# FDA should regulate the manufacturing and marketing of hookah tobacco to prevent misperceptions of harm and widespread use among youth and young adults

Docket FDA-2016-N-0173

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# **INTRODUCTION**

Hookah smoking is an alternative form of tobacco use traditionally associated with eastern societies, whose recent spread in the U.S. is a cause of public health concern.<sup>1</sup> Tobacco waterpipe smoking is known by many names (and variable spellings), including hookah, nargileh, hubble-bubble, shisha, and kalian. Although many of these names originated in the distant past, the variety of terms is not unlike the present situation for electronic cigarettes, which similarly are associated with rich alternative terminology. Analogous to electronic cigarettes,<sup>2</sup> disconnect between the broad vocabulary used in practice and the narrow language used in survey research may underestimate the prevalence of waterpipe smoking among youth. Alternative terminology may also lead to confusion, particularly among adolescents, regarding product characteristics and potential risks.

The surge in popularity of hookah in the U.S. may be driven by the introduction of flavored tobacco preparations, reduced-harm perception, social café culture, exotic appeal, and marketing of hookah bars.<sup>3,4</sup> *Given the widespread use and accumulating scientific evidence showing significant intake of nicotine, carcinogens, and other toxic chemicals and some epidemiologic data showing harm, we strongly urge the FDA to regulate the manufacture, sale, and marketing of hookah tobacco and devices used for hookah smoking as a tobacco product, including regulation of tobacco content and flavor additives, and mandating health warning labels.* 

#### **PREVALENCE OF USE**

A 2015 CDC/FDA analysis of data from the 2011-2014 National Youth Tobacco Surveys (NYTS) reported that in 2014 an estimated 1.6 million middle and high school students used hookah.<sup>5</sup> Hookah was the second most common tobacco product used (behind e-cigarettes), with

<sup>2</sup> Richtel M. E-Cigarettes, by Other Names, Lure Young and Worry Experts. *New York Times*.

http://www.nytimes.com/2014/03/05/business/e-cigarettes-under-aliases-elude-the-authorities.html?\_r=0 Published: March 4, 2014. Accessed: March 29, 2016.

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<sup>&</sup>lt;sup>1</sup> Maziak W. The waterpipe: An emerging global risk for cancer. Cancer Epidemiology. 2013;37(1):1-4.

<sup>&</sup>lt;sup>3</sup> Maziak W. The global epidemic of waterpipe smoking. Addict Behav. 2011;36(1):1-5.

<sup>&</sup>lt;sup>4</sup> Aljarrah K, Ababneh ZQ, Al-Delaimy WK. Perceptions of hookah smoking harmfulness: predictors and characteristics among current hookah users. Tobacco Induced Diseases. 2009;5(1):16.

9.4% of high school students and 2.5% of middle school students using hookah.<sup>5</sup> From 2011 to 2014, current use of hookah among high school students increased from 4.1% to 9.4%, while tobacco cigarette use decreased from 15.8% to 9.2%, with similar trends observed among middle school students.<sup>5</sup> From 2013 to 2014, substantial increases were observed for current hookah use, with prevalence almost doubling for high school students from 5.2% (770,000) to 9.4% (1.3 million), and for middle school students from 1.1% (120,000), to 2.5% (280,000) over this period.<sup>5</sup> The use rates dropped slightly in 2015 to 7.2% (1.0 million) for high school students and 2.0% (220,000), but remained substantially elevated over 2011 levels.<sup>6</sup>

A recent study of adolescents' perceptions of risks associated with use of tobacco products conducted by the UCSF TCORS found hookah use was the most prevalent among all tobacco products. In the UCSF TCORS study, 1299 students were recruited and consented, of whom 722 completed the survey. Participants included 261 (36.1%) males and 453 (62.7%) females (mean age = 16.2, SD = 1.6). Participants were ethnically diverse, with 193 (27.0%) White, 157 (21.9%) Asian/Pacific Islander, 113 (15.8%) Hispanic, and 253 (35.34%) 'Other'. Overall, 248 participants (34.7%) had ever tried any tobacco product, of whom 160 (22.4%) had ever tried hookah, 139 (19.5%) had ever tried e-cigarettes, 93 (13.0%) had ever tried cigarettes, 47 (6.5%) had ever tried cigars, and 19 (2.6%) had ever tried chew. Therefore, hookah use was most prevalent among our sample of California youth.<sup>7</sup>

In a separate analysis of the NYTS data to determine the prevalence of flavored tobacco products, CDC and FDA researchers found that in 2014 an estimated 70% (3.26 million) of all current middle and high school tobacco users had used at least one flavored tobacco product in the past 30 days, including 60.6% (1.02 million) of current users who had used flavored hookah tobacco.<sup>8</sup> The prevalence of flavored tobacco products was more than three times the prevalence of nonflavored products, with current use of at least one flavored product reported by 18.9% of all high school students, as compared to 5.8% who reported using only nonflavored tobacco products.<sup>8</sup> Hookah was the second most commonly used flavored tobacco product (after e-cigarettes), with 6.0% of high school students using flavored hookah.<sup>8</sup>

Data from the 2012 Florida Youth Tobacco Survey (FYTS)<sup>9</sup> found that in 2012 more than one in six (16.7%) Florida high school students reported trying hookah in their lifetime, with hookah rates increasing among adolescents living in Florida from 20007 to 2012.<sup>9</sup> Rates increased with each grade, with more than one fourth (26.1%) of 12th graders reporting lifetime use.<sup>9</sup> Male use increased from 12.3% to 16.8%, while female use increased at a faster rate, from 9.3% to 16.5%.<sup>9</sup> Non-Hispanic Whites demonstrated a 6% increase over 6 years, whereas Hispanic youth nearly doubled their lifetime use (11.8%–21.9%; p < .05).<sup>9</sup> In 2012, Hispanic (21.9%) and non-

<sup>&</sup>lt;sup>5</sup> Arrazola RA, Singh T, Corey CG, et al. Tobacco Use Among Middle and High School Students — United States, 2011-2014. MMWR Morb Mortal Wkly Rep. 2015;64(14):381-385.

<sup>&</sup>lt;sup>6</sup> Singh T, Arrazola RA, Corey CG, Husten CG, Neff LJ, Homa DM, King BA. Tobacco Use Among Middle and High School Students — United States, 2011-2015. MMWR Morb Mortal Wkly Rep. 2016;65(14):361-367.

<sup>&</sup>lt;sup>7</sup> Roditis M, Delucchi K, Cash D, and Halpern-Felsher B. Adolescents' Perceptions of Health Risks, Social Risks, and Benefits Differ across Tobacco Products. J Adolescent Health. (In press)

<sup>&</sup>lt;sup>8</sup> Corey CG, Ambrose BK, Apelberg BJ, et al. Flavored Tobacco Product Use Among Middle and High School Students — United States, 2011-2014. MMWR Morb Mortal Wkly Rep. 2015;64(38):1066-1070.

<sup>&</sup>lt;sup>9</sup> Barnett, TE, Forrest, JR, Porter, L, Curbow, BA. A multiyear assessment of hookah use prevalence among Florida high school students. Nicotine Tob Res 2014;16;373-377.

Hispanic White (19.0%) youth both reported more hookah use than non-Hispanic Black youth (5.2%; p < .05).<sup>9</sup> The other race/ethnicity group included American Indian, Alaska Native, Hawaiian, Other Pacific Islander, Asian, and "other," which likely included adolescents of Middle Eastern descent. This group demonstrated no significant change in hookah use over time but had the highest rate at baseline (18.0% in 2007).<sup>9</sup>

While 2009–2012 FYTS data did not indicate significant increases in current (past 30-day) use overall, current use among Hispanics increased significantly over the 4 years, from 7.9% to 11.2% (p < .05).<sup>9</sup> In 2012, males reported a significantly higher prevalence of current use (8.2%) than females (7.0%; p < .05).<sup>9</sup> Hispanic (11.2%) and "Other" (9.8%) race/ethnicity groups reported significantly higher (p < .05) rates of current use than non-Hispanic White (7.6%) and non-Hispanic Black adolescents (2.8%).<sup>9</sup> Current use also increased with each grade level. By 12th grade, 11.8% (more than one in nine) were current hookah users.<sup>9</sup>

Hookah smoking is also popular among college students. A study of undergraduate and graduate university students in Florida evaluating the prevalence of lifetime and current use found that in 2012 54.4% of students had used hookah during their lifetime, and 16.3% had used hookah within the past 30 days.<sup>10</sup> Hookah use was significantly associated with cigarette smoking, but not with alcohol use.<sup>10</sup> Almost 30% of those who never smoked hookah reported they would consider smoking hookah in the future.<sup>10</sup>

Florida's current use rate is consistent with previous prevalence studies conducted with collegeaged youth in North Carolina<sup>11</sup> and California.<sup>12 13</sup> While earlier studies associated current hookah use in college populations with being male<sup>14 15</sup> and White,<sup>16 17</sup> more recent findings have shown that females are smoking at equivalent rates to males and Hispanics are smoking hookah at similar or higher levels that non-Hispanic Whites.<sup>18</sup> A study that sampled college students from eight universities found that 40.3% of the students reported ever using hookah, and 17.4% reported current use of hookah.<sup>11</sup>

<sup>&</sup>lt;sup>10</sup> Rahman S, Chang L, Hadgu S, et al. Prevalence, Knowledge, and Practices of Hookah Smoking Among University Students, Florida, 2012. Prev. Chronic Dis. 2014;11:140099.

<sup>&</sup>lt;sup>11</sup> Sutfin EL, McCoy TP, Reboussin BA, et al. Prevalence and correlates of waterpipe tobacco smoking by college students in North Carolina. Drug Alcohol Deeepend 2011;115(1-2):131-136.

<sup>&</sup>lt;sup>12</sup> Al-Delaimy WK, White MM, Mills AL, et al. Two decades of the California Tobacco Control Program:

California Tobacco Survey, 1990-2008. Univ. of California, San Diego (2010).

<sup>&</sup>lt;sup>13</sup> Smith JR, Edland SD, Novotny TE, et al. Increasing hookah use in California. Am J Public Health 2011;101(10): 1876-1879,

<sup>&</sup>lt;sup>14</sup> Grekin ER, Ayna D. Argileh use among college students in the United States: An emerging trend. J of Studies on Alcohol and Drugs 2008;69:472-474.

<sup>&</sup>lt;sup>15</sup> Smith-Simone S, Maziak W, Ward KD, Eissenberg T. Waterpipe tobacco smoking: Knowledge, attitudes, beliefs, and behavior in two U.S. samples. Nicotine & Tob Res 2011;13:1202-1209.

<sup>&</sup>lt;sup>16</sup> Eissenberg TE, Ward KD, Smith-Simone S, Maziak W. Waterpipe tobacco smoking on a U.S. college campus: Prevalence and correlates. J of Adolescent Health 2008;42:526-529.

<sup>&</sup>lt;sup>17</sup> Primack BA, Sidani J, Agarwal AA, et al. Prevalence of and associations with waterpipe tobacco smoking among U.S. university students. Annals of Behavioral Medicine 2008;36:81-86.

<sup>&</sup>lt;sup>18</sup> Barnett TE, Smith T, He Y, et al. Evidence of emerging hookah use among university students: A cross-sectional comparison between hookah and cigarette use. BMC Public Health 2013;13:302.

#### **USE PATTERNS and PERCEPTIONS OF USE**

The health risks associated with hookah use are determined to a great extent by the use patterns and intensity of use. Although the prevalence and/or frequency of hookah use in the US may be lower than that of cigarettes, a single hookah session typically lasts for 45 minutes and may produce 50 to 100 times the smoke volume inhaled from a single cigarette.<sup>19</sup> An hour-long session of smoking hookah gives users a dose of nicotine similar to smoking two to three cigarettes, and delivers qualitatively the same toxicants, albeit at different concentrations, to the body.<sup>20</sup> Smoking hookah has become trendy in the US, especially on college campuses and among high school students. Young people are attracted to the exotic novelty of the device, as well as to the fruity flavors, and young people often smoke in a social atmosphere at hookah cafés, where the mouthpiece is passed around in a circle of friends.<sup>20</sup> Hookah cafés are popular for young adults because they often do not serve alcohol so individuals under age 21 who are not old enough to enter a traditional bar can socialize with friends at a hookah café.<sup>19</sup> Exposure to secondhand smoke is great in indoor hookah cafés, where average levels of particulate matter less than 2.5 microns (PM<sub>2.5</sub>) and carbon monoxide exceeded air quality standards.<sup>21</sup>

The UCSF TCORS has conducted qualitative research involving individual interviews with male adolescents in rural communities regarding their current and past experiences with tobacco products. Preliminarily, these interviews revealed considerable uncertainty in relation to tobacco waterpipe terminology and health risks. Multiple participants, including those who reported having tried tobacco waterpipe and those who regularly used other forms of tobacco (usually dip or chewing tobacco), were uncertain of the distinction between electronic nicotine delivery systems (ENDS) or e-cigarettes and tobacco waterpipe, possibly because terminology such as "hookah pens" or "e-hookah" is used to describe some forms of e-cigarettes.

It is plausible that similar or overlapping terminology between ENDS and tobacco waterpipes may lead some youth to ascribe perceived qualities of one product to the other. For example, youth may perceive both ENDS aerosol and waterpipe smoke as "harmless water vapor." *Efforts by the FDA or others to inform the public regarding health consequences of tobacco waterpipe smoking be clear about what product is being discussed.* 

The perceived health risks of waterpipe smoking are often formed in the context of relative comparisons between waterpipe smoking and cigarette smoking. In a recent study featuring focus groups of young adult waterpipe smokers<sup>22</sup> (age 18-24, including students and nonstudents), waterpipe users were aware of negative health consequences, but maintained a view of waterpipe smoking as an activity with an appeal to health conscious individuals, due to perceived "smoother" smoke, "natural" coals, or lower level of toxins than cigarette smoke.

<sup>&</sup>lt;sup>19</sup> Haddad L, El-Shahawy O, Ghadban R, et al. Waterpipe Smoking and Regulation in the United States: A Comprehensive Review of the Literature. Int J Environ Res Public Health 2015;12(6):6115-6135. doi:10.3390/ijerph120606115.

 <sup>&</sup>lt;sup>20</sup> Everts S. What's Hookah, And Is It Healthier Than Smoking A Cigarette? Chemical & Engineering News, Vol. 93, Issue 25, p. 41, June 22, 2015.

<sup>&</sup>lt;sup>21</sup> Zhang B, Haji F, Kaufman P, et al. 'Enter at your own risk': a multimethod study of air quality and biological measures in Canadian waterpipe cafes. Tob Control 2015;24:175-181 doi:10.1136/tobaccocontrol-2013-051180.

<sup>&</sup>lt;sup>22</sup> Castañeda G, Barnett TE, Soule EK, Young ME. Hookah smoking behavior initiation in the context of Millennials. *Public Health.* 2016 Mar 18 [Epub ahead of print]

Thus, as a means of consuming tobacco that was viewed as relatively less dangerous than cigarettes, these young adults adapted a perception of waterpipe use as a health-promoting activity.

In our UCSF TCORS study, adolescents generally rated cigarettes as most risky, followed by cigars and chew, with hookah and e-cigarettes rated as least risky. Hookah and e-cigarettes were seen as least likely to cause harm to oneself, compared to cigarettes, chew and cigars. Adolescents thought that combustible products of cigarettes, cigars and hookah would cause the most harm to others, followed by chew, and e-cigarettes. Hookah, along with cigars, chew and e-cigarettes, were seen as significantly less likely to cause harm to the environment, compared to cigarettes. Adolescents who had used hookah believed it was less likely to cause harm than those who had never used tobacco.<sup>7</sup>

Regarding specific risks and benefits, adolescents in our UCSF TCORS study rated hookah followed by cigarettes and e-cigarettes as most likely to make them look cool or fit in, and cigars and chew as least likely to confer these benefits. There were interaction effects by age and use, with older adolescents and those with tobacco experience holding lower perceptions of risk for hookah and other tobacco products. There were no significant interaction effects by race/ethnicity or gender.<sup>7</sup>

With the exception of the chance of getting mouth sores, in which adolescents perceived chew to be most risky, cigarettes and cigars were perceived to confer the greatest short-term health risks. Compared to cigarettes and cigars, adolescents believed that hookah use was significantly less likely to result in a bad cough, a cold, or trouble breathing. They also felt that friends would be less likely to be upset and less likely to get into trouble if someone was using hookah compared to cigarettes and cigars. In most cases, adolescents had similar perceptions of short- and long-term social and health risks of hookah and e-cigarettes.<sup>7</sup>

Other studies assessing general perceptions of harm have found a continuum of risk in which ecigarettes, cigars, and hookah are viewed as less harmful than other tobacco products.<sup>23 24</sup> The relationship between perceptions of risks and use of hookah, cigars, and e-cigarettes has been also found among college students.<sup>25 26 27</sup>

For the reasons discussed in detail below, FDA's public information efforts should clearly convey the message that, contrary to popular perceptions, waterpipes deliver higher levels of many toxic chemicals and create more secondhand smoke than cigarettes.

<sup>&</sup>lt;sup>23</sup> Ambrose BK, Rostron BL, Johnson SE, et al. Perceptions of the relative harm of cigarettes and e-cigarettes among US youth. Am J Prev Med. 2014;47(2):S53-S60. doi:10.1016/j.amepre.2014.04.016

<sup>&</sup>lt;sup>24</sup> Berg CJ, Stratton E, Schauer GL, et al. Perceived harm, addictiveness, and social acceptability of tobacco products and marijuana among young adults: marijuana, hookah, and electronic cigarettes win. Subst Use Misuse. 2015;50(1):79-89. doi:10.3109/10826084.2014.958857

<sup>&</sup>lt;sup>25</sup> Eissenberg T, Ward KD, Smith-Simone S, Maziak W. Waterpipe tobacco smoking on a US College campus: prevalence and correlates. J Adolesc Health. 2008;42(5):526-529. doi.org/10.1016/j.jadohealth.2007.10.004

<sup>&</sup>lt;sup>26</sup> Nyman AL, Taylor TM, Biener L. Trends in cigar smoking and perceptions of health risks among Massachusetts adults. Tob Control. 2002;11(suppl 2):ii25-ii28. doi:10.1136/tc.11.suppl\_2.ii25

<sup>&</sup>lt;sup>27</sup> Sutfin EL, McCoy TP, Morrell HE, Hoeppner BB, Wolfson M. Electronic cigarette use by college students. Drug Alcohol Depen. 2013;131(3):214-221. doi:10.1016/j.drugalcdep.2013.05.001

# **EXPOSURE TO TOXICANTS**

#### Exposure among hookah users

Several studies have measured tobacco-related toxicants in hookah smoke, including polycyclic aromatic hydrocarbons (PAHs), volatile organic compounds (VOCs) such as formaldehyde, acetone, and acrolein, and carcinogenic tobacco-specific nitrosamines (TSNAs).<sup>28 29 30</sup> Hookah smoking machine studies indicated that the amount of water pipe tobacco used in a single hookah smoking session produced 100-fold more tar, 4-fold more nicotine, 11-fold more CO, and 2- to 5-fold more polycyclic aromatic hydrocarbons than did a single cigarette.<sup>31</sup>

To date, we have conducted three comprehensive studies of systemic intake of tobacco-related toxicants from hookah use.

In the first study, involving a single use of hookahs in a hospital research ward, we measured plasma nicotine levels that were comparable to levels attained after smoking cigarettes; carbon monoxide levels were much higher than in cigarette smokers; and we measured significant increases in urine NNAL, a breakdown product of NNK (a nicotine-derived nitrosamine and known pulmonary carcinogen), as well as breakdown products of PAHs.<sup>32</sup>

We then conducted a crossover study to compare nicotine intake and carcinogen exposure from hookah and cigarette smoking. This study was also conducted in a hospital research ward. Compared to cigarette smoking, we reported lower nicotine intake, greater carbon monoxide exposure, and a different pattern of carcinogen exposure, with greater exposure to benzene and high molecular weight PAHs, and less exposure to tobacco-specific nitrosamines, 1,3-butadiene and acrolein, acrylonitrile, propylene oxide, ethylene oxide, and low molecular weight PAHs following hookah smoking.<sup>33</sup> This study showed that exposure to tobacco smoke toxicants in hookah smoke is similar qualitatively but quantitatively delivers higher levels of several toxicants than cigarette smoke. Importantly exposure to benzene, a chemical known to cause leukemia in humans, and high molecular weight PAHs, which are known to be more potent carcinogens than the lighter weight PAHs, were higher while smoking hookah than tobacco cigarettes.

The third study entailed assessing nicotine intake and exposure to tobacco-specific nitrosamines and volatile organic compounds from hookah smoking in a naturalistic setting (i.e. hookah bars or lounges) as opposed to a hospital research ward. In the natural setting, hookah users share

<sup>&</sup>lt;sup>28</sup> Schubert J, Heinke V, Bewersdorff J, Luch A, Schulz TG. Waterpipe smoking: the role of humectants in the release of toxic carbonyls. Arch Toxicol. 2012;86(8):1309-16.

<sup>&</sup>lt;sup>29</sup> Shihadeh A, Saleh R. Polycyclic aromatic hydrocarbons, carbon monoxide, "tar", and nicotine in the mainstream smoke aerosol of the narghile water pipe. Food Chem Toxicol. 2005;43(5):655-61.

<sup>&</sup>lt;sup>30</sup> Schubert J, Hahn J, Dettbarn G, Seidel A, Luch A, Schulz TG. Mainstream smoke of the waterpipe: does this environmental matrix reveal as significant source of toxic compounds? Toxicol Lett. 2011;205(3):279-84.

<sup>&</sup>lt;sup>31</sup> Shihadeh A, Saleh R. Polycyclic aromatic hydrocarbons, carbon monoxide, "tar", and nicotine in the mainstream smoke aerosol of the narghile water pipe. Food Chem Toxicol 2005;43:655–61.

<sup>&</sup>lt;sup>32</sup> Jacob P, Raddaha AHA, Dempsey D, Havel C, Peng M, Yu L, et al. Nicotine, carbon monoxide, and carcinogen exposure after a single use of a water pipe. Cancer Epidemiology Biomarkers & Prevention. 2011;20(11):2345-53.

<sup>&</sup>lt;sup>33</sup> Jacob P, Raddaha AHA, Dempsey D, Havel C, Peng M, Yu L, et al. Comparison of Nicotine and Carcinogen Exposure with Water pipe and Cigarette Smoking. Cancer Epidemiology Biomarkers & Prevention. 2013;22(5):765-72.

hookahs with multiple users. Again, this study showed substantial nicotine intake comparable to at least one cigarette as well as significant exposure to NNK (measured using urine NNAL) and breakdown products of carcinogenic VOCs such as benzene, 1,3-butadiene, acrylonitrile, and ethylene oxide.<sup>34</sup>

Carbon monoxide (CO) is a toxicant that is a risk for all users,<sup>31</sup> with some studies showing extremely high CO levels for users.<sup>35</sup> Case reports have even indicated CO poisoning among young adult hookah users.<sup>36 37 38</sup>

A study published in March 2016 assessing the effects of hookah smoking on the human lung in young, light-use hookah smokers found that young, light-use hookah-only smokers have a variety of abnormalities in multiple lung-related biologic and clinical parameters including more cough and sputum, lower lung diffusing capacity, abnormal epithelial lining fluid metabolome profile, increased proportions of small airway epithelial (SAE) secretory and intermediate cells, reduced proportions of SAE ciliated and basal cells, markedly abnormal SAE and alveolar macrophage transcriptomes, and elevated levels of apoptotic endothelial cell microparticles.<sup>39</sup> These results suggest that even limited hookah use has broad consequences on human lung biology and health.<sup>39</sup>

#### Health risks associated with secondhand and thirdhand exposure to hookah smoke

Kassem et al. reported that children living in homes of hookah smokers are exposed to significant levels of secondhand and thirdhand smoke.<sup>40</sup> They found that nicotine levels in air and on surfaces in child bedrooms of daily hookah smokers were significantly higher than in homes of nonsmokers. Uptake of nicotine, assessed by measuring cotinine in children's urine, uptake of the tobacco-specific carcinogen NNK, measured by the metabolite NNAL in urine, and uptake of the toxic volatile organic compound (VOC) acrolein, measured by a metabolite biomarker in urine, were higher in children living in homes of daily hookah smokers as compared to children living in non-smokers' homes. Uptake of nicotine and NNK were also higher in children living in weekly/monthly hookah smokers' homes than in children living in non-smokers' homes. The authors concluded that daily and occasional hookah use in homes presents a serious, emerging threat to children's health. In another study, Kassem et al. reported

<sup>&</sup>lt;sup>34</sup> St.Helen G, Benowitz NL, Dains KM, Havel C, Peng M, Jacob P, 3rd. Nicotine and carcinogen exposure after water pipe smoking in hookah bars. Cancer Epidemiol Biomarkers Prev. 2014;23(6):1055-66.

<sup>&</sup>lt;sup>35</sup> Barnett TE, Curbow BA, Weitz JR, et al. (2009) Water pipe tobacco smoking among middle and high school students. AJPH, 99, 2014-2019. doi:10.2105/AJPH.2008.151225.

<sup>&</sup>lt;sup>36</sup> Ashurst JV, Urquhart M., Cook MD (2012). Carbon monoxide poisoning secondary to hookah smoking. Journal American Osteopathic Association, 112,686–688.

<sup>&</sup>lt;sup>37</sup> Cavus UY, Rehber ZH, Ozeke O (2010). Carbon monoxide poisoning associated with Narghile use. Emergency Medicine Journal, 27, 406. doi:10.1136/emj.2009.077214

<sup>&</sup>lt;sup>38</sup> Lim BL, Lim GH, Seow E (2010). Case of carbon monoxide poisoning after smoking shisha. International Journal of Emergency Medicine, 11, 121–122. doi:10.1007/s12245-009-0097-8

<sup>&</sup>lt;sup>39</sup> Strulovici-Barel Y, Shaykhiev R, Salit J, et al. Pulmonary Abnormalities in Young, Light-use Waterpipe (Hookah) Smokers. AJRCCM Articles in Press. Published on 23-March-2016 as 10.1164/rccm.201512-2470OC.

 <sup>&</sup>lt;sup>40</sup> Kassem N, Daffa R, Liles S, Jackson S, Kassem N, Younis M, Mehta S, Menglan C, Jacob III P, Carmella S, Chatfield D, Benowitz N, Matt G, Hecht S, Hovell M. Children's Exposure to Secondhand and Thirdhand Smoke Carcinogens and Toxicants in Homes of Hookah Smokers. Nicotine Tob Res. 2014;16:961-75.

that non-smokers exposed to hookah smoke had elevated urine concentrations of the benzene biomarker S-phenylmercapturic acid.<sup>41</sup>

Of further concern is the environmental fate of exhaled hookah smoke constituents and their health effects. Hookah smoke (like cigarette smoke) deposited indoors (or outdoors) undergoes physical and chemical transformations over time resulting in the creation of secondary pollutants, or thirdhand smoke<sup>42</sup>, on various surfaces. Despite a lack of human health studies on the long-term health effects of thirdhand smoke exposure, recent studies show that thirdhand smoke is a potential source of carcinogen and toxicant exposure and animal and in vitro studies show that it has toxic effects on several organs, including liver and lungs, and is genotoxic.<sup>43 44 45</sup>

#### Charcoal and its contribution to toxicant exposure

Charcoal is produced by incomplete combustion of wood. As in incomplete combustion of other organic materials, polycyclic aromatic hydrocarbons (PAHs) are produced. It is well known that burning charcoal produces large amounts of CO. It is has been shown that burning charcoal produces benzene,<sup>46</sup> a carcinogen associated with increased incidence of leukemia. One study showed that charcoal emissions were the primary source of CO and carcinogenic PAHs; 90% of CO and 75-92% of 4- and 5-ring PAHs (the heavy molecular PAHs) originated from the charcoal.<sup>47</sup> This indicates that any regulation of waterpipes which do not include regulation of charcoal as a component of waterpipes will not fully protect public health.

# ADDICTION AND PERCEIVED RISK OF ADDICTION

The UCSF TCORS study showed that adolescents perceived the risk of addiction as lowest for ecigarettes and hookah, followed by chew, cigars and then cigarettes.<sup>7</sup> Similarly, adolescents felt it would take 16 attempts to quit cigarettes, 12 attempts to quit chew, 11 attempts to quit cigars, 9 attempts to quit hookah, and 8 attempts to quit e-cigarettes.<sup>7</sup>

<sup>&</sup>lt;sup>41</sup> Kassem NO, Kassem NO, Jackson SR, Liles S, Daffa RM, Zarth AT, Younis MA, Carmella SG, Hofstetter CR, Chatfield DA, Matt GE, Hecht SS, Hovell MF. Benzene uptake in Hookah smokers and non-smokers attending Hookah social events: regulatory implications. Cancer Epidemiol Biomarkers Prev. 2014 Dec;23(12):2793-809.

<sup>&</sup>lt;sup>42</sup> Matt GE. Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. Environmental Health Perspectives, 119, 1218-1226, 10/1/2011. 2013. Matt GE. Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. Environmental Health Perspectives, 119, 1218-1226, 10/1/2011. 2013.

<sup>&</sup>lt;sup>43</sup> Thomas JL, Hecht SS, Luo X, Ming X, Ahluwalia JS, Carmella SG. Thirdhand tobacco smoke: a tobacco-specific lung carcinogen on surfaces in smokers' homes. Nicotine Tob Res. 2014;16(1):26-32.

<sup>&</sup>lt;sup>44</sup> Martins-Green M, Adhami N, Frankos M, Valdez M, Goodwin B, Lyubovitsky J, et al. Cigarette smoke toxins deposited on surfaces: implications for human health. PloS one. 2014;9(1).

<sup>&</sup>lt;sup>45</sup> Hang B, Sarker AH, Havel C, Saha S, Hazra TK, Schick S, et al. Thirdhand smoke causes DNA damage in human cells. Mutagenesis. 2013;28(4):381-91.

<sup>&</sup>lt;sup>46</sup> Olsson M; Petersson G. Benzene emitted from glowing charcoal. Science of the Total Environment (2003), 303, 215-220.

<sup>&</sup>lt;sup>47</sup> Monzer B, Sepetdjian E, Saliba N, Shihadeh A. Charcoal emissions as a source of CO and carcinogenic PAH in mainstream narghile waterpipe smoke. Food Chem Toxicol. 2008;46(9):2991-5.

Further, adolescents perceived that you were significantly less likely to become addicted and still be using in 5 years and more likely to be able to quit if you used hookah, compared to using chew, cigars or cigarettes.<sup>7</sup> They also thought it would take less time to become addicted if using hookah compared to other tobacco products.<sup>7</sup>

FDA's labeling and public education campaigns about hookah should inform users and the public that hookah contains the same addictive nicotine as other tobacco products, which leads to the same loss of control as use of other tobacco products.

# MARKETING

A comprehensive, qualitative assessment of 144 websites promoting hookah cafes found that none of the websites required age verification, less than 1% included a tobacco-related warning on the first page, and only 4% included a warning on any page.<sup>48</sup> Although mention of the word tobacco only appeared on the first page of 26% of the sites and on any page of 58% of sites), the promotion of flavorings, pleasure, relaxation, product quality, and cultural and social aspects of hookah smoking was common.<sup>48</sup> 72% of the sites promoted flavors of hookah tobacco anywhere in the site, more than half on the opening page.<sup>48</sup>

Relaxation and pleasure were emphasized by 71% of sites.<sup>48</sup> The social aspect of hookah tobacco smoking also was emphasized, with 32% doing so on the opening page via statements such as "People gather to socialize and lounge for peaceful conversation and environment."<sup>48</sup> Product quality was emphasized in 49%.<sup>48</sup>

This analysis of 144 websites representing hookah tobacco smoking establishments suggests that these establishments, which exist in all geographic areas of the U.S., promote themselves as highly social, cultural, and fun places for young people to relax and enjoy themselves. The hookah café promotional materials de-emphasize age limits, health warnings, and even that tobacco is involved in hookah smoking. The study concluded that health education and policy changes are needed to alter misinformation and misperceptions related to hookah smoking.

# CONSEQUENCES OF WEAK AND NON-EXISTENT REGULATIONS

Hookah use carries the same health risks as cigarette smoking, and may have worse health effects for some diseases due to the addition of charcoal and shared mouthpieces. Nevertheless, many hookah users think that hookah smoking is less dangerous and less addictive and exposes them to less toxicants than cigarette smoking. Hookah smoking sessions are generally longer than cigarette smoking sessions, which result in more nicotine exposure. Hookah cafes are popular with youth and young adults, and the hookah cafes that do not serve alcohol are popular with youth under age 21. The novelty of the exotic device and flavors are especially attractive to youth. Unfortunately, the Tobacco Control Act's prohibition of characterizing flavors does not

<sup>&</sup>lt;sup>48</sup> Primack BA, Rice KR, Shensa A, et al. U.S. Hookah Tobacco Smoking Establishments Advertised on the Internet. Am J Prev Med 2012;42(2):150 –156.

apply to hookah, nor do its advertising and marketing restrictions. Health warnings are absent or not seen by most users.

Many localities grant hookah cafes exceptions to smokefree laws, and many hookah cafes are lax about checking identification and restricting smoking indoors or on attached patios. Hookah cafes are promoted online and may be advertised in other ways that are prohibited for cigarettes. This dearth of regulations has helped to increase the popularity of hookah smoking and sustain the normalization of tobacco use and tobacco and alcohol co-use.

FDA should assert authority over the manufacturing and marketing of tobacco used in hookah. In particular, FDA should prohibit flavorings in hookah tobacco, since flavors attract youth and young adults, and prohibiting flavors is likely to lessen the appeal of smoking hookah. FDA should require prominent labeling on hookah products and in advertising for hookah products, indicating that: (1) hookah contains nicotine that is the same addictive drug that is in cigarettes, e-cigarettes, and other tobacco products, and (2) hookah use produces high levels of secondhand and thirdhand exposure. Because hookah is often smoked in hookah cafes, these establishments should be required to display prominent advertisements produced by the FDA communicating these messages.