

American Academy
of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™



August 7, 2018

Dr. Scott Gottlieb
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Dr. Gottlieb:

We write to bring to your attention numerous apparent violations of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) and the FDA's deeming rule prohibiting the marketing, without a marketing order from FDA, of electronic cigarette products that were not commercially marketed as of August 8, 2016. The attached slides, taken from statements made by manufacturers themselves and bloggers who promote e-cigarettes, present evidence that these products are being marketed illegally in violation of the Tobacco Control Act and FDA's deeming rule.

This is a matter of great urgency. In response to the skyrocketing use of Juul e-cigarettes by young people, you stated in a July 17, 2018, interview with PBS News Hour that preventing the use of e-cigarettes by young people is one of "our [FDA's] top concerns right now." You added, "And so we need to be very aggressive in trying to take steps to crack down, prevent the youth use of these products," and further correctly noted, "We also can't be in a position where we're playing Whac-A-Mole, where we are just going after one particular product and don't have in place rules that address the overall category." Most recently, in your August 2 announcement summarizing recent regulatory developments you referenced "reports that some companies may be marketing new products that were introduced after FDA's compliance period and have not gone through premarket review" and pledged to "take swift action wherever appropriate."

FDA does have a rule in place that gives it the authority and regulatory tools to prevent another Juul experience from happening. However, even as new products being modeled after Juul are being introduced into the marketplace, without constraints or controls, FDA does not appear to be exercising that authority.

Under the Tobacco Control Act, no "new tobacco product" (i.e., any product not commercially marketed on February 15, 2007 and any modification of a product marketed on that date) can legally be marketed unless FDA has granted an order permitting the marketing of

that product (a “premarket order”). On May 10, 2016, FDA issued a final rule (“the deeming rule”) extending its authority to e-cigarettes, cigars, and all other finished tobacco products not previously subject to its jurisdiction and established an effective date of August 8, 2016. When FDA issued the deeming rule, it permitted manufacturers with newly deemed products *already on the market before the effective date of the rule, August 8, 2016*, to continue to market those products for up to three years.¹ However, the deeming rule prohibited any new product from being introduced after August 8, 2016, unless the manufacturer had first filed a premarket review application with FDA and FDA had issued a premarket order for that product. To the best of our knowledge, FDA has never issued a premarket order for any new tobacco product introduced after August 8, 2016.

Subsequently, in May 2017 and later in August 2017, FDA extended the compliance period for products that were on the market before August 8, 2016. However, as FDA explained in the August 2017 guidance, the extended compliance period “did not authorize the marketing of any new tobacco product that was not on the market on August 8, 2016.”² Charts included in the guidance made clear that the only products affected by the extension were “new, newly deemed finished tobacco products that were on the market as of August 8, 2016.”

Despite this clear statement, manufacturers of e-cigarette products have introduced new products at an alarming pace in total defiance of law, with no apparent concern for FDA enforcement. Moreover, such products are being introduced at an accelerating rate, including a host of new products introduced subsequent to the explosive growth in youth use of Juul.

One vaping manufacturer, while promoting its new Stigpods product as being “finally introduced” in May 2018, aptly described the state of the market: “new revolutionary inventions seem to continually be released everyday [*sic*] in the vaping industry.”³ On May 27, 2018, an Instagram account, Salt Porn, stated, “It feels like there is a new pod system released every day and we receive tons of them. So many in fact that there is no way we can review them all.”⁴ Similarly, in February 2018, the website Vape Deals, announced, “The pod systems just keep coming! I’m having a hard time keeping track of all the new devices that are hitting the market.”⁵

Many of the newly introduced e-cigarette products appear to be attempting to capitalize on the recent marketing success of Juul and present products that are sleek and easily concealed,

¹ Manufacturers were permitted to continue marketing such products until August 8, 2018, provided they filed an application for a premarket order by that date and, if such an application were filed, one additional year pending FDA action on the application.

² Food and Drug Administration, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, Docket No. FDA-2017-D-2834, Aug. 4, 2017.

³ See Slide 3 in Appendix: Stigpods, “The highly anticipated STIG is available now!” *Stigpods Blog*, May 1, 2018, <https://stigpods.com/blog/the-highly-anticipates-STIG-is-available-now/>.

⁴ See Slide 4 in Appendix: Salt Porn *Instagram* post, May 27, 2018, <https://www.instagram.com/p/BjSkidRj5HS/?tagged=suorin>.

⁵ See Slide 5 in Appendix: Vape Deals, “7 Daze Zoor Closed Pod System \$19.80,” February 27, 2018, <http://vape.deals/7-daze-zoor-closed-pod-system-19-80/>.

deliver high levels of nicotine and, most important, are attractive to kids. These include not only products introduced by independent e-cigarette manufacturers, such as Kandy Pens' Rubi, MLV's PHIX, and Mylé Vapor's Mylé,⁶ but also products manufactured by major cigarette manufacturers, including Altria's MarkTen Elite⁷ and ITG Brands' myblu.⁸ R.J. Reynolds Vapor Co. recently announced the launch of its own Juul competitor, Vuse Alto.⁹ Yet, there is no evidence that any of these products have undergone review by the FDA as the law and FDA's own current Rule requires.

On February 28, 2018, *CSP Daily News* reported that “with the recent explosion of the Juul closed-system vaping device in the convenience store channel, major tobacco manufacturer Altria Group Inc. ... announced it will enter the closed-tank segment with a product called MarkTen Elite.”¹⁰ And in March, 2018, Altria's website announced that “MarkTen Elite will be available for purchase online in your location soon.”¹¹ The website has since been updated to “Introduc[e] the MarkTen Elite...A new pod-based product from MarkTen e-vapor” and is available for purchase.¹²

In February 2018, ITG Brands announced “the launch of myblu with its most expansive flavor range yet.”¹³ And in May, 2018, in an apparent effort to compete with Juul's most popular flavor, ITG Brands announced that it was introducing mango as a “new flavor” of myblu pods.¹⁴

As mentioned above, , on July 17, 2018, R.J. Reynolds Vapor Co. announced that in August it would launch its own Juul-like product, Vuse Alto.¹⁵

⁶ See Slide 7: Kandy Pens' Rubi, <https://www.kandypens.com/rubi-ultra-portable-compact-pod-based-vaporizer.html>; MLV's PHIX, <https://phixvapor.com/products/phix-starter-kit>; Myle Vapors' Myle, <https://www.mylevapor.com/>.

⁷ See Slides 9-13 and Altria's MarkTen Elite, <https://www.markten.com/elite-intro>.

⁸ See Slides 16-18 and ITG Brands' myblu, <https://www.blu.com/en/US/e-cigs>.

⁹ See Slides 14-15 and Craver, Richard, “Reynolds Vapor prepares national launch of new e-cig rival to Juul,” *Winston-Salem Journal*, July 17, 2018, https://www.journalnow.com/business/reynolds-vapor-prepares-national-launch-of-new-e-cig-rival/article_7ba10442-d438-575e-af23-794173089a8a.html

¹⁰ See Slide 9: *Convenience Store News*, “Altria Introducing Closed Vapor System,” February 28, 2018, <http://www.cspdailynews.com/category-news/tobacco/articles/altria-introducing-closed-vapor-system#page=0>.

¹¹ See Slide 11: Markten.com, “Two Pod Pack Trial Offer,” March 8, 2018, <https://www.markten.com/shop/elite/trial-offers>.

¹² See Slide 12, Markten.com, “Introducing MarkTen Elite,” <https://www.markten.com/shop/elite/trial-offers> July 27, 2018.

¹³ See Slide 16: Blu.com, February 21, 2018, <https://www.multivu.com/players/English/8243551-my-blu-electronic-vaping-device/>.

¹⁴ See Slide 18: Blucigs Twitter post, May 14, 2018, <https://twitter.com/blucigs/status/996208772711362565>.

¹⁵ Slides 14-15 and Craver, Richard, “Reynolds Prepares Launch of New E-cigarette Rival to Juul,” *Winston-Salem Journal*, July 17, 2018, https://www.journalnow.com/business/reynolds-vapor-prepares-national-launch-of-new-e-cig-rival/article_7ba10442-d438-575e-af23-794173089a8a.html

In an April 2018 Instagram message, Mylé Vapor advertised “lush ice” as a new flavor.¹⁶ In the same month, the company’s website advised viewers to “check out our Myle Pod flavors and look forward to more exciting options soon.” In January 2018, another independent vaping company, Space Jam, described its new product, “The Byrd,” as “a product the vaping industry has never seen before.”¹⁷

Many other new products appear to mimic the sleek design of Juul, including PHIX Vapor’s PHIX, KandyPens’ Rubi, Juno Vapor’s Juno, Smoketech’s Infinix and FIT, Coilart’s UME, Vapor Storm’s Stalker, Bo Vaping’s Bo One, Cig20’s STIK, XFire Vapor’s XFire, Kilo Eliquids’ KILO 1K, and Vapeccino’s MATE1.¹⁸ Since these products appear to be imitating the design of Juul, a product that achieved popularity in 2017 and 2018, it is most unlikely that they were on the market on August 8, 2016.

Moreover, Juul itself has just announced a new line of lower-nicotine products that evidently will first be marketed in 2018.¹⁹

In addition to the Juul-style products that look like a USB stick, new concealable e-cigarettes have recently been introduced in additional shapes. An electronic cigarette known as “Suorin” was marketed online as being “new” in September 2017 and the online advertisement for it invited viewers to submit a “pre-order,” an indication that even on that date the product may not have been commercially marketed.²⁰ The earliest online review we could find for the product was dated January 2017²¹ and the first Instagram posts for the product were dated April 25, 2017.²²

Other new products in various sleek, concealable shapes include KandyPens’ Feather, SMOK’s ROLO Badge, Kado’s Stealth Pod Vape, and Daze Manufacturing’s ZOOR.²³ Based

¹⁶ See Slides 19-21: Mylé Vapor Instagram post, April 3, 2018, https://www.instagram.com/p/BhIFhSDh4_I/?taken-by=mylevapor; Mylé Vapor, April 16, 2018, <https://mylevapor.com/>.

¹⁷ See Slide 22: Space Jam, January 29, 2018, <https://globenewswire.com/news-release/2018/01/29/1313815/0/en/Space-Jam-Tells-Consumers-to-Give-Smoking-THE-BYRD-With-Its-New-Closed-Tank-Vaping-Device.html>.

¹⁸ See Slides 24-38: <http://phixvapor.com/>; <https://www.kandypens.com/>; <http://junovapor.com/shop-juno-kits/twelve-juno-menthol-kit>; <https://ejuceplug.com/products/smoktech-infinix-kit>; <https://www.smoktech.com/kit/fit>; <https://www.strictlyecig.com/coilart-ume.html>; <https://www.dhgate.com/store/product/original-vapor-storm-stalker-kit-ecig-starter/415693502.html>; <https://bovaping.co/>; <https://cig2o.com/stik>; <https://xfirevapor.com/>; <https://www.kiloeliquids.com/product/kilo-1k-device/>; <http://www.vapeccino.com/>.

¹⁹ *The Verge*, “Juul plans to release lower-nicotine vape juice starting in August,” July 12, 2018, <https://www.theverge.com/2018/7/12/17565066/juul-labs-reduces-nicotine-dose-virginia-tobacco-mint-flavors>.

²⁰ See Slide 40: Suorinair, September 25, 2017, <https://www.instagram.com/p/BZe8s5llcOC/?taken-by=suorinair>.

²¹ See Slide 42: Tony Huang vapejoy, “Suorin air coming,” YouTube, January 3, 2017, <https://www.youtube.com/watch?v=9y2Z5ADXPzY>.

²² See Slide 41: Suorinair, April 25, 2017, https://www.instagram.com/p/BTUp_B-FW1K/?taken-by=suorinair.

²³ See Slides 43-6: Vapor Nation, <https://www.vapornation.com/blog/kandypens-feather-review-ecig-vaporizer.html>; SMOK Twitter post, <https://twitter.com/SMOKTECHLOGY/status/955741967790456832>; AVAndy reviewing Kado’s Stealth Pod Vape, <https://www.youtube.com/watch?v=Pv4Sr3tCxyM>.

on the date of the initial appearance of social media posts and YouTube product reviews, it appears unlikely that these products were introduced by August 8, 2016. Joyetech announced it is launching the e-cigarette TEROS on May 18, 2018.²⁴ This announcement joins a long list of products launched after August 8, 2016, listed on Joyetech's website with specific launch dates.²⁵

It is apparent that a wave of new e-cigarette products continues to be introduced, despite the fact that no such products can legally be introduced after August 8, 2016, without a marketing order from FDA. As we have in the past, we urge FDA to take quick and aggressive action to enforce the law before one or more of these products becomes the next Juul phenomenon among our nation's youth. We hope that you will use the information provided in this letter to prevent the marketing of products that have evaded the mandatory review process without the necessity of our taking legal action.

Sincerely yours,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

cc: Mr. Mitch Zeller, Director, Center for Tobacco Products

²⁴ See Slide 47: Joyetech, May 18, 2018, : <http://www.joyetech.com/news/joyetech-teros-launching/>.

²⁵ See Slide 49: Joyetech, July 17, 2018, <http://www.joyetech.com/news/joyetech-teros-launching/>.