United States Senate

WASHINGTON, DC 20510

March 11, 2022

The Honorable Robert Califf, M.D.
Commissioner of Food and Drugs
United States Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993, United States

Dear Commissioner Califf,

We write to you to express concern about the delays in finalizing regulations related to the Tobacco 21 legislation and the lack of transparency around the implementation and enforcement of that legislation. This legislation, signed into law on December 20, 2019, raised the federal minimum age for sale of tobacco products from 18 to 21.[1] While this change became effective immediately, the Food and Drug Administration (FDA) was also required to promulgate a final rule to conform regulations to that statutory change.[2] There have already been significant delays in the rulemaking process and limited communication about these delays, resulting in a lack of clarity on enforcement. We urge the FDA to act swiftly to issue a final rule and to increase transparency around enforcement of Tobacco 21.

In addition to raising the minimum age for the sale of tobacco products, Tobacco 21 required the FDA to report back to Congress on its progress in implementation and enforcement of the legislation. Specifically, the FDA was required to provide a report on its progress in March 2020, 90 days after the legislation was enacted, and a separate report justifying any delay if a final rule was not issued by June 2020.[3] To date, the FDA has not issued any rules. While we understand and appreciate the FDA's work to help fight the COVID-19 pandemic, more than two years have passed since enactment, and 20 months have passed since the rules should have been promulgated. In the Fall 2021 Unified Agenda for the Department of Health and Human Services, the new target date for the final rule was set for March 2022.[4] However, there has been limited communication about the FDA's progress in meeting this target date.

We are concerned about the impact that the delay in issuing the final rule has had on enforcement of Tobacco 21. The Tobacco 21 legislation, if properly enforced, is an important tool to reduce the number of children in our country who attempt to access an age-restricted product, which if accessed, may lead to addiction to tobacco and nicotine products. However, without updated sales compliance regulations from the FDA, Congress cannot ensure retailers are abiding by the law. For example, the FDA has indicated that a final rule is necessary to raise

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[1] https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/tobacco-21#:~:text=On%20Dec.,from%2018%20to%2021%20years.&text=The%20new%20federal%20minimum%20age,and%20persons%20with%20no%20exceptions.

[2] https://www.fda.gov/media/149616/download

[3] https://www.congress.gov/116/plaws/publ94/PLAW-116publ94.pdf (Division N, Title I, Subtitle F, Section 603)

[4] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0910-AI51

the federal threshold for checking a tobacco product purchaser's age from under age 27 to under age 30.[5] In Fiscal Year 2019, the FDA was able to conduct 146,905 compliance checks through the Tobacco Retailer Inspection Program and issued 14,673 warning letters.[6] While in Fiscal Year 2020, the FDA conducted 65,716 compliance checks and issued 4,906 warning letters, a more limited number of inspections due to public health considerations during the COVID-19 pandemic.[7] Robust enforcement action is needed to adequately monitor the approximately 400,000 retailers in the country and ensure that the Tobacco 21 legislation is being implemented as Congress intended.[8]

To increase transparency, we specifically ask that the FDA respond to the following by March 25, 2022:

1. Please provide a timeline for issuance of the final rule to update regulations to reflect Tobacco 21, including details on the rule's current status in the review process and an explanation for why FDA did not meet the statutory deadline for issuing a final rule.
2. How has the delay in issuing a rule impacted the agency's ability to conduct enforcement around Tobacco 21?
3. How does the FDA determine how many compliance checks it will conduct in a given year?
4. How does the Center for Tobacco Products determine which states or retailers to conduct compliance checks in? What steps is the Center taking to ensure that robust enforcement occurs in all states? What metrics, if any, does the Center use to target enforcement efforts geographically?
5. What are the Center for Tobacco Products' protocols for Undercover Buy inspections when underage individuals attempt to purchase tobacco products? Has the lack of a final rule impacted the FDA's approach to Undercover Buy inspections?

Thank you for your continued efforts to protect young people from harmful tobacco products, and we look forward to your timely response.

Sincerely,

Tim Kaine
United States Senator

Mitch McConnell
United States Senator

[5] https://www.fda.gov/media/149616/download
[6] https://www.fda.gov/media/135078/download
[7] https://www.fda.gov/media/149616/download
[8] https://www.cdc.gov/statesystem/factsheets/licensure/Licensure.html