

FDA's proposed modifications to its compliance policy for e-cigarettes leaves millions of youth at risk for starting to use e-cigarettes; FDA needs to remove these products from the market now and clamp down on illegal therapeutic and modified risk claims in Juul and other e-cigarette advertising

Lauren Kass Lempert, JD, MPH; Bonnie Halpern-Felsher, PhD; Matthew L. Springer, PhD;
Stanton Glantz, PhD

UCSF TCORS

Docket No. FDA-2019-D-0661

March 21, 2019

1. Moving the compliance date up by one year is too little, too late.

FDA's proposed Modifications to Compliance Policy for Certain Deemed Tobacco Products Draft Guidance for Industry does not meaningfully tackle the youth e-cigarette epidemic. Moving the compliance date up by one year (to August 8, 2021) means that thousands of e-cigarette products will remain on the market for at least another 2-1/2 years without any FDA review. The data from the 2018 National Youth Tobacco Survey show that e-cigarette use among high school students increased by 1.3 million between 2017 and 2018. At that rate, another 3 million high school students could be using e-cigarettes between now and August 2021.

Moreover, August 8, 2021 is the date by which companies must *submit* applications for FDA review; FDA could take a year or more after that to complete its review, and the products would remain on the market unless and until FDA pulls them. Also, as FDA highlights in a black box on page 2 of the draft guidance, even if/when the guidance is finalized, it only represents FDA's "current thinking" and is not binding on FDA. FDA's notification of its intended change in enforcement discretion does not guarantee that companies will comply with the policy or that FDA will actually enforce against non-complying companies.

The e-cigarette companies are taking advantage of this delay. There is nothing stopping any of them from applying for premarket approval today, yet none have.

FDA should immediately pull from the market any e-cigarette that has not received premarket review and has not demonstrated public health benefits as the law mandates.

2. There is no scientific basis for excluding mint and menthol from FDA's flavor restrictions.

FDA's proposed restrictions on the sale of some flavored e-cigarette to age-restricted locations also does not apply to all flavored e-cigarettes; mint, menthol, and tobacco-flavored e-cigarettes would not be affected by the new compliance policy. ***There is no scientific basis for excluding mint and menthol from FDA's flavor restrictions.***

Of particular concern, the wildly popular Juul and Juul-alike pods would still be available in mint and menthol flavors at convenience stores and other non-age-restrict retail outlets. In a 2018 study, 27% of Juul users and 12% of other e-cigarette users use mint or menthol flavors.¹ If other flavors (such as fruit and candy) became unavailable, it is reasonable to assume that users would initiate with or switch to available mint and menthol flavors, since all flavors – including mint and menthol – appeal to new and existing users by masking the harsh taste and other effects of tobacco products.

FDA included in this docket a summary of the results from the 2016-2017 (Wave 4) Population Assessment of Tobacco and Health (PATH) Study² which showed that among the youth age 12 to 17 who were new users of e-cigarettes, 96 percent used flavored e-cigarette products, 97 percent of current youth e-cigarette users age 12 to 17 reported they used flavored e-cigarettes in the past month, and 70 percent of current youth e-cigarette users said they used e-cigarettes “because they come in flavors I like,” and mint and menthol flavored e-cigarettes ranked as the fourth most popular among youth age 12 to 17 years.

Recent data from the 2018 National Youth Tobacco Survey³ (conducted by the FDA and the CDC) showed that **51 percent of high school students who currently use e-cigarettes use menthol or mint products.** Recent peer-reviewed studies support these findings and show that youth are initiating with and using mint and menthol flavored e-cigarettes.⁴ A paper⁵ published in March 2019 adds to the overwhelming evidence that flavors are a key driver for youth e-cigarette use, and that the availability of appealing flavors is a more salient reason for e-cigarette use among adolescent and young adult users than for older adult users. ***A more effective policy would be for FDA to initiate a rulemaking to prohibit all flavors in e-cigarettes, including mint and menthol.***

3. FDA should prohibit online sales of e-cigarettes.

The guidance does not effectively address online sales of e-cigarettes. Youth can easily purchase e-cigarettes and other tobacco products online, and to date there is no effective age-verification method that prohibits youth from purchasing online. As FDA reported in its summary of Wave 4 PATH data included in this docket, 7 percent of youth reported that they usually get their e-cigarettes from the Internet. ***Rather than rely on online age-verification schemes that have not been shown to work, FDA should instead initiate a rulemaking to prohibit internet sales of e-cigarettes.***

¹ 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

² Population Assessment of Tobacco and Health (PATH), <https://www.drugabuse.gov/research/nida-research-programs-activities/population-assessment-tobacco-health-path-study>

³ Cullen KA, Ambrose BK, Gentzke AS, Apelberg BJ, Jamal A, King BA. Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students — United States, 2011–2018. MMWR Morb Mortal Wkly Rep 2018;67:1276–1277. DOI: <http://dx.doi.org/10.15585/mmwr.mm6745a5>

⁴ 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

⁵ Soneji, S. S., Knutzen, K. E., & Villanti, A. C. (2019). Use of Flavored E-Cigarettes Among Adolescents, Young Adults, and Older Adults: Findings From the Population Assessment for Tobacco and Health Study. Public Health Reports. <https://doi.org/10.1177/0033354919830967>

4. FDA should immediately clamp down on unauthorized cessation and modified risk claims being made by Juul and other e-cigarette companies.

Regardless of when FDA starts reviewing new e-cigarette product applications, FDA should immediately and aggressively enforce against unauthorized cessation claims currently being made by e-cigarette companies.

The FDA has the responsibility and authority to take enforcement action to require Juul to stop running the ads with unsubstantiated cessation and modified risk claims unless and until Juul gets authorization under FDA's drug/device authorities to market its products as cessation or therapeutic aids, or authorization under FDA's tobacco authorities to market them with modified risk tobacco product (MRTP) claims. In the United States, companies are prohibited from marketing products with unsubstantiated health claims.

The *Sottera* case stated that the FDA could not regulate e-cigarettes as drug delivery devices and could only regulate e-cigarettes as tobacco products under the Family Smoking Prevention and Tobacco Control Act because the products were derived from tobacco and were *not* being marketed with claims of therapeutic benefit.⁶ The Court of Appeals in *Sottera Inc. v. Food & Drug Administration*⁷ ruled that the FDA has express authority to regulate e-cigarettes as drug delivery devices when e-cigarette products are "therapeutically marketed" (e.g., as products or treatments for tobacco dependence or to help smokers quit, such as nicotine gums and transdermal patches) since then they would fall under the jurisdiction of the drug/device provisions of the Federal Food, Drug, and Cosmetic Act (FDCA)⁸.

Juul has both explicitly and implicitly made therapeutic claims about their products in their online marketing and other promotional materials. Juul's mission, boldly proclaimed on its website,⁹ clearly states that Juul's purpose is to help smokers enjoy healthier lives by quitting smoking: "Improve the lives of the world's one billion smokers by eliminating cigarettes."

Juul's website¹⁰ features testimonials from customers who are or were smokers about how Juul has helped them curb and eventually quit smoking, and invites other smokers to "join the community" and share their own stories. Following are examples of testimonials from smokers who share their experiences and tips about how they used Juul to help quit smoking:

- Robert: "Every time you want a cigarette just take ten puffs of the JUUL and you will get some satisfaction." [claim: helps relieve nicotine addiction]
- Sabrina: "Stick with it. At first it was hard to find my happy spot but now that I have my puff down I will never smoke again." [claim: helps smoker quit]

⁶ *Smoking Everywhere, Inc. v. U.S. Food and Drug Administration*, 680 F. Supp. 2d 62 (D.D.C. 2010). In *Sottera*, the company that promoted NJOY e-cigarettes sued FDA for an injunction against FDA's detention of their product in part on the basis that their e-cigarettes were *not* therapeutic drug delivery devices, but rather were intended for and marketed as recreational products. *Sottera, Inc.* prevailed at both the trial court and the Court of Appeals, which rejected FDA's position that e-cigarettes were unapproved drug devices and agreed with *Sottera, Inc.*

⁷ *Sottera Inc. v. Food and Drug Administration*, 627 F. 3d 891 (U.S. App. DC 2010)

⁸ 21 U.S.C. section 351 *et seq.*

⁹ <https://www.juul.com/mission-values>

¹⁰ <https://www.juul.com/community>

- Becky: “I appreciate the ease of use and nicotine fix.” [claim: use as nicotine replacement therapy]
- Marcy: “It’s good and it’s satisfying.” [claim: helps relieve nicotine addiction]
- Rabiye: “Try different flavors until you reach one you can enjoy and gives you the same satisfaction as your cigarettes did.” [claim: helps relieve nicotine addiction]
- Angela: “No more smoke breaks. No more chewing endless packs of gum, spraying perfume, sneaking out to smoke, not having to step outside when I am watching tv with my husband.” [claim: helps smoker quit]
- Erika: “Inhale until you feel the same fix as you would get from a cigarette.” [claim: helps relieve nicotine addiction]
- Laura: “Just replace the cigarette with the JUUL! It really helps to keep some physical habits the first week or two. Just focus on using the JUUL instead of a cigarette.” [claim: helps smokers quit]
- Regina: “JUUL means I can still enjoy the pleasure I obtain smoking/vaping, without the stink, mess, judgement and stress.” [claim: helps smokers quit]
- Lindsay: “It actually does feel just like smoking, but now I don’t stink!” [claim: helps smokers switch]
- Ricky: I appreciate that it was designed with cigarette smokers in mind. [claim: helps smokers quit]
- Dale: “This is a great alternative to actual tobacco products. Enjoy!” [claim: not a tobacco product]
- Rob: “I appreciate the draw and how it replaces a cigarette.” [claim: helps smokers quit]
- Regina: “JUUL means I can still enjoy the pleasure I obtain smoking/vaping, without the stink, mess, judgement and stress.” [claim: helps smokers quit]

Similar claims and testimonials are made in Juul’s new TV ad campaign that was launched in January 2019.¹¹ Moreover, Juul is pitching¹² its e-cigarette as an anti-smoking tool to employers and insurers.

These online and TV claims either state outright or suggest that using Juul will help smokers relieve their nicotine addiction without the stress of giving up the behavioral pleasures of smoking.

Publishing these testimonials on Juul’s website represents promotion of its e-cigarette (which is deemed a tobacco product subject to FDA’s tobacco authorities) as therapeutic devices, despite the fact that Juul’s website includes disclaimers¹³ that its products are not intended for smoking cessation.

Whether a tobacco product is marketed for therapeutic use is gleaned from the universe of the product’s marketing. For FDA regulatory purposes, the "intended use" of a product is

¹¹ <https://www.cnbc.com/2019/01/07/juul-highlights-smokers-switching-to-e-cigarettes-in-ad-campaign.html>

¹² <https://www.cnbc.com/2019/03/07/juul-e-cigarette-maker-pitches-employers-insurers.html>

¹³ <https://www.juul.com/our-responsibility#regulation>

determined by "the objective intent of the persons legally responsible" for labeling the product. 21 C.F.R. § 201.128.¹⁴ Objective intent may be shown, for example, "by labeling claims, advertising matter, or oral or written statements" by the labeler. *Id.* It may also be shown "by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." *Id.* By posting customer comments and testimonials on websites controlled by Juul or other e-cigarette marketers, they clearly have knowledge that their products are "used" by those customers as either a smoking cessation therapeutic device. Furthermore, Juul and other e-cigarette companies and their trade associations (e.g., CASAA, SFATA, AVA) have perpetuated therapeutic claims by encouraging their consumers to testify before state and municipal governmental agencies about their use of e-cigarettes as smoking cessation products to argue against regulations (e.g., flavor and age restrictions, taxes).

In the *Sottera* decision, Judge Williams wrote: "Still, the district court noted that the factual record on NJOY is meager and that the FDA may establish that NJOY does in fact make therapeutic claims regarding its electronic cigarettes. Mem. Op. at 25 n.17. Until such time, the definitional line laid down in *Brown & Williamson* (as we understand it) leaves the FDA without jurisdiction over these products under the FDCA's drug/device provisions." The *Sottera* decision holds that the FDA could and should regulate e-cigarettes as drugs/devices under the FDCA if they are found to be "therapeutically marketed."

To help clarify FDA's approach to the *Sottera* case, the FDA issued a final rule¹⁵ (effective February 8, 2017) that describes the circumstances in which a product made or derived from tobacco (including e-cigarettes) would be subject to FDA's drug/device regulations.

The rule¹⁶ provides:

If a product made or derived from tobacco that is intended for human consumption is intended for use for any of the purposes described in paragraph (a) or (b) of this section, the product is not a tobacco product as defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act and will be subject to regulation as a drug, device, or combination product.

- (a) The product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, including use in the cure or treatment of nicotine addiction (e.g., smoking cessation), relapse prevention, or relief of nicotine withdrawal symptoms;
- (b) The product is intended to affect the structure or any function of the body in any way that is different from effects related to nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000.

¹⁴ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=201.128>

¹⁵ Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses" AGENCY: Food and Drug Administration, HHS. ACTION: Final rule. 21 CFR Parts 201, 801, and 1100 [Docket No. FDA-2015-N-2002]. 82 FR 2193 Available at: <https://www.federalregister.gov/documents/2017/01/09/2016-31950/clarification-of-when-products-made-or-derived-from-tobacco-are-regulated-as-drugs-devices-or>

¹⁶ 21 CFR § 1100.5 - Exclusion from tobacco regulation. Available at: <https://www.law.cornell.edu/cfr/text/21/1100.5>

In its discussion of that rule, FDA stated: “FDA has long considered claims related to smoking cessation in the context of curing or treating nicotine addiction and its symptoms to bring products within FDA’s ‘disease prong’ jurisdiction.” FDA explained, “...claims related to smoking cessation have long been recognized as evidence of intended use conferring drug or device jurisdiction. Smoking cessation claims have also long been associated with intended uses of curing or treating nicotine addiction and its symptoms.” Further, “...smoking cessation claims on any product generally create a strong suggestion of intended therapeutic benefit to the user that generally will be difficult to overcome absent clear context indicating that the product is not intended for use to cure or treat nicotine addiction or its symptoms, or for another therapeutic purpose.”

The regulatory language regarding “intended uses” for drugs¹⁷ and for devices¹⁸ states:

The words intended uses or words of similar import ... refer to the objective intent of the persons legally responsible for the labeling of [drugs or devices]. *The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.* The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the [drug or device], such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a [drug or device] introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a [drug or device] which accords with such other uses to which the article is to be put. (Emphasis added.)

FDA made clear in the final rule that companies’ disclaimers are not enough to change the intended use from drug/device jurisdiction to tobacco jurisdiction: In the final rule’s¹⁹ discussion of intended uses that bring products within the “disease prong” and FDA’s drug/device regulatory authority, FDA stated: “Where products making claims related to quitting smoking also attempt to disclaim that use in some way, FDA intends to view such disclaimers skeptically because of the likelihood of consumer confusion. In most cases, as

¹⁷ 21 CFR 201.128 – Meaning of “intended uses.” Available at:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=201.128>

¹⁸ 21 CFR 801.4 – Meaning of intended uses. Available at:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=801.4>

¹⁹ 82 FR 2193 at 2199, Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses” AGENCY: Food and Drug Administration, HHS. ACTION: Final rule.

21 CFR Parts 201, 801, and 1100 [Docket No. FDA–2015–N–2002]. Available at:

<https://www.federalregister.gov/documents/2017/01/09/2016-31950/clarification-of-when-products-made-or-derived-from-tobacco-are-regulated-as-drugs-devices-or>

discussed in more detail in response to Comment 13, FDA does not believe that disclaimers will sufficiently mitigate consumer confusion due to the product’s claimed therapeutic benefit.” In its response to Comment 13, FDA stated: “A consumer might be confused about a product’s intended use, for example, if a ‘satisfying smoking alternative’ claim is accompanied by other text or images indicating that the product can help smokers reduce withdrawal symptoms associated with quitting smoking. In that case, the product may be subject to regulation as a drug or device.”²⁰ The testimonials posted on Juul’s website²¹ describing smoking “satisfaction” that are accompanied with other text and images associated with quitting smoking clearly fall into the zone subjecting the products to FDA’s drug/device regulations.

Of particular concern, FDA stated that “unsubstantiated cessation claims that reach adolescents may confuse teens and lead teens to believe that these products are FDA-approved smoking cessation products.”²² ***If FDA is serious about stemming the youth e-cigarette epidemic, it must crack down on unsubstantiated cessation claims made by e-cigarette companies, as well as cessation claims issued by FDA itself.***

Juul and other e-cigarette companies cannot have it both ways. They cannot claim they are regular tobacco products that, as “customarily marketed,” may only be regulated as a tobacco product under the Family Smoking Prevention and Tobacco Control Act²³, thus avoiding regulation as medical devices and the burden of proving safety and therapeutic benefit, and then create the impression through their marketing and direct consumer communication they have submitted therapeutic claims to the FDA and won approval for them.

Further, to the extent that Juul’s advertising and communications state or imply that Juul is safer or less harmful than conventional cigarettes, these claims are unauthorized modified risk claims under section 911 of the Tobacco Control Act²⁴ that are illegal absent a prior MRTP order issued by FDA on the basis of sound scientific evidence. ***It is time for the FDA to start enforcing the law, as specified in its own regulations.***

²⁰ Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses” AGENCY: Food and Drug Administration, HHS. ACTION: Final rule. 21 CFR Parts 201, 801, and 1100 [Docket No. FDA–2015–N–2002]. Available at: <https://www.federalregister.gov/documents/2017/01/09/2016-31950/clarification-of-when-products-made-or-derived-from-tobacco-are-regulated-as-drugs-devices-or>

²¹ <https://www.juul.com/community>

²² Response to Comment 28, 82 FR 2193 at 2212, Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses” AGENCY: Food and Drug Administration, HHS. ACTION: Final rule. 21 CFR Parts 201, 801, and 1100 [Docket No. FDA–2015–N–2002]. Available at: <https://www.federalregister.gov/documents/2017/01/09/2016-31950/clarification-of-when-products-made-or-derived-from-tobacco-are-regulated-as-drugs-devices-or>

²³ 21 USC 387 et seq., Pub. L. 111-31, June 22, 2009

²⁴ 21 USC 387k