

ONE HUNDRED SIXTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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February 25, 2020

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

Dear Commissioner Hahn:

I am writing to voice my concern that the Food and Drug Administration (FDA) appears to be reconsidering regulations that would set a maximum nicotine level in cigarettes in order to make them less addictive. My concern stems from the fact that the FDA omitted this proposal from its most recent Unified Agenda of Regulatory Actions.

As you know, this proposal was announced in July 2017 by your predecessor, former Commissioner Scott Gottlieb, as part of FDA's comprehensive regulatory plan to reduce tobacco-related disease and death.¹ Following this announcement, FDA issued an Advanced Notice of Proposed Rulemaking (ANPRM) in March 2018 and solicited comments and information for consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes.

After the comment period ended, FDA continued to include this ANPRM as part of the agency's Unified Agenda through the spring of 2019. In the Unified Agenda, FDA noted that such a standard "could help limit the addictiveness of the most toxic and widely used tobacco products, which would have significant public health benefits for youth, young adults, and adults, as well as potentially vast economic benefits."² However, when FDA issued its Fall 2019 Unified Agenda, this regulation was not included.

¹ FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of tobacco-related disease, death, July 27, 2019, (www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death).

² Office of Information and Regulatory Affairs, Office of Management and Budget, Tobacco Product Standard for Nicotine Level of Certain Tobacco Products; Request for Information, RIN: 0910-AH86, Spring 2019 (www.reginfo.gov/public/do/eAgendaViewRule?pubId=201904&RIN=0910-AH86).

It is disappointing that FDA appears willing to shelve this critically important solution instead of working towards specific regulatory actions that could result in significant public health benefits. In fact, one study found that enacting a regulation that lowers the nicotine content of cigarettes to minimally addictive levels in the United States would lead to “a substantial reduction in tobacco-related mortality.”³ It also estimated that a nicotine product standard in the United States “could save millions of lives and tens of millions of life-years over the next several decades.”⁴ Given these substantial benefits, I am concerned the agency is not moving forward with implementing this policy as quickly as possible.

Even more concerning is that this proposal was put forward at the same time FDA chose to significantly delay the compliance deadlines for premarket tobacco applications (PMTAs) for newly regulated tobacco products, including e-cigarettes that were on the market prior to August 8, 2016. When announcing both actions, FDA explained that the PMTA compliance deadline delays, in conjunction with the ANPRM on nicotine levels in cigarettes, were a way to “make certain that the FDA is striking an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes.”⁵

This short-sighted action has permitted certain e-cigarette products like JUUL to remain on the market without sufficient FDA review for several additional years, while the youth tobacco epidemic has taken hold and continues to worsen.⁶ It is clear that FDA is not working to strike the right balance at all, but instead has continually delayed any action that will address the ongoing scourge of tobacco-related disease and death. If this was not the case, FDA would be moving forward with the nicotine level ANPRM, fully limiting kid-appealing flavors that are intended to hook the next generation on tobacco products, and swiftly requiring compliance for all provisions included in the 2016 Final “Deeming Rule,” which deemed all tobacco products to be subject to FDA’s regulations.

I strongly urge you in your new role as Commissioner to reconsider FDA’s decision to remove the nicotine level ANPRM from FDA’s Fall 2019 Unified Regulatory Agenda and move forward with proposing and finalizing regulations on this issue as soon as possible.

³ Benjamin Apelberg, et. al, Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States, *New England Journal of Medicine*, May 3, 2018 (www.nejm.org/doi/full/10.1056/NEJMSr1714617).

⁴*Id.*

⁵ FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of tobacco-related disease, death, July 27, 2019, (www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death).

⁶ *See* Centers for Disease Control and Prevention, 6.2 Million Middle and High School Students Used Tobacco Products in 2019, Dec. 5, 2019 (www.cdc.gov/media/releases/2019/1205-nyts-2019.html).

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I also request you provide me with answers to the following questions, no later than March 10, 2020.

1. Why did FDA remove the tobacco product standard for a maximum nicotine level in combustible cigarettes from the Fall 2019 Unified Regulatory Agenda? Please provide a detailed rationale for such decision, including information related to when this decision was made.
2. Does FDA plan to resume consideration of regulatory action to set a tobacco product standard for a maximum nicotine level in combustible cigarettes in the future and does it plan to include this proposal in a future Unified Regulatory Agenda? If so, when? If not, please explain why.
3. Does FDA continue to believe that such product standard, if ultimately promulgated, "could help to limit the addictiveness of the most toxic and widely used tobacco products?"⁷ If yes, please explain the timeline for promulgating such standard. If not, please explain why.
4. What other regulatory priorities that were announced in July 2017 as part of FDA's comprehensive regulatory plan to reduce tobacco-related disease and death is the agency actively pursuing? Please also provide a detailed timeline for action on these priorities.

Thank you for your prompt attention to this important issue and I look forward to your response. Should you have any questions or would like to discuss compliance with this request further, please contact Jacquelyn Bolen on the Committee staff at (202) 225-5056.

Sincerely,



Frank Pallone, Jr.
Chairman

⁷ Office of Information and Regulatory Affairs, Office of Management and Budget, Tobacco Product Standard for Nicotine Level of Certain Tobacco Products; Request for Information, RIN: 0910-AH86, Spring 2019 (www.reginfo.gov/public/do/eAgendaViewRule?pubId=201904&RIN=0910-AH86).