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ONE HUNDRED SIXTEENTH CONGRESS

JIM JORDAN, OHIO
RANKING MINORITY MEMBER

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

MAJORITY (202) 225–5051
MINORITY (202) 225–5074

http://oversight.house.gov

September 25, 2019

Mr. Richard Hill
Chief Executive Officer
Fontem Ventures
1100 South Tryon Street, Suite 350
Charlotte, NC 28203

Dear Mr. Hill:

Today, e-cigarette market leader JUUL Labs announced its decision to cease all of its print, broadcast, and digital advertisements of e-cigarettes in the United States, effective immediately.[1] In the interest of safeguarding the health and well-being of one of our nation's most precious resources—our youth—I am writing today to respectfully, but strongly, request your company to do the same.

The U.S. Surgeon General, the Secretary of the Department of Health and Human Services (HHS), the Director of the Centers for Disease Control and Prevention (CDC), and the former Commissioner of the Food and Drug Administration (FDA) have all declared that e-cigarette use among teenagers is an epidemic.[2]

From 2017 to 2018, youth e-cigarette and vaping use increased by 78% among high school students.[3] The most recent figures from CDC's National Youth Tobacco Survey (NYTS)

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show another significant jump in youth use, with 27.5% of high school students reporting e-cigarette use. That is a 32% increase in the past year, and a 135% increase over two years.[4]

As Chair of the Subcommittee on Economic and Consumer Policy, I have led an aggressive investigation into the youth e-cigarette epidemic. The Subcommittee held two days of hearings on July 24 and July 25, during which we uncovered significant evidence that JUUL's marketing and advertising practices were violating the law. On September 5, 2019, the Subcommittee sent a letter notifying Acting FDA Commissioner Ned Sharpless that testimony from the Subcommittee's hearings revealed that JUUL was violating FDA regulations against making unapproved express and implied claims that its product helps users stop smoking cigarettes and is safer than cigarettes.[5]

Claims that a product helps users quit smoking are "therapeutic claims" subject to FDA jurisdiction under the drug/device provisions of the Food, Drug, and Cosmetic Act (FD&C Act). Such drugs or devices must be approved by FDA. If they are not, they are unapproved drugs or devices being marketed illegally under the FD&C Act.[6]

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[5] Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Ned Sharpless, Acting Commissioner, Food and Drug Administration (Aug. 30, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2019-09-05.RK%20to%20Sharpless-%20FDA%20re%20JUUL.pdf).

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consider the company's knowledge of how the product is being "offered and used for a purpose for which it is neither labeled nor advertised."[7]

Manufacturers of tobacco products may not claim that their products are healthier or safer than cigarettes ("modified risk claims") unless they have a marketing order from FDA. JUUL did not have a marketing order from FDA that would have allowed it to make these "modified risk claims." Making modified risk claims without a marketing order violates Section 911 of the FD&C Act, as amended by the Family Smoking Prevention and Tobacco Control Act.[8]

Currently, no e-cigarette or vaping company, including yours, has been approved for cessation or modified risk claims.[9]

On September 9, 2019, four days after I sent my letter urging FDA to investigate JUUL's illegal advertising, the agency issued a warning letter to JUUL declaring that it illegally marketed its product as safer than cigarettes.[10] FDA directly cited testimony from our Subcommittee in its letter.[11]

In addition, CDC has identified 530 cases of lung illness associated with the use of e-cigarette products in 38 states and one U.S. territory. The outbreak has resulted in at least nine deaths, and these figures may grow as state health departments conduct retro-analyses of state health records to ascertain the breadth of adverse health events.[12]

On September 24, 2019, during testimony before the Subcommittee, CDC's Principal Deputy Director, Dr. Anne Schuchat, reported that the process of vaping itself may be risky and that not enough is known about the aerosol that vaping produces or its potential to negatively

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affect the lungs. She also expressed concern that the recent outbreak of lung injuries may cause permanent harm.[13]

Due to the e-cigarette and vaping-related lung illness outbreak, CDC has warned the American people to "consider refraining from using e-cigarette or vaping products," as CDC is unable to rule out any brand, flavor, or component chemical as a cause of lung illness. Dr. Schuchat also refused to rule out the process of vaping itself as a contributing factor to the outbreak.[14]

Other severe health effects have been linked to e-cigarette use as well. For example, as of August 7, 2019, FDA had received 127 reports of seizures and other neurological conditions caused by e-cigarette use.[15] Seizures and convulsions are symptoms of nicotine toxicity.[16]

The American people should not serve as guinea pigs for the e-cigarette and vaping industry or be subject to their misleading marketing and advertising. I ask that you **please notify me whether you will halt all television, radio, print, and digital advertising for your e-cigarette products.**

Thank you for your attention to this critical issue. I look forward to your response.

Sincerely,

Raja Krishnamoorthi
Chairman
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cc: The Honorable Michael Cloud, Ranking Member

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September 25, 2019

Mr. Eddy Pirard
President and Chief Executive Officer
Japan Tobacco International, USA, Inc.
Glenpointe Centre West
500 Frank W. Burr Boulevard, #24
Teaneck, NJ 07666

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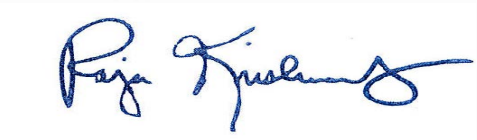

Raja Krishnamoorthi
Chairman
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September 25, 2019

Mr. Ricardo Oberlander
President and Chief Executive Officer
Reynolds American Inc.
401 North Main Street
Winston Salem, NC 27101

Dear Mr. Oberlander:

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Therapeutic claims need not be express for a product to be subject to FDA's drug and device jurisdiction. FDA must look past the overt claims and determine the product's intended use, which it may do by considering "labeling claims, advertising matter, or oral or written

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[5] Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Ned Sharpless, Acting Commissioner, Food and Drug Administration (Aug. 30, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2019-09-05.RK%20to%20Sharpless-%20FDA%20re%20JUUL.pdf).

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statements" by the company and its representatives. In determining intended use, FDA also must consider the company's knowledge of how the product is being "offered and used for a purpose for which it is neither labeled nor advertised."[7]

Manufacturers of tobacco products may not claim that their products are healthier or safer than cigarettes ("modified risk claims") unless they have a marketing order from FDA. JUUL did not have a marketing order from FDA that would have allowed it to make these "modified risk claims." Making modified risk claims without a marketing order violates Section 911 of the FD&C Act, as amended by the Family Smoking Prevention and Tobacco Control Act.[8]

Currently, no e-cigarette or vaping company, including yours, has been approved for cessation or modified risk claims.[9]

On September 9, 2019, four days after I sent my letter urging FDA to investigate JUUL's illegal advertising, the agency issued a warning letter to JUUL declaring that it illegally marketed its product as safer than cigarettes.[10] FDA directly cited testimony from our Subcommittee in its letter.[11]

In addition, CDC has identified 530 cases of lung illness associated with the use of e-cigarette products in 38 states and one U.S. territory. The outbreak has resulted in at least nine deaths, and these figures may grow as state health departments conduct retro-analyses of state health records to ascertain the breadth of adverse health events.[12]

On September 24, 2019, during testimony before the Subcommittee, CDC's Principal Deputy Director, Dr. Anne Schuchat, reported that the process of vaping itself may be risky and that not enough is known about the aerosol that vaping produces or its potential to negatively

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[7] 82 Fed. Reg. at 2201.

[8] Food and Drug Administration, *Section 911 of the Federal Food, Drug, and Cosmetic Act-Modified Risk Tobacco Products* (Jan. 7, 2018) (online at www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-911-federal-food-drug-and-cosmetic-act-modified-risk-tobacco-products) ("No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product") and (defining "modified risk tobacco product" as "any tobacco product that is sold or distributed for use to reduce harm of the risk of tobacco-related disease associated with commercially marketed tobacco products.").

[9] *Does the Food and Drug Administration Even Regulate E-Cigs? Actually Kinda Not,* Wired (Sept. 18, 2019) (online at www.wired.com/story/dangerous-levels-of-carcinogen-in-mint-flavored-vapes/).

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[11] Committee on Oversight and Reform, *Oversight Subcommittee Investigation Prompts the Food and Drug Administration to Issue Warning Letter to JUUL* (Sept. 9, 2019) (online at https://oversight.house.gov/news/press-releases/oversight-subcommittee-investigation-prompts-fda-to-issue-warning-letter-to-juul).

[12] Centers for Disease Control and Prevention, *Outbreak of Lung Disease Associated with E-Cigarette Use, or Vaping* (Sept. 19, 2019) (online at www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html).

affect the lungs. She also expressed concern that the recent outbreak of lung injuries may cause permanent harm.[13]

Due to the e-cigarette and vaping-related lung illness outbreak, CDC has warned the American people to "consider refraining from using e-cigarette or vaping products," as CDC is unable to rule out any brand, flavor, or component chemical as a cause of lung illness. Dr. Schuchat also refused to rule out the process of vaping itself as a contributing factor to the outbreak.[14]

Other severe health effects have been linked to e-cigarette use as well. For example, as of August 7, 2019, FDA had received 127 reports of seizures and other neurological conditions caused by e-cigarette use.[15] Seizures and convulsions are symptoms of nicotine toxicity.[16]

The American people should not serve as guinea pigs for the e-cigarette and vaping industry or be subject to their misleading marketing and advertising. I ask that you **please notify me whether you will halt all television, radio, print, and digital advertising for your e-cigarette products.**

Thank you for your attention to this critical issue. I look forward to your response.

Sincerely,

Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member

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[13] Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, Testimony of Dr. Anne Schuchat, Principal Deputy Director, Centers for Disease Control and Prevention, *Hearing on Don't Vape: Examining the Outbreak of Lung Disease and the Centers for Disease Control and Prevention's Urgent Warning Not to Use E-Cigarettes* (Sept. 24, 2019) (online at https://oversight.house.gov/legislation/hearings/don-t-vape-examining-the-outbreak-of-lung-disease-and-cdc-s-urgent-warning-not).

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[16] Illinois Department of Public Health, *E-cigarettes and Vapes* (Sept. 12, 2019) (online at http://dph.illinois.gov/topics-services/prevention-wellness/tobacco/e-cigarettes-and-vapes).

ELIJAH E. CUMMINGS, MARYLAND
CHAIRMAN

ONE HUNDRED SIXTEENTH CONGRESS

JIM JORDAN, OHIO
RANKING MINORITY MEMBER

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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http://oversight.house.gov

September 25, 2019

Mr. Ryan Nivakoff
Chief Executive Officer
NJOY, LLC
15211 North Kierland Boulevard, Suite 200
Scottsdale, AZ 85254

Dear Mr. Nivakoff:

Today, e-cigarette market leader JUUL Labs announced its decision to cease all of its print, broadcast, and digital advertisements of e-cigarettes in the United States, effective immediately.[1] In the interest of safeguarding the health and well-being of one of our nation's most precious resources—our youth—I am writing today to respectfully, but strongly, request your company to do the same.

The U.S. Surgeon General, the Secretary of the Department of Health and Human Services (HHS), the Director of the Centers for Disease Control and Prevention (CDC), and the former Commissioner of the Food and Drug Administration (FDA) have all declared that e-cigarette use among teenagers is an epidemic.[2]

From 2017 to 2018, youth e-cigarette and vaping use increased by 78% among high school students.[3] The most recent figures from CDC's National Youth Tobacco Survey (NYTS)

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[1] *JUUL Chief Executive Officer Steps Down Amid Public Outrage Over Vaping,* The Hill (Sept. 25, 2019) (online at https://thehill.com/policy/healthcare/462930-juul-ceo-steps-down-amid-public-outrage-over-vaping).

[2] Food and Drug Administration, *Statement from Food and Drug Administration Commissioner Scott Gottlieb, M.D., on New Steps to Address Epidemic of Youth E-cigarette Use* (Sept. 12, 2018) (online at www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use); Department of Health and Human Services, *Surgeon General Releases Advisory on E-cigarette Epidemic Among Youth* (Dec. 18, 2018) (online at www.hhs.gov/about/news/2018/12/18/surgeon-general-releases-advisory-e-cigarette-epidemic-among-youth.html); Centers for Disease Control and Prevention, *Sales of JUUL E-cigarettes Skyrocket, Posing Danger to Youth* (Oct. 2, 2018) (online at www.cdc.gov/media/releases/2018/p1002-e-Cigarettes-sales-danger-youth.html); Centers for Disease Control and Prevention, *Progress Erased: Youth Tobacco Use Increased During 2017-2018* (Feb. 11, 2019) (online at www.cdc.gov/media/releases/2019/p0211-youth-tobacco-use-increased.html); *The Future of E-cigarettes Depends on the Industry's Willingness to Protect Teens*, Washington Post (Mar. 20, 2019) (online at www.washingtonpost.com/opinions/2019/03/19/future-e-cigarettes-depends-industrys-willingness-protect-teens/?noredirect=on&utm_term=.907f5dc750cb).

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Therapeutic claims need not be express for a product to be subject to FDA's drug and device jurisdiction. FDA must look past the overt claims and determine the product's intended use, which it may do by considering "labeling claims, advertising matter, or oral or written statements" by the company and its representatives. In determining intended use, FDA also must

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