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May 9, 2019

Dr. Norman E. Sharpless
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: JUUL Marketing Claims of Smoking Cessation

Dear Dr. Sharpless:

We write to urge the Food and Drug Administration (FDA) to conduct a thorough investigation of, and take appropriate enforcement action against, the marketing of JUUL e-cigarettes with express or implied claims that the products help users stop smoking. These claims indicate that the JUUL products are intended for use in the prevention of disease (namely addiction to cigarettes, a deadly product) and therefore should be considered drugs, devices, or combination drug/device products within the jurisdiction of the FDA. As JUUL is being sold without the requisite approval, it is an unapproved drug or device and is therefore being marketed illegally under the Federal Food, Drug and Cosmetic Act (FD&C Act).

FDA should immediately initiate an investigation of JUUL's marketing and take enforcement action against these unapproved products.[1] Unless it acts, FDA will create an avenue for JUUL and other e-cigarette companies to flout the statutory requirements designed to protect the public against products being marketed for therapeutic purposes, but that lack the requisite showing of safety and efficacy.

I. LEGAL BACKGROUND

FDA set out the legal framework for assessing the JUUL advertising claims in its final rule on Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices or Combination Products; Amendments to Regulations Regarding "Intended Uses" (the

[1] Any FDA investigation of JUUL's marketing also should consider whether JUUL's advertisements and other promotional efforts involve the marketing of modified risk tobacco products without a marketing order, in violation of Section 911 of the F,D&C Act, as amended by the Family Smoking Prevention and Tobacco Control Act.

Tobacco Intended Use Rule").[2] That rule addresses the circumstances under which a tobacco product may be regulated as a drug, device or combination product.[3]

The FD&C Act defines "drug" (in relevant part) as an article intended either: (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (the "disease prong") or (2) to affect the structure or any function of the body (the "structure/function prong"). 21 U.S.C. § 321(g). In 1996, FDA issued a regulation asserting jurisdiction over cigarettes and smokeless tobacco under the FD&C Act on the ground that those products were intended to affect the structure and function of the body due to nicotine's pharmacological effects. This rule was invalidated by the U.S. Supreme Court in *FDA v. Brown & Williamson Tobacco Corp*, 529 U.S. 120 (2000), in which the Court held that FDA lacked jurisdiction over tobacco products "as customarily marketed."

Brown & Williamson did not question prior case law upholding FDA jurisdiction over tobacco products under the first prong of the definition of drug, which covers products intended to treat diseases. This jurisdiction was recognized by the D.C. Circuit in *Action on Smoking and Health v. Harris*, 655 F.2d 236, 238 (1980), which was cited with approval by the Supreme Court in *Brown & Williamson*, 529 U.S. at 152. *See also, United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J.1953) (tobacco products sold with leaflets claiming effectiveness in treating respiratory and other diseases are drugs). It also did not question FDA's jurisdiction over tobacco products under the second prong, which covers products intended to affect the structure or function of the body; *United States v. 354 Bulk Cartons * * * Trim Reducing-Aid Cigarettes,*178 F.Supp. 847 (D.N.J.1959)(tobacco products sold for treating weight loss are drugs).

Consistent with the case law and FDA's longtime treatment of tobacco cessation products as drugs, the Tobacco Intended Use Rule is unambiguous that smoking cessation claims fall under the treatment prong of the statute and require prior approval by FDA. The Rule treats all such products as subject to FDA's drug jurisdiction. A product will be regulated as a drug, device or combination product if:

> (a) The product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, including use in the cure or treatment of nicotine addiction *(e.g. smoking cessation)*, relapse prevention, or relief of nicotine withdrawal symptoms.[4]

As FDA explained in the preamble to the Tobacco Intended Use Rule:

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[2] 82 Fed. Reg. 2193 (Jan. 9, 2017). The effective date of the portion of the rule describing the circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug was March 19, 2018. See 83 Fed. Reg. 11639 (March 16, 2018).

[3] Because, for present purposes, the relevant legal standards are sufficiently similar whether e-cigarettes are considered drugs, devices, or combination products, this discussion will address only the legal standards governing e-cigarettes as drugs.

[4] 82 Fed. Reg. at 2217 (emphasis added).

> FDA considers claims about smoking cessation to be more than simply "consumer-oriented marketing statements." As noted in the preamble to the proposed rule, claims related to smoking cessation have long been recognized as evidence of intended use, conferring drug or device jurisdiction, and smoking cessation claims also have long been associated with the intended uses of curing or treating nicotine addiction and its symptoms.[5]

Thus, FDA emphasized that "smoking cessation claims generally create a strong suggestion of intended therapeutic benefit to the user that generally will be difficult to overcome absent clear context indicating that the product is not intended for use to cure or treat nicotine addiction or its symptoms, or for another therapeutic purpose."[6] Indeed, FDA stated that the suggestion of therapeutic benefit in smoking cessation claims to be so strong that disclaimers of intended therapeutic use are ineffectual and simply create consumer confusion. Thus, the Tobacco Intended Use Rule preamble stated that "[i]n most cases, FDA does not believe that disclaimers will sufficiently mitigate consumer confusion related to the intended therapeutic use of the product."[7] [8]

II. THE POTENTIAL FOR CONSUMER CONFUSION ABOUT THE THERAPEUTIC USE OF E-CIGARETTES

The preamble to the Tobacco Intended Use Rule makes clear that one of the purposes of the Rule is to alleviate consumer confusion about the intended use of e-cigarettes. FDA comments that "studies have shown that many consumers are using e-cigarettes to attempt to quit smoking . . . despite the fact that no e-cigarette has been approved for use as a smoking cessation aid. We believe that the rule will help to mitigate this confusion and help ensure that consumers do not mistakenly use tobacco products, which are inherently dangerous, for medical uses."[9]

This potential for consumer confusion is especially acute in adolescents. As FDA recognized, "unsubstantiated cessation claims that reach adolescents may confuse teens and lead teens to believe that these products are FDA-approved smoking cessation products."[10] FDA cited an example of such confusion as to e-cigarettes:

> For example, a teenager in a recent qualitative study said, "I heard that the only reason they were made is to help people get off from cigarettes for people that want to quit. You would use an e-cigarette to help you quit supposedly. It was on the news.[11]

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[5] *Id. at* 2196.
[6] *Id*. at 2198.
[7] *Id*. at 2212.
[8] A claim that the product addresses addiction to cigarettes would also qualify as a structure-function claim.
[9] *Id*. at 2203.
[10] *Id*. at 2212.
[11] *Id*.

The current epidemic of e-cigarette usage by teens should heighten FDA's commitment to identify and take enforcement action against unsubstantiated claims that e-cigarettes will "help people get off from cigarettes"—particularly where such claims are likely to reach adolescents. If teens are led to believe that such claims imply that e-cigarettes are FDA-approved as "safe," teens who do not smoke could be more likely to initiate use of e-cigarettes and teen e-cigarette users may be more likely to continue their use.

As the following discussion shows, JUUL Labs has been engaged in a sustained marketing campaign that causes precisely the consumer confusion that the Tobacco Intended Use Rule was issued to prevent. JUUL's marketing blitz, which includes full-page print ads in major national newspapers, promotion through its website, and radio and television ads, communicates the message that an intended use of JUUL e-cigarette products is for therapeutic purposes. This marketing is directed at the general public and thus will reach millions of young people and millions of non-smokers of every age group. Particularly given JUUL's remarkable appeal to adolescents, and the epidemic of youth nicotine addiction that the product has caused, this massive marketing of the product for unapproved therapeutic uses should be of urgent concern to FDA.

II. JUUL'S ADVERTISING ESTABLISHES THAT THE INTENDED USE OF ITS PRODUCTS IS FOR THERAPEUTIC PURPOSES.

When JUUL was introduced to the market in 2015, and for some years thereafter, it was promoted with social media and other advertising using images that overtly targeted young people and, indeed, mimicked the imagery long used by cigarette companies to appeal to youth.[12] Its marketing during that period also focused on the social media platforms most used by teens, including Instagram, YouTube, and Twitter.[13] After JUUL came under intense public scrutiny and criticism for this youth-directed social media marketing, the company changed its marketing strategy to make it appear to be targeted only at adult smokers. A central theme of its recent and current message is that smokers should "Make the switch" from cigarettes to JUUL. As the following examples of JUUL advertising indicate, "Make the switch" is a message establishing that the intended use of JUUL now is for smoking cessation, a clear therapeutic purpose, making the advertised products drugs, devices, or combination products that must be approved prior to sale.

<u>Print Advertisements.</u> Exhibit 1 to this letter is a print ad from JUUL that communicates the message that the average cigarette smoker goes through a pattern of quitting and then relapsing to smoking. This idea is conveyed by the repetition of the phrase "Quit. Start smoking again." The repetition of this phrase is followed by the word "Switch" and then the statement: "The average smoker tries to quit 30 times. Make the switch."

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[12] Jackler, Robert K. et al., "JUUL Advertising Over its First Three Years on the Market" (Jan. 24, 2019).
[13] See J. Huang, et al., "Vaping versus JUULing: how the extraordinary growth and marketing of JUUL transformed the US retail e-cigarette market," *Tobacco Control* 2018: 1-6; Chu, D-H, et al., "JUUL: Spreading Online and Offline," *Journal of Adolescent Health*, 2018, 63(5), 582-586.

The ad clearly communicates the message that by switching to JUUL, the smoker can achieve what he/she had previously been unable to achieve: quitting smoking. It is, unmistakably, a smoking cessation claim for JUUL. As FDA noted in the Tobacco Intended Use Rule, because "smoking has been causally linked to diseases of nearly all organs of the body, diminished health status, and fetal harm" and because "[m]ost current adult smokers want to quit smoking completely for health reasons," "we believe that statements related to quitting smoking generally create a strong suggestion that a product is intended for a therapeutic purpose."[14] Exhibit 1 suggests that JUUL is intended to give smokers the health benefits of quitting cigarette smoking.

This is equally the case with Exhibit 2, an ad stating that "34 million Americans still smoke cigarettes" followed by "Make the switch." This ad clearly equates switching to JUUL with cigarette smoking cessation. Again, given the undeniable fact that, as noted by FDA, most smokers want to quit "completely for health reasons," the ad should be presumed to indicate an intended use to enable smokers to stop smoking for therapeutic reasons. Similarly, Exhibit 3 features a JUUL user who is identified as a "smoker for 30 years" and who "switched to JUUL in October, 2016." She says JUUL is "a smart, really well thought-out alternative to smoking." Once again, the tag line is: "Make the switch." Exhibit 4 features a "make the switch" testimonial from a smoker who "was looking to find something to replace cigarettes," saying the switch to JUUL "was easy." The testimonial in Exhibit 5 is from a 23-year smoker who started switching after a week of trying JUUL, again with the tagline "Make the switch." In each of these ads, switching to JUUL is presented as equivalent to smoking cessation. Presumably, the JUUL user has switched in order to realize the health benefits of smoking cessation.[15] [16]

Television Advertisements. This same "switching" theme appears in JUUL's TV ads, featuring testimonials by JUUL users. For example, in one Mimi says, "I decided I needed to find an alternative, so I started looking and then JUUL came up. I did both for a while and eventually I just switched over. It's very quick." https://www.youtube.com/watch?v=Iq5ZXhT8bIA&list=PLABBGxYqbJvoajgqkg72nxGm5TpiKkNvg&index=2&frags=wn Patrick says: I gave the JUUL a real chance and found out I liked it. Found out it really works. The switch was easy. It was a no-brainer really. But now that I look at people who smoke, I'm like, 'Dude really? You're still doing that? You know there's an alternative to that right? You don't have to do that." https://www.youtube.com/watch?v=pg4ojRg4rNw&list=PLABBGxYqbJvoajgqkg72n Like the

[14] 82 Fed. Reg. at 2214.

[15] Even if a JUUL ad mentioned some non-health related reason for "switching," this would not overcome the presumption that the claim relating to smoking cessation is a therapeutic claim, i.e. that the intended use of JUUL is to treat the disease of addiction to cigarettes.

[16] In the Tobacco Intended Use Rule preamble, FDA states that "evidence may be developed showing that, in some situations, 'smoking cessation' is understood in context as referring to ending the use of traditional cigarettes and switching to a non-combustible product made or derived from tobacco." 82 Fed. Reg. at 2214. As FDA recognizes, any express or implied reference to smoking cessation, whether put in terms of "switching" from cigarettes to another product or not, is presumptively a claim indicating a health-related intended use. Thus, the preamble makes clear that "FDA intends to closely scrutinize 'smoking cessation' claims to ensure that consumers are not misled about the intended use of a product made or derived from tobacco." Id. at 2214.

print ads, the TV testimonials' statements about "need[ing] to find an alternative," and "You don't have to do that" indicate the intended use of JUUL is to enable smokers to switch to JUUL and no longer smoke cigarettes for health reasons.

Other JUUL ads suggest an intended use to derive the health benefits of quitting smoking, even though they do not use the phrase "Make the switch" or otherwise refer to "switching." Exhibit 6 includes the phrase "The alternative for adult smokers" and quotes a JUUL user as saying: "I think it's an amazing invention…I don't know how we lived without that." The double-entendre conveys a therapeutic message: using JUUL as a smoking alternative will save your life. Exhibit 7 is entitled "What parents need to know about JUUL" and states that "JUUL Labs is on a mission to improve the lives of the world's one billion adult smokers by eliminating cigarettes." The message conveyed is that JUUL is a means by which smokers can improve their lives through stopping smoking ("eliminating cigarettes"). That this is a message about quitting cigarettes is reinforced by the ad's description of JUUL devices as using "JUULPad cartridges that contain a salt-based nicotine e-liquid "to satisfy smokers when transitioning away from cigarettes." Again, given that most smokers want to quit smoking entirely for health reasons, the ad at least implicitly conveys an intended use for smokers to eliminate cigarettes and thus to derive the health benefits of stopping smoking.

Website Statements. JUUL's website also features testimonials from JUUL users recommending the product as a means to stop smoking by replacing cigarettes with JUUL https://www.juul.com/community:

- Sabrina: "Stick with it. At first it was hard to find my happy spot but now that I have my puff down I will never smoke again."

- Laura: "Just replace the cigarette with the JUUL! It really helps to keep some physical habits the first week or two. Just focus on using the JUUL instead of a cigarette."

- Rob: "I appreciate the draw and how it replaces a cigarette."

Even apart from whether JUUL's ads and testimonials convey a message about quitting smoking, FDA should examine whether some of them signal that JUUL is less hazardous than cigarettes. Thus, even if an ad does not speak in terms of "switching," or equate "switching" with smoking cessation, the reference to JUUL as an "alternative" to smoking (in Exhibit 4) with the testimonial "I don't know how we lived without that" implies that JUUL is less hazardous to health than cigarettes. Such an implied reduced risk claim would at least require a premarket order from FDA permitting the sale of the products as a modified risk product under Section 911 of the F,D&C Act, as amended by the Tobacco Control Act. FDA has not issued any such order for any JUUL product.

Moreover, FDA should consider not just the health-related message conveyed by each example of JUUL advertising and marketing, but also the cumulative impact of the entire JUUL campaign

focused on the use of JUUL to switch from smoking cigarettes. It is incumbent on FDA to investigate all of JUUL's recent marketing and to determine whether the entire JUUL campaign, viewed cumulatively, is evidence that the intended use of this product is therapeutic.

Although JUUL features multiple disclaimers on its website, none can be regarded as sufficient to overcome the therapeutic messages of JUUL's ads, taken individually or cumulatively. The most relevant disclaimer attempts to distinguish between "switching products" and "cessation products": "JUUL is a switching product. JUUL products are not intended to be used as cessation products, including for the cure or treatment of nicotine addiction (e.g. smoking cessation), relapse prevention, or relief of nicotine withdrawal symptoms." Yet, as shown above, the JUUL ads typically equate switching with quitting smoking and say nothing to overcome the presumption that the intended use of the product is to derive the health benefits of no longer smoking cigarettes. Indeed, Exhibit 1 straightforwardly conveys the message that JUUL's intended use is to "switch" as a means of relapse prevention ("Quit. Start smoking again. Switch."). Calling JUUL a "switching product" in a website disclaimer (a disclaimer that does not appear in JUUL ads) does nothing to dispel the health-related message inherent in JUUL's repeated equation of "switching" with quitting smoking. As noted above, FDA generally regards the suggestion of therapeutic benefit in smoking cessation claims to be so strong that disclaimers of therapeutic use are ineffectual. That is certainly the case here.

III. JUUL'S EFFORTS TO MARKET ITS PRODUCTS TO EMPLOYERS AND INSURERS FURTHER ESTABLISHES THAT ITS INTENDED USE IS THERAPEUTIC

That JUUL intends its product to be used therapeutically (i.e., to aid in the treatment of addiction to cigarettes) is further established by the company's new program to market its e-cigarettes to insurers and to companies that want to help their employees stop smoking. According to CNBC, JUUL has established a new "enterprise markets team," with 17 employees, "focused on striking deals with health plans, insurers, providers, self-insured employers and the public sector."[17] The recently-hired leader of this team told CNBC that "Juul is planning to design a program to help smokers switch from combustible cigarettes to e-cigarettes."[18] JUUL said its program "will involve sending a survey to identify eligible participants, creating a unique website where participants can sign up and buy discounted devices and nicotine pods and offering coaching and other support like educational articles and instructional videos."[19]

Thus, JUUL is not hiding the fact that its program is designed to use JUUL as part of a smoking cessation initiative. Its target market for its "enterprise markets team"—health plans, insurers, providers, self-insured employers, etc.—would be interested in the JUUL program only if they thought it yielded health-related benefits for employees or customers that reduced health care costs. The efforts of JUUL's "enterprise markets team" are themselves strong evidence of a

[17] "Juul is pitching its e-cigarette as an anti-smoking tool to employers and insurers," CNBC.com., March 7, 2019.
[18] Id.
[19] Id.

therapeutic intended use of these products. Moreover, JUUL's health-related marketing of the product in this way reinforces the therapeutic messages of its advertising and other promotional material.

IV. CONCLUSION

JUUL, a product that FDA has found to be largely responsible for the current epidemic of youth usage of highly-addictive e-cigarettes, is being advertised and marketed on a massive scale as a smoking cessation product, without the required review and approval by FDA. JUUL's campaign not only creates consumer confusion among smokers, but it also may cause non-smokers, particularly youth who already regard JUUL as highly appealing, to mistakenly believe the product is FDA-approved as "safe," thus leading to greater initiation and continuation of its use. We urge FDA to launch a full-scale investigation of all aspects of JUUL's advertising and marketing to determine the scope of its statutory violations and to take strong enforcement action to sanction the company and bring these violations to an end.

Thank you for your consideration.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

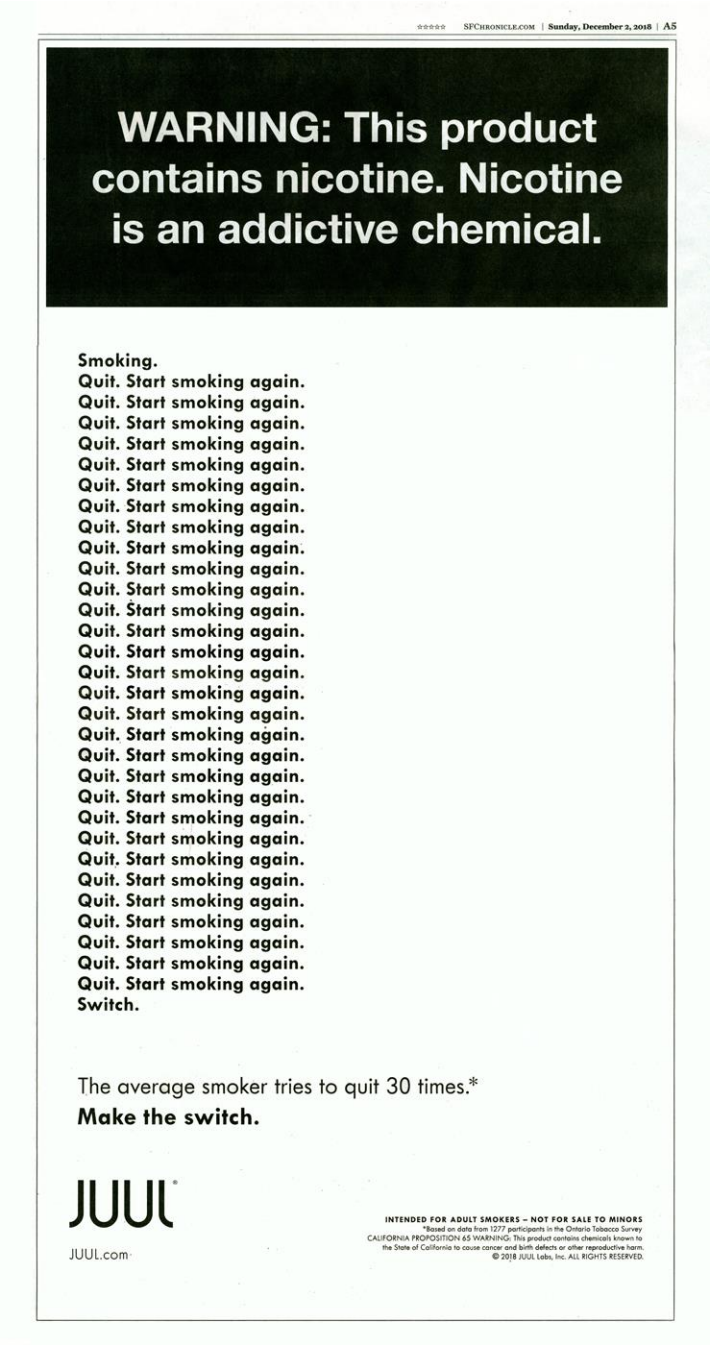
American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

Cc: Dr. Janet Woodcock
Director, FDA Center for Drug Evaluation and Research

Mr. Mitch Zeller, J.D.
Director, FDA Center for Tobacco Products



SFCHRONICLE.COM | Sunday, December 2, 2018 | A5

WARNING: This product contains nicotine. Nicotine is an addictive chemical.

Smoking.
Quit. Start smoking again.
Quit. Start smoking again.
Quit. Start smoking again.
Quit. Start smoking again.
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Quit. Start smoking again.
Quit. Start smoking again.
Quit. Start smoking again.
Quit. Start smoking again.
Switch.

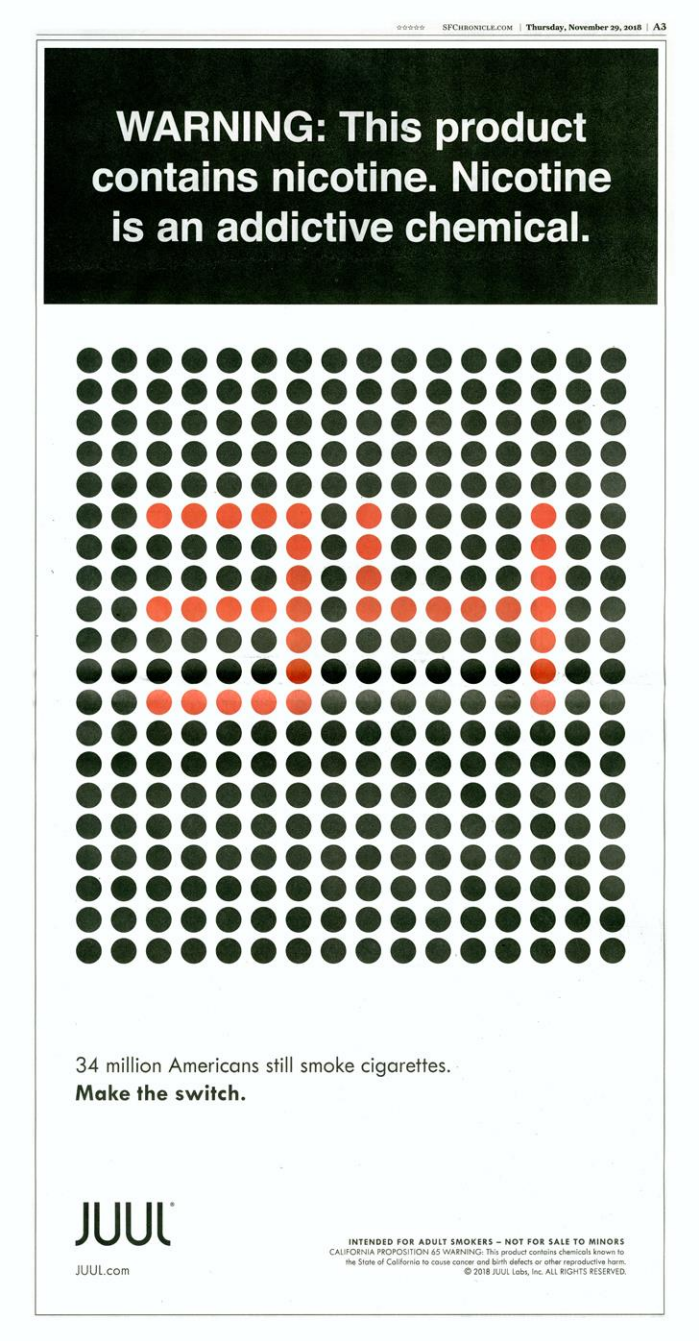
The average smoker tries to quit 30 times.*
Make the switch.

JUUL

JUUL.com

INTENDED FOR ADULT SMOKERS – NOT FOR SALE TO MINORS
*Based on data from 1277 participants in the Ontario Tobacco Survey
CALIFORNIA PROPOSITION 65 WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.
© 2018 JUUL Labs, Inc. ALL RIGHTS RESERVED.

Exhibit 1



SFCHRONICLE.COM | Thursday, November 29, 2018 | A3

WARNING: This product contains nicotine. Nicotine is an addictive chemical.

34 million Americans still smoke cigarettes.
Make the switch.

JUUL

JUUL.com

INTENDED FOR ADULT SMOKERS – NOT FOR SALE TO MINORS
CALIFORNIA PROPOSITION 65 WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.
© 2018 JUUL Labs, Inc. ALL RIGHTS RESERVED.

Exhibit 2

SFCHRONICLE.COM | Thursday, December 13, 2018 | A3
WARNING: This product contains nicotine. Nicotine is an addictive chemical.
"It's a smart, really well thought-out alternative to smoking."
Carolyn, 54, Smoker for 30 years.
Switched to JUUL October 2016.
Make the switch.
JUUL
JUUL.com
INTENDED FOR ADULT SMOKERS – NOT FOR SALE TO MINORS.

Exhibit 3

WARNING: This product contains nicotine. Nicotine is an addictive chemical.
"I was looking to find something to replace cigarettes. The switch was easy."
Patrick, 47. Smoker for 34 years.
Switched to JUUL December 2017.
Make the switch.
JUUL
JUUL.com
INTENDED FOR ADULT SMOKERS – NOT FOR SALE TO MINORS
© 2017 JUUL Labs, Inc. ALL RIGHTS RESERVED.

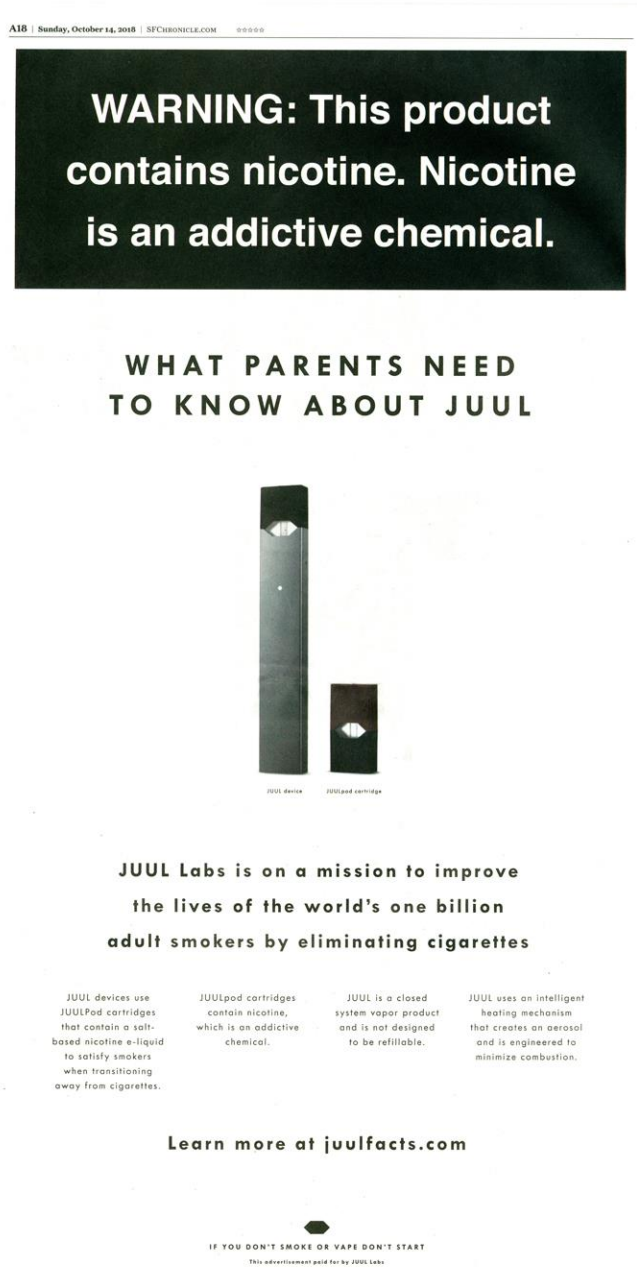
Exhibit 4

WARNING: This product contains nicotine. Nicotine is an addictive chemical.
Sage smoked for 23 years, and switched to JUUL in 2018.
"I hadn't planned to switch. But after about a week of having the JUUL in my hand, I started reaching for it over my pack of cigarettes."
Make the Switch
JUUL
JUUL.com
Designed for adult smokers. Not for sale to minors.

Exhibit 5

A12 | Tuesday, October 2, 2018 | SFCHRONICLE.COM
This advertisement paid for by JUUL Labs
WARNING: This product contains nicotine. Nicotine is an addictive chemical.
“I think it’s an amazing invention... I don’t know how we lived without that.”
JUUL
THE ALTERNATIVE FOR ADULT SMOKERS
Reuven, 41
JUUL customer since Sep 2017

Exhibit 6



A18 | Sunday, October 14, 2018 | SFCHRONICLE.COM

WARNING: This product contains nicotine. Nicotine is an addictive chemical.

WHAT PARENTS NEED TO KNOW ABOUT JUUL

JUUL device

JUULpod cartridge

JUUL Labs is on a mission to improve the lives of the world's one billion adult smokers by eliminating cigarettes

JUUL devices use JUULPod cartridges that contain a salt-based nicotine e-liquid to satisfy smokers when transitioning away from cigarettes.

JUULpod cartridges contain nicotine, which is an addictive chemical.

JUUL is a closed system vapor product and is not designed to be refillable.

JUUL uses an intelligent heating mechanism that creates an aerosol and is engineered to minimize combustion.

Learn more at juulfacts.com

IF YOU DON'T SMOKE OR VAPE DON'T START

This advertisement paid for by JUUL Labs

Exhibit 7