United States Senate
WASHINGTON, DC 20510

August 3, 2021

Janet Woodcock
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock:

We write to bring to your attention to recent revelations that Juul Labs (Juul) purchased an entire issue of a medical journal—publishing 11 company-funded studies in what appears to be an effort to argue that Juul products are benefiting public health by helping people to stop smoking cigarettes. The tobacco industry has a decades-long history of misleading the public and public health officials about the dangers of its products,[1] and this appears to be yet another example of the industry's abhorrent behavior.

The FDA is currently reviewing premarket applications for e-cigarettes and certain other tobacco products and will soon reach a determination about whether these products can remain on the market.[2] The "Deeming Rule," which was promulgated under authority granted to FDA by the Tobacco Control Act, placed e-cigarettes under the rubric of FDA regulatory authority, including the requirement that generally manufacturers must demonstrate that a new tobacco product is "appropriate for the protection of the public health."[3] A court-ordered September 9, 2020 deadline for applications has passed, and FDA is allowing products to stay on the market for one year pending review, at which time, under the court's order, products without FDA authorization must be removed from the market or risk FDA enforcement.[4]

Juul has mounted "an all out campaign … sparing no expense to fight back" against any agency action that would impact their profits.[5] Juul's efforts to influence the agency include "pa[ying] $51,000 to have the entire May/June issue of the *American Journal of Health Behavior* devoted to publishing 11 studies funded by the company offering evidence that Juul products help

[1] The New York Times, "Why Tobacco Companies Are Paying to Tell You Smoking Kills," Sapna Maheshwari, November 24, 2017, https://www.nytimes.com/2017/11/24/business/media/tobacco-companies-ads.html.
[2] U.S. Food and Drug Administration, "Perspective: FDA's Preparations for the September 9 Submission Deadline," Mitch Zeller, August 31, 2020, https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-preparations-september-9-submission-deadline; Congressional Research Service, "FDA Regulation of Tobacco Products," July 9, 2021, pp. 8, https://fas.org/sgp/crs/misc/R45867.pdf.
[3] U.S. Food and Drug Administration, "Perspective: FDA's Preparations for the September 9 Submission Deadline," Mitch Zeller, August 31, 2020, https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-preparations-september-9-submission-deadline
[4] U.S. Food and Drug Administration, "Deemed New Tobacco Product Application Lists," June 15, 2021, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/deemed-new-tobacco-product-applications-lists
[5] The New York Times, "Juul Is Fighting to Keep Its E-Cigarettes on the U.S. Market," Sheila Kaplan, July 5, 2021, https://www.nytimes.com/2021/07/05/health/juul-vaping-fda.html.

smokers quit."[6] The issue of the journal that Juul paid for appears to be an effort to provide a veneer of scientific objectivity for its own self-interested research: "there are 26 named co-authors on the 11 studies. According to the "Conflict of Interest" statements associated with them, 18 of the co-authors are either current full-time employees of Juul, or were full-time employees at the time they conducted the research. Five others are consultants with Pinney Associates, working 'on an exclusive basis to Juul Labs.' And the final three, who co-authored one of the 11 studies, are employees of the Centre for Substance Use Research, an "independent" consultancy that designed that study under a contract with … Juul Labs."[7]

This is an egregious example of the industry "taking academic corruption to a new level," raising questions about decisions made by the Journal's editors and about Juul's behavior. It also underscores the need for close FDA scrutiny of Juul and its effort to shape the public discussion and scientific review of its products through unfair and deceptive practices. The FDA should not allow itself to be swayed by a long-time tobacco industry PR tactic of dressing up self-interested industry research as non-biased academic research.

Juul has a well-earned reputation for deceptive marketing tactics towards youth and still maintains control over 40% of the youth e-cigarette market.[8] From 2017 to 2019, e-cigarette use rates doubled among youth, and more than one in five high school students reported vaping.[9] This increase was unparalleled. Despite this, Juul's pitch that vaping is less harmful than cigarettes has not changed since 2019 even though Juul has failed to undergo the required FDA review to make such modified-risk claims. The unauthorized claims earned them a warning from the FDA and is part of the narrative they pushed in the May/June issue of the American Journal of Health Behavior.[10]

In 2018, the Surgeon General released an advisory warning about the spike in e-cigarette usage among youth and the negative impact on ongoing brain development, noting that "nicotine exposure during adolescence can impact learning, memory, and attention."[11] Despite this, Juul continued to promote their products "despite their popularity with young people who never smoked, but became addicted to nicotine."[12]

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[6] The New York Times, "Juul Is Fighting to Keep Its E-Cigarettes on the U.S. Market," Sheila Kaplan, July 5, 2021, https://www.nytimes.com/2021/07/05/health/juul-vaping-fda.html.

[7] The American Prospect, "Juul: Taking Academic Corruption to a New Level," David Dayen, July 7, 2021, https://prospect.org/health/juul-taking-academic-corruption-to-new-level/

[8] The New York Times, "Juul Illegally Marketed E-Cigarettes, F.D.A. Says," Sheila Kaplan and Matt Richtel, Sept 9, 2019, https://www.nytimes.com/2019/09/09/health/vaping-juul-e-cigarettes-fda.html; Richard Miech, Adam Leventhal, Lloyd Johnston, et al., "Trends in Use and Perceptions of Nicotine Vaping Among US Youth from 2017 to 2020," *JAMA Pediatrics*, December 15, 2020, https://jamanetwork.com/journals/jamapediatrics/article-abstract/2774132

[9] National Institute on Drug Abuse, "Study: Surge of teen vaping levels off, but remains high as of early 2020," press release, December 15, 2020, https://www.drugabuse.gov/news-events/news-releases/2020/12/study-surge-of-teen-vaping-levels-off-but-remains-high-as-of-early-2020.

[10] The New York Times, "Juul Illegally Marketed E-Cigarettes, F.D.A. Says," Sheila Kaplan and Matt Richtel, Sept 9, 2019, https://www.nytimes.com/2019/09/09/health/vaping-juul-e-cigarettes-fda.html; [10] The American Prospect, "Juul: Taking Academic Corruption to a New Level," David Dayen, July 7, 2021, https://prospect.org/health/juul-taking-academic-corruption-to-new-level/.

[11] *Id.*

[12] The New York Times, "Juul Is Fighting to Keep Its E-Cigarettes on the U.S. Market," Sheila Kaplan, July 5, 2021, https://www.nytimes.com/2021/07/05/health/juul-vaping-fda.html.

Juul's ongoing actions to influence the FDA are deeply disturbing. I urge the agency to carefully review this behavior and its public health consequences, and to not allow itself to be influenced by thinly-veiled Big Tobacco PR tactics dressed up as objective science" as it considers whether Juul's products and others can remain on the market. This behavior also underscores the need for FDA to carefully scrutinize all industry-funded research, including research published in a peer-reviewed journal. I also ask that you provide answers to the following questions as quickly as possible.

1. Is the FDA seeking to identify, review, and assess potential conflicts of interest as it reviews scientific evidence as part of the premarket review process?

2. How does the FDA evaluate published scientific studies submitted as part of premarket applications where the authors have a clear conflict of interest?

3. What protocols does FDA use to assess the accuracy and validity of research it receives from manufacturers through the premarket review process (e.g. assessing such studies against independent, third-party research)?

4. Has the FDA received complaints about Juul regarding the independent review process, and if so, how has the agency assessed and handled these complaints?

5. To what extent, if any, has FDA officials communicated with e-cigarette companies regarding their activities to fund their own research or sponsor academic journals?

Sincerely,

Elizabeth Warren
United States Senator

Richard Blumenthal
United States Senator