettes spawn a form of teen addiction that worries doctors, parents and schools, Wash. Post (July 26, 2019), https://www.washingtonpost.com/local/education/helpless-to-the-drawof-nicotine-doctors-parents-and-schools-grapple-with-teens-addicted-to-e-cigarettes/2019/07/25/e1e8ac9c-830a11e9-933d-7501070ee669_story.html.

[111] Greta Jochem, Juuling in School: e-Cigarette Use Prevalent Among Local Youth, Daily Hampshire Gazette (Nov. 13, 2018), https://www.gazettenet.com/Juuling-in-Schools-21439655.

[112] Juul Hashtag Meme, Stanford U. Res. into the Impact of Tobacco Advert. (2018), http://tobacco.stanford.edu/tobacco_main/images_pods.php?token2=fm_pods_st681.php&token1=fm_pods_im%20g37610.php&theme_file=fm_pods_mt068.php&theme_name=JUUL&subtheme_name=%23juul.

[113] High school students say about 20% of their peers are vaping, some as young as 8th grade, CBS News (Aug. 31, 2019), https://www.cbsnews.com/news/high-school-students-say-about-20-of-their-peers-are-vaping-some-asyoung-as-8th-grade/.

[114] Barbara A. Schillo, et al., JUUL in School: Teacher and Administrator Awareness and Policies of E-Cigarettes and JUUL in U.S. Middle and High Schools, Truth Initiative (Sep. 2019), https://journals.sagepub.com/doi/full/10.1177/1524839919868222?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed.

78. Across the United States, schools have had to divert resources and administrators have had to go to extreme lengths to respond to the ever-growing number of students using JUULs on school grounds. According to the Truth Initiative, more than 40 percent of all teachers and administrators reported that their school uses camera surveillance near the school's restroom, almost half (46 percent) reported camera surveillance elsewhere in the school, and 23 percent reported using assigned teachers for restroom surveillance.[115] Some schools have responded by removing bathroom doors or even shutting bathrooms down,[116] and schools have banned flash drives to avoid any confusion between flash drives and JUULs.[117] Schools have also paid thousands of dollars to install special monitors to detect vaping, which they say is a small price to pay compared to the plumbing repairs otherwise spent as a result of students flushing vaping paraphernalia down toilets.[118] Other school districts have sought to create new positions for tobacco prevention supervisors, who get phone alerts when vape smoke is detected in bathrooms.[119]

79. Many schools have shifted their disciplinary policies in order to effectively address the JUUL epidemic. Rather than immediately suspending students for a first offense, school districts have created anti-vaping curricula which students are required to follow in sessions held outside of normal school hours, including on Saturdays.[120] Teachers prepare lessons and study materials for these sessions with information on the marketing and health dangers of vaping[121]—extra work which requires teachers

[115] How are schools responding to JUUL and the youth e-cigarette epidemic?, Truth Initiative, (Jan. 18, 2019), https://truthinitiative.org/research-resources/emerging-tobacco-products/how-are-schools-responding-juul-andyouth-e-cigarette.

[116] Ana B. Ibarra, The Juul's So Cool, Kids Smoke It In School, Kaiser Health News (Mar. 26, 2018), https://khn.org/news/the-juuls-so-cool-kids-smoke-it-in-school/; Evie Blad, 'Juuling' Craze: Schools Scramble to Deal With Student Vaping, Educ. Wk. (May 4, 2018), https://www.edweek.org/ew/articles/2018/05/09/juuling-craze-schools-scramble-to-deal-with.html.

[117] Ana B. Ibarra, Why 'juuling' has become a nightmare for school administrators, Kaiser Health News (Mar. 26, 2018), https://www.nbcnews.com/health/kids-health/why-juuling-has-become-nightmare-school-administratorsn860106.

[118] Suzanne Monaghan, Many schools installing vape detectors in bathrooms to discourage e-cigarette use, KYW Newsradio (June 10, 2019), https://kywnewsradio.radio.com/articles/news/many-schools-installing-vapedetectors-bathrooms-address-rise-e-cigarette-use.

[119] Lauren Katims, California Fights Vaping in Schools, U.S. News & World Report (Apr. 30, 2019), https://www.usnews.com/news/best-states/articles/2019-04-30/california-focuses-on-education-to-curb-vaping-in-schools.

[120] Id.

[121] Pat Eaton-Robb, Discipline or treatment? Schools rethinking vaping response, Concord Monitor (May 26, 2019), https://www.concordmonitor.com/Discipline-or-treatment-Schools-rethinking-vaping-response-25822972.

to work atypical hours early in the mornings and on weekends.[122] Some schools will increase their drug-testing budget to include random nicotine tests for students before they join extracurricular activities. Under this drug testing protocol, first offenders will undergo drug and alcohol educational programming; second and third offenders with be forced to sit out from extracurriculars and attend substance abuse counseling.[123]

80. JUUL actively sought to enter school campuses. The Subcommittee on Economic and Consumer Policy ("Subcommittee") conducted a months-long investigation of JUUL, including reviewing tens of thousands of internal documents, and concluded that JUUL "deliberately targeted children in order to become the nation's largest seller of e-cigarettes."[124] The Subcommittee found that "(1) Juul deployed a sophisticated program to enter schools and convey its messaging directly to teenage children; (2) Juul also targeted teenagers and children, as young as eight years-old, in summer camps and public out-of-school programs; and (3) Juul recruited thousands of online "influencers" to market to teens."[125]

81. According to the Subcommittee, JUUL was willing to pay schools and organizations hundreds of thousands of dollars to have more direct access to kids. Such attempts included paying a Baltimore charter school organization $134,000 to start a summer camp to teach kids healthy lifestyles, for which JUUL itself would provide the curriculum; offering schools $10,000 to talk to students on campus; and giving the Police Activities League in Richmond, California, $90,000 to provide JUUL's own vaping education program, "Moving On," to teenage students suspended for using cigarettes.[126] Meanwhile, JUUL would collect data about test scores, surveys, and activity logs about the students.

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[122] Kathy Brown, School trustees OK discipline for juuling/vaping offenses, Gillette News Record (Aug. 29, 2019), https://www.gillettenewsrecord.com/news/local/article_5ec28c96-fd48-5ae0-b267-4e417272d020.html.

[123] Christine Hauser, This School District Has a Way to Combat Vaping: Random Nicotine Tests, N.Y. Times (June 17, 2019), https://www.nytimes.com/2019/06/17/us/nebraska-vaping-schools.html.

[124] Supplemental Memorandum for Hearing on 'Examining JUUL's Role in the Youth Nicotine Epidemic: Parts I & II' from Committee Staff, to Democratic Members of the Subcommittee on Economic and Consumer Policy (July 25, 2019), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Supplemental%20Memo.pdf . [hereinafter "JUUL's Role in Youth Nicotine Epidemic"]

[125] Id

[126] Sheila Kaplan, Juul Targeted Schools and Youth Camps, House Panel on Vaping Claims, N.Y. Times (July 25, 2019), https://www.nytimes.com/2019/07/25/health/juul-teens-vaping.html.

82. Among the more egregious incidents reported by the Subcommittee was a July 24, 2019 presentation -- during which no parents or teachers were in the room – which conveyed the message that the JUUL product was "totally safe," and the presenter even demonstrated to the students how to use a JUUL.[127] The school was presumably paid for this meeting, which was marketed to the school as an anti-smoking initiative. A JUUL spokesman said JUUL is no longer funding such programs.[128]

E. Impact on Los Angeles Unified School District.

83. The epidemic has severely impacted the District. On August 19, 2019, the Los Angeles County Department of Public Health announced that more than 30% of LA County high school students reported using e-cigarette products, and 10% of those students are regular users. This is up 6.4% from the previous year.[129]

84. JUUL use has interrupted the educational environment – and is impeding learning – in schools throughout the District. The District has suffered at least four types of harm.

85. *First*, the surge of vaping disrupts the learning environment as educators have to deal with the prevention and detection of student vaping and modify school property and school operations in response to the problem. With respect to students who are caught vaping, administrators must expend time and resources to deal with the problem and provide supports (e.g., positive behavioral interventions). From 2013 to the present, vaping incidents on school campuses in the District increased tenfold. In fact, there have been 435 critical incidents reported related to vaping and e-cigarettes in the 2018-2019 academic year. That number is expected to be substantially higher in the 2019-2020 year, with closer to 500 such critical incidents reported at the current pace. These numbers dramatically underestimate the total incidence of vaping and e-cigarette use on campus, as they reflect only critical incidents reported by principals. Los Angeles School Police estimate they respond to over a thousand vaping incidents each year. For example, bathrooms cannot be utilized as designed due to the high incidence of bathroom vaping. As another example, because standard smoke detectors are not sufficiently sensitive to detect vape smoke and interferes with fire alarm detectors, the District would

[127] JUUL's Role in Youth Nicotine Epidemic, supra note 125.
[128] Id.
[129] http://publichealth.lacounty.gov/phcommon/public/media/mediapubhpdetail.cfm?prid=2117

need to retrofit its detector systems or procure vaping detectors to fully monitor and prevent in-school vaping on middle school and high school campuses.

86. *Second*, the vaping epidemic hurts individual student learning. Vaping has led to a rise in student absences due to sickness or absenteeism. Research shows that students who attend school more often do better in school.[130] In Massachusetts, the National Bureau of Economic Research found "poor attendance can account for up to a quarter of the math achievement gap between poor and non-poor students."[131] A study of Chicago Public Schools shows "course attendance is eight times more predictive of ninth grade failure than eighth grade test scores."[132] In sum, vaping-related school absences directly impact the academic achievement of the District's students.

87. *Third*, vaping hurts all students in the District, not just those who do it, through less school funding from the State for school operations. The vast majority of revenue the District receives is tied to daily student attendance. Student absences due to vaping related issues cause a reduction in state funding for the District, which inherently results in a reduction in school-site staff for all students. The District receives funding from the State only if students attend school. The more vaping-related students absences from school, the less funding the District gets to spend on learning for all students.

88. *Fourth*, vaping hurts all students by diverting funding away from learning toward educational campaigns, prevention, and treatment. For example, the District would divert services and funding away from implementing specialized programs, lower class size, improved technology, enhanced curricular materials, and academic reading and math instructional intervention programs for students who are struggling academically. The District has instead had to launch an internal task force to specifically address vaping.[133] The task force is made up of administrators and staff including health and counseling professionals, representatives from after school programs, school police, environmental health and safety, and the District's instruction division. The task force actively seeks to prevent the use

[130] Department of Education, 2013-14 Civil Rights Data Collection, https://www2.ed.gov/datastory/chronicabsenteeism.html#intro

[131] Joshua Goodman, "Flaking out: Student absences and snow days as disruptions of instructional time." No. w20221. National Bureau of Economic Research (2014).

[132] Elaine M. Allensworth, & John Q. Easton, "What Matters for Staying On-Track and Graduating in Chicago Public Highs Schools: A Close Look at Course Grades, Failures, and Attendance in the Freshman Year. Research Report." Consortium on Chicago School Research (2007).

[133] https://www.latimes.com/california/story/2019-09-29/vaping-students-california-schools

of JUUL and other vaping materials through coordination of a public awareness campaign. But that's not all. The task force must also address the number of other problems that accompany JUUL use among students; for example, the task force is developing a procedure for disposing of confiscated JUULpods and other vaping paraphernalia. The District will continue to incur extensive costs to orchestrate outreach regarding the risks of vaping, to enforce restrictions regarding vaping in school (for example, through vape smoke detectors), and to develop and carry out protocol associated with the collection and disposal of vape products. In the absence of student vaping, these funds could have gone to the District's core activity – educating LA's youth.

FIRST CAUSE OF ACTION

PUBLIC NUISANCE

89. Plaintiff hereby re-alleges and incorporates by reference each and every allegation contained above as though the same were set forth herein in full.

90. Defendants created a condition that is harmful to human health; indecent and offensive to the senses; obstructed the free use of property and resources, so as to interfere with the comfortable enjoyment of such property and resources.

91. Defendants' actions and omissions have caused an unreasonable and substantial interference in the educational environments in schools across the State of California, including those within the District. This interference is ongoing and continuing.

92. Defendants created a condition that affected a substantial number of people at the same time – specifically, Defendants have created a vaping epidemic that affects hundreds of thousands, if not millions, of students and all school districts throughout California.

93. An ordinary person would be reasonably annoyed and disturbed by Defendants actions as described throughout this Complaint, including marketing and promoting the use of e-cigarettes by minors and the disruption of normal school operations.

94. The social utility of Defendants' products do not outweigh the gravity of the harm inflicted on the District and other school districts throughout California.

95. The District did not consent to Defendants' conduct.

96. The District suffered and continues to suffer harm different from the type of harm suffered by the general public. Among other reasons discussed throughout the Complaint, vaping has interfered with the educational environment within the District's schools and has required the District to take certain measures to prevent continued vaping on District campuses.

97. Defendants' conduct was a substantial factor in causing the District's harm.

98. Defendants' conduct was willful, knowing, and reckless, warranting punitive and exemplary damages.

SECOND CAUSE OF ACTION

STRICT LIABILITY – DESIGN DEFECT

99. Plaintiff hereby re-alleges and incorporates by reference each and every allegation contained above as though the same were set forth herein in full.

100. Plaintiff was and is continuing to be harmed by Defendants' vaping products, which were designed, manufactured, sold, and distributed by Defendants, and which were defectively designed; did not include sufficient instructions; were not properly researched, inspected, or tested; and did not include sufficient warning of potential safety hazards.

101. The design of Defendants' vaping products were defective because the vaping products did not perform as safely as an ordinary consumer would have expected them to perform, especially when Defendants' misrepresentations are taken into consideration.

102. The gravity of the harm resulting from Defendants' vaping products was, is, and will be enormous. Defendants have created an epidemic among young people that will take enormous resources, time, and effort to curb.

103. Defendants' vaping products' failure to incorporate sufficient safety features is a substantial factor in causing Plaintiff's harm.

104. Defendants' design of vaping products has resulted in increased harm to young people, such as Plaintiff's students. As a result, school districts, including Plaintiff, must take extensive action – incurring significant costs -- to address in-school vaping.

105. Defendants knew that their vaping products cause the type of harm suffered by Plaintiff.

106. At all times, there have been safer alternative designs that were and are feasible, cost effective, and advantageous.

107. Defendants' conduct lacked any care and was an extreme departure from what a reasonably careful company would do in the same situation to prevent harm to others, and thus Defendants were and are grossly negligent.

108. Defendants, its officers, directors, and managing agents, engaged in despicable conduct and acted or failed to act with malice, oppression, and fraud, warranting punitive or exemplary damages.

THIRD CAUSE OF ACTION

STRICT LIABILITY - FAILURE TO WARN

109. Plaintiff hereby re-alleges and incorporates by reference each and every allegation contained above as though the same were set forth herein in full.

110. At all times, Defendants' vaping products have been defective as a result of Defendants' failure to adequately test for safety, failure to give adequate warnings or instructions regarding the possibility of adverse health consequences. Defendants also failed to inform and warn consumers and users through their advertising that they had failed to perform adequate testing of the JUUL e-cigarettes and pods to ensure safety, including long-term testing of the product, testing for injury to the lungs, brain, and cardiovascular systems, and other related medical conditions.

111. Defendants failed to both adequately test JUUL e-cigarettes and pods before making it available to consumers and users and failed to disclose through their advertising that extensive health-related testing had not been done and which testing would have disclosed the magnitude of the potential risks associated with the use of the JUUL e-cigarettes and pods.

112. In the alternative, Defendants conducted adequate testing but failed to warn about the dangers of using JUUL e-cigarettes and pods in their advertising.

113. Defendants' failure to warn was intentional, willful, and malicious. The conduct was carried on with a conscious disregard for the safety and the rights of others, such as Plaintiff.

114. As a proximate cause of Defendants' actions, Plaintiff has and will continue to incur substantial expense to address the vaping epidemic at its schools.

FOURTH CAUSE OF ACTION

NEGLIGENCE

115. Plaintiff hereby re-alleges and incorporates by reference each and every allegation contained above as though the same were set forth herein in full.

116. Defendant had a duty to Plaintiff to exercise due care.

117. Defendant breached that duty, as set forth throughout the Complaint.

118. Plaintiff was and continues to be harmed by Defendants' negligent conduct as described throughout the Complaint.

119. Plaintiff's harm was foreseeable result of Defendants conduct.

120. Defendants' negligence was a substantial factor in causing Plaintiff's harm.

121. Defendants' above-described conduct was willful, knowing, and reckless, warranting punitive and exemplary damages.

CLASS ACTION ALLEGATIONS

122. Plaintiff and members of the Class have all suffered injury in fact as a result of JUUL and its products, which was the result of JUUL's unlawful, intentional, and grossly negligent conduct.

123. Plaintiff brings this lawsuit on behalf of itself and all other California school districts that are similarly situated. Subject to additional information obtained through further investigation and/or discovery, the proposed "Class" consists of the following: "All school districts in the State of California that have spent resources addressing, or whose property or operations have been affected by, student use of JUUL products."

124. Certification of Plaintiff's claims for classwide treatment is appropriate because Plaintiff can prove the elements of its claims regarding liability and entitlement to injunctive relief, abatement, and damages on a classwide basis using the same evidence as would be used to prove those elements in individual actions alleging the same claim.

125. Plaintiff reserves the right to modify the Class definition prior to class certification

126. **Ascertainability.** The members of the Class are readily ascertainable through public records held by the California Department of Education. In fact, the Department's website contains a list of all public school districts (https://www.cde.ca.gov/ds/si/ds/pubschls.asp). Members of the Class

may be notified of the pendency of this action by recognized, Court-approved notice dissemination methods, which may include U.S. mail, electronic mail, Internet postings, social media, and/or published notice.

127. **Numerosity.** The members of the Class are so numerous that their individual joinder is impracticable. There are several hundred school districts in California.

128. **Existence and predominance of Common Questions of Law and Fact.** Common questions of law and fact that exist as to all members of the Class predominate over any questions affecting only individual class members. All members of the Class have been subject to the same conduct and exposure. The common legal and factual questions include, but are not limited to, the following:

a. Whether Defendants engaged in the conduct alleged herein;

b. Whether Defendants created a public nuisance;

c. Whether Defendants unlawfully contributed to a public nuisance;

d. Whether Defendants failed to sufficiently test their vaping products;

e. Whether Defendants' warnings were sufficient;

f. Whether Defendants' actions constitute violations of California common law, as plead herein;

g. Whether the rise in youth vaping and nicotine addiction was substantially caused by Defendants' conduct;

h. Whether Defendants' conduct injures or endangers the health and safety of students across California;

i. Whether Defendants continued to market JUUL products to minors after they were on notice that JUUL products were being used in schools;

j. Whether Defendants' conduct was negligent and/or grossly negligent;

k. Whether Defendants' conduct was intentional, malicious, or reckless;

l. Whether Defendants should be liable for compensatory damages.

129. **Typicality.** Plaintiffs' claims are typical of the claims of the members of the Class in that Plaintiff is a member of the Class that Plaintiff seeks to represent. Plaintiff, and the other members of

the Class suffered damages as a direct proximate result of the same wrongful practices by Defendants. Plaintiff's claims arise from the same practices and courses of conduct that give rise to the claims of the other members of the Class. Plaintiff's claims are based upon the same legal theories as the claims of the other members of the Class.

130. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has retained counsel experienced in complex mass and class actions, including MDL litigation and other similar public nuisance litigation. Plaintiff intends to prosecute this action vigorously. Neither Plaintiff nor counsel have any adverse or antagonistic interests to those in the Class, and both Plaintiff and counsel will fairly and adequately protect the interests of the Class. Therefore, the interests of the members of the Class will be fairly and adequately protected.

131. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. The damages or other financial detriment suffered by individual Class members may be relatively small compared to the burden and expense that would be entailed by individual litigation of the claims against the Defendants. It would likely be impractical for all members of the proposed Class to individually redress effectively the wrongs to them. Furthermore, individualized litigation increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court. Therefore, a class action is maintainable under California Civil Code section 382.

PUNITIVE DAMAGES ALLEGATIONS

132. Plaintiff hereby re-alleges and incorporates by reference each and every allegation contained above as though the same were set forth herein in full.

133. Defendants expressed a reckless indifference to the safety of users of JUUL e-cigarettes and pods, including students attending Plaintiff's schools. Defendants' conduct, as described herein, knowing the dangers and risks of JUUL e-cigarettes and pods, yet concealing and/or omitting this

information in their advertising, in furtherance of their conspiracy and concerted action was outrageous because of Defendants' willful a reckless indifference to the safety of users of JUUL e-cigarettes and pods.

134. Plaintiff is entitled to punitive damages because Defendants' failure to warn and other actions as described herein were malicious, wanton, willful or oppressive or were done with reckless indifference to the Plaintiff and the public's safety and welfare. Defendants misled both the FDA and the public at large, including the Plaintiff herein, by making false representations about the safety of their product. In their advertising, Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects associated with the use of their product, despite available information demonstrating that JUUL e-cigarettes and pods were likely to cause serious side effects.

135. Defendants were or should have been in possession of evidence demonstrating that their products caused serious side effects. Nonetheless, they continued to advertise the products by providing false and misleading information with regard to safety and efficacy.

136. Defendants' actions described above were performed willfully, intentionally and with reckless disregard for the rights of Plaintiff and the public. As a direct and proximate result of the willful, wanton, evilly, motivated and/or reckless conduct of Defendants, Plaintiff sustained damages as set forth above. Accordingly, Plaintiff seeks and is entitled to punitive damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on its own behalf, and on behalf of the Class Members, prays for judgment as follows:

a. For an order certifying the proposed Class as requested herein;

[*Remainder of the Page Intentionally Blank*]

b. That Plaintiff be appointed as the representative of the Class, and counsel for Plaintiff be appointed as class counsel;

c. Compensatory damages as allowable by law;

d. Costs to abate and/or mitigate the continuing nuisance;

e. Injunctive relief and abatement;

f. Punitive damages;

g. Reasonable attorneys' fees as allowed by law;

h. Statutory pre-judgment and post-judgment interest allowable by law;

i. Costs of this suit allowable by law; and,

j. Any and all other relief that this Court deems necessary or appropriate.

DATED: October 28, 2019

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By: _____

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Rahul Ravipudi
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DATED: October 28, 2019

BARON & BUDD, P.C

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John Fiske
Scott Summy
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DATED: October 28, 2019

LOS ANGELES UNIFIED SCHOOL DISTRICT

By: _____

David Holmquist
Alexander Molina
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Attorneys for Plaintiffs

Communication from Public

Name:	American Cancer Society Cancer Action Network
Date Submitted:	10/30/2019 10:04 AM
Council File No:	18-1104
Comments for Public Posting:	Juul Shipped At Least A Million Contaminated Pods, New Lawsuit Says

SCIENCE

Juul Shipped At Least A Million Contaminated Pods, New Lawsuit Says

"Half our customers are drunk and vaping like mo-fos, who the fuck is going to notice the quality of our pods," the former CEO allegedly said. Juul says the lawsuit is "baseless."

By Stephanie M. Lee

Reporting From
San Francisco, CA

Last updated on October 30, 2019, at 11:39 a.m. ET
Posted on October 29, 2019, at 10:11 p.m. ET

Julio Cortez / AP

SAN FRANCISCO — A former Juul executive is alleging in a lawsuit that the fast-growing startup shipped out 1 million contaminated e-

cigarette pods earlier this year — but did not tell customers or issue a recall.

The lawsuit was filed Tuesday by Siddharth Breja, a former senior vice president of global finance who worked at the San Francisco–based company from May 2018 to March 2019. In the lawsuit — filed in US District Court for the Northern District of California on the same day that Juul confirmed its plans to lay off about 500 people — Breja claims he was retaliated against for raising concerns about the contaminated shipment.

In another instance, Breja says he was worried when the company, in February 2019, wanted to resell pods that were at that point almost one year old. He protested their resale and urged the company to at least include an expiration or "best by" date, or a date of manufacture, on the packaging.

The lawsuit claims that then-CEO Kevin Burns shot down that idea, saying, "Half our customers are drunk and vaping like mo-fos, who the fuck is going to notice the quality of our pods."

Do you work for Juul or have you worked for Juul? You can contact this reporter at stephanie.lee@buzzfeed.com or stephaniemlee@protonmail.com. For more ways to securely get in touch, visit tips.buzzfeed.com.

Burns, who was replaced by Altria executive K.C. Crosthwaite in September, did not immediately respond to a request for comment.

"Mr. Breja became aware of very concerning actions at the company, and he performed his duty to shareholders and to the board by reporting these issues internally," Harmeet Dhillon, an attorney for Breja, told BuzzFeed News when reached for comment. "In exchange for doing that, he was inappropriately terminated. This is very concerning, particularly since some of the issues he raised concerned matters of public safety."

A Juul spokesperson said that the company would "vigorously defend" against Breja's "baseless" claims, adding that he was terminated "because he failed to demonstrate the leadership qualities needed in his role."

The representative also said that Breja's safety concerns were unfounded, while acknowledging that the "manufacturing issue" that he described had taken place.

"The allegations concerning safety issues with Juul products are equally meritless, and we already investigated the underlying manufacturing issue and determined the product met all applicable specifications," the spokesperson said.

Juul is fighting off a firestorm from government agencies, public health advocates, and clinicians, who blame the e-cigarette giant for addicting millions of teens to nicotine. A nationwide lung injury outbreak, now standing at 1,604 cases and 34 deaths, is being investigated by public health agencies, which have primarily linked the illnesses to vaping black-market THC. But the connection to nicotine-containing devices, such as Juul, has not been fully ruled out, either.

Breja alleges that on March 12, in an executive team meeting, he learned that some batches of mint e-liquid had been found to be contaminated. Approximately 250,000 mint refill kits, the equivalent of one million pods, were manufactured with the contaminated e-liquid, shipped to retailers, and sold to customers. The lawsuit does not specify what the batches were allegedly contaminated with.

Breja was concerned about the public's safety, the lawsuit alleges, especially in the wake of consumers recently having reported seizures after Juuling.

And he was asked to charge the supplier of the e-liquid, Alternative Ingredients, Inc., for $7 million for the contaminated batches. (That company did not immediately return a request for comment.) Breja was concerned by "this hypocritical approach of not informing the customers about the contamination on one hand (claiming it was not a serious issue) and charging the supplier for it on the other hand," according to the lawsuit.

That same day, Breja "protested Juul's refusal to issue a product recall for the contaminated pods, or at a minimum issue a public health and safety notice to consumers." Tim Danaher, the chief finance officer at the time, reportedly "questioned his financial acumen," since these suggestions would lead to billions of dollars in lost sales and hurt Juul's then–$38 billion valuation, according to the lawsuit.

Danaher, whose departure was announced by the company on Tuesday, allegedly told Breja that he should remember his loyalty to Juul. (Danaher did not immediately respond to a request for comment.)

According to the lawsuit, Breja was terminated on March 21, just over a week after he raised concerns about the contaminated pods. He was told it was because he had misrepresented himself as the chief financial officer at Uber. Breja says that he never made that claim, but had accurately stated that he was the chief financial officer of a division of Uber. Juul's claim is "preposterous" and "intentionally invented" to hurt Breja's reputation and employment prospects, the lawsuit alleges.

UPDATE

October 30, 2019, at 8:23 a.m.

This story has been updated to include a response from Juul, a link to the lawsuit itself, and a clarification that the lawsuit did not specify which contaminant was allegedly in the pods.

Stephanie M. Lee is a science reporter for BuzzFeed News and is based in San Francisco.

Contact Stephanie M. Lee at stephanie.lee@buzzfeed.com.

Got a confidential tip? Submit it here.