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ONE HUNDRED SEVENTEENTH CONGRESS

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July 6, 2021

Dr. Janet Woodcock
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock:

Enclosed are questions that have been directed to you and submitted for the official record for the hearing on Wednesday, June 23, 2021, titled "A Crisis Continues: Youth Vaping in America."

Please return your written responses to these questions by Tuesday, July 20, 2021, including each question in full as well as the name of the Member. Your responses 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 responses by email to Amy Stratton, Deputy Chief Clerk, at Amy.Stratton@mail.house.gov.

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,

Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Enclosure

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

Questions for Dr. Janet Woodcock
Acting Commissioner, Food and Drug Administration

Questions from Chairman Raja Krishnamoorthi
Subcommittee on Economic and Consumer Policy

June 23, 2021, Hearing: "An Epidemic Continues: Youth Vaping in America"

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1. During the hearing, you stated that the Food and Drug Administration (FDA) is prioritizing review of five premarket tobacco product applications (PMTAs) of the companies with the highest market share. Please identify all companies being prioritized for review.

2. During the hearing, you testified that you were not familiar with the Tobacco Products Scientific Advisory Committee (TPSAC). Since the hearing, I assume you have familiarized yourself with TPSAC, so will you now commit to referring JUUL's PMTA to TPSAC for review?

3. What is FDA's formula for weighing the benefits against the harms of a PMTA—how many adult smokers would have to quit tobacco to justify the risk of addicting one non-using youth to nicotine through use of the product?

4. Section 910(c)(4)(A) of the Food, Drug, and Cosmetic Act requires FDA to take into account "the increased or decreased likelihood that existing users of tobacco products will stop using such products." Confirm that, for purposes of FDA's PMTA analysis:

   a. "such products" means all tobacco products,

   b. a combustible cigarette smoker who began smoking fewer cigarettes did not "stop using such products,"

   c. a combustible cigarette smoker who now uses both cigarettes and e-cigarettes did not "stop using such products," and

   d. a combustible cigarette smoker who stopped smoking cigarettes and now exclusively uses e-cigarettes did not "stop using such products."

5. As FDA found in its July 20, 2020, warning letter, sales of Puff Bar products are illegal because they were not on the market as of the deeming date. Even after your warning letter, sales of these products continued. One reason is because multiple companies are selling Puff Bar products. In fact, two companies even

submitted PMTAs for Puff Bar products: DS Technology Licensing and Al Khalifa Group LLC.

a. As you consider their PMTA applications, will you commit to determining:

   i. the ownership structure of each organization,

   ii. the manufacturer of each product, and

   iii. the individuals involved with importing, distributing, and marketing the products?

b. Once you determine the people responsible for illegal sales of Puff Bar, will you commit to using all tools available to hold them accountable, including not only civil money penalties, but also the full extent of your authority to pursue criminal prosecutions?

6. During the hearing, you stated that menthol makes e-cigarettes more addictive. The same is true about similar cooling agents used in e-cigarettes such as WS-3, WS-5, and WS-23, correct?

7. Studies indicate that new chemical compounds can form in e-liquid after mixing constituents and during storage and can have unexpected toxicological effects.[1] Do you agree that during FDA's consideration of PMTAs, FDA should base any safety and toxicity determinations on a review of the finished product that is the subject of a PMTA? Do you agree that it would be inappropriate and unreasonable for FDA to base safety and toxicity determinations on a review of just the individual ingredients, as opposed to a review of the finished products that are the subject of PMTAs?

8. Do you agree that it would be inappropriate and unreasonable for FDA to only review the safety or toxicity of individual ingredients, without analyzing how all ingredients act in concert when combined?

9. Do you commit to finalizing the ban on menthol combustible cigarettes as soon as possible?

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[1] *See* Zimmerman et al., *Formation of Flavorant-Propylene Glycol Adducts with Novel Toxicological Properties in Chemically Unstable E-Cigarette Liquids* (Aug. 19, 2019) (online at https://pubmed.ncbi.nlm.nih.gov/30335174/); Jordt et al., *Chemical Adducts of Reactive Flavor Aldehydes Formed in E-Cigarette Liquids Are Cytotoxic and Inhibit Mitochondrial Function in Respiratory Epithelial Cells* (Dec. 15, 2020) (online at https://pubmed.ncbi.nlm.nih.gov/33320255/).

Questions for Dr. Janet Woodcock
Acting Commissioner, Food and Drug Administration

Questions from Rep. Mark DeSaulnier

June 23, 2021, Hearing: "An Epidemic Continues: Youth Vaping in America"

JUUL products are used by 41% of youth vapers, which makes JUUL the most popular brand among youth vapers.

1. Do you agree that a nicotine product used by 41% of youth vapers is hurting the public health?

In 1954, an article published in the British Medical Journal confirmed the link between smoking and lung cancer. Despite some progress at the federal, state, and local levels on tobacco regulation in the following decades, it was not until 2009 that federal law granted FDA regulatory authority over tobacco products. While the tobacco industry misled the American public into believing that tobacco products were safe, the U.S. Surgeon General found that 20 million Americans died from smoking between 1964 and 2014. Given all the deaths caused by tobacco products despite the knowledge that they were harmful, there was clearly a missed opportunity to enact regulations earlier and reduce the public health burden of tobacco. We cannot let that happen again with e-cigarettes.

2. Do you agree that allowing youth-preferred products to remain on the market could constitute a similar missed opportunity?

3. If yes, how does this not subject future generations to further health risks and premature death?

Questions for Dr. Janet Woodcock
Acting Commissioner, Food and Drug Administration

Questions from Rep. Byron Donalds

June 23, 2021, Hearing: "An Epidemic Continues: Youth Vaping in America"

DONALDS QFR #1

FDA has jurisdiction over and regulates products containing nicotine derived from tobacco. A nascent category using synthetic nicotine in its products instead of nicotine from tobacco is emerging in the U.S. This potential "loophole" regarding the source of the nicotine could allow these products to potentially circumvent regulation. The concern is that this new product category, just like the vapor category 10 years ago, could lead to unregulated and underage use very quickly if the FDA does not assert jurisdiction over these products quickly.

1) Does the FDA have concerns that there are products being sold in the United States containing synthetic nicotine and that synthetic nicotine is not currently regulated by the FDA's Center for Tobacco Products?

2) Is the FDA aware that these products are largely being made in China with no oversight by the FDA in terms of ingredients or manufacturing processes?

3) Is FDA working with Customs and Border Patrol to at least have importers of these products attest to where the synthetic nicotine is manufactured? If not, can you commit to doing that?

4) We need to avoid manufacturers and importers claiming "synthetic nicotine" loophole when really, they are importing tobacco derived nicotine products. How will the FDA know if the nicotine in imported products is synthetic rather than from tobacco, which would make the products subject to FDA jurisdiction?

5) Does the FDA have a plan to assert regulatory jurisdiction over synthetic nicotine products? What is that plan?

DONALDS QFR #2

The FDA has made multiple public statements, even has a public website, dedicated to distinguishing between the harms associated with nicotine, which is addictive, and smoke, which is the most harmful way to consume nicotine. The regulators and scientists know that the harm from tobacco products largely comes from cigarettes – and the smoke inhaled after it is lit on fire. But this is not well known by the American public or even their doctors.

A Rutgers study,[2] published last year in the *Journal of General Internal Medicine,* found that 80% of physicians mistakenly believe that nicotine itself leads to smoking related diseases. If physicians have misperceptions around the harms of nicotine vs. smoke, then how can we expect adult cigarette consumers to know the benefits of switching from smoking to any non-combustible nicotine products.

Patients, smokers specifically, deserve better information. They deserve to know what the FDA knows. That not all nicotine consumption is created equal.

Misperceptions surrounding nicotine must be addressed if we are to reduce tobacco harm in America.

a) With better education from the FDA on the continuum of risk surrounding nicotine and on awareness about FDA's reduced risk authorizations, physicians would better serve their patients. What are your plans for educating physicians about FDA's modified risk product approvals and more broadly about the misperceptions around nicotine v. tobacco smoke?

b) How will the Agency educate adult smokers about harm reduction and encourage them to move away from cigarettes to FDA-authorized non-combustible products?

c) How can smokers know what products have received PMTAs, or modified risk claims, would be worth trying as an alternative to cigarettes? It seems like you could use electronic data to reach them in a targeted way just like you are using electronic data to reach at risk youth with the Real Cost campaign. Will you commit to running an information campaign specifically for them?

DONALDS QFR #3

It is well known that cigarettes and other tobacco products are sold underground almost everywhere in the world – evading taxes and regulations and profiting criminal networks. These products are often made in unregulated facilities and consumers buy them without being age verified and have no way to verify the ingredients.

In the Unites States, a joint task force of five federal agencies – HHS, DOJ, DHS, State, and Treasury – published a report under the Obama Administration,[3] titled *"The Global Illicit Trade in Tobacco: A Threat To National Security."* The report explains that *"for decades, cigarette smuggling has been a sizeable and dependable revenue stream for organized crime. Estimates for the annual state and local U.S. tax loss caused by the illicit trade in tobacco*

[2] Rutgers-Led National Survey Uncovers Doctors' Misconceptions About Nicotine Risks | Rutgers University

[3] STATE DOJ TRE DHS HHS Report Obama Admin.pdf

products range from $2.95 to $6.92 billion." This means about 8-10% of cigarettes consumed in the U.S. today are "illicit" – sold outside of the stream of legal, regulated, tax-paid commerce. When the Senate was passing the 2009 bill giving the FDA regulatory authority over tobacco products, Senator Durbin explained why regulation, not product bans, was preferable to avoid a spike in the illicit market:

> *"People often say to me: Well, why don't we just ban this product? If I thought that would end smoking in America, I might consider it. But we know better. With 43 million Americans currently addicted, they are not going to quit cold turkey tomorrow. A black market would emerge, and then the next thing you know the underground economy would be sustaining tobacco. That would not be the result we are looking for." Senator Dick Durbin, Extension of Morning Business, 111 `Cong., 155 CONG. REC. 56405, S6406 (2009)*[4]

The FDA has publicly announced its intention to ban whole categories of legal products – specifically menthol cigarettes, which make up 1/3 of the U.S. cigarette market today. Similarly, if the FDA were to no longer allow the sale of legally manufactured, regulated flavored vapor products or flavored cigars, adult consumers who have been buying these products for years will be left without a lawful market location to purchase their products. The illicit market will undoubtedly grow to meet consumer demand and criminal networks will benefit. State and federal tax collections will be reduced, and consumers will turn to underground sources for their tobacco products. The products won't be made in regulated facilities, illicit imports from countries like China will probably skyrocket, and the sellers sure are not going to check I.D.s to make sure the purchaser is 21 or older.

a) Prohibition did not work for alcohol. Many currently argue that prohibition is not working for marijuana. Why does the agency believe that prohibition will work now for flavored vapor or for menthol cigarettes?

b) If you move forward with prohibitionary policies such as no flavored tobacco products, what percentage illicit product market expansion do you estimate will immediately occur?

c) What is the human cost associated with those illicit markets – products breathed into lungs – I'm thinking specifically of the cost paid in the EVALI illness breakout. What other harms does Congress need to anticipate?

d) Wouldn't it make more sense for the FDA to achieve the intended health benefit of lowering adult smoking rates by spending time and effort getting more reduced harm nicotine products to market and educating smokers about the benefits of switching their nicotine source?

[4] https://www.congress.gov/111/crec/2009/06/10/CREC-2009-06-10-pt1-PgS6406.pdf

e) During the hearing, Acting Commissioner Woodcock explained her belief that menthol smokers find it harder to quit than non-menthol smokers, but she also explained that the average menthol smoker today smokes fewer total cigarettes than the non-menthol smoker. If menthol cigarettes are banned, isn't it logical that they will turn to non-nicotine cigarettes to meet their needs and that they will therefore begin smoking more cigarettes on average? This does not seem wise.

f) Are you aware that every state has laws on the books making the production, sale, and distribution of illegal tobacco products a crime? I know that FDA and its enforcement staff will not be in my congressional district on the streets enforcing the law when a carton of menthol cigarettes or a U-Haul truck of flavored vape pods is found during a routine traffic stop, but state and local law enforcement will find themselves in these situation. They can't just look away and ignore the violation of state law. Do you agree that with an increase in illicit market products caused by prohibitionary product bans, state and local law enforcement will need more training and more resources to deal with these incidents properly?

DONALDS QFR #4

In reaction to the increasing youth vaping numbers, Congress acted quickly to determine what the biggest sourcing problem was – we knew underage individuals couldn't legally buy the products so one of three things had to be happening:

1) Friends who were 18 and up might be purchasing and then passing the products along

2) Fake IDs could be used to purchase by the 17 or under individual at retail; or

3) Products could be coming via mail to underage individuals who enter parents or friend's ages / verification data to complete the order.

Looking at these possibilities found the following:

1) The Population Assessment of Tobacco and Health (PATH) Study,[5] a joint project of the National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA), data told us that "social sourcing" accounted for almost 75% of products that were getting into the hands of minors. These sources included giving someone old enough money to buy for them, buying them from someone else that already had them, asking someone for them, or being offered them without payment. This data drove Congress to act quickly to dry up these social sources – if friends ages 18, 19, and 20 could no longer buy for minors 17 and under, we believed great progress could quickly be made. The latest available data says we were right. According to the National Youth Tobacco Survey released in October 2020, not only do traditional tobacco products

[5] Wave 3 data (2015-16)

continue to be at historic lows – low single digits, but the data show the vapor use rate among high school students dropped by 1/3 – 8 million less high school vapers in just 3 months after 21 was made law of the land.
Do you acknowledge that FDA had long concluded that age 21 was a good policy idea for combating youth usage? Do you acknowledge that the current data shows that its passage did just that?

2) My understanding that, in compliance cases involving minors, the FDA compliance check data improved *significantly* between data published in FFY2019, 2020, and 2021. Is this correct?

3) Additionally, are all state compliance rates recorded by SAMSHA[6] currently at or below the violation percentages required receive federal matching funds under the Synar Amendment – with the guidance[7] now being updated to age 21?

4) On the issue of mail access, Congress didn't have as much information to work with. But, we knew we had made traditional products non-mailable by the U.S. Postal Service a decade earlier with the passage of the PACT Act, so it made sense to extend this same non-mailability to nicotine vapor products. Starting this year, all vapor products will need to be purchased in person at a brick and mortar location with a valid I.D. Do you agree that this is good policy and that this is also likely to decrease the availability of youth access via the mail system if it was occurring?

DONALDS QFR #5

In recent news we've read a lot about a UC Davis Study published in Preventative Medicine[8] that gave us great news about daily smoking rates in the group of adults that fall between the age that used to be legal to smoke – 18 – and the age that is now legal to smoke – 21. According to the UC Davis News release[9]:

[6] https://www.samhsa.gov/synar

[7] https://www.samhsa.gov/sites/default/files/synar-guidance-tobacco-21.pdf

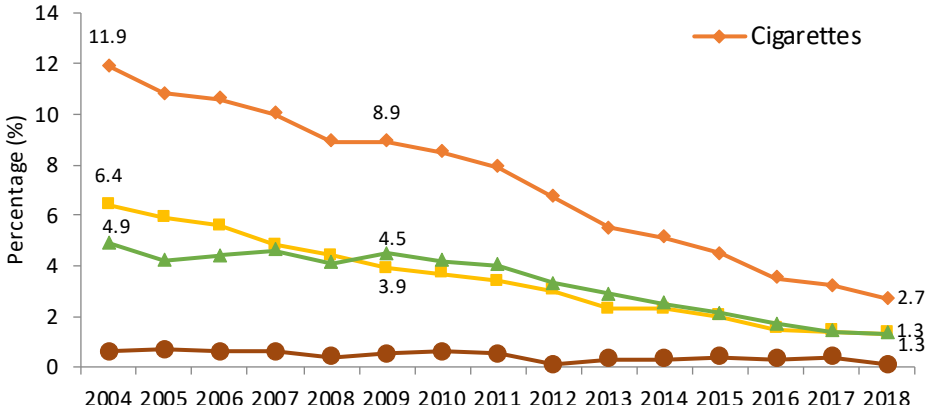
[8] https://reader.elsevier.com/reader/sd/pii/S0091743521001377?token=D0BAD37CBA67CDA787336739CECD8469D71D17A2CB3D0B98BA78585DE972A86B1754A7CA2B370E1B7A53C29865D6710C&originRegion=us-east-1&originCreation=20210621224553

[9] https://health.ucdavis.edu/health-news/newsroom/is-raising-the-sales-age-of-tobacco-reducing-youth-smoking/2021/04#:~:text=%E2%80%9CThe%20great%20news%20is%20that,Health%20Sciences%2C%20Division%20of%20Biostatistics.

"The great news is that the prevalence of 'daily' smoking among 18-20-year-olds went from 2.2% in 2016 to **nearly zero** in 2019," said Stewart, professor with UC Davis Department of Public Health Sciences, Division of Biostatistics.

Similarly, all-time record LOWS were recorded in the under 18 group in the last set of national data from the National Youth Tobacco Survey – an average of less than 2%.

Past 30-day Cigarette Smoking Overall, Menthol, Nonmenthol (12 to 17 year-olds)



a) I want to congratulate the FDA and the Center for Tobacco Products specifically for the terrific progress that has been made on the rates of young adult as well as youth smoking. This success is what we are now attempting to achieve in the area of vaping.

When it comes to the under 18 group, in the 1990s the problem seemed insurmountable – about 1/3 of high schoolers were smoking regularly in 1995. Now, the number is the lowest on record – an average of less than 2% nationwide.

I would ask the FDA to comment publicly on that success and to explain how the same principles can be used in the current vaping situation at a much quicker rate – now that we have the benefits of Age 21, technology that can target youth vapers with the "Real Cost" campaign, and improvements to age verification technology being made at retail.

DONALDS QFR #6

Can a new tobacco product be legally marketed to consumers as harm-reducing or reduced exposure without FDA's authorization?

DONALDS QFR #7

Does the FDA consider there to be important differences in how a modified exposure MRTP such as IQOS may be marketed, compared to a product that has not completed the MRTP review process?

DONALDS QFR #8

With regard to MRTP reviewed products, does the FDA have an on-going monitoring role or other tools to protect against youth marketing or access? Does this differ from how the FDA monitors or protects against youth marketing or access to products that have not participated in the PMTA or MRTP process?

DONALDS QFR #9

Can you describe the relative rigor of the MRTP review and authorization process, especially as compared to the process for permitting the sale of a non-MRTP product?

DONALDS QFR #10

Can you clarify the distinction between a PMTA and a MRTP application, including any differences in the health-related analyses engaged by the FDA? Is it fair to characterize the scientific analysis required by the MRTP review process as more extensive and rigorous?

DONALDS QFR #11

Does the MRTP authorization process set a higher bar for demonstration of exposure reduction than the PMTA process?