Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Vaping in America: E-Cigarette Manufacturers' Impact on Public Health"

February 5, 2020

Mr. Ricardo Oberlander, President and Chief Executive Officer, Reynolds American Inc.

The Honorable Frank Pallone, Jr. (D-NJ)

Request 1: **How has Reynolds worked with its retailers to ensure compliance with the Food and Drug Administration (FDA) guidance in effect as of February 6, 2020, regarding the unauthorized marketing of closed-cartridge non-tobacco and non-menthol flavored products?**

Response: In January 2020, Reynolds American Inc. sent letters to direct buying customers and retail and subjobber customers selling Reynolds' VUSE vapor products. The letters alerted the various customer groups to FDA's final guidance regarding closed-cartridge non-tobacco and non-menthol flavored ENDS products. The letters also specifically identified the Reynolds' VUSE products that were affected by FDA's final guidance and that would no longer be available for orders. The letters alerted the customers that these products would, therefore, be eligible for return and explained the process of direct buying customer returns and returns from retailers and subjobbers.

The Honorable Diana DeGette (D-CO)

Request 1: **Do you expect that the guidance issued by FDA on January 2, 2020, and in effect as of February 6, 2020, will reduce youth use of JUUL's products or of e-cigarette products in general? Why or why not?**

Response: Yes. FDA's final guidance relating to the Agency's enforcement policy on certain flavored vapor products is based on evidence of increasing youth use of flavored vapor products as demonstrated by one of the largest surveys of tobacco use among youth—the Monitoring the Future Study. When FDA issued its final guidance, FDA Commissioner Stephen Hahn stated:

> By prioritizing enforcement against the products that are most widely used by children, our action today seeks to strike the right public health balance by maintaining e-cigarettes as a potential off-ramp for adults using combustible tobacco while ensuring these products don't provide an on-ramp to nicotine addiction for our youth.

Further, FDA's final guidance provides that "FDA intends to prioritize enforcement of any ENDS product that is offered for sale after May 12, 2020, and for which the manufacturer has not submitted a premarket application (or after an negative action by FDA on a timely submitted application)." Reynolds American Inc. believes it is important that all ENDS products, including disposables and open systems, should be subject to the final guidance and FDA's enforcement priorities. Reynolds also believes that FDA should publish a list of all ENDS products for which a PMTA was submitted by May 12, 2020, and to indicate whether those applications have been accepted for filing and are undergoing review. This published list would help retailers, state officials, and the public know which vapor products are undergoing FDA review. This also would enable the identification and removal from the market of other products that have not pursued FDA premarket review and clearance prior to May 12, 2020 and thus should not be eligible for enforcement discretion.

In addition to its January 2020 guidance, FDA's Youth Tobacco Prevention Plan generally includes actions aimed to stop youth use of vapor products, with a focus on preventing access to tobacco products, curbing the marketing of tobacco products aimed at youth, educating teens about the dangers of vapor products, and reinforcing retailers' understanding of their roles in protecting youth. Reynolds encourages FDA to use its Youth Tobacco Prevention Plan to discourage adults from providing vapor products to youth, since studies show youth overwhelmingly obtain tobacco products from social sources.

Reynolds also believes that the recently enacted legislation establishing 21 as the minimum age of purchase for tobacco products in the United States—which the Company supported—will help to reduce youth use of vapor products in general.

Request 2: **Do you believe FDA or other federal agencies have the resources (financial or otherwise) to monitor data and evolving trends with respect to youth use of e-cigarettes? If not, what more needs to be done?**

Response: Yes, through the user fees collected each year, FDA should have the resources to monitor data and evolving trends with respect to youth use of vapor products. Indeed, FDA has reported a strong track record of success with its youth prevention program.

Reynolds also supports and encourages additional action by the Administration and Congress to help address youth use of vapor products. Indeed, Mr. Oberlander provided the following recommendations during his February 5, 2020 testimony:

> First, transparency in the PMTA process is critical. We suggest FDA disclose which products have been submitted for PMTA approval. This would help retailers and the public know which vapor products

are undergoing PMTA review and are eligible to remain on the market, and would help FDA and state officials enforce the law.

Second, FDA needs to adopt regulations that expedite important innovations. For example, we are exploring technologies that could provide additional measures for reducing potential youth usage. However, the current PMTA process -- although thorough and welcome -- will significantly delay bringing this type of responsible innovation to market.

Third, FDA should consider adopting additional and rotating warnings for vapor products. These warnings could reinforce that vaping products are not safe and not for youth. We already include many such statements on our packaging and brand website.

In addition, FDA and other government agencies need to prioritize and enhance enforcement efforts against illicit THC vaping products. The Company supports the efforts of FDA and encourages FDA enforcement of illicit tobacco products.

The Honorable Brett Guthrie (R-KY)

Request 1: **Currently, the Food, Drug and Cosmetic Act limits the ability of the U.S. Food and Drug Administration (FDA) to disclose receipt of premarket tobacco product applications (PMTA)**.

Request 1(a): **After May 12, 2020, what is your understanding of how distributors, retailers, and other relevant entities will be able to determine which products have a PMTA submitted to FDA, and thus can remain on the market while under review, and which products do not have a PMTA submitted to FDA?**

Response: Reynolds American Inc. does not believe that distributors, retailers, consumers, and other state and local regulators will be able to identify the vapor products that have complied with FDA's May 12, 2020 PMTA deadline and thus, are permitted to remain on the market. We are not aware of a current plan by FDA to provide this information to the public.

Request 1(b): **Are any regulatory or legislative changes necessary to help inform the public and enforcement authorities about which products will be allowed on the market after May 12, 2020?**

Response: Going forward, Reynolds believes that FDA should publish a list of all ENDS products for which a PMTA was submitted by May

12, 2020, and to indicate whether those applications have been accepted for filing and are undergoing review.

It is critical that manufacturer compliance with the May 12, 2020 deadline be transparent. Reynolds proposes that a mechanism be adopted that allows FDA to disclose the vapor products that are currently on the market pursuant to FDA's enforcement discretion that have submitted PMTAs and to update the record when these PMTAs are accepted for scientific review and ultimately cleared. This transparency would help retailers, state regulators, and the public know which vapor products are undergoing FDA review and assist in identifying other products that have not pursued FDA premarket review and clearance prior to May 12, 2020 that should be subject to enforcement by FDA and state officials.

It is also important for FDA to encourage—not impede—the innovation of tobacco products that potentially present less risk. FDA should adopt regulations that expedite these important innovations. For example, we are exploring technologies that could provide additional measures for reducing potential youth usage. The current PMTA process—although thorough and welcome—would significantly delay bringing this type of responsible innovation to market.

Request 2: **During the summer of 2018, FDA conducted an enforcement blitz of retailers nationwide, resulting in more than 1,100 Warning Letters and approximately 130 civil monetary penalties being issued to retailers for underage sale of e-cigarettes. Those cases included the illegal sale of Logic, JUUL, Fontem, and JTI products to minors. As such, each company received a letter from FDA in September 2018 requesting a meeting with FDA and that each company submit a detailed plan to address and mitigate widespread use by minors.**

Request 2(a): **What was the result of your company's response to this request from FDA?**

Response: On September 25, 2018, Reynolds submitted an initial response to then-FDA Commissioner Scott Gottlieb's September 12, 2018 letter requesting a detailed plan to address youth use of ENDS products. Subsequently, the Company met with then-FDA Commissioner Scott Gottlieb on October 11, 2018. On November 9, 2018, Reynolds provided a detailed written response to FDA's September 12, 2018 letter.

In its November 9, 2018 letter, Reynolds detailed a series of steps it intended to take and has taken to address youth access to its VUSE vapor products. Among other steps, the Company implemented additional online sales controls, including specific controls on online purchases to reduce the risk of "straw purchases" that are made indirectly on behalf of underage consumers by limiting purchases per customer, monitoring purchase patterns, and banning purchasers who attempt to purchase products for resale. The Company already required adult tobacco consumers to be independently age verified by a third party prior to any purchase.

Reynolds also held face-to-face meetings with contracted retailers to re-emphasize the importance of checking identification before selling VUSE products and an enhanced penalty system for contracted retailers that sell VUSE products illegally to minors. Further, the Company continued its support for the *We Card* program, and contract retailers are obligated to participate in this age-verification training and signage program.

Reynolds also expressed that it would support changing the legal age to purchase tobacco to 21 and supported the recently enacted legislation establishing 21 as the minimum age of purchase for tobacco products in the United States.

Separately, Reynolds sponsors a youth tobacco prevention program—Right Decisions, Right Now – Be Tobacco Free—for use by parents, teachers, and third-party youth groups. Program materials were updated to include information concerning vapor products.

Request 3: **In addition to the Customs and Border Patrol, does your company have a direct line of communication with other law enforcement entities for reporting illicit products?**

Response: Yes. Reynolds appropriately assists various law enforcement organizations, regulatory agencies, and tax enforcement organizations, including the FBI, the Bureau of Alcohol, Tobacco, and Firearms, FDA's Office of Criminal Investigations, U.S. Homeland Security Investigations, and U.S. Customs and Border Protection, with their investigations of illicit trade of tobacco products. The Company has also assisted various state and local enforcement organizations. To date, Reynolds is not aware of any reports of illicit or suspected counterfeit VUSE vapor products, but the Company continuously monitors the market for such illicit and/or counterfeit products.

Request 3(a): **If so, has information that your company has provided to law enforcement resulted in criminal enforcement actions?**

Response: As discussed above, Reynolds works with federal, state, and local law enforcement organizations and, to date, Reynolds is not aware of any reports of illicit or counterfeit VUSE vapor products.

Request 4: **What does your company do to ensure the safety of the supply chain for your ENDS products?**

Reynolds has implemented a detailed and sophisticated management and oversight process regarding its ENDS product supply chain. In brief, this process involves thorough vetting of potential suppliers and continuous oversight of contracted suppliers. The supplier vetting process involves a preliminary assessment of the supplier, a manufacturing capability assessment, and a qualifications audit. These assessments are comprehensive and include evaluation of each supplier's (and key sub-tier suppliers') quality management systems, product realization processes, and manufacturing and resource management systems. Additionally, contracted suppliers are subject to ongoing performance management and other oversight against defined business standards (*e.g.*, product standards and specifications, procurement practices, material handling/storage, control of measurement devices and instruments, monitoring and measurement processes, control of nonconforming materials, site security). This oversight is supported by production audits as part of the ongoing supplier management process.