The Department of Justice and Drug Enforcement Agency should reclassify marijuana from Schedule I to Schedule III to allow consideration of the health, safety, and abuse liability impacts of cannabis and tobacco co-use along with cannabis use alone and proactively identify regulatory approaches from tobacco product regulation that can be applied to cannabis regulations

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We support the Department of Justice proposal to transfer "marijuana" (we prefer to use the term "cannabis") from Schedule I to Schedule III of the Controlled Substances Act to allow better definition of evidence-based medical usages. The current assignment of marijuana to Schedule I makes it exceptionally difficult to conduct meaningful medical research about the health effects (both positive and negative) of cannabis use. 

This situation allows unsubstantiated health claims for cannabis use to go unchallenged and makes it exceptionally difficult to identify specific therapeutic uses for cannabis, appropriate indications, and dosing. This evidence vacuum supports widespread use of cannabis for perceived health indications without a scientific basis. In addition, moving cannabis to Schedule III will facilitate development of effective regulatory strategies, which should take into account the interactions between cannabis and tobacco.

## The cannabis/tobacco cross-over

Our research has shown that cannabis and cannabis-tobacco co-use is a significant public health issue that must be addressed at the federal level. Therefore, we believe that as

<sup>&</sup>lt;sup>1</sup> Bowling CM, Hafez AY, Glantz SA. Public Health and Medicine's Need to Respond to Cannabis Commercialization in the United States: A Commentary. J Psychoactive Drugs. 2020 Sep-Oct;52(4):377-382. doi: 10.1080/02791072.2020.1761040. Epub 2020 May 19. PMID: 32429772; PMCID: PMC7674246.

part of the regulatory decision-making process, DEA, DOJ, FDA, HHS, and other federal agencies should consider cannabis and tobacco co-use along with cannabis use alone when weighing the potential for therapeutic benefits against the potential for health, safety, and abuse liability harms. Further, our own research supports the view that all federal agencies should apply best practices from tobacco regulation and lessons learned from tobacco regulatory science to inform future cannabis regulation.

- 1. DEA, DOJ, HHS, FDA, and other federal agencies must consider the individual and additive health effects of tobacco and cannabis co-use in all its decision-making, and
- 2. DEA and DOJ should proactively identify best practices from tobacco regulatory science that can inform cannabis regulation.

Moving cannabis from Schedule I to Schedule III will facilitate coordination among DEA, DOJ, HHS, FDA, and other federal agencies in order to proactively evaluate the interaction between cannabis and tobacco, identify best practices from tobacco product regulation, and determine what can and should be applied to cannabis regulation.

a. While cigarette smoking rates are falling,<sup>2</sup> cannabis use rates are increasing among adults and youth.<sup>3,4</sup> 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.<sup>5</sup> In Wave 4 of the PATH study, 28%-48% of those who use tobacco were also using cannabis.<sup>6</sup> E-cigarette use more than triples the odds of cannabis use.<sup>7</sup> In addition to THC-containing 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.<sup>8</sup>

<sup>3</sup> 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 
<sup>4</sup> 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.

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

<sup>&</sup>lt;sup>5</sup> 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.

<sup>&</sup>lt;sup>6</sup> 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.

<sup>&</sup>lt;sup>7</sup> 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

<sup>&</sup>lt;sup>8</sup> 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

- b. Tobacco and cannabis co-users are more likely to use tobacco (and cannabis) products heavily, develop dependence, have greater nicotine dependence, exhibit problem behaviors related to cannabis use, and poorer cessation outcomes for tobacco and cannabis 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.<sup>17</sup> 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.<sup>18</sup> 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 exposure to cannabis smoke or aerosols could have similar health consequences.<sup>19,20,21,22,23,24</sup>

<sup>&</sup>lt;sup>9</sup> 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.

<sup>&</sup>lt;sup>10</sup> 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

<sup>&</sup>lt;sup>11</sup> 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.

<sup>&</sup>lt;sup>12</sup> 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

<sup>&</sup>lt;sup>13</sup> 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.

<sup>&</sup>lt;sup>14</sup> 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.

<sup>&</sup>lt;sup>15</sup> 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.

<sup>&</sup>lt;sup>16</sup> 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)

<sup>&</sup>lt;sup>17</sup> 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.

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

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

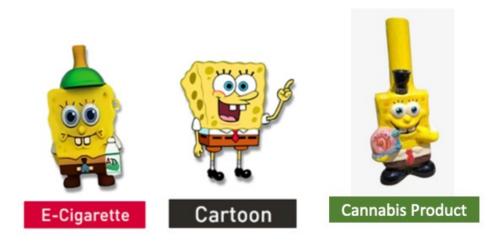
<sup>&</sup>lt;sup>20</sup> Huang AS, Murphy MBC, Jacob P, Schick SF. PM2.5 Concentrations in the Smoking Lounge of a Cannabis Store. *Environ Sci Technol Lett.* 2022;9(6):551-556. doi:10.1021/acs.estlett.2c00148

<sup>&</sup>lt;sup>21</sup> 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

<sup>&</sup>lt;sup>22</sup> Particle Pollution | Air | CDC. Published February 21, 2023. Accessed May 18, 2023. https://www.cdc.gov/air/particulate matter.html

<sup>&</sup>lt;sup>23</sup> 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 
<sup>24</sup> 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

- d. The evolving tobacco marketplace affects the cannabis market. The exploding popularity of nicotine vaping<sup>25</sup> was accompanied by a parallel increase in cannabis vaping among youth.<sup>26</sup> 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.<sup>27</sup> DEA, DOJ, FDA, and other federal agencies need 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's Center for Tobacco Products (CTP) issued warning letters<sup>28</sup> 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. DEA and DOJ should leverage CTP's experience in this area to inform regulations related to cannabis products.
- f. On the following pages we present examples of cannabis products that use images 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:

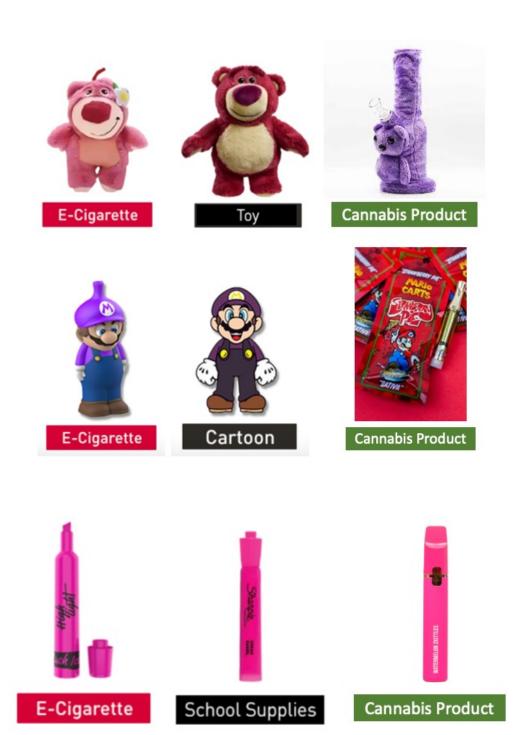


<sup>&</sup>lt;sup>25</sup> Office of the Surgeon General. <u>E-cigarette Use among Youth and Young Adults: A Report of the Surgeon General [PDF–8.47 MB]</u>. Washington, DC: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2016.

<sup>&</sup>lt;sup>26</sup> 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.

<sup>&</sup>lt;sup>27</sup> 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.

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









Toy



Cannabis Product







Toy



**Cannabis Product** 



E-Cigarette



Food Product



**Cannabis Product** 



Food Product



## **Image Sources:**

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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 coused products, so DEA and DOJ should use these experiences to help inform their own regulatory decision-making. 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.<sup>29</sup> DEA and DOJ should leverage this opportunity to address tobacco and cannabis co-use.
- h. Best practices from tobacco control should be applied to cannabis regulation because tobacco companies are entering the cannabis marketplace. The cannabis industry seeks to influence policy to increase cannabis consumption similar to past tobacco industry efforts. In 2019, Philip Morris bought a 45% stake in Cronos, which sells loose-leaf cannabis, joints, flavored cannabis oils, vape pens, edibles, tinctures, and lotions, and in 2021 its parent company Altria registered to lobby on cannabis issues. In 2021, British American Tobacco (parent of Reynolds American in the US) began selling a flavored CBD vape (Vuse CBD, formerly Vype) as its formal entry into the cannabis market. Marketing cannabis products allows tobacco companies to integrate cannabis into existing tobacco corporate social responsibility and "harm reduction" platforms, building on the perception of cannabis as a medical product, and facilitates cannabis industry use of tobacco industry tactics to influence policy.

<sup>29</sup> 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.

<sup>&</sup>lt;sup>30</sup> Richter KP, Levy S. Big marijuana--lessons from big tobacco. N Engl J Med. 2014;371(5):399-401.

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<sup>&</sup>lt;sup>31</sup> Hirsch L. Altria to invest \$1.8 billion in cannabis company Cronos Group, exits some e-cig brands. 2018; <a href="https://www.cnbc.com/2018/12/07/altria-to-invest-1point8-billion-in-cannabis-company-cronos-group.html">https://www.cnbc.com/2018/12/07/altria-to-invest-1point8-billion-in-cannabis-company-cronos-group.html</a>. Accessed February 19, 2021. Reuters. Cannabis producer Canopy Growth enters U.S. vape market. 2021; <a href="https://www.theglobeandmail.com/business/article-cannabis-producer-canopy-growth-enters-us-vape-market/">https://www.theglobeandmail.com/business/article-cannabis-producer-canopy-growth-enters-us-vape-market/</a>. Accessed September 14 2021.

<sup>&</sup>lt;sup>32</sup> Martin A. Altria, Maker of Marlboro Cigarettes, Is Lobbying on Cannabis Sales in Virginia. 2021; <a href="https://cannabiswire.com/2021/02/07/altria-maker-of-marlboro-cigarettes-is-lobbying-on-cannabis-sales-in-virginia/">https://cannabiswire.com/2021/02/07/altria-maker-of-marlboro-cigarettes-is-lobbying-on-cannabis-sales-in-virginia/</a>. Accessed February 23, 2021.

<sup>&</sup>lt;sup>33</sup> Shead S. Lucky Strike-maker British American Tobacco is looking carefully at the cannabis trend. 2021; <a href="https://www.cnbc.com/2021/02/17/lucky-strike-seller-british-american-tobacco-is-looking-at-cannabis-cbd.html">https://www.cnbc.com/2021/02/17/lucky-strike-seller-british-american-tobacco-is-looking-at-cannabis-cbd.html</a>. Accessed February 23, 2021.

<sup>&</sup>lt;sup>34</sup> Dewhirst T. 'Beyond nicotine' marketing strategies: Big Tobacco diversification into the vaping and cannabis product sectors. *Tobacco Control*. 2021:tobaccocontrol-2021-056798.

<sup>&</sup>lt;sup>35</sup> Wakefield T, Glantz SA, Apollonio DE. Content Analysis of the Corporate Social Responsibility Practices of 9 Major Cannabis Companies in Canada and the US. JAMA Netw Open. 2022 Aug 1;5(8):e2228088. doi: 10.1001/jamanetworkopen.2022.28088. PMCID: PMC9399867.

- i. Lessons learned from tobacco product regulation that can be readily applied to cannabis include:
  - Prohibition of unsubstantiated health claims
  - Limitations on advertising and packaging that appeal to youth
  - Implementing effective warning labels
  - Prohibiting product formulations that increase health risks
  - Prohibiting flavors, including menthol, in combustible and vaporized products
  - Recognizing the problem of conflicts of interest and acting to prevent regulators and public employees from having conflicts of interest with the cannabis industry.
  - Establish product standards to regulate manufacturing, marketing, and sale of products.
  - 3. DEA and DOJ should translate the evidence-based and effective tobacco control principles and practices to inform cannabis regulation.

As part of the process to reschedule cannabis, DEA and DOJ should identify best practices from tobacco control and tobacco regulation to inform a comprehensive regulatory regime for cannabis. To protect public health, if cannabis is rescheduled from Schedule I to Schedule III, 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, exposure, and associated health problems.<sup>36</sup>

<sup>&</sup>lt;sup>36</sup> 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

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