House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Vaping in America: E-Cigarette Companies' Impact on Public Health
Responses to Questions for the Record to:
Ryan Nivakoff, CEO of NJOY, LLC

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

1. *As of February 6, 2020, the Food and Drug Administration (FDA) is prioritizing enforcement with respect to the unauthorized marketing of closed-cartridge non-tobacco and non-menthol flavored products. On January 28, 2020, NJOY informed FDA it would be voluntarily suspending its non-tobacco and non-menthol flavored disposable products. However, NJOY has two menthol products currently available for sale ("Cool Menthol" Loop Pods and NJOY Daily "Menthol") that are both marketed as "Menthol with a vanilla essence." Do these products contain flavor components beyond menthol? Is it possible that consumers, including young people under the age of 21, may view these menthol products as having an additional vanilla flavor profile? Either way, why would these products not be subject to FDA's guidance or NJOY's voluntary suspension of certain disposable products?*[1]

When FDA discusses "flavor" in the context of a regulated "tobacco product," it is referring to a product's "characterizing" flavor. *See*, *e.g.*, 21 U.S.C. § 387g (a)(1)(A); 21 C.F.R. § 1105.10 (a)(7). Combustion cigarettes are restricted to only "tobacco" and "menthol" characterizing flavors; nevertheless menthol combustion cigarettes permissibly contain multiple different secondary flavorants beyond menthol, including vanilla extract, vanillin, cocoa, and coffee extract, among others, while still properly being considered—and labeled as—"menthol." *See* https://www.rjrt.com/commercial-integrity/ingredients/cigarette-ingredients/; https://www.philipmorrisusa.com/-/media/Project/Altria/PMUSA/Products/Our-Products-and-Ingredients/pmusa-tobacco-and-flavor-ingredients.pdf.

Similarly, in the case of the flavor formulations for the NJOY Loop menthol and NJOY Daily menthol, these products overwhelmingly contain menthol and in sufficient quantity to have an unmistakable menthol content and flavor in general, and in comparison to the trace amounts of vanilla and vanillin in the products (*i.e.*, .09% of the total e-liquid formulation). As a consequence, the "characterizing flavor" of each of these two SKUs is "menthol." Therefore, each is properly labeled as "menthol" and neither is subject to removal from the market, either pursuant to the January 2, 2020 Guidance or NJOY's own voluntary decision with respect to Daily SKU's in characterizing flavors other than tobacco or menthol.[2]

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[1] The text of the operative Question for the Record is set forth in italics.

[2] Notwithstanding the foregoing, NJOY is not planning on filing a PMTA for the NJOY Loop product or its pods, which have not been distributed to retail for a substantial period of time, and, as a consequence, the NJOY Loop (including its menthol pods) will no longer be available for purchase after May 11, 2020.

The Honorable Diana DeGette (D-CO)

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 NJOY's products or of e-cigarette products in general? Why or why not?*

There are extremely low levels of youth use of NJOY products. The 2019 National Youth Tobacco Survey (NYTS) data shows that 1.2% of "current" high school ENDS users and no measurable amount of "current" middle school ENDS users use an NJOY product. Similarly, in FDA's own store inspection data for the two most recent complete inspection periods and five months of the current period, there were more than 351,119 FDA inspections and only 60 youth purchases of NJOY products.

FDA INSPECTION DATA			
	Oct 17 - Sep 18	**Oct 18 - Sep 19**	**Oct 19 - Feb 20**
Inspection Count	146,372	146,903	57,844
VIOLATIONS:			
JUUL	342	1,800	620
Vuse	1,729	1,768	317
blu	741	936	181
MarkTen	119	112	1
NJOY	20	28	12

NJOY continues to believe that its own responsible marketing and sales practices, and those of its retail partners, will remain the critical factor that will continue to minimize youth awareness and access to NJOY products. To the extent the January 2 guidance indicates that FDA will pursue enforcement action against companies that, unlike NJOY, are not adhering to responsible marketing and/or distribution practices, we believe that the guidance should have a salutary impact on further reducing youth use of ENDS products generally.

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?*

NJOY believes the NYTS, the Monitoring the Future Survey, the Youth Risk Behavior Survey, and FDA's own store inspection efforts are important to FDA's ability to monitor data and evolving trends with respect to youth e-cigarettes use. NJOY notes that, as part of its premarket tobacco products application (PMTA) filings to FDA, it will supplement this data with survey and other information regarding awareness and usage patterns and anticipates that the Agency will

receive similar data from multiple other sources. NJOY believes that these tools and data are sufficient for FDA and other federal agencies to monitor evolving trends with respect to youth use, but defers to FDA's own assessment on this issue. Nevertheless, NJOY strongly agrees that FDA and other federal agencies should have the resources (financial and otherwise) to monitor data and evolving trends with respect to youth use of e-cigarettes and would support reasonable proposals to further enhance the Agency's capabilities in this regard.

The Honorable Brett Guthrie (R-KY)

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).*

    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?*

NJOY believes that distributors, retailers, customers, and other interested parties will want, and should be able, to determine which products are the subject of a pending PMTA to FDA after the PMTA deadline. ENDS companies and manufacturers will be able to communicate, either through press release or direct communications with relevant parties, whether they have filed a PMTA for their products.

    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?*

In the unique circumstances of the transition from the issuance of the Deeming Rule and FDA's compliance policy to the implementation of the PMTA process, NJOY would support a targeted regulatory or legislative change that would permit FDA to publish a list of companies and products for which a PMTA is pending and, just as importantly, for which a PMTA is not pending, while preserving existing rules that preserve the confidentiality of a pending application. This would address the situation where there are products on the market pursuant to the Agency's compliance policy and for which there is legitimate interest in knowing whether they are the subject of a PMTA. This would also be distinct from the situation where a company files a PMTA on an entirely new product that is not currently on the market pursuant to FDA's compliance policy and for which a company has a reasonable expectation of non-disclosure by FDA of the existence of such filing, absent a prior public disclosure by the company itself.

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.

a. What was the result of your company's response to this request from FDA?

NJOY did not receive a letter from FDA following the enforcement blitz during the summer of 2018. FDA also did not request that NJOY submit a detailed plan to address and mitigate widespread use by minors. As noted above, FDA's data reveals that there has been no widespread use by minors of NJOY products.

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?*

a. If so, has information that your company has provided to law enforcement resulted in criminal enforcement actions?

NJOY only sells its products through tobacco retailers and on NJOY's company-owned website. NJOY closely monitors the marketplace for the counterfeit sale of NJOY products and, to date, has not uncovered evidence of counterfeit sales. Should that occur, NJOY would take all reasonable steps necessary to communicate with all relevant law enforcement entities regarding such activity.

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

NJOY adheres to best practice standards and protocols for the safety and protection of its supply chain, from selection of its e-liquid ingredients, blending of its e-liquids, manufacturing and filling of its devices, shipment of the finished product, through to ultimate retail sale to the consumer.

First, NJOY's e-liquids are made with high purity ingredients, including United States Pharmacopeia (USP)-grade nicotine, propylene glycol and vegetable glycerin, which are tested for purity prior to use. These ingredients are then blended in cleanrooms certified pursuant to standards set by the International Organization of Standards (ISO). The finished batches of e-liquid undergo analytical testing prior to release.

Second, NJOY's manufacturing partner for final assembly follows a Quality Control System that is certified to ISO 9001:2015. Products are assembled and filled in an ISO-certified cleanroom and undergo rigorous in-process and release testing. NJOY employs in-house and third-party inspectors to oversee its manufacturing process and conduct additional verification testing of components and finished products.

Third, NJOY tracks all quality test results associated with each batch of product it produces for sale. Further, full documentation of the components, composition, manufacturing, and quality protocols related to NJOY's products (spanning thousands of pages) have been shared with the FDA as part of NJOY's PMTA filings for its Ace and Daily products, and NJOY expects that FDA will conduct inspections of NJOY's manufacturing facilities as part of the Scientific Review process.

Fourth, post-manufacture, NJOY products are shipped and stored in temperature-controlled environments. NJOY products are also sold in tamper-evident packaging and each salable unit is printed with a code that identifies the specific manufacturing line and date of production.

Finally, NJOY's supply chain analytics allow it to track distribution of its products from the point of manufacturing to the end retail location. NJOY products are only sold through tobacco retailers and on NJOY's company-owned website.