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Dockets Management Staff (HFA-305)  
U.S. Food and Drug Administration  
530 Fishers Lane, Rm 1061  
Rockville, MD 20852

RE: Written comments in connection with the May 15, 2019 public scientific workshop on “Youth Tobacco Cessation: Science and Treatment Strategies,” Docket No. FDA-2019-N-1107

The Campaign for Tobacco-Free Kids (Tobacco-Free Kids) submits these comments in the above-referenced Docket established in connection with the May 15, 2019 public hearing convened by the U.S. Food and Drug Administration (FDA) on the Science and Treatment Strategies for Youth Tobacco Cessation. 84 Fed. Reg. 12619 (April 2, 2019).

**The Continuing Youth E-Cigarette Epidemic is Addicting Young People to Nicotine**

Tobacco-Free Kids commends the FDA for its timely convening of the Youth Tobacco Cessation Workshop. The agency’s felt need to convene such a Workshop is a measure of the scope and seriousness of the youth e-cigarette epidemic that has swept the nation. According to the 2018 National Youth Tobacco Survey, there has been a dramatic surge in e-cigarette use among youth, with 1.5 million more high school students using e-cigarettes in 2018 vs. 2017.<sup>1</sup> Given this alarming increase, it is essential for the FDA to address both youth tobacco cessation and prevention strategies. Several factors have contributed to the e-cigarette epidemic in youth, including products with sleek designs that are easy to conceal, use of flavors and marketing strategies that appeal to young people, high nicotine content and youth perceptions that e-cigarettes are low risk and/or safe.<sup>2</sup>

The youth e-cigarette epidemic threatens to undermine the historic gains in reducing youth smoking made over the last several decades. The spike in youth e-cigarette use has driven a 38 percent increase in use of any tobacco product among high school students, from 19.6 percent in 2017 to 27.1 percent in 2018.<sup>3</sup> Further, while youth cigarette rates have been declining since the late 1990s, these

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<sup>1</sup> CDC, “Vital Signs: Tobacco Product Use Among Middle and High School Students—United States, 2011-2018,” *MMWR*, 68, (February 12, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6806e1-H.pdf>. (*MMWR*).

<sup>2</sup> Mitch Zeller, “Evolving “The Real Cost” Campaign to Address the Rising Epidemic of Youth E-cigarette Use,” *American Journal of Preventive Medicine*, 56(2S1): S76-78, (February 2019); *MMWR* at 68; Johnston, L. D., Miech, R. A., O’Malley, P. M., Bachman, J. G., Schulenberg, J. E., & Patrick, M. E., “Monitoring the Future national survey results on drug use: 1975-2017: Overview, key findings on adolescent drug use,” Ann Arbor: Institute for Social Research, The University of Michigan (2018).

<sup>3</sup> *MMWR* at 68, *supra* note 1.

declines have stalled in recent years. There has been no significant change in the high school smoking rate since 2014, and the most recent data from 2018 reflect a possible uptick in cigarette smoking.<sup>4</sup> These data demonstrate that it is essential for the FDA to regulate all tobacco products, including e-cigarettes.

It is well recognized that Juul is a major contributor to this epidemic.<sup>5</sup> Surgeon General Adams, in his December, 2018 Advisory, cited the 600% increase in Juul sales during 2016-17 and described the features of these products that are so appealing to young people, including their minimal exhaled aerosol, reduced odor, small size and similarity in appearance to a USB flash drive, making them easy to conceal from parents and teachers.<sup>6</sup> The availability of flavors also contributes to JUUL's popularity among youth. Data from the 2016-2017 wave of the FDA's Population Assessment of Tobacco and Health (PATH) study found that 96.1 percent of 12-17 year olds who had initiated e-cigarette use since the last survey wave started with a flavored product. Additionally, it found that 97 percent of current youth e-cigarette users had used a flavored e-cigarette in the past month and 70.3 percent say they use e-cigarettes "because they come in flavors I like."<sup>7</sup>

The current crisis is due not only to Juul's design and chemistry; it also has been fueled by Juul's sophisticated use of social media and other strategies to reach young people. When Juul was first launched in 2015, the company used colorful, eye-catching designs and youth-oriented imagery and themes, such as young people dancing and using Juul. Its original marketing campaign included billboards, YouTube videos, advertising in Vice Magazine, launch parties and a sampling tour. One study of Juul's marketing showed that "the growth of JUUL was accompanied by innovative marketing across a variety of new media platforms."<sup>8</sup> It found that "JUUL was one of the first major retail e-cigarette brands that relied heavily on social media to market and promote its products," and it did so effectively. The study "found the number of JUUL-related tweets was highly correlated with quarterly retail sales" of the product and that its Instagram account, reaching a quarter million followers, used artsy photographs to display its products and "evoke lifestyle feelings such as relaxation, freedom and sex appeal," while emphasizing Juul's flavors.<sup>9</sup> A later study found that Juul's official Twitter account was being followed by adolescents and that 25% of people retweeting official Juul tweets were under 18.<sup>10</sup>

The number of youth using e-cigarettes, including JUUL, is alarming and raises serious concerns that e-cigarettes could be an entryway to nicotine addiction and use of regular cigarettes for some kids. There is no question that nicotine exposure is very harmful for youth. The Surgeon General's Advisory warns that "[n]icotine exposure during adolescence can harm the developing brain," impacting

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<sup>4</sup>*Id.*

<sup>5</sup> Alex M. Azar and Scott Gottlieb, "We cannot let e-cigarettes become an onramp for teenage addiction," *Washington Post* (Oct. 11, 2018).

<sup>6</sup> Surgeon General's Advisory on E-Cigarette Use Among Youth, 1-2 (Dec. 18, 2018). (SG Advisory).

<sup>7</sup> FDA, "Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance," (March 13, 2019), <https://www.fda.gov/media/121384/download>. (March 2019 Draft Guidance).

<sup>8</sup> Huang, J, et al., "Vaping versus JUULing: how the extraordinary growth and marketing of JUUL transformed the US retail e-cigarette market," *Tobacco Control*, epub ahead of print, doi: 10.1136/tobaccocontrol-2018-054382, (May 31, 2018).

<sup>9</sup> Huang at 5.

<sup>10</sup> Chu, K-H, et al., "JUUL: Spreading Online and Offline," *Journal of Adolescent Health* 63(5):582-586, (November 2018).

“learning, memory, and attention.”<sup>11</sup> In addition, nicotine is highly addictive, particularly for youth. As Dr. Sharon Levy, Director of Adolescent Substance Abuse and Addiction Program at Boston Children’s Hospital, noted in her statement at the Workshop, nicotine has the ability to alter the chemistry of the brain. Moreover, she stated that adolescents “are developmentally vulnerable to develop substance abuse disorder.” According to Dr. Levy, “the biggest problem...is clearly the amount of nicotine being used.” The Surgeon General has concluded that, “the use of products containing nicotine poses dangers to youth, pregnant women, and fetuses. The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.”<sup>12</sup> Educating youth about the dangers of JUUL and nicotine use is critical; a study from Truth Initiative found that 63 percent of 15-24 year old JUUL users did not know the product always contains nicotine (all pods sold from JUUL do contain nicotine).<sup>13</sup>

Dr. Brian King, the Deputy Director for Research Translations at the Office on Smoking and Health at CDC, shared research on the particularly harmful effects of Juul’s use of nicotine salts on youth: “the nicotine salts lower the acidity of the product and....it will go down a lot easier.” This allows Juul users to inhale high levels of nicotine more easily and with less irritation than the nicotine traditionally used in tobacco products.<sup>14</sup> According to Dr. King, this increases the risk of initiation for kids. The use of nicotine salts could also make it easier for young people to progress to regular e-cigarette use and nicotine dependence.

E-cigarette use is strongly associated with the use of other tobacco products among youth. According to a 2018 report of the National Academy of Sciences, Engineering and Medicine, “there is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.”<sup>15</sup> An analysis of data from the FDA’s nationally representative PATH study found that from 2013 to 2016, youth e-cigarette use was associated with more than four times the odds of trying cigarettes and nearly three times the odds of current cigarette use.<sup>16</sup>

Youth perception that e-cigarettes are safe further contributes to the epidemic. A recurring theme at the Youth Cessation Workshop was that the messaging to youth around e-cigarettes is very confusing to youth. Kathleen Crosby of the Center of Tobacco Products at FDA, told the Workshop that youth “understand risky behavior as well but they don’t see e-cigarettes as risky so they have limited knowledge and need more information.” The youth perception that e-cigarettes are low-risk has

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<sup>11</sup> SG Advisory at 1, *supra* note 6.

<sup>12</sup> HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, (2016).

<sup>13</sup> Willett, J, et al., “Recognition, use and perceptions of JUUL among youth and young adults,” *Tobacco Control*, published online, (April 18, 2018). See also Truth Initiative, “JUUL e-cigarettes gain popularity among youth, but awareness of nicotine presence remains low,” (April 18, 2018), <https://truthinitiative.org/news/juul-e-cigarettes-gain-popularity-among-youth>.

<sup>14</sup> Office of the Surgeon General, “Surgeon General’s Advisory on E-Cigarette Use Among Youth,” December 18, 2018, <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>.

<sup>15</sup> National Academies of Sciences, Engineering, and Medicine, “Public health consequences of e-cigarettes,” Washington, DC: the National Academies Press, (2019), <http://nationalacademies.org/hmd/REports/2018/public-health-consequences-of-e-cigarettes.aspx>.

<sup>16</sup> Berry, KM, et al., “Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths,” *JAMA Network Open*, 2(2), published online, (February 1, 2019).

attracted youth who would otherwise not use tobacco. Marketing e-cigarettes with the implicit message of safety exacerbates this problem. As several panelists reported during the workshop, the advertising of e-cigarettes as a safer alternative to combustible cigarettes has led to youth making the assumption that e-cigarettes are safe.

### **The Need for More High-Quality Research to Better Understand Youth Nicotine Addiction and Effective Youth Cessation Strategies**

Although there is a large body of research on adult smoking cessation, the methods to treat tobacco product addiction among adolescents, and particularly addiction to e-cigarettes are not well understood. There is little information about how drug<sup>17</sup> or behavioral interventions might support youth e-cigarette cessation. The expert testimony delivered at the workshop confirms the dearth of data and understanding about the treatment of youth and nicotine addiction.

Therefore, FDA should fund studies to better understand adolescent nicotine addiction and also identify effective interventions for the adolescent population of e-cigarette users. But the dearth of information on addiction and vaping in adolescents sharply highlights the necessity of an effective prevention strategy to respond to the current youth epidemic. The elements of such a strategy are presented below.

### **Elements of an Effective Prevention Strategy**

Given the challenges with developing pharmacological and other treatment solutions to help already addicted youth with tobacco cessation, it is essential that FDA simultaneously develop and implement an effective prevention strategy to respond to the current epidemic. As part of this prevention strategy, FDA must take strong action to regulate e-cigarettes and their marketing to prevent the population of addicted youth from growing.

We encourage the FDA to implement the following regulatory approach to address the current epidemic.

First, FDA must reverse its suspension of premarket review and subject all e-cigarettes to public health review to determine whether e-cigarettes are appropriate for the protection of public health. The United States District Court for the District of Maryland recently vacated the FDA August 2017 Guidance that suspended premarket review for years into the future.<sup>18</sup> In vacating the August 2017 Guidance the court recognized the harm to public health FDA has caused by allowing highly addictive and harmful tobacco products to remain on the market without public health review. Former Commissioner Gottlieb recently expressed regret that the agency had “struck the wrong balance” on e-cigarettes.<sup>19</sup>

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<sup>17</sup> Tobacco-Free Kids has separately addressed the potential role for drug therapies in treating youth tobacco use, including e-cigarettes, in comments filed on January 30, 2019 in Docket No. FDA-2018-N-3952, which are incorporated by reference. In those comments, we also address the need for FDA to maximize the public health impact of existing FDA-approved smoking cessation medications for adults and to help stimulate innovation in smoking cessation medicines for adults.

<sup>18</sup> *American Academy of Pediatrics v. FDA*, No. PWG-18-883, 2009 WL 2123397 (D. Md. 2019).

<sup>19</sup> Angelica LaVito, “Former FDA Chief Gottlieb: We struck the wrong Balance” on e-cigarettes, (May 21, 2019), <https://www.cnbc.com/2019/05/21/former-fda-chief-gottlieb-we-struck-the-wrong-balance-on-e-cigarettes.html>

The FDA's March, 2019 Draft Guidance,<sup>20</sup> which proposes to shorten the compliance period for e-cigarettes to 2021, and proposes restricting certain flavored products to all-adult facilities, would not be sufficient to combat the current epidemic.<sup>21</sup> Moreover, the exceptions provided for mint and menthol flavored products under the Draft Guidance are not justified. Indeed, the data indicate that many current youth e-cigarette users are using mint e-cigarettes.<sup>22</sup> To bring the epidemic under control, FDA should ban all flavored e-cigarettes, including mint and menthol. As then-Commissioner Gottlieb noted in January of this year, more than two-thirds of regular high school e-cigarette users are using flavored products.<sup>23</sup> FDA should also expedite issuance of a proposed and final rule establishing product standards prohibiting non-tobacco characterizing flavors in all tobacco products, including menthol in e-cigarettes.

Second, FDA must move to curb marketing of e-cigarettes to youth. Juul has been using sophisticated and effective ways of marketing its products to a broader audience of youth. Juul was launched with social media and other advertising using images that overtly targeted young people and, indeed, mimicked the imagery long used by cigarette companies to appeal to youth. FDA must use its authority under the Tobacco Control Act to curb the marketing techniques and strategies used by e-cigarette companies like Juul that are calculated to reach large numbers of young people with appealing images and messaging.

Third, FDA must enforce the law against unauthorized smoking cessation claims or modified risk claims for e-cigarettes. In a May 9 letter to Acting Commissioner Sharpless, Tobacco-Free Kids and five other public health and medical organizations urged the FDA to conduct a thorough investigation of, and take appropriate enforcement action against, the marketing of Juul e-cigarettes with express or implied claims that the products help users stop smoking. These claims indicate that the Juul products are intended for use in the prevention of disease and therefore should be considered drugs, devices, or combination drug/device products within the jurisdiction of the FDA. As Juul is being sold without the requisite approval, it is an unapproved drug or device and is therefore being marketed illegally under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Unless it acts, FDA will create an avenue for Juul and other e-cigarette companies to flout the statutory requirements designed to protect the public against products being marketed for therapeutic purposes, even though no showing has been made that they meet the requisite safety and efficacy standards.

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<sup>20</sup> See March 2019 Draft Guidance, *supra* note 7.

<sup>21</sup> Tobacco-Free Kids and 35 other public health and medical organizations have separately addressed the insufficiency of these proposals in comments filed on Apr. 30, 2018 in Docket No. FDA-2019-D-0661, which are incorporated by reference.

<sup>22</sup> CDC, DC Morbidity and Mortality Weekly Report (MMWR), "Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students – United States, 2011-2018," 67(45): 1276-7 (Nov. 16, 2018) (use of menthol and mint-flavored e-cigarettes increased from 42.3 percent in 2017 to 51.2 percent in 2018); Truth Initiative, "Juul fails to remove all of youth's favorite flavors from stores," (Nov. 15, 2018) (for current Juul users from 12-17 years old, 16 percent used the mint flavor the last time they used a Juul. For those between 18-21 years old, mint was the most popular flavor, with nearly a third (32 percent) using mint the last time they vaped).

<sup>23</sup> Remarks by Scott Gottlieb, M.D., Public Hearing on Eliminating Youth Use of Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies (January 18, 2019) (Gottlieb remarks).

As FDA has recognized, “unsubstantiated cessation claims that reach adolescents may confuse teens and lead teens to believe that these products are FDA-approved smoking cessation products.”<sup>24</sup> The current epidemic of e-cigarette usage by teens should heighten FDA’s commitment to identify and take enforcement action against unsubstantiated claims that e-cigarettes will “help people get off from cigarettes”—particularly where such claims are likely to reach adolescents. If teens are led to believe that such claims imply that e-cigarettes are FDA-approved as “safe,” teens who do not smoke could be more likely to initiate use of e-cigarettes and teen e-cigarette users may be more likely to continue their use.

JUUL Labs has been engaged in a sustained marketing campaign that causes precisely the consumer confusion that the Tobacco Intended Use Rule was issued to prevent. JUUL’s marketing blitz, which includes full-page print ads in major national newspapers, promotion through its website, and radio and television ads, communicates the message that an intended use of JUUL e-cigarette products is for therapeutic purposes. This marketing is directed at the general public and thus will reach millions of young people and millions of non-smokers of every age group. Particularly given JUUL’s remarkable appeal to adolescents, and the epidemic of youth nicotine addiction that the product has caused, this massive marketing of the product for unapproved therapeutic uses should be of urgent concern to FDA.

Fourth, FDA should not grant any Premarket Tobacco Applications (PMTAs) or Modified Risk Tobacco Product applications (MRTPs) unless the applicant has established, through credible scientific evidence, that the product will not appeal to young people. Instead, FDA has established a dangerous precedent by granting a marketing order allowing the U.S. marketing of Philip Morris International’s (PMI) IQOS heated tobacco products.

In the Technical Project Lead Review that accompanied its IQOS PMTA decision, FDA ignored the evidence that PMI had marketed IQOS in country after country to make the product appealing to young people. These marketing tactics cannot be reconciled with PMI’s representations to FDA that it would limit IQOS marketing to adult smokers as an alternative to cigarettes. Our concerns about the IQOS marketing order are set out in a May 14, 2019 letter to Director Zeller from Tobacco-Free Kids and five other public health and medical organizations.

It was significant that the social science experts at FDA, in assessing the possible impact of IQOS on youth, concluded that the premarket applications for IQOS “*do not contain sufficient information* to address these concerns from a Social Science perspective.”<sup>25</sup> This conclusion was overruled by the Technical Project Lead of the Office of Science, and the IQOS PMTA was granted by FDA, based on two studies and limited experience in two different countries (Japan and Italy) with different cultures, different marketing rules and different circumstances. There was no meaningful data or analysis to demonstrate the applicability of the limited experience in those countries to the American setting.

We are deeply troubled by FDA’s reliance on youth studies conducted in other countries and by FDA’s approval of IQOS despite the lack of youth data in the U.S. If FDA allows new tobacco products on the market without requiring manufacturers to present evidence establishing that their products and

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<sup>24</sup> FDA Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses,” 82 Fed. Reg. 2193, 2212 (Jan. 9, 2017).

<sup>25</sup> FDA, Technical Project Lead Review for PMI heated tobacco products, at 83 (April 29, 2019) (emphasis added).

their marketing will not appeal to youth, it can be expected to exacerbate the youth nicotine epidemic. Moreover, certainly no authorization should be given to market modified risk products without credible scientific evidence that such products will not lead to youth initiation and use.

Finally, FDA should continue its efforts through its public education campaigns to educate youth about the risks of e-cigarettes. As noted above, several speakers at the Youth Cessation Workshop made clear that a major contributing reason for the youth e-cigarette epidemic is that youth believe that e-cigarettes are safe. Campaigns should be designed to have the broadest possible reach to youth, regardless of possible exposure of adults to the message. These messages should send a clear message to youth that they should not be using e-cigarettes and e-cigarettes are not safe.

As FDA seeks answers to important questions surrounding youth tobacco cessation, it should recognize that, while devoting time and resources to better understanding the science and treatment strategies for tobacco cessation is essential, solutions resulting from this investment in greater knowledge will take many years before they are realized. Therefore, FDA must develop and implement an effective prevention strategy that includes strong regulation of e-cigarettes and forceful public education campaigns educating youth about the health risks associated with e-cigarette use. The current crisis of youth e-cigarette addiction demands strong FDA action right now.

Respectfully submitted,

Campaign for Tobacco-Free Kids