September 17, 2019

Mr. Mitchell Zeller
Director, Center for Tobacco Products
U.S. FOOD AND DRUG ADMINISTRATION
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Transmitted via email to: Mitchell.Zeller@fda.hhs.gov

## RE: JUUL Labs Inc.'s product representations in its San Francisco-based campaign

Dear Mr. Zeller:

I write to call your attention to advertisements and other communications activities orchestrated by JUUL around its ballot initiative for the upcoming election in San Francisco (Proposition C). Many of its communications conflict with provisions of the Family Smoking Prevention and Tobacco Control Act prohibiting the marketing of electronic nicotine delivery systems (ENDS) like JUUL as modified risk tobacco products without FDA authorization. This is in specific violation of FDA's Warning Letter of September 9, 2019 to Mr. Kevin Burns, chief executive officer of JUUL Labs, Inc., which cited the company for marketing its devices and nicotine pods "as modified risk tobacco products without an FDA order in effect that permits such sale or distribution."

JUUL's representatives have also made smoking cessation claims for its product inconsistent with the FDA Center for Tobacco Products, Office of Compliance and Enforcement of September 9, 2019 letter to Mr. Burns, requesting "documents and information...regarding JUUL's marketing, advertising, promotional, and education campaigns." FDA's letter noted that "[f]or the purposes of all requests in this letter, in any instance where we refer to JUUL, we are also referring to any person or entity acting on JUUL's behalf or at its direction (e.g., agents, representatives, third-party contractors, consultants)."

These letters clearly include political consultants that JUUL has hired to promote its initiative to overturn San Francisco's regulations of e-cigarettes.

## **BACKGROUND**

On May 14 of this year, JUUL filed the legal text for an initiative ballot measure in the City and County of San Francisco entitled, "An Act to Prevent Youth Use of Vapor Products." The

- 1 U.S. Food & Drug Administration Warning Letter to JUUL Labs, Inc., MARCS-CMS 590950, September 9, 2019.
- 2 U.S. Food & Drug Administration, Center for Tobacco Products, Office of Compliance and Enforcement, <u>letter of request for documents and information</u>, September 9, 2019.
- 3 Initiative Measure to be Submitted Directly to the Voters: "An Act to Prevent Youth Use of Vapor Products," San Francisco Department of Elections, filed May 14, 2019.

official proponent for the measure as reported to the San Francisco Department of Elections is Jennifer Hochstatter, the vice president for supply and demand planning for JUUL Labs Inc. (See Exhibit A, included herein.)

On June 3, 2019, JUUL filed its Statement of Organization for a Recipient Committee (California Form 410) with the San Francisco Ethics Commission, creating a corporate-sponsored campaign committee entitled, "Coalition for Reasonable Vaping Regulation, including Neighborhood Grocers and Small Businesses. Committee Major Funding from JUUL Labs."

According to its most recently filed campaign disclosure statement filed on August 8, 2019, JUUL's corporate-sponsored campaign committee is almost entirely self-funded.5 JUUL's committee expended nearly \$4.3 million for election-related efforts through July 31, 2019. These expenditures include millions of dollars for television advertisements. These TV ads notably reach far beyond the municipal boundaries where JUUL's ballot measure will be decided by voters, broadcasting to the full breadth of the San Francisco-Oakland-San Jose Designated Market Area (DMA) — the nation's eighth most populous media market.

## JUUL'S ADVERTISING AND PROMOTIONAL CAMPAIGN FOR PROP C

For several weeks, I have had mounting concerns about product marketing messages advanced by JUUL's sponsored campaign committee, which routinely tout the health benefits of ecigarettes generally and JUUL's devices and nicotine pods specifically. JUUL appears to be using the electioneering in San Francisco to systematically advance unauthorized health-related marketing claims about its products' advantages to consumers throughout the San Francisco Bay Area. These messages do not merely portray JUUL as a safer alternative to traditional cigarettes—but also as a more effective smoking cessation option than FDA-approved products as Chantix®, Nicorette®, nicotine patches and gum.

An illuminating example may be found in the public domain from an online video posted to the Facebook page of the San Francisco Eastern Neighborhoods Democratic Club,6 a chartered membership organization of the San Francisco Democratic Party. The video features ballot measure and candidate presentations at SFENDC's August 19, 2019 endorsement meeting. For the "Yes on Proposition C" campaign's presentation, a paid consultant to JUUL made multiple representations that go beyond the claims your agency cited the company in its September 9 warning letter to JUUL.

- 4 California Form 410, Statement of Organization: "Coalition for Reasonable Vaping Regulation, including Neighborhood Grocers and Small Businesses. Committee Major Funding from JUUL Labs," FPPC ID No. 1418922, filed June 3, 2019.
- 5 <u>California Form 460</u>, <u>Recipient Committee Campaign Statement</u>, "Coalition for Reasonable Vaping Regulation," FPPC ID No. 1418922, filed Aug. 8, 2019.
- 6 San Francisco Eastern Neighborhoods Democratic Club Facebook Page, "Live from the Ballot Prop and Candidate Forum," August 19, 2019, <a href="https://www.facebook.com/SFENDC/videos/2147277032232590/">https://www.facebook.com/SFENDC/videos/2147277032232590/</a>.

The "Yes on Proposition C" campaign proponent appearing in the video is Mr. Tom Hsieh, a paid consultant to JUUL through Hsieh and Associates, according to JUUL's campaign finance statements. The JUUL campaign's presentation to the SFENDC begins approximately at the 17:20-minute mark of the online video. In it, JUUL's paid consultant represented that vapor products are "a legitimate off-ramp for people who are addicted to cigarettes."

So, I want to separate some of the fiction and help give you some facts. I'm hoping by the end of this short presentation you'll see vaping products in a whole new light. This is the truth about vaping products. There's a lot of misinformation out there about it. The bottom line is it's a legitimate off-ramp for people who are addicted to cigarettes... (SFENDC Video, approximately 17:20, emphasis added.)

JUUL's consultant then drew parallels to harm-reduction policies in the realm of public health, for which San Francisco has been a long-recognized national leader. His statements made health-related claims about cigarettes that unequivocally characterize e-cigarettes as "less harmful."

Let's get back to that less-harmful product. This is important. As a moderate Democrat, someone who had a hard time understanding concepts like distributing condoms in public schools, free needle exchange, housing alcoholics in wet houses, putting heroin users in safe-injection sites — these are all progressive harm-reduction concepts. And what they're doing is they are actually reducing harm by making better health outcomes. The same thing is true with e-cigarettes and vaporizers. People are switching from something that has carcinogenics [sic], the tar, the formaldehyde and everything that's related to a burning cigarette, and switching to a vaporize product that is less harmful. (SFENDC Video, approximately 18:55, emphasis added.)

These are modified exposure and modified risk claims that can only be made after the FDA has issued an order specifically authorizing them. To the best of our knowledge, JUUL has not yet submitted an application to make such modified risk and modified exposure claims, much less been granted permission to make such statements by the FDA.

Later, JUUL's paid consultant explained the rationale for JUUL's benefits as "legitimate adult tool as an off-ramp for harm reduction," conclusively stating that "[n]one of those [carcinogens] are in a JUUL or a vaporizer product." He added that users "are not going to die from carcinogenic effects if they switch to a vaporizer product."

And what the company, like Juul or the other vaping companies, are saying is that this is a legitimate adult tool as an off-ramp for harm reduction. The things that kill people with cigarette smoking are all the carcinogenics [sic]. None of those are in a JUUL or a vaporizer product. There's nicotine in there, and that's highly addictive and not good for kids, and not intended for them. But for an adult, they are not going to die from carcinogenic effects if they switch to a vaporizer product. (SFENDC Video, approximately 23:45, emphasis added.)

<sup>7</sup> California Form 460, Recipient Committee Campaign Statement, "Coalition for Reasonable Vaping Regulation," FPPC ID No. 1418922, filed Aug. 8, 2019.

Despite the fact that, to the best of our knowledge, JUUL has not applied for authorization to market its products for smoking cessation, JUUL's consultant then unfavorably compared FDA-approved smoking cessation medications, including Nicorette® and Chantix®, to JUUL for smoking cessation. (JUUL apparently views these FDA-approved cessation medications as marketplace competitors.) The consultant conclusively represented that: "They just don't work."

And just don't take our word for it. You can go on to our website and you can look. There are hundreds of San Francisco — thousands of San Francisco smokers who have made the switch, who say they've tried the patches, they've tried the Nicorette® gum, they've tried the Chantix® and all the anti-smoking cessation products. They just don't work. (SFENDC Video, approximately 23:45, emphasis added.)

These statements are precisely the kinds of unauthorized therapeutic statements that FDA's second letter seeks to prevent.

## JUUL-FUNDED HEALTH CLAIMS IN THE SAN FRANCISCO VOTER GUIDE

JUUL has also included unauthorized modified risk and therapeutic claims in the voter guide that will be mailed to nearly 500,000 registered voters in San Francisco in advance of the vote on the JULL initiative, Proposition C, in the November 5, 2019 election.8

Specifically, JUUL's "Coalition for Reasonable Vaping Regulation" paid for the placement of several ballot arguments that portray JUUL as having "a lower risk of tobacco-related disease" or being "less harmful than one or more other commercially marketed tobacco products" without FDA authorization to make these modified risk and therapeutic claims:.:

- "I tried using patches, gum, and other products meant to help me quit that only worked temporarily or had extreme side effects." (Exhibit B, emphasis added.)
- "Vaping proved to be the only real opportunity for me to transition away from cigarettes in a way that would improve my own health but more importantly drastically reduce the risk of second-hand smoke to those around me." (Exhibit B, emphasis added.)
- "By banning e-cigarettes, City Hall is denying Big Tobacco's victims an effective tool to break free. Prop C will ensure LGBTQ adults access to the cigarette alternatives they deserve...." (Exhibit C, emphasis added.)
- "If we don't support an adults' right to choose a potentially less harmful option, many nicotine users will go back to smoking cigarettes." (Exhibit D, emphasis added.)
- "If we regulate these products we can stop youth from getting them but still allow smokers

like me to have access to the best means to quit cigarettes." (Exhibit E, emphasis added.)

## OTHER JUUL-FUNDED PROMOTIONAL CHANNELS

These violations have continued after FDA's September 9, 2019 warning letter in which FDA directed JUUL to "immediately correct the violations" you reported, "as well as violations that are the same as or similar." Despite this warning, JUUL continues to fund the distribution of informational material that make health-related claims describing e-cigarettes as modified risk tobacco products. Among the most recent examples is a campaign mailer received by a San Francisco voter on or about September 14, 2019 featuring a cancer survivor:9

"When I was diagnosed with cancer, vaping was the most successful tool to keep me off cigarettes...I started smoking when I was 26 years old. When I was diagnosed with cancer, I needed to quit. I tried gum, I tried patches — the urge was still daily. I was so worried that I was going to die that I just needed a lifeline. Vaping has been the most successful tool to keep me off of cigarettes... Vaping is not for kids, it's a tool for adults." (Coalition for Reasonable Vaping Regulation mailer, received on or about September 14, 2019, emphasis added)

Still more instances of JUUL-funding messaging that impliedly or directly characterizes JUUL as a modified risk tobacco product persist days after your warning letter instructing the company to "immediately correct" these unauthorized claims. At the time I write this letter, apparent examples located using a Google advanced search of regulatenotban.com, JUUL's campaign website, <<make a PDF or other copy of what you found and attach it to this etter>> include:

- 39 references to "health"
- 21 references to "harm reduction"
- 18 references to "smoking cessation"
- 9 references to "safer"
- 8 references to nicotine "gum"
- 8 references to nicotine "patches"

## **CONCLUSION**

I applaud FDA's work to hold JUUL accountable for illegally marketing its devices and pods "as modified risk tobacco products." Your warning letter offers compelling evidence that JUUL's promotional activities "could be reasonably expected to result in consumers believing" that its ENDS holds lower risk of tobacco-related diseases and is less harmful than products with which it competes. I moreover commend your investigation into JUUL and your request for "documents and information...regarding JUUL's marketing, advertising, promotional, and education campaigns." I am concerned, however, that JUUL may withhold relevant and

responsive documentation about its high-profile advertising and promotional activities now underway for Proposition C in the San Francisco Bay Area.

In addition to continuing to make unauthorized modified risk claims as part of its campaign in the San Francisco Bay Area on behalf of its Proposition C, JUUL is working to diminish consumer confidence in perceived market competitors that FDA has found to be safe and effective smoking cessation medications. Unlike JUUL itself, these perceived market competitors submitted to FDA scrutiny in accordance with federal law, and secured FDA's authorization as smoking cessation medications.

I request that, after considering this material, you amplify your warning to JUUL to stop making these illegal claims in the Proposition C campaign (and, likely, in other places that are considering restrictions on the marketing of e-cigarettes); add this information to your ongoing investigation of JUUL's behavior; and implement the appropriate legal sanctions.

Thank you for your consideration. I welcome the chance to discuss my concerns in more detail; please email Natalie Gee, my chief of staff and confidential assistant, at <a href="mailto:ynatalie.gee@sfgov.org">ynatalie.gee@sfgov.org</a>.

Sincerely,

SHAMANN WALTON

Member, San Francisco Board of Supervisors,

District 10

Cc:

Mr. Anthony Villa, Senior Regulatory Counsel, Office of Compliance and Enforcement FDA Center for Tobacco Products Anthony.Villa@fda.hhs.gov

Ms. Ann Simoneau, J.D.
Director, Office of Compliance and Enforcement
FDA Center for Tobacco Products
Ann.Simoneau@fda.hhs.gov

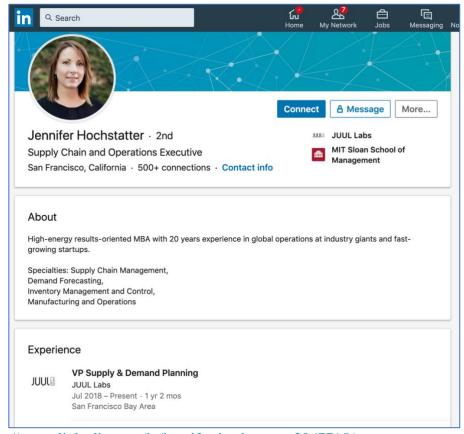
Hon. Nancy Pelosi Speaker of the House, U.S. House of Representatives

Hon. Raja Krishnamoorthi U.S. House of Representatives, Chairman, Oversight Subcommittee on Economic and Consumer Policy

## **EXHIBIT A**

Letter	City and County Propositions	Proponent(s)	Proponent(s) Contact Information	Proponent Argument Author(s)*	Opponent Argument Author(s)*
С	Vapor Products  • Legal Text (PDF)  • Title and Summary (PDF)	Jennifer Hochstatter	Jim Sutton The Sutton Law Firm 150 Post St, Ste 405 jsutton@campaignlawyers.com	TBD	Supervisor Shamann Walton

Source: https://sfelections.sfgov.org/measures



Source: https://www.linkedin.com/in/jennifer-hochstatter-3867715/

# **EXHIBIT B**

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do with my	body. I tried using pat	tches, gum, and other products meant to help me			
the only re	ally worked temporarily all opportunity	or had extreme side effects. Vaping proved to be paransition away from cigarettes in a way that			
would impr	ove my own health bu	t more importantly drastically reduce the risk of			
second-ha	nd smoke to those aro	und me.			
Now, our c	Now, our city is telling me that the tool that I used to transition away from smoking				
is too dang	erous to keep in store:	s, while cigarettes remain on the shelves. Say no			
to hypocris	y and lazy politics. Vot	te YES on Prop C!			
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	By banning e-cigarettes, City Hall is denying Big Tobacco's victims an effective tool to break free. Prop C will ensure LGBTQ adults access to the cigarette alternatives they deserve while protecting children with strict rules and enforcement against	
	youth sales.	
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# **EXHIBIT D**

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	We need to limit youth access to all kinds of tobacco and nicotine products. The	
	regulations in Prop C would create the strongest restrictions of vapor products in	
	the country without harming adult choice and creating a black market for vapor	
	products.	
	Please support common sense regulation. Please support Proposition C.	
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## **EXHIBIT E**

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	I smoked 5 packs of cigarettes a week for 12 years. The only thing that worked for me to stop smoking was JUUL. It's been two and half years, and I haven't smoked a cigarette.			
	<ul> <li>I went to work for JUUL Labs, Inc. because I believe in our mission to end cigarettes once and for all.</li> </ul>			
	I've seen first-hand the power of vaping products to help smokers like me. And I'm one of 12 friends all who have been able to quit because of JUUL. Vaping products were the only thing worked for us.			
	Youth should never start vaping or smoking. And I believe that we have to prevent youth access to vaping. But the answer is not a ban—it's regulation.			
	If we regulate these products we can stop youth from getting them but still allow smokers like me to have access to the best means to			
	quit cigarettes.			
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