

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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October 1, 2019

Dr. Francis Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins:

I write to strongly urge the National Institutes of Health (NIH) to increase support for research into the long-term health effects of electronic cigarette usage. Life threatening lung injuries caused by vaping may have killed and injured hundreds of Americans, while clever marketing and flavored products have induced epidemic numbers of teens to start using e-cigarettes. Action by NIH now to support more scientific research into the risks associated with e-cigarette usage and vaping could save countless lives.

E-Cigarette Use Causing Life Threatening Lung Injuries

The Centers for Disease Control and Prevention (CDC) has identified 805 cases of lung illness associated with the use of e-cigarette products in 46 states and one U.S. territory. The outbreak has resulted in at least twelve 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.¹

Patients have experienced a range of respiratory symptoms including cough, shortness of breath, and chest pain, that developed in a matter of several weeks, and in some cases, only a few days. Many patients have sought medical care in ambulatory settings often resulting in hospital admittance. Patients have required medical treatment such as supplemental oxygen, assisted ventilation, and corticosteroids to improve their health and respiratory function.²

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

¹ 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).

² *Id.*

affect the lungs. She also expressed concern that the recent outbreak of lung injuries may cause permanent harm.³

Due to the e-cigarette and vaping-related lung illness outbreak, CDC has warned the public 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.⁴

Early scientific research may be addressing potential causes of this outbreak. *The Journal of Clinical Investigation* recently published an NIH-funded study, “Electronic Cigarettes Disrupt Lung Lipid Homeostasis and Innate Immunity Independent of Nicotine.” The study found that e-cigarette aerosol disrupted lung function and raised the risk of viral infections, like influenza, in mice. These results did not depend on the presence of nicotine in the e-cigarette aerosol. Even mice that were exposed to aerosolized liquid containing only propylene glycol and vegetable glycerin—solvents commonly used across all e-cigarettes—experienced these effects.⁵

Other severe health effects have been linked to e-cigarette use as well. For example, as of August 7, 2019, the Food and Drug Administration (FDA) had received 127 reports of seizures and other neurological conditions caused by e-cigarette use.⁶ Seizures and convulsions are symptoms of nicotine toxicity.⁷

Teen Use of E-Cigarettes Is ‘Epidemic’

The U.S. Surgeon General, the Secretary of the Department of Health and Human Services, the Director of the CDC, and the former FDA Commissioner have all declared that e-cigarette use among teenagers is an epidemic.⁸

³ 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 CDC’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>).

⁴ Centers for Disease Control and Prevention, *Outbreak of Lung Illness Associated with Using E-Cigarette Products, Investigation Notice* (Sept. 11, 2019) (online at www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information).

⁵ Dr. Matthew C. Madison et al., *Electronic Cigarettes Disrupt Lung Lipid Homeostasis and Innate Immunity Independent of Nicotine*, *Journal of Clinical Investigation* (Sept. 4, 2019) (online at <https://jci.org/articles/view/128531>).

⁶ Food and Drug Administration, *In Brief: The Food and Drug Administration Encourages Continued Submission of Reports Related to Seizures Following E-cigarette Use as Part of Agency’s Ongoing Scientific Investigation of Potential Safety Issue* (Aug. 7, 2019) (online at www.fda.gov/news-events/fda-brief/fda-brief-fda-encourages-continued-submission-reports-related-seizures-following-e-cigarette-use).

⁷ 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>).

⁸ 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).

Over the past several years, youth e-cigarette and vaping usage has surged to crisis levels. Preliminary numbers from CDC's National Youth Tobacco Survey indicate that youth use of e-cigarettes has risen to an all-time high, 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.⁹

This teen vaping epidemic did not happen by accident. It was a deliberate strategy by e-cigarette makers.

JUUL, the largest e-cigarette manufacturer in the United States, hosted youth-oriented launch parties in 2015 and 2016 in major metropolitan locations featuring musical artists and sample distribution to foster product awareness in young consumers.¹⁰ Initial JUUL advertisements closely resembled ads and themes traditional tobacco companies used in their advertising that were known to attract younger consumers.¹¹ Upon entering the market, JUUL differentiated itself by advertising almost exclusively via social media. In November 2018, JUUL deleted its American Instagram and Facebook social media accounts, but as of May 2019, nearly half of JUUL's official Twitter account followers were underage.¹² In a report issued in early 2019, Stanford University researchers concluded that JUUL's marketing strategy from the company's 2015 debut to 2018 was "patently youth oriented."¹³

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).

⁹ Food and Drug Administration, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019) (online at www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non).

¹⁰ *The Disturbing Focus of Juul's Early Marketing Campaigns*, Forbes (Nov. 16, 2018) (online at www.forbes.com/sites/kathleenchaykowski/2018/11/16/the-disturbing-focus-of-juuls-early-marketing-campaigns/#728a02d514f9).

¹¹ *Juul Exposed: How Big Vape Took a Page from Big Tobacco's Old Ad Playbook*, Yahoo (May 30, 2019) (online at <https://finance.yahoo.com/news/juul-advertising-tobacco-lawsuits-115746073.html>).

¹² *Silicon Valley's Favorite E-cig Company Shut Down Its Social Media Accounts—But Juul's Advertising Now Has a Life of Its Own*, Business Insider (Nov. 17, 2018) (online at www.businessinsider.com/why-juul-shut-down-social-media-facebook-instagram-vaping-2018-11); *Most of Juul's Twitter Followers Are Underage*, Truth Initiative (May 21, 2019) (online at <https://truthinitiative.org/research-resources/emerging-tobacco-products/most-juuls-twitter-followers-are-underage>).

¹³ Robert K. Jackler et al., *Stanford Research Into the Impact of Tobacco Advertising*, Stanford University School of Medicine (Jan. 31, 2019) (online at http://tobacco.stanford.edu/tobacco_main/publications/JUUL_Marketing_Stanford.pdf).

As youth use has soared, JUUL's e-cigarette market share took a directly parallel path, growing from 24% to 75%. Financial analysts report that "JUUL has single-handedly reaccelerated the U.S. e-vapor category."¹⁴ Researchers believe JUUL attracts kids and young adults that otherwise would not have begun smoking cigarettes, addicting kids that were statistically at much lower risk of tobacco use.¹⁵ JUUL's initial use of fruity and sweet flavors is linked to the rise of youth e-cigarette use.¹⁶ Eighty-five percent of youth aged 12 to 17 that use e-cigarettes use flavored products.¹⁷

Many young users are not aware that JUUL even contains nicotine. In fact, 63% of JUUL users between the ages of 15 and 24 did not know that JUUL always contains nicotine. Market leading e-cigarette pods deliver at least as much nicotine as a pack of combustible cigarettes.¹⁸

Nicotine is a highly addictive neurotoxin, poisonous to the human brain. Nicotine use by teenagers alters the brain in a manner that makes it more likely a child will become addicted to traditional cigarettes or illegal drugs.¹⁹

On September 24, 2019, during testimony before the Subcommittee, CDC's Principal Deputy Director, Dr. Anne Schuchat, testified that "JUUL and related products use nicotine salts which lead to much more available nicotine—which leads the product to cross the blood brain barrier to a more potential effect on the developing brain of adolescents." She continued that the nicotine salts give it "easier access to the brain" and lead to "higher risk of the issues mentioned, learning difficulty, attention problems, memory issues as well as priming for addiction."²⁰

Recent studies have found a strong causal association between underage e-cigarette use as an initiator of subsequent combustible cigarette use. Researchers have concluded that e-

¹⁴ *Wall Street Tobacco Industry Update*, Wells Fargo (Feb. 11, 2019) (online at www.natocentral.org/uploads/Wall_Street_Update_Slide_Deck_February_2019.pdf)

¹⁵ *Behind the Explosive Growth of JUUL*, Truth Initiative (Jan. 3, 2019) (online at <https://truthinitiative.org/research-resources/emerging-tobacco-products/behind-explosive-growth-juul>).

¹⁶ *Id.*

¹⁷ *The Disturbing Focus of Juul's Early Marketing Campaigns*, Forbes (Nov. 16, 2018) (online at www.forbes.com/sites/kathleenchaykowski/2018/11/16/the-disturbing-focus-of-juuls-early-marketing-campaigns/#728a02d514f9).

¹⁸ *How Much Nicotine is in JUUL?* Truth Initiative (Feb. 26, 2019) (online at <https://truthinitiative.org/research-resources/emerging-tobacco-products/how-much-nicotine-juul>).

¹⁹ Department of Health and Human Services, Center for Disease Control and Prevention, National Center for Chronic Disease, Prevention and Health Promotion, Office on Smoking and Health, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* (2016) (online at https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_exec_summ_508.pdf).

²⁰ 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 CDC'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>).

cigarettes ultimately will increase the amount of combustible cigarette smokers as children and adults that were not statistically likely to ever smoke cigarettes eventually transition.²¹

Recent U.S. Response: Good First Steps

Until recently, FDA weakly enforced its regulations with respect to e-cigarette makers. On September 5, 2019, the Subcommittee sent a letter notifying Acting FDA Commissioner Ned Sharpless that testimony from the Subcommittee's July 24 and July 25, 2019, hearing revealed that the e-cigarette company with the largest market share, 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.²²

Claims that a product helps users quit smoking are "therapeutic claims," subject to FDA jurisdiction under the drug and 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.²³

I implored FDA to consider the full picture in order to determine if therapeutic claims were being made. Therapeutic claims need not be express for a product to be subject to FDA's drug/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. It also may be shown how the company knows that product is being "offered and used for a purpose for which it is neither labeled nor advertised."²⁴

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 does not have a marketing order from FDA that would allow it to make these "modified risk

²¹ Samir Soneji, et al., *Quantifying Population-Level Health Benefits and Harms of E-cigarette Use in the United States*, National Center for Biotechnology Information, National Library of Medicine National Institutes of Health (Mar. 14, 2018) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC5851558/).

²² 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>).

²³ 21 U.S.C. § 321(g); *Sottera Inc. v. Food and Drug Administration*, 627 F. 3d 891 (U.S. App. DC 2010); Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices or Combination Products; Amendments to Regulations Regarding "Intended Uses," 82 Fed. Reg. 2193 (Jan. 9, 2017) ("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.") (emphasis added) and ("statements related to quitting smoking generally create a strong suggestion that a product is intended for a therapeutic purpose.").

²⁴ 82 Fed. Reg. at 2201.

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.²⁵ Currently no e-cigarette or vaping company has been approved for cessation or modified risk claims.²⁶

On September 9, 2019, four days after I sent my letter to the FDA, the agency issued a warning letter to JUUL declaring that it illegally marketed its product as safer than cigarettes.²⁷ FDA directly cited testimony from our Subcommittee in the letter.²⁸

On September 11, 2019, the Trump Administration announced a ban on flavored e-cigarettes, including mint and menthol flavors. The Administration’s press release cited our Subcommittee’s hearing, the evidence we uncovered about JUUL’s presentations in schools, and JUUL’s outreach and marketing practices, including those targeting students, tribes, health insurers and employers.²⁹

Request for Action

I strongly urge the NIH to allocate new research grants and to announce the availability of supplements to current grants to fund research into the human health impact of vaping. In particular, the public deserves to know more regarding the potential human impacts of findings within the NIH-funded study, “Electronic Cigarettes Disrupt Lung Lipid Homeostasis and Innate Immunity Independent of Nicotine.” Strong scientific research into the long-term health risks of vaping is needed now by government, physicians and consumers; lives depend on it.

²⁵ 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.”).

²⁶ *Does the FDA 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/).

²⁷ Food and Drug Administration, *Warning Letter: JUUL LABS, Inc.* (Sept. 9, 2019) (online at www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/juul-labs-inc-590950-09092019).

²⁸ 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>).

²⁹ Department of Health and Human Services, *Statement from Centers for Disease Control and Prevention Director Robert R. Redfield, M.D., on The Food and Drug Administration’s Plan to Remove Non-Tobacco-Flavored E-Cigarettes from Market* (Sept. 11, 2019) (online at www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html).

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Thank you for your attention to this critical issue.

Sincerely,



Raja Krishnamoorthi
Chairman

Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member