

# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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April 1, 2020

The Honorable Dr. Stephen M. Hahn  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

Earlier this week, the Food and Drug Administration (FDA) submitted a request in federal court to delay by four months a court order requiring e-cigarette manufacturers to submit applications to remain on the market by May 12, 2020.<sup>1</sup> Although FDA's request cited the coronavirus crisis as a reason for this delay, it did not explain why it was necessary in terms of FDA's operational capacity. The court-imposed deadline applies to e-cigarette manufacturers, and FDA then has a year to review the applications.

The Subcommittee is not necessarily opposing FDA's request for a delay or suggesting that FDA divert staff away from responding to the coronavirus crisis. Instead, the Subcommittee is requesting that FDA clear the market of e-cigarettes during this delay. Allowing e-cigarettes to remain on the market during this period would harm children and adults throughout the country and exacerbate the coronavirus crisis in critical ways, as described in detail below.

For these reasons, the Subcommittee requests that FDA take the following steps for the duration of the coronavirus crisis: (1) use all available tools to encourage Americans to stop smoking combustible cigarettes and using e-cigarettes; (2) suspend all approvals of Premarket Tobacco Product Applications (PMTA); and (3) commit to immediately clearing the market of all e-cigarettes by prioritizing enforcement against them.

### **Coronavirus Crisis Could Overwhelm U.S. Hospitals**

Hospitals face an impending shortage of available beds.<sup>2</sup> New York Governor Andrew Cuomo recently estimated that his state would soon need 140,000 hospital beds, while only

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<sup>1</sup> *American Academy of Pediatrics v. FDA*, 18-cv-883-PWG (Doc. No. 175) (D. Md. Mar. 30, 2020).

<sup>2</sup> *No Part of the U.S. Has Enough Hospital Beds for a Coronavirus Crisis*, Axios (Mar. 18, 2020) (online at [www.axios.com/coronavirus-hospital-bed-crunch-capacity-18e22c81-006b-4654-a74c-40ff86488431.html](http://www.axios.com/coronavirus-hospital-bed-crunch-capacity-18e22c81-006b-4654-a74c-40ff86488431.html)).

53,000 were available for use.<sup>3</sup> A 2017 Department of Health and Human Services (HHS) report found that a “very severe” influenza outbreak, like that of 1918, would require 2.9 million patients to be placed in intensive care.<sup>4</sup>

Hospitals also face an impending shortage of ventilators. Many cases of coronavirus will result in severe respiratory failure requiring intensive care and mechanical ventilation.<sup>5</sup> Estimates indicate that U.S. hospitals have approximately 160,000 ventilators currently available to treat coronavirus patients.<sup>6</sup> The federal government’s current emergency reserve in the Strategic National Stockpile includes another 13,000 ventilators.<sup>7</sup> Healthcare providers are also severely lacking in necessary personal protective equipment, such as N95 respirator masks.<sup>8</sup>

In addition, the Society of Critical Care Medicine “estimate[s] that the shortage of ICU physicians, advanced practice providers, respiratory therapists, and nurses trained in mechanical ventilation would limit the maximum number of ventilated patients to approximately 135,000.”<sup>9</sup>

### **Need to Reduce Burdens on Hospitals**

Reducing the number of smokers and vapers that fall ill with coronavirus will not only help them, but the entire health system. According to the National Institute on Drug Abuse (NIDA), vaping and smoking present serious risks for coronavirus patients. As part of the National Institutes of Health (NIH), NIDA has warned that “because it attacks the lungs, the coronavirus that causes COVID-19 could be an especially serious threat to those who smoke tobacco ... or who

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<sup>3</sup> *Coronavirus in N.Y.: “Astronomical” Surge Leads to Quarantine Warning*, New York Times (Mar. 24, 2020) (online at [www.nytimes.com/2020/03/24/nyregion/coronavirus-new-york-apex-andrew-cuomo.html](http://www.nytimes.com/2020/03/24/nyregion/coronavirus-new-york-apex-andrew-cuomo.html)).

<sup>4</sup> Department of Health and Human Services, *Pandemic Influenza Plan: 2017 Update* (online at [www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf](http://www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf)).

<sup>5</sup> *Coronavirus Disease 2019 (COVID-19) Provides Potent Reminder of the Risk of Infectious Agents*, Cardiology Magazine (Mar. 6, 2020) (online at [www.acc.org/latest-in-cardiology/articles/2020/03/01/08/42/feature-coronavirus-disease-2019-covid-19-provides-potent-reminder-of-the-risk-of-infectious-agents](http://www.acc.org/latest-in-cardiology/articles/2020/03/01/08/42/feature-coronavirus-disease-2019-covid-19-provides-potent-reminder-of-the-risk-of-infectious-agents)).

<sup>6</sup> Johns Hopkins Bloomberg School of Public Health, Center for Health Security, *Ventilator Stockpiling and Availability in the US* (Feb. 14, 2020) (online at [www.centerforhealthsecurity.org/resources/COVID-19/200214-VentilatorAvailability-factsheet.pdf](http://www.centerforhealthsecurity.org/resources/COVID-19/200214-VentilatorAvailability-factsheet.pdf)).

<sup>7</sup> *More Lifesaving Ventilators are Available. Hospitals Can’t Afford Them*, Washington Post (Mar. 18, 2020) (online at [www.washingtonpost.com/health/2020/03/18/ventilator-shortage-hospital-icu-coronavirus/](http://www.washingtonpost.com/health/2020/03/18/ventilator-shortage-hospital-icu-coronavirus/)).

<sup>8</sup> *HHS Clarifies US Has About 1% of Face Masks Needed for ‘Full-Blown’ Coronavirus Pandemic*, CNBC (Mar. 4, 2020) (online at [www.cnbc.com/2020/03/04/hhs-clarifies-us-has-about-1percent-of-face-masks-needed-for-full-blown-pandemic.html](http://www.cnbc.com/2020/03/04/hhs-clarifies-us-has-about-1percent-of-face-masks-needed-for-full-blown-pandemic.html)).

<sup>9</sup> *U.S. ICU Resource Availability for COVID-19*, Society of Critical Care Medicine (Mar. 13, 2020) (online at [www.sccm.org/getattachment/Blog/March-2020/United-States-Resource-Availability-for-COVID-19/United-States-Resource-Availability-for-COVID-19.pdf](http://www.sccm.org/getattachment/Blog/March-2020/United-States-Resource-Availability-for-COVID-19/United-States-Resource-Availability-for-COVID-19.pdf)).

vape,” and smokers and vapers “could find themselves at increased risk of COVID-19 and its more serious complications.”<sup>10</sup>

Smokers appear much more likely than non-smokers to suffer severe outcomes. A recent study in China concluded that smoking is a risk factor that leads “to the progression of COVID-19 pneumonia,” and that coronavirus patients who used tobacco were 14 times more likely to develop pneumonia than coronavirus patients who did not.<sup>11</sup> A study in the *New England Journal of Medicine* found that smokers made up twice the percentage of people who needed mechanical ventilation, who sought treatment in an intensive care unit, or who ultimately died.<sup>12</sup>

Last fall, a study funded by NIH found that e-cigarettes disrupt lung function, harm the lungs’ ability to fight viral infections, and increase the chances of a viral infection leading to death. Otherwise healthy mice exposed to e-cigarette aerosol lost the ability to protect themselves from even minor lung infections. When exposed to small amounts of flu virus that normally would not affect mice, they died.<sup>13</sup> Nearly six months ago, the Subcommittee wrote to NIH, imploring it to fund an expansion of this research into humans.<sup>14</sup>

In light of this evidence, the New York State Academy of Family Physicians has called for a ban on the sale of all tobacco or vaping products during the pandemic.<sup>15</sup> Tobacco control experts like Stanton Glantz, the Director of the Center for Tobacco Control Research and Education at the University of California, San Francisco, advise that people “stop smoking and stop vaping—and avoid secondhand exposure.”<sup>16</sup>

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<sup>10</sup> National Institute on Drug Abuse, *COVID-19: Potential Implications for Individuals with Substance Use Disorders* (Mar. 24, 2020) (online at [www.drugabuse.gov/about-nida/noras-blog/2020/03/covid-19-potential-implications-individuals-substance-use-disorders](http://www.drugabuse.gov/about-nida/noras-blog/2020/03/covid-19-potential-implications-individuals-substance-use-disorders)).

<sup>11</sup> Dr. Wei Liu et al., *Analysis of Factors Associated with Disease Outcomes in Hospitalized Patients with 2019 Novel Coronavirus Disease*, *Chinese Medical Journal (English)* (Feb. 28, 2020) (online at <https://pubmed.ncbi.nlm.nih.gov/32118640/>).

<sup>12</sup> Dr. Wei-Jie Guan et al., *Clinical Characteristics of Coronavirus Disease 2019 in China*, *New England Journal of Medicine* (Feb. 28, 2020) (online at [www.nejm.org/doi/full/10.1056/NEJMoa2002032](http://www.nejm.org/doi/full/10.1056/NEJMoa2002032)).

<sup>13</sup> 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>).

<sup>14</sup> Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Dr. Francis Collins, Director, National Institutes of Health (Oct. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2019-10-01.RK%20to%20Collins-%20NIH%20re%20Request%20for%20Action.pdf>).

<sup>15</sup> *NYSAFP Calls for Ban on the Sale of All Tobacco and Vaping Products During Pandemic*, WBNG (Mar. 22, 2020) (online at <https://wbng.com/2020/03/22/nysafp-calls-for-ban-on-the-sale-of-all-tobacco-and-vaping-products-during-pandemic/>).

<sup>16</sup> *Smoking or Vaping May Increase the Risk of a Severe Coronavirus Infection*, *Scientific American* (Mar. 17, 2020) (online at [www.scientificamerican.com/article/smoking-or-vaping-may-increase-the-risk-of-a-severe-coronavirus-infection1/](http://www.scientificamerican.com/article/smoking-or-vaping-may-increase-the-risk-of-a-severe-coronavirus-infection1/)).

### **FDA Must Act to Protect the Public Health**

According to FDA and the Tobacco Control Act, “all deemed new tobacco products on the market without authorization are illegally marketed products.” FDA *could be* enforcing the law against all e-cigarettes, but has chosen not to do so. Recently, FDA chose to start enforcing the law against the makers of only certain flavors of cartridge-based e-cigarettes.<sup>17</sup>

FDA has both the authority and an obligation to start enforcing the law against *all* e-cigarettes in order to protect the public health. Vaping will add to the stress on our hospitals as more people take up intensive care beds and require ventilators and other critical equipment. Eliminating the preventable accelerant of vaping is a public health necessity.

For these reasons, the Subcommittee requests that you respond to the following questions by April 4, 2020:

1. Will FDA use all available tools to encourage Americans to stop smoking combustible cigarettes and using e-cigarettes?
2. Will FDA suspend all approvals of Premarket Tobacco Product Applications?
3. Will FDA commit to immediately clearing the market of all e-cigarettes by prioritizing enforcement against them?

I also request that you contact the Subcommittee by April 3, 2020, to schedule a staff briefing on this matter by April 7, 2020. I also encourage you to inform the Subcommittee of any additional tools or resources FDA believes are necessary to encourage Americans to reduce or eliminate use of cigarettes and e-cigarettes for the duration of the coronavirus crisis.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



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Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and Consumer Policy

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<sup>17</sup> Food and Drug Administration, *Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market without Premarket Authorization* (Jan. 2020) (online at [www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market)).

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cc: The Honorable Michael Cloud, Ranking Member