



American
Heart
Association.



August 11, 2021

Mr. Mitchell Zeller
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: Inadequacy of Possible Marketing Order Restrictions for Flavored E-Cigarettes

Sent by e-mail.

Dear Director Zeller:

The undersigned public health and medical organizations have previously urged FDA not to grant marketing authorization for any non-tobacco flavored e-cigarette or e-liquid products, including menthol flavored products.¹ Our opposition to such marketing orders is based on the compelling real-world evidence that flavored products have fueled the epidemic of e-cigarette use, and resulting nicotine addiction, among young people.

It has been suggested by some that it may be possible for a company to demonstrate that its flavored product meets the statutory standard of being “appropriate for the protection of the public health,”² even if the product has attracted youth, if the company agrees to certain restrictions and conditions on the sale of its product, or if FDA imposes such restrictions and conditions, in an effort to reduce youth usage of e-cigarettes. FDA itself suggested this possibility in its response to the January 13, 2021 letter from Senator Dick Durbin (D-III.) and eleven other U.S. Senators, when it wrote that “we might consider an applicant’s proposal to include specific restrictions on sale and distribution” that could support a showing that permitting the marketing of the product would meet the public health standard.³ This possibility also is indicated by the requirements imposed, for example, as part of the Premarket Tobacco Product Application (PMTA) marketing order issued to Philip Morris for its IQOS heated

¹ See e.g., Letter from Am. Acad. of Pediatrics et al. to Dr. Stephen M. Hahn, M.D., Comm’r, FDA, re Enforcement Priorities and Premarket Review of E-Cigarettes (Oct. 23, 2020), https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2020_10_23_Letter_to_FDA_on_2020_MMWR_Data.pdf; Am. Acad. of Pediatrics et al., Principles to Guide FDA Premarket Review of E-Cigarettes and Other Deemed Products, https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2020_08_10_Premarket-Principles.pdf. Our organizations also oppose marketing orders for other flavored tobacco products.

² 21 U.S.C. §387j(c)(2)(A).

³ Letter from Andrew Tantiillo, Acting Assoc. Comm’r for Legislative Affairs, FDA, to The Honorable Dick Durbin (Apr. 28, 2021).

tobacco product in 2019.⁴ It should be noted that the IQOS marketing order is now being used by Philip Morris International to mislead consumers and regulators across the globe to believe that FDA, and you personally, have strongly endorsed IQOS.⁵ (See exhibit to this letter, a flyer about IQOS distributed outside the US by Philip Morris International in June, 2019.) Thus, the stakes are high, in the U.S. and in the international tobacco control arena.

We write now, with the September 9th deadline rapidly approaching, to share our strongly-felt view that no non-tobacco flavored e-cigarette or e-liquid products can meet the public health standard, even if a marketing order were to include restrictions and conditions regarding youth access and use.⁶ This is particularly the case because e-cigarette marketing by Juul and others have already firmly created the view among adolescents that these products are cool and attractive. As Dr. Robert Jackler of the Stanford University School of Medicine recently testified before the Subcommittee on Consumer Protection, Product Safety and Data Security of the Senate Committee on Commerce, Science and Transportation, the image Juul has created as a “youth brand” cannot be undone and must be taken into consideration by the FDA.⁷

The discussion below considers three categories of possible marketing order restrictions and conditions: (1) youth access restrictions; (2) voluntary marketing restrictions; and (3) post-market surveillance in the form of various reporting and study requirements. As long as flavored e-cigarettes remain on the market, such restrictions and conditions will prove entirely inadequate to protect kids.

Youth Access Restrictions

For decades, tobacco companies have argued that the best way to prevent youth use of tobacco products is through youth access restrictions. However, it has long been apparent that the industry has argued for such restrictions as a shield against implementation of far more effective policies to curb youth usage of tobacco products. The industry has known that, at best, youth access restrictions have a modest impact on youth use and more often are not enforced well enough to have any major impact.

As applied to flavored e-cigarettes, which already are intensely popular among youth, even enhanced youth access restrictions, though necessary, will hardly be sufficient to stem the

⁴ FDA, PMTA Marketing Order for Marlboro Heatsticks, et al., Appendix B, at 14-15 (Apr. 30, 2019), <https://www.fda.gov/media/124248/download> (“PMTA Marketing Order”).

⁵ Lauren K. Lempert & Stanton Glantz, *Analysis of FDA’s IQOS marketing authorization and its policy impacts*, 30 Tobacco Control 413, Fig. 2 (2021) (Information flyer about IQOS being distributed outside the USA by Philip Morris International in June 2019).

⁶ This should not be taken to imply an endorsement of the authorization of a PMTA for any particular tobacco-flavored e-cigarette as meeting the public health standard.

⁷ *Toxic Marketing Claims and Their Dangers*, 117th Cong. (2021), <https://www.commerce.senate.gov/2021/7/toxic-marketing-claims-and-their-dangers>.

tide of youth e-cigarette usage.⁸ As long as flavored e-cigarettes are on the market, kids will find ways to get them, particularly those products that already have addicted millions of youth users.

First, youth access laws were in place during the period when youth e-cigarette use rose to epidemic levels; plainly they were inadequate to prevent the epidemic. According to the 2020 National Youth Tobacco Survey (NYTS), 22.2% of high school e-cigarette users report obtaining e-cigarettes from a gas station or convenience store in the past month and 17.5% from a vape shop.⁹ There are simply too many ways for underaged kids to get these products, such as “social sources” like legal-age friends and relatives. The core problem is the product itself – its appeal to youth and its addictiveness – not simply youth access to the product.

Second, youth access restrictions in marketing orders leave the design and enforcement of the restrictions to the company, which has every incentive to design systems that have the appearance of effectiveness, but still allow sales to kids. Indeed, North Carolina’s lawsuit against Juul featured detailed allegations that Juul knowingly created a system of internet sales with age-verification techniques that appeared to use third-party verification, but in practice had numerous loopholes that Juul knew continued to allow sales to underage individuals.¹⁰ Prior to the settlement of that lawsuit, the court found that Juul would be subject to sanctions for having deleted data concerning the company’s age-verification system instead of producing it in pretrial discovery.¹¹

The tobacco industry has a long history of implementing completely ineffective programs to limit youth access to its products in response to public concern about youth usage. For example, a study of the cigarette companies’ We Card program in the 1990s found that stores with the We Card signs had average youth sales rates roughly equal to stores with no signs at all and were significantly more likely to make illegal sales to minors than those retail outlets with government-sponsored no-youth-sales signs.¹²

Third, even effective youth access restrictions only reduce youth usage in the long-term, as found by the Institute of Medicine,¹³ which studied raising the age of sale to 21, a reform

⁸ See, e.g., Rebecca S. Williams, Jason Derrick, & K. Jean Phillips, *Cigarette sales to minors via the internet: how the story has changed in the wake of federal regulation*, 26 Tobacco Control 415 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5236008/>.

⁹ Teresa W. Wang et al., *Characteristics of e-Cigarette Use Behaviors Among US Youth, 2020*, 4 J. Am. Med. Ass’n Network Open 1, 6 (2021), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780705>.

¹⁰ Complaint and Motion for Preliminary Injunction, *State of North Carolina v. JUUL Labs, Inc.*, Superior Court No. 19-CVS-2885 (May 15, 2019), ¶¶ 74-95.

¹¹ Virginia Bridges, *Judge’s ruling could be ‘death penalty’ for e-cigarette maker Juul in NC lawsuit*, News & Observer (May 18, 2021), <https://www.newsobserver.com/news/business/article251468028.html>.

¹² David W. Cowling & Doug M. Robbins, Research Letter, *Rates of Illegal Tobacco Sales to Minors Varies by Sign Type in California*, 90 Am. J. Pub. Health 1792, 1792 (2000), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1446391/>.

¹³ Institute of Medicine, *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products*, at 214 (2015).

enacted in 2019 by Congress. Given the continuing epidemic of youth use of e-cigarettes, this problem must be addressed now by removing flavored products from the market.

Finally, in his May 26, 2021 remarks to the E-cigarette Summit, Matt Holman, Director of the Office of Science at the Center for Tobacco Products, indicated that FDA is interested in technology that would allow only adults to activate e-cigarettes. Press reports indicate that “device-locking” technology may be featured in Juul’s PMTA, which may also feature devices that are Bluetooth-enabled.¹⁴ The effectiveness of technology in blocking youth access to e-cigarette devices is speculative, with no publicly available data showing that they actually work. Moreover, any technological “fix,” in which the tobacco company is the recipient of user data, particularly involving Bluetooth technology that the company designs and controls, raises substantial risks. Trusting tobacco companies to use this invasive technology to learn more about the e-cigarette use patterns of consumers opens the door to those companies using the technology to inappropriately increase use and market their products, such as monitoring nicotine delivery to sustain addiction.¹⁵ Such technology also raises substantial privacy concerns. Tobacco companies and e-cigarette companies, including Juul specifically, have sworn that they don’t seek to attract youth or other non-tobacco users, but the evidence is overwhelming that they have used modern technological advances to do just that.

There is no reason to believe that further enhanced technology will effectively prevent youth usage of e-cigarettes. Greater technological sophistication in these products – in the hands of the companies that have caused the youth e-cigarette epidemic, and an industry with a record of deception that goes back decades – puts our nation’s kids at even greater risk. As experience shows, any policy that depends on the good faith and truthfulness of a tobacco company leads to a public health nightmare. Tobacco companies have a long history of product “innovation” calculated to attract and addict youth.

Marketing Restraints

It also has been suggested that because e-cigarette marketing to kids contributed to the youth usage epidemic, a curb on such marketing may make it possible for flavored products to remain on the market despite their youth appeal. Thus, manufacturers of flavored e-cigarettes may seek premarket authorization based on promises made to voluntarily curb marketing directed at young people. But such promises are no substitute for action to remove the kid-appealing products from the market.

¹⁴ Richard Craver, *Juul plans to include Bluetooth device-locking technology with FDA regulatory application*, Winston-Salem Journal (Feb. 26, 2020), https://www.journalnow.com/business/juul-plans-to-include-bluetooth-device-locking-technology-with-fda-regulatory-application/article_eb4797cd-db62-5130-a46f-d86ecd846eeb.html.

¹⁵ See generally Letter from Am. Acad. of Pediatrics et al. to Mitch Zeller, Dir., Ctr. for Tobacco Products, FDA re Bluetooth Technology in Tobacco Products (July 16, 2020), https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2020_07_16-Letter-to-FDA-re-Bluetooth-Technology-in-Tobacco-Products.pdf.

First, the evidence is clear: voluntary marketing restrictions adopted by tobacco companies don't work. This is not the first time the tobacco companies have adopted voluntary marketing restrictions and then claimed they would solve the problem of marketing to youth. Throughout the 1960's and 1970's the tobacco companies contended that mandatory government restrictions on marketing were unnecessary because the industry had adopted voluntary marketing restraints. Study after study proved these claims false;¹⁶ indeed, it was precisely because of the number of times the tobacco industry had falsely claimed that voluntary restrictions were sufficient that Congress determined that mandatory rules were necessary by passing the Family Smoking Prevention and Tobacco Control Act in 2009.

Nothing in the history of the tobacco industry, or the vaping industry, suggests that this time is different. The industry is well aware that virtually all initiation of tobacco products occurs during adolescence; thus, the industry's long-term viability has always depended on recruiting youth to use its products. The e-cigarette companies are no different. Their actions have resulted in a prevalence rate among high school students at around 20%,¹⁷ whereas adult prevalence is 4.5%.¹⁸ In short, even while claiming it does not market to youth, these companies have made e-cigarettes a recreational product for kids. The tobacco industry has often found it useful to appear concerned about youth usage of its products, but it has never kept its promises to limit marketing to kids. There is no reason to expect it to do so now.

Second, since the FDA was given jurisdiction over tobacco products by Congress, it has been reluctant to impose any substantial new marketing restrictions, presumably out of concern that the industry would attack any such rules in court as a violation of the First Amendment. The concerns about the threat of industry attack are not misplaced. The industry sued over the marketing restrictions in the 2009 law and has sued repeatedly on First Amendment grounds over the FDA's proposed warning labels. Thus, to the extent that FDA is willing to *require* marketing restrictions as a condition of a premarket order, those restrictions have been very limited. For example, neither the IQOS PMTA nor the Modified Risk Tobacco Product (MRTTP) marketing orders foreclosed the use of social media by Philip Morris; rather,

¹⁶ See e.g., Richard W. Pollay, *Promises, promises: self-regulation of US cigarette broadcast advertising in the 1960s*, 3 Tobacco Control 134 (1994), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1759332/>; John W. Richards et al., *The tobacco industry's code of advertising in the United States: myth and reality*, 5 Tobacco Control 295 (1996), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1759528/>; Charles King, III & Michael Siegel, *The Master Settlement Agreement with the Tobacco Industry and Cigarette Advertising in Magazines*, 346 New Eng. J. Med. 504 (2001), <https://pubmed.ncbi.nlm.nih.gov/11519505/>; Elizabeth M. Barbeau et al., *Does cigarette print advertising adhere to the Tobacco Institute's voluntary advertising and promotion code: An assessment*, 19(4) J. Pub. Health Pol'y 473 (1998). See also NATIONAL CANCER INSTITUTE, NIH PUB. NO. 07-6242, *THE ROLE OF THE MEDIA IN PROMOTING AND REDUCING TOBACCO USE*, TOBACCO CONTROL MONOGRAPH NO. 19, at 78-82 (2008), http://cancercontrol.cancer.gov/tcrb/monographs/19/m19_complete.pdf; U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION, *PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL* 507, 555 (2012), <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html>.

¹⁷ Teresa W. Wang et al., *E-cigarette Use Among Middle and High School Students – United States, 2020*, 69 Morbidity & Mortality Wkly. Rep. 1310, 1310 (Sept. 18, 2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf>.

¹⁸ Monica E. Cornelius et al., *Tobacco Product Use Among Adults – United States, 2019*, 69 Morbidity & Mortality Wkly. Rep. 1736, 1736 (Nov. 20, 2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6946a4-H.pdf>.

FDA simply imposed age- and identity-verification requirements for the websites, applications and social media platforms on which IQOS will be promoted.¹⁹ Any more extensive restrictions, such as prohibiting the use of social media or prohibiting themes, imagery or models that appeal to youth, are likely to prompt the industry to raise First Amendment issues.²⁰ Unlike in other countries that are able to more extensively ban marketing that will impact youth, if FDA is to live up to its mandate to protect kids, the agency must place a higher priority on removing from the market the products that have the greatest appeal to youth. FDA cannot rely on voluntary post-market restrictions to fully curb marketing that impacts youth, or to respond rapidly to identify and require the removal of advertising targeting youth, as a sufficient means to protect our nation's young people.

Third, any voluntary marketing restraints promised now cannot undo the harm already done by the industry's egregious marketing directed at young people. Juul and other e-cigarette companies' sophisticated use of social media and other marketing succeeded in creating extraordinary demand for e-cigarettes among young people. Companies still benefit from that marketing, as the epidemic of youth usage continues long after Juul voluntarily ceased social media marketing and FDA's enforcement blitz against e-cigarette companies clearly targeting youth. As researchers at the Stanford University School of Medicine found, "In the 3.3 years before JUUL halted its promotional social media posting, #juul had accumulated about a quarter of a million posts. In the 7 months since the cessation, the average number of daily posts tripled with the result that posts grew rapidly to over half a million."²¹

In the words of former FDA Commissioner Scott Gottlieb, "They cleaned [their marketing] up and it's currently focused on adult smokers . . . *But you can't un-ring the bell and undo what was done since they launched.*"²² (emphasis added). The only way to effectively bring the epidemic of youth usage under control is to take off the market the flavored products that youth continue to use.

¹⁹ PMTA Marketing Order, *supra* note 4,; FDA, MRTP Marketing Order for Marlboro Heatsticks, et al., Appendices B and C, at 6, 9, 11-12 (July 7, 2020), <https://www.fda.gov/media/139797/download>.

²⁰ It should be noted that extensive restrictions imposed as part of a consent order settling a lawsuit, like those agreed to by Juul in its settlement of the North Carolina lawsuit, do not raise similar First Amendment concerns because they are part of an agreement by the parties to the lawsuit and are not being imposed by the government as a condition of allowing the continued sale of a product. See Final Consent Judgment, *State of North Carolina v. Juul Labs, Inc.*, Superior Court No. 19-CVS-2885 (June 28, 2021).

²¹ Robert K. Jackler et al., Rapid Growth of Juul Hashtags After the Company Ceased Social Media Promotion 7 (2019), https://tobacco-img.stanford.edu/wp-content/uploads/2021/07/21231755/HashtagJUUL_Project_2.5.2021F.pdf.

²² Deanna Paul, *North Carolina sues JUUL, setting up a fresh legal fight for the embattled e-cigarette company*, Wash. Post, May 15, 2019, https://www.washingtonpost.com/health/2019/05/15/north-carolina-sues-juul-setting-up-fresh-legal-fight-embattled-e-cigarette-company/?noredirect=on&utm_term=.b49e601ae199.

Post-market Surveillance and Studies

In its orders authorizing the IQOS heated tobacco product, including its menthol-flavored product, FDA imposed on-going post-market reporting and study requirements.²³ Any suggestion that such post-market surveillance is sufficient to protect our youth from flavored e-cigarettes is seriously misguided.

Post-market reporting is no substitute for a rigorous premarket assessment of the likely impact of flavored e-cigarettes on youth and on public health generally. The devastating impact of Juul on our nation's youth happened with stunning speed and took FDA by surprise. Only after millions of kids became – and remain – addicted did the data demonstrate the seriousness of the problem. Juul is only one example where the industry was able to engage in marketing practices out of sight of the FDA, and by the time the FDA could react, the harm had already been done and other companies followed suit with products emulating Juul. Post-market surveillance is simply too little, too late.

Reliance on post-market surveillance is an even less appropriate measure for the e-cigarette PMTAs FDA is currently reviewing, which were submitted on or before September 9, 2020, *because those products have been on the market for years and their impact on youth, and public health, has already been shown by real-world experience. They are already seen by youth as products that are cool and appealing.* In effect, the evaluations FDA is currently undertaking as to those products are *post-market* evaluations, and surveillance has shown the lack of effectiveness of youth access and voluntary marketing restrictions. For products with characteristics, like flavors, that have fueled the current e-cigarette youth epidemic, it would make no sense to authorize their continued sale on the ground that FDA can conduct product surveillance going forward to determine their impact on youth and public health more generally. FDA already knows, and can rely on, the real-world post-market experience with these products. That experience should determine whether e-cigarette products are authorized for continued sale, regardless of what reporting FDA can require after the authorization is made.

For these reasons, and those presented in our previous correspondence with FDA, non-tobacco flavored e-cigarettes and e-liquids cannot possibly meet the public health standard for issuance of marketing orders, even with restrictions and conditions relating to youth access, marketing restraints and post-market surveillance. Protection of the nation's young people from flavored e-cigarettes requires that PMTAs for those products be denied.

Thank you for your consideration of our views.

²³ PMTA Marketing Order, *supra* note 4, Appendix B at 9-13; MRTP Marketing Order *supra* note 18.

Sincerely,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

CC: Dr. Janet Woodcock, FDA Acting Commissioner

FDA Permits Sale of IQOS in the US

The FDA has authorized* the marketing of IQOS, which allows it to be sold in the US. The FDA determined that **this authorization is appropriate for the protection of public health** taking into account the risks and benefits to the population as a whole, including users and non-users of tobacco products, particularly youth.

*Authorization does not mean this product is safe or "FDA Approved."

Some key considerations of the FDA, among others:

1



IQOS produces fewer or lower levels of some toxins than combustible cigarettes.

The FDA's rigorous science-based review found that **the aerosol produced by IQOS contains fewer toxic chemicals than cigarette smoke**, and many of the toxins identified are present at lower levels than in cigarette smoke.

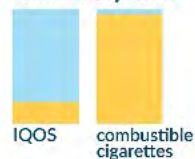
Carbon monoxide exposure from IQOS aerosol **is comparable** to environmental exposure

Levels of acrolein are



89% to 95% lower than from combustible cigarettes

Levels of formaldehyde are



66% to 91% lower than from combustible cigarettes

2



Available data, while limited, indicate that **few non-tobacco users would be likely to choose to start using IQOS, including youth.**

3



IQOS delivers nicotine in levels close to combustible cigarettes

suggesting a likelihood that IQOS users may be able to completely transition away from combustible cigarettes and use IQOS exclusively.



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While the authorization of new tobacco products doesn't mean they are safe, the review process makes certain that **the marketing of the products is appropriate for the protection of the public health**, taking into account the risks and benefits to the population as a whole. This includes how the products may impact youth use of nicotine and tobacco, and the potential for the products to completely move adult smokers away from use of combustible cigarettes.”

Mitch Zeller, J.D.,
Director of the FDA's Center for Tobacco Products.

Regulations



The FDA has placed stringent marketing restrictions and postmarket requirements on IQOS, in an effort to prevent youth access and exposure.



As required by the US tobacco law, FDA must be notified among other things of IQOS labeling, advertising, marketing plans, including information about specific adult target audiences, and plans to restrict youth access and limit youth exposure to the products' labeling, advertising, marketing and promotion, particularly websites and through social media platforms.



The FDA also requires all package labels and advertisements for IQOS to include a warning about the addictiveness of nicotine, in addition to other warnings required for cigarettes, to prevent consumer misperceptions about the relative addiction risk of using IQOS compared to combustible cigarettes.

WARNING: This product contains nicotine. Nicotine is an addictive chemical.