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ONE HUNDRED FIFTEENTH CONGRESS

# Congress of the United States

## House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
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May 16, 2017

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

We write to urge you to ensure the continued implementation of the May 2016 final deeming rule, which extended the authority of the Food and Drug Administration (FDA) to all tobacco products and strengthened the agency's ability to regulate these products. We are concerned by FDA's decision to delay the future compliance deadlines related to the final rule and the Department of Justice's (DOJ) request for extensions of time in two related court challenges. Prompt implementation and vigorous defense of the rule is essential in order for FDA to perform needed regulatory oversight of all tobacco products and to protect Americans from the harmful effects of tobacco usage.

It has been nearly eight years since Congress passed the Family Smoking Prevention and Tobacco Control Act – the landmark law that provided FDA with rulemaking authority to deem all tobacco products subject to FDA regulation. Following years of consideration and input from stakeholders, on May 10, 2016 the agency finalized the long-awaited rule that extended its authority to all categories of tobacco products, including electronic nicotine delivery systems (ENDS), such as e-cigarettes and vape pens, cigars, hookah and pipe tobacco, as well as other tobacco products not already overseen by FDA.

The final rule also established important provisions to regulate these products. These provisions – like the requirement that manufacturers list product ingredients, and seek pre-market approval from FDA for new tobacco products not on the market before February 15, 2007 – will improve consumer protections and ensure FDA has the tools necessary to regulate all tobacco products, including those specifically targeted at children, teens, and young adults.

Unfortunately, many of these provisions have not yet been fully implemented and FDA's recent decision to postpone future compliance deadlines for three months further delays critical

oversight of certain products, including e-cigarettes and cigars. We are concerned that any delay in implementation will slow down the agency's ability to protect the public from the harm of tobacco products, especially at a time when children and teens are using these products with increasing frequency. The Centers for Disease Control and Prevention (CDC) found that in 2015, 16 percent of high school aged students reported usage of e-cigarettes in the past 30 days – an increase from 1.5 percent just four years earlier in 2011.[1] The CDC also determined that in 2015 a higher percentage of high school aged boys smoked cigars (14 percent) than cigarettes (11.8 percent).[2]

Additionally, we remain concerned about possible carcinogenic chemicals used in e-cigarette vapor and flavorings,[3] as well as reports regarding the risk of overheating, fire, and explosion of e-cigarette batteries, which can cause severe burns and other injuries to users.[4] FDA must use all available tools at its disposal to monitor these issues and to protect the American public from these potential harms.

The three month delay in enforcement of future compliance deadlines announced by FDA, and DOJ's requests for delay in pending court cases, are not based on new data or factual changes. In fact, the overwhelming scientific evidence of the public health risks associated with tobacco use remains unchanged, and the DOJ utilized this strong scientific evidence last year to defend the deeming rule during consideration of the *Nicopure Labs LLC v. FDA* case. We urge the Administration to swiftly move to implement the outstanding provisions of the final deeming rule and to vigorously defend the rule in ongoing litigation.

In written responses to members of the Senate Health, Education, Labor, and Pensions Committee during your confirmation process, you emphasized that "responsibly implementing the TCA [Tobacco Control Act] is an integral part of FDA's core mission to protect and promote public health."[5] You also stated that if confirmed, you would ensure that FDA "implements provisions in a timely fashion, and in a manner that is consistent with Congressional intent under

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[1] Centers for Disease Control and Prevention, *Youth and Tobacco Use*, (https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/)

[2] Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report (MMWR), Youth Risk Behavior Surveillance – United States, 2015* (June 10, 2016) (https://www.cdc.gov/mmwr/volumes/65/ss/ss6506a1.htm#T45_down)

[3] *See* Jacob Bogage, *E-cig vapor releases two cancerous chemicals, new study says,* WASH POST (July 28, 2015); *Chemicals linked with severe respiratory disease found in common e-cigarette flavors,* Harvard T.C. Chan School of Public Health (Dec. 8, 2015) (https://www.hsph.harvard.edu/news/press-releases/e-cigarette-flavoring-chemicals-linked-to-respiratory-disease/)

[4] *See Explosion Injuries from E-Cigarettes*, N ENGL J MED (Oct. 6, 2016) (http://www.nejm.org/doi/pdf/10.1056/NEJMc1608478)

[5] Nomination of Scott Gottlieb, M.D. to Serve as Commissioner of Food and Drugs, Questions for the Record, S. Comm. Health, Ed., Labor, and Pensions (Apr. 5, 2017)

the TCA."[6] Now that you have been confirmed, we expect you to follow through on your testimony. Congress was clear when it passed the Tobacco Control Act that it intended for FDA to promulgate regulations to protect public health, and any attempts to delay or roll back the final deeming rule defies Congressional intent.

Tobacco use remains the leading cause of preventable death and disease in the United States. We strongly urge you to ensure that the final deeming rule is implemented without delay in order to protect the American public.

Sincerely,

Frank Pallone, Jr.
Ranking Member

Gene Green
Ranking Member
Subcommittee on Health

[6] *Id.*