

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND REFORM

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December 13, 2019

Mr. Mitch Zeller  
Director, Center for Tobacco Products  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Mr. Zeller:

Enclosed are post-hearing questions that have been directed to you and submitted to the official record for the hearing that was held on Wednesday December 4, 2019, entitled "The Federal Response to the Epidemic of E-Cigarette Use, Especially Among Children, and the Food and Drug Administration's Compliance Policy."

In order to ensure a complete hearing record, please return your written response to the Committee on or before Tuesday, December 24, 2019, including each question in full. Your response should be addressed to the Committee office at 2157 Rayburn House Office Building, Washington, D.C. 20515. Please also send an electronic version of your response by e-mail to Joshua Zucker, Assistant Clerk, at [Joshua.Zucker@mail.house.gov](mailto:Joshua.Zucker@mail.house.gov).

None of the enclosed questions call for an answer that would be subject to privilege. If you fail to provide a full and detailed answer to any question on the basis of privilege, clearly state the privilege upon which you rely, and provide a detailed justification of the legal basis of the privilege (including citations to applicable legal authority) and explain why you believe that the stated privilege applies to the facts. The Chairman will rule on any such assertions of privilege and will inform you of any subsequent required actions.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Elisa LaNier, Chief Clerk, at (202) 225-5051.

Sincerely,



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Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and Consumer Policy

cc: The Honorable Mike Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy

**Questions for Mr. Mitch Zeller,  
Director of the Center for Tobacco Products of the Food and Drug Administration**

**Questions from Chairman Raja Krishnamoorthi  
Oversight Subcommittee on Economic and Consumer Policy**

December 4, 2019 Hearing: "The Federal Response to the Epidemic Of E-Cigarette Use,  
Especially Among Children, and the Food And Drug Administration's Compliance Policy"

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1. OIRA has completed its review of FDA's compliance policy entitled "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Tobacco Products on the Market Without Premarket Tobacco Authorization" ("Compliance Policy"). From a regulatory process standpoint, is there any legal impediment to the Food and Drug Administration (FDA) publishing the Compliance Policy today?
2. In order for FDA to publish the Compliance Policy, does FDA need additional approval from:
  - a. The Office of Information and Regulatory Affairs (OIRA)?;
  - b. The President?;
  - c. Any other individual or office within the White House other than OIRA or the President, and if so, which individual or office within the White House?;
  - d. The Department of Health and Human Services (HHS), and if so, which individual or office within HHS?; and/or
  - e. If you answered "yes" to any of subparts a through d, above, explain how it was conveyed to you that such additional approval would be necessary, and your understanding as to how that approval will be conveyed and by whom.
3. You explained that "parallel policy discussions" are the reason that the Compliance Policy is not being published. State:
  - a. When, how, and from whom, you first learned about the "parallel policy discussions";
  - b. The identity of all individuals involved in the "parallel policy discussions," by both name and office;
  - c. Whether the substance of the Compliance Policy is final, or whether additional changes to the Compliance Policy are being considered as part of the "parallel policy discussions";
  - d. How the "parallel policy discussions" impact the finalization of the Compliance Policy, including whether the Compliance Policy cannot be

- finalized until some other action is decided, and if so, identify the other actions that must be decided; and
- e. Whether specific potential rules, executive orders, or legislation are being considered in connection with the Compliance Policy, and if so, state the subject matter of any such rules, executive orders, or legislation.
4. When asked if FDA can issue the guidance now that OIRA has completed its review, Mr. Zeller said: "if the complete executive branch review of the policy was done, but there were still, as I said, in parallel, other ongoing policy-related discussions going on."
    - a. On what grounds is FDA withholding the Compliance Policy until the "complete executive branch review" is complete?
    - b. Provide citation to the definition of "complete executive branch review."
    - c. If there is no formal definition of "complete executive branch review," provide one, as you understand it.
    - d. Provide all examples of FDA guidance documents that have been withheld pending parallel discussions or "complete executive branch review" beyond that outlined in Executive Order 12866.
  5. Explain whether, and how, compliance with Executive Order 13771 is contributing to the delay in publishing the Compliance Policy.
  6. Explain whether, and how, the Regulatory Reform Task Force is contributing to the delay in publishing the Compliance Policy. Identify the Regulatory Reform Officer.
  7. Identify all FDA rules, compliance policies, guidance documents, and regulatory actions that FDA failed to publish in the Federal Register within the first month after OIRA completed its 12866 review of that FDA rule, compliance policy, guidance document, or regulatory action.
  8. Identify all FDA rules, compliance policies, guidance documents, and regulatory actions about which you are aware of any president taking meetings after that FDA rule, compliance policy, guidance document, or regulatory action had passed through OIRA review but had not yet been published in the Federal Register.
  9. Identify all specific FDA rules, compliance policies, guidance documents, and regulatory actions that you are aware of a president publicly supporting, and then opposing and/or actively working against that specific FDA rule, compliance policy, guidance document, or regulatory action after it passed through OIRA review but had not yet been published in the Federal Register.

10. State your understanding of the President's ability to change the substance of an FDA rule, compliance policy, guidance document, or regulatory action after it has passed through OIRA review but has not yet been published in the Federal Register.
11. You have acknowledged that OIRA's review of the Compliance Policy is complete. Therefore, deliberations about that specific Compliance Policy are complete.
  - a. State whether the Compliance Policy that you sent to OIRA on October 25, 2019, proposed to clear the market of all flavors, or if there were any exemptions, including for menthol and/or for vape shops.
  - b. State whether OIRA made any changes to the Compliance Policy FDA sent to OIRA.
  - c. State whether any changes made by OIRA to FDA's Compliance Policy added exemptions, and state what those exemptions were, including whether OIRA added exemptions for menthol and/or vape shops.
12. You testified that "[t]he options that FDA put on the table for consideration, going to what the scope of what this guidance should be, went to the issue of 'menthol in' or 'menthol out.'" Having started into that subject matter, describe all other options FDA put on the table, and to whom FDA proposed the options.
13. Identify dates and times in the next week for Subcommittee staff to conduct an in-camera review of FDA's Compliance Policy sent to OIRA on October 25 and the Compliance Policy OIRA sent back to FDA after completing its review on November 4. As a matter of courtesy, we are willing to make this accommodation, rather than seeking production of those documents.
14. The United States District Court for the District of Maryland ordered FDA to require PMTA submissions by May 12, 2020. The government has appealed that order. Unless, the order is stayed on appeal, will FDA comply with the order and require Premarket Tobacco Product Applications (PMTA) by May 2020?
15. The product design of the current generation of e-cigarettes makes them very concealable. They are small and put out small plumes of quickly dissipating aerosol. Does FDA have the authority to regulate device design, including aspects such as size, shape, and color?
16. Identify all instances of FDA being lobbied on the topic of the Compliance Policy and/or on the "parallel policy discussions," and identify all individuals involved.
17. JUUL publicly stated that it would not lobby against the Compliance Policy. Did JUUL, Altria, or anyone acting on their behalfs lobby or otherwise communicate

with the administration about the Compliance Policy and/or on the “parallel policy discussions”?

18. Why did FDA choose to make Mint and Menthol one category on the National Youth Tobacco Survey?
19. On September 11, when the administration promised to clear the market of all flavors, there was a specific effort to add the words “including mint and menthol.” Please state whether the following facts factored into the decision to specifically identify mint and menthol:
  - a. That 63.9% of youth users use mint or menthol?; and/or
  - b. That JUUL has historically tried to distinguish mint and menthol from other flavors, at one point even claiming that mint and menthol were not flavors at all?
20. The Big Vaping Industry is celebrating victory. The President of the American Vaping Association stated quote “it’s a great feeling in two months to go from thinking that prohibition was inevitable to actually proving that your issue has resonance with voters to such an extent that the President of the United States takes notice.” Emboldened by his presumed victory over public health, the President of the vaping lobby set his sights on FDA’s PMTA process, stating quote “we need to make the administration and the reelection team aware that the magnitude of the threat in May 2020 is just as huge and industry-crushing as the flavor ban is today” (emphasis added). He’s indicating that Big Vaping again plans to exert political influence on President Trump, this time to interfere with FDA’s PMTA process.
  - a. Would you be concerned if the vaping association was meeting with the White House to exercise political pressure on the PMTA process?;
  - b. Has the White House engaged FDA about how to conduct the PMTA process?;
  - c. How could the White House, theoretically, exert influence over how FDA conducts the PMTA process?;
  - d. Will FDA allow the White House to dictate how FDA conducts the PMTA process?; and
  - e. Do you commit to informing this Subcommittee if the White House engages FDA about weakening the PMTA process?
21. Mint and menthol are very similar flavors. We understand that FDA is considering removing, mint-flavored e-cigarettes from the market but allowing menthol-flavored e-cigarettes to remain on the market.



- a. Has FDA issued definitions of mint and menthol? If not, how would you define them?
  - b. If menthol-flavored e-cigarettes are allowed to remain on the market, how will FDA prevent companies from simply renaming their mint products as menthol to keep them on the market?
22. After August 2016, no new e-cigarette could enter the market without undergoing an FDA review. Does FDA have a list of products that were on the market prior to August 2016 so that it knows which ones illegally entered the market after that date? If so, provide that list.
23. In May of next year, manufacturers of e-cigarettes will have to submit PMTA applications to FDA, and the Center for Tobacco Products will determine whether these products are “appropriate for the protection of public health.” Under this “public health” standard, could FDA approve a product that a significant number of youths are currently using?