

CTP should actively integrate the relationship between cannabis and tobacco use into its tobacco regulation and proactively identify regulatory approaches from tobacco product regulation that can be applied to cannabis

Docket No. FDA–2023–N–2873
Developing FDA’s Center for Tobacco Products’ Strategic Plan

Pamela M. Ling, MD, MPH; Nhung Nguyen, PhD; Neal L. Benowitz, MD;
Lauren Kass Lempert, JD, MPH; Stanton A. Glantz, PhD; Matthew L. Springer, PhD;
Leila Mohammadi, MD, PhD; Bonnie Halpern-Felsher, PhD;
Benjamin W. Chaffee, DDS MPH PhD; Sabrina Islam, PhD;
Vira Pravosud, PhD; Hai-Yen Sung, PhD; Dorie Apollonio, PhD, MPP;
Stella Aguinaga Bialous, DrPH; Wendy Max, PhD; Janet Wojcicki, PhD, MPH;
Karla Llanes, PhD; Yingning Wang, PhD; Michael A. Matthay, MD; Minji Kim, PhD*;

UCSF TCORS
*University of South Carolina

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FDA announced¹ a Public Meeting and Listening Session and an opportunity to submit written public comments to obtain feedback on five proposed strategic goals it is using to develop a strategic plan for FDA’s Center for Tobacco Products’ (CTP) comprehensive Strategic Plan. In addition, CTP asked for comment on the question, “Are there any important features, activities, or initiatives not encapsulated by these proposed goal areas that you believe CTP should consider as part of its strategic plan?” One important activity not included in the proposed goals is to integrate impact of cannabis and cannabis-tobacco co-use on tobacco product regulation, and conversely, to apply best practices from tobacco regulation and lessons learned from tobacco regulatory science to inform future cannabis regulation.

- 1. The Center for Tobacco Products must consider the individual and additive health effects of tobacco and cannabis co-use in all its decision-making, and**
- 2. The Center for Tobacco Product strategic plan should include proactive identification of best practices from tobacco regulatory science that can inform cannabis regulation.**

While cannabis is not included under CTP’s current regulatory authority, the FDA requested scientific data and information about cannabis in 2019, and CTP should proactively integrate the

¹ US Food and Drug Administration, CTP Newsroom, Listening Session: Developing FDA’s Center for Tobacco Products’ Strategic Plan, August 22, 2023 (July 21, 2023). Available: https://www.fda.gov/tobacco-products/ctp-newsroom/listening-session-developing-fdas-center-tobacco-products-strategic-plan-08222023?utm_campaign=ctp-ruf&utm_content=landingpage&utm_medium=email&utm_source=govdelivery&utm_term=stratcomms#Proposed%20Strategic%20Goals

interaction between cannabis and tobacco and identify best practices from tobacco product regulation that can be applied to cannabis regulation.

- a. While cigarette smoking rates are falling,² cannabis use rates are increasing among adults and youth.^{3,4} Tobacco and cannabis co-use is common, with Wave 2 of FDA's PATH study showing more than 21% of all young adults reported currently using both cannabis and tobacco in the past month.⁵ In Wave 4 of the PATH study, 28%-48% of those who use tobacco were also using cannabis.⁶ E-cigarette use more than triples the odds of cannabis use.⁷ In addition to THC products, in 2022 more than 1 in 5 adolescent e-cigarette users reported current past-month CBD vaping, with higher rates among Hispanic and sexual and gender minority youth.⁸
- b. Tobacco and cannabis co-users are more likely to use tobacco (and cannabis) products heavily, develop dependence, have greater nicotine dependence,⁹ exhibit problem behaviors related to cannabis use, and poorer cessation outcomes for tobacco and

² Cornelius ME. Tobacco Product Use Among Adults — United States, 2019. *MMWR Morb Mortal Wkly Rep*. 2020;69. doi:10.15585/mmwr.mm6946a4.

³ Hasin DS, Saha TD, Kerridge BT, et al. Prevalence of Marijuana Use Disorders in the United States Between 2001-2002 and 2012-2013. *JAMA Psychiatry*. 2015;72(12):1235-1242. doi:10.1001/jamapsychiatry.2015.1858

⁴ Lim CC, Sun T, Leung J, Chung JY, Gartner C, Connor J et al. Prevalence of adolescent cannabis vaping: a systematic review and meta-analysis of US and Canadian studies. *JAMA pediatrics*. 2021.

⁵ Cohn AM, Abudayyeh H, Perreras L, Peters EN. Patterns and correlates of the co-use of marijuana with any tobacco and individual tobacco products in young adults from Wave 2 of the PATH Study. *Addict Behav*. 2019 May;92:122–127. doi: 10.1016/j.addbeh.2018.12.025.S0306-4603(18)30598-7.

⁶ Cohn AM, Chen S. Age groups differences in the prevalence and popularity of individual tobacco product use in young adult and adult marijuana and tobacco co-users and tobacco-only users: Findings from Wave 4 of the population assessment of tobacco and health study. *Drug Alcohol Depend*. 2022 Apr 1;233:109278. doi: 10.1016/j.drugalcdep.2022.109278. Epub 2022 Jan 10.

⁷ Chadi N, Schroeder R, Jensen JW, Levy S. Association between electronic cigarette use and marijuana use among adolescents and young adults: a systematic review and meta-analysis. *JAMA Pediatr*. 2019;173(10):e192574-e. doi: 10.1001/jamapediatrics.2019.2574

⁸ Dai HD, Subramanian R, Mahroke A, Wang M. Prevalence and Factors Associated With Vaping Cannabidiol Among US Adolescents. *JAMA Netw Open*. 2023;6(8):e2329167. doi:10.1001/jamanetworkopen.2023.29167

⁹ Wang JB, Ramo DE, Lisha NE, Cataldo JK. Medical marijuana legalization and cigarette and marijuana co-use in adolescents and adults. *Drug and alcohol dependence*. 2016 Sep 1;166:32-8.

cannabis¹⁰ than single product users.¹¹ Co-use also presents additive psychiatric, psychosocial, mental health disorders, and toxicological risks.^{12,13,14,15,16}

- c. Cannabis use and exposure to cannabis smoke are increasingly perceived as safe.¹⁷ However, tobacco and cannabis smoke share many chemical compounds that are known carcinogens, and smoking cannabis is associated with increased risk of head/neck cancers and other cancers.¹⁸ Though less research has been done on cannabis, studies have found combustion of cannabis, whether through smoking or vaping, produces a greater amount of particulate matter than tobacco, raising concerns that it could have similar health consequences.^{19,20,21,22,23,24}
- d. The evolving tobacco marketplace affects the cannabis market. The exploding popularity of nicotine vaping²⁵ was accompanied by a parallel increase in cannabis vaping among

¹⁰ Rabin, R.A., George, T.P., 2015. A review of co-morbid tobacco and cannabis use disorders: possible mechanisms to explain high rates of co-use. *Am. J. Addict.* 24, 105–116. <https://doi.org/10.1111/ajad.12186>

¹¹ Tucker JS, Pedersen ER, Seelam R, Dunbar MS, Shih RA, D'Amico EJ. Types of cannabis and tobacco/nicotine co-use and associated outcomes in young adulthood. *Psychology of Addictive Behaviors*. 2019 Jun;33(4):401.

¹² Sokolovsky AW, Rubenstein D, Gunn RL, White HR, Jackson KM. Associations of daily alcohol, cannabis, combustible tobacco, and e-cigarette use with same-day co-use and poly-use of the other substances. *Drug Alcohol Depend.* 2023;251:110922. doi:10.1016/j.drugalcdep.2023.110922

¹³ Meier E, Hatsukami DK. A review of the additive health risk of cannabis and tobacco co-use. *Drug and alcohol dependence*. 2016 Sep 1;166:6-12.

¹⁴ Peters EN, Schwartz RP, Wang S, O'Grady KE, Blanco C. Psychiatric, psychosocial, and physical health correlates of co-occurring cannabis use disorders and nicotine dependence. *Drug and alcohol dependence*. 2014 Jan 1;134:228-34.

¹⁵ Ramo DE, Liu H, Prochaska JJ. Tobacco and marijuana use among adolescents and young adults: a systematic review of their co-use. *Clinical psychology review*. 2012 Mar 1;32(2):105-21.

¹⁶ Nguyen N, Peyser N, Olgin JE, Pletcher MJ, Beatty AL, Modrow MF, Carton TW, Khatib R, Djibo DA, Ling PM, Marcus GM. Associations between tobacco and cannabis use and anxiety and depression among adults in the United States: findings from the COVID-19 Citizen Science Study. *PLOS ONE* (in press)

¹⁷ Chambers J, Keyhani S, Ling PM, Hoggatt KJ, Hasin D, Nguyen N, Woods A, Ryder A, Cohen BE. Perceptions of Safety of Daily Cannabis vs Tobacco Smoking and Secondhand Smoke Exposure, 2017-2021. *JAMA Netw Open*. 2023 Aug 1;6(8):e2328691. doi: 10.1001/jamanetworkopen.2023.28691.

¹⁸ van Eeden S, Yeung A, Quinlan K, Hogg J. Systemic Response to Ambient Particulate Matter | Relevance to Chronic Obstructive Pulmonary Disease. *Proceedings of the American Thoracic Society*. 2005;2(1).

¹⁹ Nguyen PK, Hammond K. Fine Particulate Matter Exposure From Secondhand Cannabis Bong Smoking. *JAMA network open*. 2022;5(3):224-244.

²⁰ Huang AS, Murphy MBC, Jacob P, Schick SF. PM2.5 Concentrations in the Smoking Lounge of a Cannabis Store. *Environ Sci Technol Lett*. 2022;9(6):551-556. doi:10.1021/acs.estlett.2c00148

²¹ Ott WR, Zhao T, Cheng KC, Wallace LA, Hildemann LM. Measuring indoor fine particle concentrations, emission rates, and decay rates from cannabis use in a residence. *Atmospheric Environment: X*. 2021;10:100106. doi:10.1016/j.aeaoa.2021.100106

²² Particle Pollution | Air | CDC. Published February 21, 2023. Accessed May 18, 2023. https://www.cdc.gov/air/particulate_matter.html

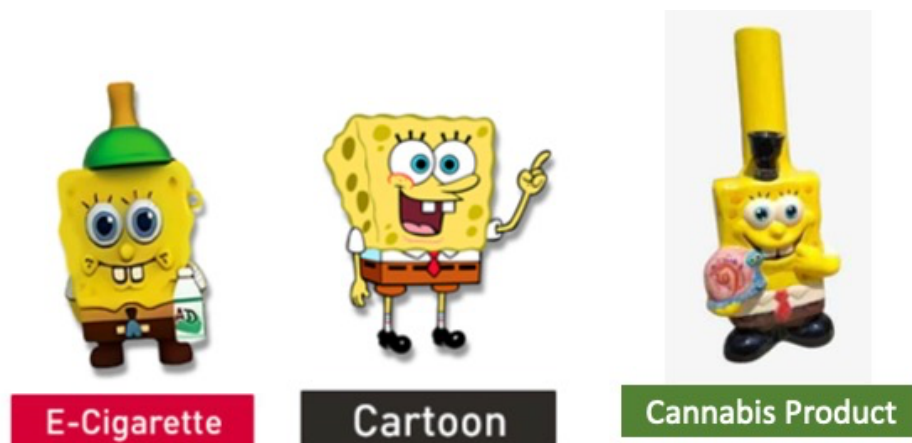
²³ Wang X, Derakhshandeh R, Liu J, et al. One Minute of Marijuana Secondhand Smoke Exposure Substantially Impairs Vascular Endothelial Function. *J Am Heart Assoc*. 2016;5(8):e003858. doi:10.1161/JAHA.116.003858

²⁴ Ott WR, Wallace LA, Cheng KC, Hildemann LM. Measuring PM2.5 concentrations from secondhand tobacco vs. marijuana smoke in 9 rooms of a detached 2-story house. *Sci Total Environ*. 2022;852:158244. doi:10.1016/j.scitotenv.2022.158244

²⁵ Office of the Surgeon General. [E-cigarette Use among Youth and Young Adults: A Report of the Surgeon General \[PDF–8.47 MB\]](#). Washington, DC: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2016.

youth.²⁶ Furthermore, tobacco product regulations such as prohibition of flavored products open market opportunities for cannabis products such as flavored CBD vapes, which have begun to appear in nicotine vape shops.²⁷ FDA needs to take into account the increases in cannabis and CBD use as a (unintended) consequence of tobacco product regulation.

- e. On August 23, 2023 FDA issued warning letters²⁸ to 15 online retailers for selling and/or distributing unauthorized e-cigarette products packaged to look like youth-appealing characters, school supplies, toys, and drinks. Simple web searching revealed it was not difficult to find examples of cannabis products closely matching the images from the FDA's announcement. This suggests that the youth-targeted marketing for e-cigarettes is also happening for cannabis products. CTP's experience in this area is well suited to apply to cannabis products.
- f. On the following pages we present examples of cannabis products that closely match the images of e-cigarettes products that were the target of FDA's announcement. On the left are the images from the FDA announcement, and on the right we present cannabis products with similar packaging. Sources for these images are listed below the chart:



²⁶ Miech RA, Patrick ME, O'Malley PM, Johnston LD, Bachman JG. Trends in reported marijuana vaping among US adolescents, 2017-2019. *Jama*. 2020 Feb 4;323(5):475-6.

²⁷ Leas EC, Moy N, McMenamin SB, Shi Y, Benmarhnia T, Stone MD, Trinidad DR, White M. Availability and Promotion of Cannabidiol (CBD) Products in Online Vape Shops. *Int J Environ Res Public Health*. 2021 Jun 22;18(13):6719. doi: 10.3390/ijerph18136719.

²⁸ <https://www.fda.gov/tobacco-products/ctp-newsroom/retailers-warned-stop-selling-illegal-e-cigarettes-resembling-youth-appealing-characters-school>



E-Cigarette



Toy



Cannabis Product



E-Cigarette



Cartoon



Cannabis Product



E-Cigarette



School Supplies



Cannabis Product



E-Cigarette



Toy



Cannabis Product



E-Cigarette



Toy



Cannabis Product



E-Cigarette



Food Product



Cannabis Product



Food Product



E-Cigarette



Food Product



Cannabis Product



E-Cigarette



Food Product



Cannabis Product

Image Sources:

<https://www.eater.com/2016/10/25/13402724/starbucks-bong-lawsuit-trademark>
<https://www.dhgate.com/product/jack-in-the-box-burger-king-glass-mcdonalds/371720809.html>
<https://pilotdiarystore.com/products/poto-water-bottle-bong?variant=39747209396324>
<https://inhalco.com/blogs/guides/8-best-spongebob-bongs>
<https://hazebongshop.com/products/11-5-adorable-fuzzy-bear-bong>
<https://www.eightcig.com/wizvapor-stoned-boy-alternative-vaporizer/>
<https://www.elementvape.com/canna-river-d8-d10-disposable>
<https://delta8resellers.com/product/flying-monkey-heavy-hitter-disposable-2g/>
<https://www.luvbrite.com/product/mario-carts-strawberry-pie-1g>

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- g. In addition, FDA’s experience with tobacco regulatory science including safety assessment and health impact of product use is highly relevant to these crossover and co-used products. Many studies of tobacco perceptions (including the PATH study) and health effects already include cannabis measures or can be adapted to cannabis products. Lessons learned from the EVALI outbreak can be applied to address cannabis vaping products (e.g., delta-8-THC-O acetate) that hold similar health risks.²⁹ FDA should leverage this opportunity to address tobacco and cannabis co-use.
- h. Lessons learned from tobacco product regulation that can be readily applied to cannabis include:
 - a. Prohibition of unsubstantiated health claims
 - b. Limitations on advertising and packaging that appeal to youth
 - c. Implementing effective warning labels
 - d. Prohibiting product formulations that increase health risks
 - e. Prohibiting menthol and other flavors in combustible and vaporized products
 - f. Recognizing problem of conflicts of interest and acting to prevent regulators and public employees from having conflicts of interest in the cannabis industry.
 - g. Establish product standards to regulate manufacturing, marketing, and sale of products.

3. Regardless of which division or agency ultimately obtains regulatory authority over cannabis, FDA should translate evidence-based and effective tobacco control principles and practices to inform cannabis regulation.

As part of its strategic plan, FDA CTP should identify best practices from tobacco control and tobacco regulation to inform a comprehensive regulatory regime for cannabis. To protect public health, if cannabis becomes legal it should be subject to a robust demand reduction program modeled on successful evidence-based tobacco control programs. A key goal of the public health framework would be to make it harder for a new, wealthy, and powerful cannabis industry to manipulate the policy environment and thwart public health efforts to minimize use and associated health problems.³⁰

²⁹ Benowitz NL, Havel C, Jacob P, O’Shea DF, Wu D, Fowles J. Vaping THC-O Acetate: Potential for Another EVALI Epidemic. *J Med Toxicol*. 2023 Jan;19(1):37-39. doi: 10.1007/s13181-022-00921-3. Epub 2022 Dec 12. PMID: 36508081; PMCID: PMC9813278.

³⁰ Barry RA, Glantz S (2016) A Public Health Framework for Legalized Retail Marijuana Based on the US Experience: Avoiding a New Tobacco Industry. *PLoS Med* 13(9): e1002131. <https://doi.org/10.1371/journal.pmed.1002131>