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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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August 31, 2017

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

Dear Commissioner Gottlieb:

We are writing to seek additional information about the Food and Drug Administration's (FDA) recent decision to delay important provisions of the 2016 final deeming rule, which extended FDA's authority to regulate all tobacco products and provided the agency with needed oversight mechanisms. FDA's decision will permit certain newly deemed products to stay on the market for as long as five years – until 2022 – with little oversight, and risks exposing a new generation to the health consequences of deadly tobacco products. These delays stand in stark contrast to the agency's general mission of protecting public health and completely disregard the Tobacco Control Act's requirement that FDA act in ways that are "appropriate for the protection of the public health."[1]

In 2016, FDA issued a final rule deeming all categories of tobacco products, including cigars, hookah and pipe tobacco, and electronic nicotine delivery systems (ENDS), such as e-cigarettes and vape pens, to be subject to its oversight authority under the Tobacco Control Act.[2] The rule required manufacturers of these tobacco products to submit them for premarket review before marketing them to consumers.[3] Manufacturers would have been obligated to begin submitting certain categories of approval applications starting in the next year.[4]

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[1] Pub. L. No. 111-31.

[2] FDA, *Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act*, 81 Fed. Reg. 28974 (May 10, 2016) (Final Rule).

[3] *Id.* at 28994.

[4] *Id.* at 29003.

In May, FDA postponed all future compliance deadlines for the requirements under the final deeming rule for three months. At that time, Democratic leaders of this Committee urged you to implement the 2016 rule without delay,[5] and noted that FDA's postponement decision came despite overwhelming scientific evidence showing that these products cause significant harm, including evidence that the Department of Justice used last year to defend the deeming rule in the *Nicopure Labs LLC v. FDA* case.[6] The science on this issue remains the same today – the use of these products has serious health consequences, especially for young people for whom e-cigarettes and cigars serve as a "gateway" to traditional combustible tobacco products.[7]

Now, FDA has decided to postpone important aspects of this regulation even longer. Newly regulated tobacco products that were on the market as of August 2016 will now have until 2021 or 2022 to submit tobacco product review applications. As a result, manufacturers are and will continue to be free to market tobacco products featuring flavors such as "gummy bear," "cotton candy," and "peanut butter cup"[8] with few restrictions or limitations for several more years. Based on their names alone, it's not surprising that these products are uniquely appealing to youth. The Centers for Disease Control and Prevention (CDC) has already determined that e-cigarettes are now the most commonly used form of tobacco by youth.[9] We are deeply concerned that FDA's decision will result in an increase in youth experimentation with tobacco and an increase in addiction to nicotine products in the future.[10]

Furthermore, we are concerned that FDA's announcement of the postponement suggests that ENDS might offer a "less dangerous" way for users to obtain nicotine. This contradicts FDA's previous stance that "FDA is concerned that the growth in ENDS use, particularly among youth and young adults, could lead to the re-normalization of cigarette smoking," and that "FDA

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[5] Letter from Rep. Frank Pallone, Jr., Ranking Member, House Committee on Energy and Commerce, and Rep. Gene Green, Ranking Member, Subcommittee on Health, House Committee on Energy and Commerce, to FDA Commissioner Scott Gottlieb, M.D. (May 16, 2017).

[6] *Id.*

[7] Durbin, R., et al., ''Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth,'' (April 14, 2014).

[8] *See* The Flavor Trap: How Tobacco Companies are Luring Kids with Candy-Flavored E-Cigarettes and Cigars, *American Academy of Pediatrics et al.* (March 15, 2017).

[9] Centers for Disease Control and Prevention, *E-Cigarettes and Young People: A Public Health Concern,* (https://www.cdc.gov/features/ecigarettes-young-people/index.html); *Youth and Tobacco Use* (https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data /tobacco_use/index.htm).

[10] A 2015 study reported in the Journal of the American Medical Association (JAMA) reported that the majority of young people ages 12 to 17 "who self-reported ever experimenting with tobacco started with a flavored product, and most current youth tobacco users reported use of flavored products." BK Ambrose et al., *Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,* Journal of the American Medical Association (Oct. 26, 2015).

believes that subjecting ENDS to its tobacco control authorities, and requiring compliance with the various statutory and regulatory requirements, will help to address the common misunderstanding that these products are safe to use."[11]

FDA has also announced its willingness to reevaluate the public health impacts from premium cigars. Cigar smoking is associated with oral cancer, lung cancer, cancer of the larynx, and esophageal cancer.[12] FDA has previously noted that cigars are addictive and that "cigar use of all types can lead to negative health effects."[13] The agency has also noted that cigar smoking is a growing problem among minors and young adults, and CDC recently determined that a higher percentage of high school aged boys are now smoking cigars than traditional cigarettes.[14] For all of these reasons, the FDA previously concluded that "there is no appropriate public health justification to exclude premium cigars from the scope of the final deeming rule."[15] We agree with FDA's earlier logic, and fail to understand why FDA is reconsidering this approach.

We are encouraged by FDA's announcement that the agency will consider steps to reduce tobacco addiction and nicotine reduction, but remain unconvinced that reducing nicotine levels in traditional combustible cigarettes must come at the expense of delaying needed public health oversight for newly deemed products. We are seeking a better understanding and explanation for this decision, as well as other aspects of FDA's newly announced regulatory framework for tobacco products.

Accordingly, we ask that you provide us the following information by Thursday, September 21, 2017.

1. Please provide an explanation of FDA's intended timeframe for lowering nicotine levels in combustible cigarettes to non-addictive levels and how FDA plans to ensure these measures are implemented in a timely and efficient manner.

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[11] FDA, *Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act*, 81 Fed. Reg. 29036 (May 10, 2016) (Final Rule).

[12] National Cancer Institute, Cigar Smoking and Cancer (www.cancer.gov/about-cancer/causes-prevention/risk/tobacco/cigars-fact-sheet) (accessed Aug. 10, 2017).

[13] FDA, *Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act*, 81 Fed. Reg. 29021-22 (May 10, 2016) (Final Rule).

[14] *Id.* at 29023; Centers for Disease Control and Prevention, *E-Cigarettes and Young People: A Public Health Concern,* (https://www.cdc.gov/features/ecigarettes-young-people/index.html); *Youth and Tobacco Use* (https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data /tobacco_use/index.htm).

[15] FDA, Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 29020 (May 10, 2016) (Final Rule).

2. Please explain in detail why FDA's new plan to reduce nicotine levels in combustible cigarettes must be paired with extensions to the compliance deadlines for newly regulated products, and whether it is possible for the agency to reduce nicotine levels in combustible cigarettes while also fully implementing the final deeming rule as promulgated.

3. Please explain why FDA chose the length of delay for compliance deadlines relating to premarket review requirements for newly regulated products, specifically for substantial equivalence exemption requests, substantial equivalence reports, and premarket tobacco product applications, and why the delays differ in length for newly regulated combustible products and noncombustible products.

4. FDA's press release accompanying the recent announcement on this issue stated that the goal is to "demonstrat[e] a greater awareness that nicotine – while highly addictive – is delivered through products that represents a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes."[16]

    a. Please explain the scientific evidence relied upon for determining a "continuum of risk," an explanation of where unregulated ENDS products may fall on this continuum, and the basis for claiming that unregulated ENDS products may present less risk.

5. FDA in recent years has solicited public comments regarding the role flavors – including menthol -- play in attracting youth and other users to tobacco products.[17,18] Please explain what new information FDA is seeking and why an advance notice of proposed rulemaking is necessary regarding the role flavors – including menthol – play in attracting youth and other users given the well-known evidence already available that flavors appeal to users and lead to increased usage by youth.[19]

6. How does FDA plan to ensure that children and adolescents are not conveyed a message that ENDS products, such as e-cigarettes, are a "less dangerous" or "safer" alternative to traditional combustible cigarettes and thus an acceptable option for use?

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[16] FDA, *FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death* (July 28, 2017) (press release).

[17] FDA, Menthol in Cigarettes, Tobacco Products, 78 Fed. Reg. 44484 (July 24, 2013) (Advance Notice of Proposed Rulemaking).

[18] FDA, Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 79 Fed Reg. 23142 (April 25, 2014) (Proposed Rule).

[19] *See* BK Ambrose et al., *Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,* Journal of the American Medical Association, (Oct. 26, 2015).

7. Please explain why, after determining in its 2016 deeming regulation that "there is no appropriate public health justification to exclude premium cigars from the scope of the final deeming rule", FDA is reconsidering the inclusion of these products under the regulatory framework of the final deeming rule.[20]

Your assistance in this matter is greatly appreciated. If you have any questions, please contact Jacquelyn Bolen or Christina Calce of the Democratic Committee staff at (202) 226-3400.

Sincerely,

Frank Pallone, Jr.
Ranking Member

Gene Green
Ranking Member
Subcommittee on Health

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

[20] FDA, Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 29020 (May 10, 2016) (Final Rule).