FDA should use its regulatory authority and take immediate steps to tackle the youth e-cigarette epidemic

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FDA's recent statements addressing the alarming youth e-cigarette epidemic called on companies to take voluntary actions[1] and proposed steps FDA might take[2] to reduce youth access to flavored tobacco products. These tentative steps will not have any practical effects in the foreseeable future to address youth e-cigarette use. The Family Smoking Prevention and Tobacco Control Act[3] (Tobacco Control Act) gives FDA broad authority to regulate e-cigarettes and other tobacco products in several ways. FDA should use that authority by withdrawing its previous discretionary decision to not enforce the Tobacco Control Act's premarket review and approval requirements for e-cigarettes, and should immediately issue and implement regulations that would more effectively tackle the crisis and prevent more youth from initiating with e-cigarettes and becoming addicted to nicotine.

1. FDA should remove from the market all e-cigarettes that have not received FDA premarket review and authorization – Tobacco Control Act section 910

A fundamental purpose of the Tobacco Control Act is "to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco."[4] Central to achieving this public health purpose is the Act's requirement that all "new tobacco products" (tobacco products not marketed in the United States as of February 15, 2007, including all newly "deemed" tobacco products such as e-cigarettes, hookah, and cigars) must obtain FDA premarket review and authorization under Tobacco Control Act section 910(a) before they can be sold in the United States.[5]

After a company submits a premarket tobacco product application (PMTA), FDA reviews the

[1] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm
[2] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm
[3] Family Smoking Prevention and Tobacco Control Act, Public Law 111-31, (June 22, 2009).
[4] Family Smoking Prevention and Tobacco Control Act, Public Law 111-31, section 3(2), 21 U.S.C. 387 note, (June 22, 2009).
[5] Family Smoking Prevention and Tobacco Control Act, Public Law 111-31, section 910(a), 21 U.S.C. 387j, (June 22, 2009). A marketing authorization order under section 910(c)(1)(A)(i) is required unless FDA issues an order under section 905(j) finding the product "substantially equivalent" to a predicate product that was sold in the U.S. as of February 15, 2007 or FDA issues an order finding the product exempt from the requirements of substantial equivalence because it only has "minor modifications" to a grandfathered product. These pathways are not available for e-cigarettes because they were not marketed in the U.S. before February 15, 2007.

application to determine if the product meets statutory standards, including whether it is "appropriate for the protection of the public health." In making this public health determination, FDA is required to consider (among other factors) the risks and benefits to the population as a whole, including whether it is likely that non-users (including youth) will start using the product. All newly deemed tobacco products, such as e-cigarettes and e-liquids, are subject to the premarket requirements. New tobacco products, including e-cigarettes, sold in the U.S. without the required marketing authorization orders are considered adulterated under section 902 and misbranded under section 903. The sale of adulterated or misbranded tobacco products is prohibited under 21 U.S.C. 331 and subject to FDA enforcement actions including seizure, injunctive actions, and civil money and criminal penalties.

As a matter of enforcement discretion, in August 2017 FDA issued a revised guidance[6] that further extended certain future compliance dates for requirements under the Deeming Rule. In particular, the revised compliance policy extended the compliance dates for the submission of the required premarket applications (i.e., premarket tobacco applications, substantial equivalence reports, and substantial equivalence exemption requests) to August 8, 2022 for deemed noncombustible new tobacco products (such as e-cigarettes and e-liquids) that were on the market as of August 8, 2016. (FDA extended the compliance date for deemed combustible new tobacco products such as cigars, pipe tobacco, and hookah to August 8, 2021.) This policy meant that e-cigarette manufacturers were not required to submit premarket applications until August 2022 – ***six years*** after the effective date of the Deeming Rule – for products that were on the market as of August 8, 2016 (which included most ENDS or e-cigarettes). What's more, this revised policy allowed products to remain on the market indefinitely after that date unless and until FDA denies the application.

Despite the Tobacco Control Act's clear intent and wording, FDA's steps have emasculated the law. Thousands of e-cigarettes remain on the market without any agency review and without demonstrating public health benefit. On November 15, 2018, FDA Commissioner Scott Gottlieb directed FDA's Center for Tobacco Products (CTP) to "revisit" this discretionary compliance policy[7] as it applies to e-cigarettes and other ENDS products that are flavored (but excluding tobacco, mint, and menthol flavored e-cigarettes); that are not sold in age-restricted, in-person locations; or that are not sold online.

This means that CTP could, in its discretion, take enforcement action against e-cigarette and e-liquid manufactures who are selling products without a premarket authorization order if those products have flavors other than tobacco, mint, or menthol, are not sold in age-restricted, in-person locations, or if sold online, are not sold under "heightened practices for age verification." But FDA's announcement that it would reconsider this policy ***for some e-cigarettes*** is unlikely to be effective. First, it leaves mint, menthol, and tobacco-flavored Juuls and other e-cigarette products on the market despite their not having received any agency review

[6] https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf
[7] Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes, November 15, 2018. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm

and without demonstrating public health benefits. Second, as discussed below, to date no age verification scheme exists that effectively prevents youth from purchasing tobacco products online (discussed below). ***FDA should fulfill its legal mandate and immediately remove from the market all e-cigarettes that have not obtained FDA premarket review and authorization, including mint, menthol, and tobacco-flavored Juuls and other e-cigarettes and nicotine products widely used by youth.***

2. FDA should remove from the market all e-cigarettes that make unauthorized modified risk claims, including implicit as well as explicit claims – Tobacco Control Act section 911

For e-cigarettes that remain on the market, FDA should use its authority under Tobacco Control Act section 911 to clamp down on companies making unauthorized cessation, health, and other modified risk claims in their labeling and advertising. Section 911 prohibits companies from making these claims without first obtaining FDA authorization based on sound scientific evidence. To be granted a modified risk tobacco product (MRTP) order, a company must demonstrate that the product, as actually used by consumers, will both (1) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (2) benefit the health of the population as a whole taking into account both users of tobacco products and non-users, including youth. Hundreds are e-cigarettes are currently being marketed with not only explicit, but also implicit modified risk claims, but have not received a MRTP marketing order. Juul's advertising campaigns (Figure 1) featuring testimonials from cigarettes smokers who say they used Juul to help them quit smoking are examples of implicit modified risk claims.

Figure 1: Implicit claims in Juul advertisement featuring testimonials from cigarette smokers.

At FDA's January 18, 2019 public hearing on e-cigarettes, a panelist asked if there is data showing the impact of implicit advertising claims on youth. One recent study[8] looking at how adolescents and young adults perceive e-cigarette advertisements with implicit (as well as explicit) smoking cessation claims found that more than 20% of the participants selected "helps me quit smoking" as applicable to the implicit advertisements, and the phrases "less harmful to my health" and "healthier than regular cigarettes" were consistently identified by many participants as applicable to the implicit ads even though the ads do not say a single word about health.

However, it is essential to recognize that it is not incumbent upon the public health community to prove that implicit claims harm youth. Rather, the Tobacco Control Act is crystal clear that ***the burden is on the applicant to demonstrate that a modified risk product (a product marketed with implicit or explicit advertising or labeling claims that it is less harmful or reduces the risk of tobacco related disease) will reduce harm to individuals and will benefit the public health.***

Section 902 states that any tobacco product marketed in violation of section 911 ***shall*** be deemed to be adulterated. The many e-cigarettes marketed with unauthorized modified risk claims violate section 911 and are therefore adulterated under Section 902 and should be immediately enforced against.

Products that are sold for the treatment of tobacco dependence, including smoking cessation, or for other therapeutic purposes are not modified risk products if they have been approved for sale under FDA's drug and device authorities. However, products that are sold as cessation or therapeutic aids but have not received FDA drug or device approval are subject to enforcement and should be immediately removed from the market.

No e-cigarette to our knowledge has obtained either MRTP authorization or FDA approval to be sold as a cessation or therapeutic aid. FDA has the authority to and should immediately enforce against these products.

3. FDA should stop making unsupported cessation claims

FDA has issued a variety of statements characterizing e-cigarettes as less harmful nicotine delivery devices. These statements may be misinterpreted by youth to suggest that youth should e-cigarettes to help them quit smoking, or that e-cigarettes are generally safe for youth to use. It would be illegal for an e-cigarette company to make these statements without first presenting supporting scientific evidence to the FDA.

For example, on March 15, 2018, FDA Commissioner Scott Gottlieb said, "… to successfully address cigarette addiction, we must make it possible for current adult smokers who still seek nicotine to get it from alternative and ***less harmful sources."***[9] And on November 15,

[8] Kim M, Ling P, Ramamurthi D, Halpern-Felsher B.Youth's Perceptions of E-cigarette Advertisements with Cessation Claims Tob Regul Sci.™ 2019;5(2):94-104 DOI: https://doi.org/10.18001/TRS.5.2.1 (in press)

[9] Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette

2018, Dr. Gottlieb said, "We must recognize the potential for innovative, ***less harmful products*** that can efficiently deliver satisfying levels of nicotine to adults who want them."[10]

The MRTP claims that e-cigarettes are "less harmful" nicotine delivery devices have not been substantiated. In fact, as discussed above, if e-cigarette companies made these exact statements, they would be illegal modified risk claims because they have not been proven with rigorous scientific evidence. FDA should stop making these claims and others like them that state or imply that e-cigarettes are effective for adult cessation unless and until FDA demonstrates their validity.

4. FDA should prohibit all flavors in e-cigarettes, including mint and menthol – Tobacco Control Act section 907

There is no dispute that the removal of flavors from all tobacco products, especially e-cigarettes, would make them less attractive to kids. Most kids report that it is the flavors that first attracted them to use e-cigarettes; the majority of youth in the US who try tobacco initiate with flavored tobacco products.[11] We incorporate by reference a separate comment we submitted that provides scientific data and a detailed analysis supporting a prohibition of flavors in e-cigarettes.[12]

To minimize e-cigarettes' appeal to youth, ***FDA should use its authority under section 907 to prohibit all flavors in e-cigarettes, including mint and menthol.***

FDA's proposed policy[13] requiring flavored e-cigarettes and e-liquids to be sold only in age-restricted, in-person locations would apply to fruit, candy, and many other flavored e-cigarette products. However, products with tobacco, mint, or menthol flavors are specifically excluded from any policy revisions. FDA made this distinction among flavors to "maintain access for adult users of these products… while evidence of their impacts continues to develop." But ***FDA offered no scientific basis for excluding mint and menthol flavors from the flavor restrictions.***

use, September 12, 2018. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm

[10] Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes, November 15, 2018. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm

[11] Ambrose B, Day H, Rostron B, et al. Flavored tobacco product use among us youth aged 12-17 years, 2013-2014. *J Am Med Assoc*. 2015;314(17):1-3. doi:10.1001/jama.2015.13802.

[12] Halpern-Felsher B, Lempert LK, Watkins S, et al. FDA must use its existing authority to combat the youth e-cigarette use epidemic by preventing addiction now, rather than by seeking to treat it after the fact. Docket No. FDA-2018-N-3952

[13] Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes, November 15, 2018. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm

As we discussed in our separate comment,[14] youth are initiating with and using mint and menthol flavored e-cigarettes. One recent study[15] showed that among ever users of pod-based e-cigarettes, 26.5% reported their first e-liquid was flavored menthol or mint. Anecdotal evidence supports this data, including a November 2018 New York Times article[16] about Juul that featured a teen who initiated with, and became addicted to, mint-flavored Juuls.

Because there is no scientific basis for excluding mint and menthol from flavor restrictions, FDA should include mint and menthol in its flavor restrictions.

Also, the proposed policy would not apply to so-called "age-restricted locations" such as vape shops and stand-alone tobacco retailers that "adequately prevent persons under the age of 18 from entering" or sections of retail establishments that "adequately prevents" persons under the age of 18 from entering *and* the flavored e-cigarette products are not visible or accessible to under-age customers at any time. Judging from the huge number of "brick and mortar" shops to whom FDA issued warning letters and civil money penalties for retailer noncompliance,[17] it is unclear that vape shops and other tobacco stores successfully limit access to adult customers. Similarly, the proposed policy provides that "applicable" flavored ENDS products" (i.e., tobacco, mint, and menthol flavored products) may not be sold online without "heightened age verification processes." FDA said it will be working to identify such "heightened measures for age verification" and other restrictions to prevent youth access via online sales, and will make these "best practices" available "soon" so "sites can quickly adopt them." As described below, no age verification schemes effectively prevent youth from purchasing tobacco products online.

5. FDA should impose marketing and advertising restrictions on e-cigarettes to reduce their appeal and availability to youth – Tobacco Control Act section 906(d)

FDA has broad authority under Tobacco Control Act section 906(d) to impose marketing and advertising restrictions on all tobacco products, including e-cigarettes. There are a number of steps FDA should take to restrict marketing that appeals to kids and to regulate youth access.

a. FDA should prohibit all internet sales of e-cigarettes

Internet sales of tobacco products have been a significant source of sales to minors,[18] and online sales provide underage youth an easy way to evade youth access laws and purchase e-

[14] Halpern-Felsher B, Lempert LK, Watkins S, et al. FDA must use its existing authority to combat the youth e-cigarette use epidemic by preventing addiction now, rather than by seeking to treat it after the fact. Docket No. FDA-2018-N-3952

[15] McKelvey K, Baiocchi M, Halpern-Felsher B, Adolescents' and Young Adults' Use and Perceptions of Pod-Based Electronic Cigarettes. JAMA Network Open. 2018;1(6):e183535. doi:10.1001/jamanetworkopen.2018.3535

[16] Hoffman J, The Price of Cool: A Teenager, A Juul, and Nicotine Addiction, November 16, 2018. https://www.nytimes.com/2018/11/16/health/vaping-juul-teens-addiction-nicotine.html

[17] https://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm

[18] National Association of Attorneys General comment in response to FDA's Advance Notice of Proposed Rulemaking, Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, promotion and Marketing of Tobacco Products, Docket No. FDA-2011-N-0467, January 19, 2012. https://www.regulations.gov/document?D=FDA-2011-N-0467-0110

cigarettes. Tobacco Control Act section 906(d)(4)(A)(i) states unambiguously that FDA was required to promulgate regulations regarding non-face-to-face sales – including online sales – of tobacco products to youth by October 1, 2011. FDA issued an Advance Notice of Proposed Rulemaking[19](ANPRM) in September 2011 to seek comments on how to best regulate internet sales and advertising of tobacco products. In response, the National Association of Attorneys General (NAAG) submitted a comment[20] to FDA explaining the problems with existing age-verification methods and how they do not adequately protect public health. NAAG reached the sobering conclusion: "Unless such [age and ID verification] systems pass the challenges that tech-savvy youth can pose, **a complete ban on non-face-to-face sales of tobacco products may be the only way to prevent such sales from resulting in youth access to such products**." [NAAG comment, page 9, emphasis added] While youth have become even more "tech-savvy" since NAAG wrote this statement, age and ID verification schemes have not kept up. The WHO Framework Convention on Tobacco Control reached a similar conclusion, recognizing that "Internet sales of tobacco should be banned as they inherently involve tobacco advertising and promotion."[21] For example, Brazil, France, Greece, Hungary, the Republic of Korea, Macao, Singapore, Spain, South Africa, Turkey, and other countries prohibit all internet sales of tobacco.[22]

Despite the specific deadline set in the Tobacco Control Act for issuing regulations, FDA withdrew the ANPRM on August 1, 2017[23] and has not issued any regulations on internet sales.

We previously submitted comments[24] to the Deeming Rule Docket discussing the problems associated with internet sales of tobacco products, and how age-verification schemes

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[19] Advance Notice of Proposed Rulemaking, Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, promotion and Marketing of Tobacco Products, Docket No. FDA-2011-N-0467, September 9, 2011. https://www.regulations.gov/document?D=FDA-2011-N-0467-0001

[20] National Association of Attorneys General comment in response to FDA's Advance Notice of Proposed Rulemaking, Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, promotion and Marketing of Tobacco Products, Docket No. FDA-2011-N-0467, January 19, 2012.

[21] WHO Framework Convention on Tobacco Control, Guidelines for Implementation of Article 13 (Tobacco advertising, promotion and sponsorship), November 22, 2008. http://apps.who.int/gb/fctc/PDF/cop3/FCTC_COP3_DIV3-en.pdf

[22] WHO report on the global tobacco epidemic, 2015, Appendix VII Country profiles:
France, http://www.who.int/tobacco/surveillance/policy/country_profile/fra.pdf?ua=1
Brazil, http://www.who.int/tobacco/surveillance/policy/country_profile/bra.pdf?ua=1
Greece, http://www.who.int/tobacco/surveillance/policy/country_profile/grc.pdf?ua=1
Hungary http://www.who.int/tobacco/surveillance/policy/country_profile/hun.pdf?ua=1
The Republic of Korea, http://www.who.int/tobacco/surveillance/policy/country_profile/kor.pdf?ua=1
Macao, http://www.who.int/tobacco/surveillance/policy/country_profile/chn.pdf?ua=1
Singapore, http://www.who.int/tobacco/surveillance/policy/country_profile/sgp.pdf?ua=1
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South Africa http://www.who.int/tobacco/surveillance/policy/country_profile/zaf.pdf?ua=1
Turkey, http://www.who.int/tobacco/surveillance/policy/country_profile/tur.pdf?ua=1

[23] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0910-AG43

[24] https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/FDA-Comment-BHF-Submitted%20in%20Response%20to%20FDA%20Deeming%20Rule_Internet%20Sales_FINAL.pdf ; https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/FDA-comment-resubmitting-internet-comments-1jy-8c53-tjmc.pdf ; https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/FDA%20comments%20-%20Internet%20sales-

do not work to prevent kids from purchasing restrict products online. We incorporate those comments here by reference.

In November 2018 FDA announced that it would require more robust age-verification systems, that flavored ENDS products would not be permitted to be sold online without "heightened age verification processes," that FDA would be working to identify such "heightened age verification" schemes and other restrictions to prevent youth access via online sales, and that it would makes these "best practices" available "soon" so that "sites can quickly adopt them."[25] Unfortunately, however, FDA gave no indication about what these "heightened measures for age verification" might be, how such "best practices" would be determined, whether or how their efficacy has or would be tests, how soon they would be available, or how soon online merchants would be required to use them.

Because scientific evidence demonstrates that online age-verification schemes do not effectively prevent youth from purchasing tobacco products, FDA's announcement does not protect youth or public health. FDA should instead prohibit all internet sales of e-cigarettes.

b. **FDA should prohibit all e-cigarette advertisements targeting youth**

Although tobacco companies are prohibited from advertising cigarettes on TV and face other rigorous advertising and sponsorship restrictions, e-cigarette companies have been aggressively targeting youth on TV and in other media including online and social media, which is especially effective with youth. E-cigarette companies have been using tried and true methods including using celebrities, sex, and brand sponsorships to entice vulnerable youth with their addictive products.

FDA should prohibit all e-cigarette ads targeting youth and prohibit companies from using e-cigarette brand names to sponsor sporting and cultural events.

Conclusion

FDA has several regulatory tools it can use now to tackle the youth e-cigarette epidemic and prevent youth from initiating with and becoming addicted to e-cigarettes. FDA should:

- Immediately pull from the market any e-cigarette that has not received premarket review and has not demonstrated public health benefits.
- Aggressively enforce against unauthorized modified risk and cessation claims

In addition to these two steps, which can and should be taken immediately because they do not require any rulemaking, FDA should immediately initiate rulemaking to:

OMB-1jy-8de5-tdar.pdf ; https://tobacco.ucsf.edu/fda-kids-not-18-no-problem-buy-your-e-cigs-and-cigars-and-other-tobacco-products-online

[25] Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes, November 15, 2018. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm

- Prohibit all flavors in e-cigarettes, including mint and menthol
- Prohibit internet sales of e-cigarettes
- Prohibit e-cigarette advertisements targeting youth