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Food and Drug Administration (FDA)
Center for Tobacco Products (CTP)
FDA White Oak Conference Center
Building 31, Room 1503
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Docket No. FDA-2016-N-1073

Ladies and Gentlemen:

The undersigned organizations submit these comments in the above-designated docket regarding the scientific and regulatory issues concerning the proposed regulation of waterpipe tobacco¹. Waterpipe tobacco is among the products that would become subject to FDA regulation pursuant to the rule proposed by the FDA on April 25, 2014 in Docket No. FDA-2014-N-1089. These comments reach the following conclusions and make the following recommendations.

1. The toxicity of waterpipe tobacco, coupled with its increasing popularity with underage and young adult users, makes it imperative for FDA to subject waterpipe tobacco to regulation. Youth usage of waterpipe tobacco has increased sharply in recent years. The current absence of regulation of this product has contributed to the sharp growth in its use.
2. The way waterpipe tobacco is used differs in many respects from the way other tobacco products are used and the regulation of this product should be tailored to address the particular manner in which the product is used.
3. Flavoring of waterpipe tobacco contributes to its attractiveness to underage users and should be prohibited.
4. A high percentage of users and potential users of waterpipe tobacco do not recognize either the danger or the addictiveness of the product. These misperceptions have played an important role in increasing waterpipe usage. Measures, such as warning labels, to provide accurate information about both the toxicity and the addictiveness of the product should be a central part of the regulatory scheme.

¹ The terms “waterpipe tobacco” and “hookah” are used synonymously in this document.

Discussion

I. FACTUAL BACKGROUND

A. WATERPIPE TOBACCO DELIVERS NICOTINE AND KNOWN CARCINOGENS TO ITS USERS AND TO NON-USERS EXPOSED TO SECONDHAND WATERPIPE SMOKE.

The tobacco used in waterpipe smoking is typically combined with other substances, usually sweetly flavored, and placed in a bowl above the water chamber. The sweetly flavored mixture is known as maassel and shisha. This mixture is subjected to external heat produced by the burning of charcoal. The tobacco mixture does not burn but rather releases volatile components in the tobacco that combine with the smoke from charcoal combustion. This smoke, combined with components from the tobacco mixture and the products of charcoal combustion, bubbles through the water and is inhaled by the user.

Studies have shown that hookah smoke contains many of the toxins and carcinogens found in cigarettes.² Some of these harmful components are in gaseous form and others are particulates. At least 82 toxicants and carcinogens have been identified in waterpipe tobacco smoke, including tobacco-specific nitrosamines (TSNAs), polycyclic aromatic hydrocarbons (PAHs), and heavy metals.^{3,4} In addition, the aerosol contains the toxins and carcinogens from the burning of the charcoal, including carbon monoxide. A recently published meta-analysis that analyzed 17 studies of waterpipe tobacco smoking found that a single waterpipe tobacco smoking session was associated with carbon monoxide exposure equivalent to more than half a pack of cigarettes and exposure to tar equivalent to more than two full packs of cigarettes.⁵ None of these harmful components are eliminated by the passage of the smoke through the water and many of these harmful substances are delivered to the user's lungs.

Waterpipe tobacco use delivers nicotine, the same highly addictive drug found in other tobacco products. The meta-analysis described above found that in a typical waterpipe session, smokers are subjected to up to more than twice the nicotine exposure as the smoker of a single

² HHS, *Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012.

³ Ward, KD, et al., "The waterpipe: an emerging epidemic in need of action," *Tobacco Control*, 24(S1): i1-i2, 2015.

⁴ See e.g., Sepetdijian, E, et al., "Measurement of 16 Polycyclic Aromatic Hydrocarbons in Narghile Waterpipe Tobacco Smoke," *Food and Chemical Toxicology*, 46: 1582-1590, 2008. Schubert, J., et al., "Mainstream Smoke of the Waterpipe: Does this Environmental Matrix Reveal as Significant Source of Toxic Compounds?" *Toxicology Letters*, 205(3): 279-284, 2011. Jacob, P., et al. "Nicotine, Carbon Monoxide and Carcinogen Exposure After a Single Use of a Water Pipe," *Cancer Epidemiology, Biomarkers, & Prevention*, 20: 2345-2353, 2011.

⁵ Primack B, et al. Systematic review and meta-analysis of inhaled toxicants from waterpipe and cigarette smoking. Public Health Reports Jan. 2016. See also, HHS, *Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012, <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html>. Eissenberg, T and Shihadeh, A. "Waterpipe tobacco and cigarette smoking: direct comparison of toxicant exposure," *American Journal of Preventive Medicine*, 37(6): 518-523, 2009. Mazziak, W, et al., "CO exposure, puff topography, and subjective effects in waterpipe tobacco smokers," *Nicotine & Tobacco Research*, 11(7): 806-811.

cigarette.⁶ The evidence indicates that waterpipe tobacco use is associated with nicotine dependence, including experiences of withdrawal and difficulty quitting, at least among some users.⁷ Nicotine is an addictive drug that can have lasting damaging effects on adolescent brain development and has been linked to a variety of adverse health outcomes for the developing fetus.⁸ Adolescents are particularly susceptible to the addictive properties of nicotine.⁹ A March 2015 report by the Institute of Medicine (IOM), found that “adolescent brains are uniquely vulnerable to the effects of nicotine and nicotine addiction.”¹⁰ Nicotine elicits acute, adverse cardiovascular responses and with chronic use impairs the cardiovascular system.¹¹

Because the flavors and the smoking technique create a more soothing (“smooth”) experience, waterpipe tobacco users can inhale more deeply and spend more time in a “hookah session,” which typically lasts for 40 to 45 minutes (several times longer than it takes to smoke a cigarette). While a typical cigarette requires 20 puffs or fewer, an hour-long waterpipe tobacco session may involve 100 to 200 puffs,¹² potentially exposing the user to more smoke over a greater period of time than a smoker encounters when smoking a cigarette.¹³ Furthermore, the soothing sensation may make it easier for novice users to inhale waterpipe smoke than unflavored cigarette smoke.

B. WATERPIPE TOBACCO USE IS ASSOCIATED WITH ACUTE AND LONG-TERM HEALTH EFFECTS.

Causal evidence of the health impacts of waterpipe tobacco use is limited. Several studies from countries where hookah use is prevalent suggest that waterpipe use is associated with

⁶ Primack B, et al. Systematic review and meta-analysis of inhaled toxicants from waterpipe and cigarette smoking. *Public Health Reports* Jan. 2016. HHS, *Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012, <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html>. Eissenberg, T and Shihadeh, A. “Waterpipe tobacco and cigarette smoking: direct comparison of toxicant exposure,” *American Journal of Preventive Medicine*, 37(6): 518-523, 2009. Maziak, W, et al., “CO exposure, puff topography, and subjective effects in waterpipe tobacco smokers,” *Nicotine & Tobacco Research*, 11(7): 806-811, 2006.

⁷ Aboaziza, E and Eissenberg, T., “Waterpipe tobacco smoking: what is the evidence that it supports nicotine/tobacco dependence?” *Tobacco Control*, published online December 9, 2014.

⁸ HHS, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, CDC, Office of Smoking and Health (OSH), 2014, <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>.

⁹ U.S. Department of Health and Human Services (HHS), *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, HHS, U.S. Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health (OSH), 2012, at 457.

¹⁰ Institute of Medicine, *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products*, Washington, DC: The National Academies Press, 2015 at 2, http://www.iom.edu/~media/Files/Report%20Files/2015/TobaccoMinAge/tobacco_minimum_age_report_brief.pdf.

¹¹ HHS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*, Centers for Disease Control and Prevention, Office on Smoking and Health, 2010 <http://www.ncbi.nlm.nih.gov/books/NBK53017/>.

¹² Centers for Disease Control and Prevention. “Dangers of Hookah Smoking.” Available at <http://www.cdc.gov/features/hookahsmoking/>. Accessed March 4, 2016

¹³ World Health Organization. WHO Advisory Note: “Waterpipe Tobacco Smoking: Health Effects, Research Needs and Recommended Actions by Regulators,” WHO 2005; HHS, *Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012, <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html>; American Lung Association, *An Emerging Deadly Trend: Waterpipe Tobacco Use*, February 2007, http://www.lungusa2.org/embargo/slati/Trendalert_Waterpipes.pdf. American Lung Association, *Hookah Smoking: A Growing Threat to Public Health*, 2011, <http://www.lung.org/assets/documents/tobacco/hookah-policy-brief-updated.pdf>.

increased morbidity and mortality.¹⁴ An aggregate assessment of these studies is difficult because of the different populations examined and the different methodological approaches used to examine the health effects. There are few longitudinal studies of waterpipe usage in the United States because until very recently waterpipe tobacco use in the United States was rare. Moreover, the fact that most waterpipe users also use one or more other tobacco products makes it difficult to differentiate the health effects of the different products.¹⁵ Despite these limitations, the evidence base establishing the health effects of waterpipe use and exposure to the toxins and carcinogens and to nicotine is more than sufficient to warrant and necessitate regulatory action.

According to the CDC, using a waterpipe to smoke tobacco poses serious health risks to smokers and others exposed to the smoke from the waterpipe tobacco.¹⁶ Waterpipe tobacco use is linked to many of the same adverse health effects as cigarette smoking, such as lung, bladder and oral cancers and heart disease.¹⁷ Other documented long-term effects include impaired pulmonary function, chronic obstructive pulmonary disease, esophageal cancer and gastric cancer.¹⁸ As a result of exposure to the dangerous chemicals in waterpipe tobacco smoke, research shows that even short-term waterpipe tobacco use is associated with acute health effects, including increased heart rate, blood pressure, reduced pulmonary function and carbon monoxide intoxication.¹⁹ In a 2015 report, the World Health Organization Study group on tobacco product regulation surveyed the research to date and corroborated these findings.²⁰

C. WATERPIPE TOBACCO USE IS ON THE RISE, ESPECIALLY AMONG YOUTH AND YOUNG ADULTS

Waterpipe use in the United States has increased sharply in the past five years. Moreover, the large majority of users are either underage or young adults. Data from the 2014 Youth Tobacco Survey (YTS) underscores the importance of FDA regulation of waterpipe tobacco. According to the 2014 Youth Tobacco Survey (YTS), 9.4 percent of high schoolers, totaling 1,380,000 youth, used waterpipe tobacco in the past month.²¹ The same survey found that 2.5 percent of middle schoolers used waterpipe tobacco in the past month. Although these usage rates declined somewhat in the 2015 YTS, to 7.2% and 2.0%, respectively, hookah use among both high school and middle school students has still increased sharply since 2011, when the

¹⁴ Akl, EA, et al., “The effects of waterpipe tobacco smoking on health outcomes: a systematic review,” *International Journal of Epidemiology*, 39: 834-857, 2010.

¹⁵ El-Zaatari, ZM, et al., “Health effects associated with waterpipe smoking,” *Tobacco Control*, 24(S1): i31-i43, 2015.

¹⁶ Centers for Disease Control and Prevention. “Hookahs.” Available at http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/hookahs/. Accessed March 4, 2016.

¹⁷ HHS, *Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012, <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html>; Knishkowsky B, Amitai, Y. “Waterpipe (narghile) smoking: an emerging health risk behavior,” *Pediatrics* 2005.

¹⁸ El-Zaatari, ZM, et al., “Health effects associated with waterpipe smoking,” *Tobacco Control*, 24(S1): i31-i43, 2015.

¹⁹ El-Zaatari, ZM, et al., “Health effects associated with waterpipe smoking,” *Tobacco Control*, 24(S1): i31-i43, 2015.

²⁰ World Health Organization, Study Group on Tobacco Product Regulation (“TobReg”), 2015.

²¹ U.S. Centers for Disease Control and Prevention (CDC), “Tobacco Use Among Middle and High School Students — United States, 2011–2014,” *Morbidity and Mortality Weekly Report (MMWR)* 64(14):381-385, April 2015, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6414a3.htm?s_cid=mm6414a3_e.

prevalence of current use among high school students was only 4.1%. Furthermore, unlike other tobacco products, rates of use are similar among boys and girls.

Waterpipe tobacco is also widely used by young adults. The 2012-2013 Adult Tobacco Survey (ATS) found that 18-24 year olds had the highest use rate among all adult cohorts, with 18.2 percent using hookah every day, some days or rarely.²² While other tobacco products show higher use among low-income and low-education groups, waterpipe tobacco use does not follow the same socioeconomic pattern of use, with the greatest use among adults with some college education.²³ The Spring 2015 National College Health Assessment found that 22.5 percent of undergraduates had used waterpipe tobacco at least once and 7.6 percent had used it in the past month.²⁴

Recent studies have associated waterpipe tobacco use with subsequent cigarette initiation, increased intensity of cigarette smoking, and reduced cessation success:

- A longitudinal study of over 1,000 15-23 year olds who were never cigarette smokers at baseline found that ever use of waterpipe tobacco at baseline was associated with increased odds of cigarette initiation, current cigarette smoking, and higher intensity of cigarette smoking at two-year follow-up.²⁵
- A longitudinal study of 256 college students who were current smokers found that dual cigarette and waterpipe tobacco use at baseline was associated with increased frequency and intensity of cigarette smoking at 6 month follow up.²⁶
- According to the 2012-2013 ATS, 15.7 percent of young adults aged 18-24 who were not established cigarette smokers were hookah users, and were two times as susceptible to cigarette smoking as those who were not current hookah users.²⁷
- Several studies have found a significant prevalence of dual use of waterpipe tobacco and cigarettes.²⁸

²² Agaku, IT, et al., "Tobacco Product Use Among Adults—United States, 2012-2013," *Morbidity and Mortality Weekly Report*, 63(25): 542-547, 2014. <http://www.cdc.gov/mmwr/pdf/wk/mm6325.pdf>.

²³ King, B. "Patterns and Correlates of Waterpipe/Hookah Use Among US Adults and Youth: Findings from National Surveillance Data," Presentation at the FDA "Waterpipes: A Public Workshop," March 17, 2016.

²⁴ American College Health Association. American College Health Association-National College Health Assessment: Undergraduate Student Reference Group Executive Summary Spring 2015. http://www.acha-ncha.org/docs/NCHA-II_WEB_SPRING_2015_UNDERGRADUATE_REFERENCE_GROUP_EXECUTIVE_SUMMARY.pdf.

²⁵ Soneji, S, et al., "Associations between initial water pipe tobacco smoking and snus use and subsequent cigarette smoking: Results from a longitudinal study of US adolescents and young adults," *JAMA Pediatrics*, published online December 8, 2014.

²⁶ Doran, N, et al., "Hookah use predicts cigarette smoking progression among college smokers," *Nicotine & Tobacco Research*, 17(11): 1347-1353, 2015.

²⁷ Salloum, RG, et al., "Waterpipe Tobacco Smoking and Susceptibility to Cigarette Smoking Among Young Adults in the United States, 2012-2013," *Preventing Chronic Disease*, 13, 2016.

²⁸ See e.g., Sterling, KL, et al., "Examining Hookah Smoking Among a Cohort of Adolescent Ever Smokers," *Nicotine & Tobacco Research*, 113(12): 1202-1209, 2011. Rath, JM, et al., "Patterns of Tobacco Use and Dual Use in US Young Adults: The Missing Link between Youth Prevention and Adult Cessation," *Journal of Environmental and Public Health*, 2012.

- A study of over 1,000 college students enrolled in a smoking cessation trial found that those who were dual cigarette smokers and waterpipe tobacco users at baseline had significantly lower odds of successfully quitting all tobacco use at 6 months.²⁹

D. WATERPIPE TOBACCO USERS UNDERESTIMATE THE HEALTH RISKS; HEALTH WARNINGS ARE NEEDED TO EDUCATE AND CORRECT MISPERCEPTIONS

Misperceptions about the health risks of waterpipe tobacco use are widespread. Studies show that youth and young adults, both users and non-users, consistently underestimate the health risks of waterpipe tobacco use and many believe that waterpipe smoking is less addictive than cigarette smoking.³⁰

- The government-sponsored 2013-2014 Population Assessment on Tobacco and Health (PATH) study found that 60.6 percent of current waterpipe tobacco users aged 12-17 use hookah because they think it might be less harmful than cigarettes.³¹ The same survey found that almost a quarter of 12-17 year old waterpipe tobacco users use waterpipe tobacco because they think it helps in quitting smoking.
- The 2011 National Young Adult Health Survey, found that about a quarter of young adults aged 18-34 believe that waterpipe tobacco use is “less risky” than cigarettes, with higher agreement among younger adults and current hookah users.³²
- Many smaller studies of college students have consistently found that young adults view waterpipe tobacco use as less harmful, less addictive, and more socially acceptable than cigarette smoking.³³
- A 2011 study of high school students in San Diego found that nearly half of students (46.3%) thought that waterpipe tobacco use was safer or less addictive than cigarettes,

²⁹ Thomas, JL, et al., “Abstinence rates among college cigarette smokers enrolled in a randomized clinical trial evaluating Quit and Win contests: The impact of concurrent hookah use,” *Preventive Medicine*, 76: 20-25, 2015.

³⁰ See, e.g., Primack, AB, et al., “Prevalence of and Associations with Waterpipe Tobacco Smoking among US University Students,” *Annals of Behavioral Medicine*, 36(1): 81-86, 2008; Grekin ER and Ayna D, “Waterpipe Smoking Among College Students: A Review of the Literature,” *Journal of American College Health*, 60(3): 244-49, 2012; Smith-Simon SY et al., “Differing psychosocial risk profiles of college freshman waterpipe, cigar and cigarette smokers,” *Addictive Behaviors*, 33(12):1619-24; Smith JR, et al., “Determinants of Hookah Use among High School Students,” *Nicotine & Tobacco Research*, 13(7): 565-72, 2011.

³¹ Ambrose, BK, et al., “Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,” *Journal of the American Medical Association*, published online October 26, 2015.

³² Wackowski, OA and Delnevo, CD. “Young Adults’ Risk Perceptions of Various Tobacco Products Relative to Cigarettes: Results from the National Young Adult Health Survey,” *Health Education & Behavior*, published online August 24, 2015.

³³ See e.g., Primack, AB, et al., “Prevalence of and Associations with Waterpipe Tobacco Smoking among U.S. University Students,” *Annals of Behavioral Medicine*, 36(1): 81-86, 2008. Grekin, ER and Ayna, D., “Waterpipe Smoking Among College Students: A Review of the Literature,” *Journal of American College Health*, 60(3): 244-249, 2012. Smith-Simone, SY, et al., “Differing psychosocial risk profiles of college freshman waterpipe, cigar and cigarette smokers,” *Addictive Behaviors*, 33(12): 1619-1624, 2008. Smith, SY, et al., “Harm perception of nicotine products in college freshman,” *Nicotine & Tobacco Research*, 9: 977-982, 2007. Eissenberg, T, et al., “Waterpipe tobacco smoking on a U.S. college campus: prevalence and correlates,” *Journal of Adolescent Health*, 42: 526-529, 2008.

and among those students, one-third thought this because they presumed waterpipe tobacco to have no or less nicotine and one-quarter thought that it had fewer chemicals and was cleaner.³⁴

- Not only is the perception that hookah is less harmful more common among current waterpipe tobacco users, but a longitudinal study of 18-24 year olds found that this belief is a significant predictor of future waterpipe tobacco trial.³⁵

Moreover, the fact that waterpipe tobacco is typically sweetly flavored contributes to user beliefs that hookah smoking is less harmful than cigarette smoking.³⁶ Globally, the belief that waterpipe tobacco is less harmful than cigarettes is often based on the misperceptions that the water filtration process makes it safer, that it contains little or no nicotine, and that it contains fewer chemicals.³⁷

E. WATERPIPE USAGE OFTEN TAKES PLACE IN HOOKAH BARS OR OTHER SETTINGS IN WHICH USAGE IS COMMUNAL.

Unlike usage of most other tobacco products, waterpipe usage is frequently communal, with several users taking turns using the same waterpipe and socializing over an extended period of time. Often such sessions take place in commercial establishments, many of which are located in close proximity to college campuses. Even when usage takes place in private residences, however, it is common for several users to use the same waterpipe.

It is common practice for waterpipes to be used in social settings. In fact, according to PATH, 79.6 percent of current waterpipe tobacco users aged 12-17 say that they use waterpipe tobacco because they like socializing while using the product.³⁸ Hookah bars and cafes have grown in popularity, particularly in urban areas and around college campuses.³⁹ These establishments are often exempt from state and local smoke-free laws.

This pattern of use, which differs from that for other tobacco products, means that many waterpipe users do not participate in the preparation of the waterpipe and therefore never come in contact with the package of tobacco mixture. This leads to a high degree of ignorance among users about the contents of the mixture in the waterpipe bowl.

³⁴ Smith, JR, et al., “Determinants of Hookah Use among High School Students,” *Nicotine & Tobacco Research*, 13(7): 565-572, 2011.

³⁵ Villanti, AC, et al., “Correlates of Hookah Use and Predictors of Hookah Trial in U.S. Young Adults,” *American Journal of Preventive Medicine*, 48(6): 742-746, 2015.

³⁶ Akl, EA, et al., “The allure of the waterpipe: a narrative review of factors affecting the epidemic rise in waterpipe smoking among young persons globally,” *Tobacco Control*, 24(S1): i13-i21, 2015.

³⁷ Akl, EA, et al., “The allure of the waterpipe: a narrative review of factors affecting the epidemic rise in waterpipe smoking among young persons globally,” *Tobacco Control*, 24(S1): i13-i21, 2015.

³⁸ Ambrose, BK, et al., “Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,” *Journal of the American Medical Association*, published online October 26, 2015.

³⁹ American Lung Association, *An Emerging Deadly Trend: Waterpipe Tobacco Use*, February 2007, http://www.lungusa2.org/embargo/slati/Trendalert_Waterpipes.pdf.

II. REGULATORY POLICIES APPROPRIATE FOR WATERPIPE TOBACCO

A. FDA SHOULD ASSERT JURISDICTION OVER HOOKAH, CHARCOAL, AND WATERPIPES THEMSELVES.

The evidence cited above makes it clear that waterpipe tobacco exposes users to lethal substances and increases the risk of death and disease both to users and to others exposed to waterpipe tobacco smoke. The increased prevalence of waterpipe use among adolescents and young adults underscores the importance of regulating this product. All varieties and types of waterpipe should be subject to regulation.⁴⁰

Regulation should extend to the charcoal burned in waterpipe usage, which contributes to the quantity of lethal components delivered to the lungs of the user, and to the waterpipe itself. As FDA noted in the proposed rule, all elements used in the consumption of the product are components of the product and regulation should extend to all such components.⁴¹ Both the charcoal and the waterpipe itself are used in the consumption of the product and therefore are components that should be subjected to regulation.

B. HEALTH WARNINGS APPROPRIATE TO THE WAY IN WHICH THE PRODUCT IS USED SHOULD BE REQUIRED.

As noted above, a substantial percentage of waterpipe users have misperceptions about the health risks of waterpipe tobacco use. Given this widespread lack of information, FDA should implement risk communication strategies that target specific populations of users and provide effective warnings through warning labels or other means.

The FDA should require health warnings on both the tobacco packaging and the waterpipe itself. Warnings cannot be limited to the tobacco packaging because when used in hookah bars and social settings, hookah users are often not actually exposed to the tobacco package or labeling because the mixture in the waterpipe bowl is prepared by others. Many waterpipe users never see the package in which the tobacco, shisha or maassel is contained.

It is important, therefore, for warnings to appear conspicuously on both the packaging of the tobacco, shisha or maassel and on the waterpipe itself. For these reasons, Article 11 of the World Health Organization's Framework Convention on Tobacco Control (WHO FCTC) requires health warnings on all tobacco products and recommends warnings on the waterpipe itself.⁴² Turkey currently requires that warnings covering 65% of the surface of the waterpipe

⁴⁰ Products marketed as e-hookah should also be subject to regulation. FDA should ensure that regulations governing e-cigarettes also cover products marketed as e-hookah.

⁴¹ 79 Fed. Reg. 23141, April 25, 2014.

⁴² World Health Organization, "Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and labelling of tobacco products)", http://www.who.int/fctc/guidelines/article_11.pdf, Accessed March 29, 2016.

bottle.⁴³ In addition to the FCTC’s requirements, the WHO Study Group on Tobacco Product Regulation developed policy options and best practices for waterpipe tobacco regulation, which will be submitted at the Conference of the Parties in November 2016.⁴⁴ These recommendations include the following requirements:

- “Waterpipe tobacco packaging and all waterpipe parts and accessories must not promote any misleading understanding about tobacco or give an erroneous view of the dangers inherent in its use.”
- “Waterpipe tobacco, product packaging and waterpipes themselves should be labeled with health warnings in accordance with Article 11 of the WHO FCTC.”

C. USE OF MISLEADING TERMS ON PRODUCT PACKAGING SHOULD BE PROHIBITED.

Hookah tobacco, most of which is imported from the Middle East or North Africa, is sold in the United States in packages with misleading labels. Some such labels claim, for example, that the tobacco has “0.5% nicotine and 0% tar,” or that it is “natural” or “chemical-free.”⁴⁵ Such statements constitute implied health claims and, in the absence of an FDA order, they would be prohibited by the modified risk provisions of the Tobacco Control Act. When FDA makes the deeming rule final, section 911 will apply to waterpipe tobacco. FDA should ensure that the provisions are enforced to prevent such misleading claims.

D. FDA SHOULD PROHIBIT CHARACTERIZING FLAVORS IN WATERPIPE TOBACCO

When it implemented the statute’s prohibition of characterizing flavors in cigarettes, FDA cited studies showing that 17-year-old smokers are three times as likely to use flavored cigarettes as are smokers over the age of 25.⁴⁶ FDA noted that “[i]n addition to being more attractive to young people, flavored products make it easier for new smokers to start smoking by masking the unpleasant flavor of tobacco” as well as leading young people to believe that flavored tobacco products are safer than unflavored ones.⁴⁷ There is every reason to believe that the use of sweet and fruity flavors in waterpipe tobacco is having the same effect it has had for other tobacco products – making a harmful and addictive product more appealing to youth.

⁴³ World Health Organization, *Waterpipe tobacco smoking: health effects, research needs and recommended actions for regulators, 2nd edition*, WHO Study Group on Tobacco Product Regulation, http://www.who.int/tobacco/publications/prod_regulation/waterpipesecondedition/en/, 2015.

⁴⁴ World Health Organization, *Waterpipe tobacco smoking: health effects, research needs and recommended actions for regulators, 2nd edition*, WHO Study Group on Tobacco Product Regulation, http://www.who.int/tobacco/publications/prod_regulation/waterpipesecondedition/en/, 2015.

⁴⁵ World Health Organization, *Waterpipe tobacco smoking: health effects, research needs and recommended actions for regulators, 2nd edition*, WHO Study Group on Tobacco Product Regulation, http://www.who.int/tobacco/publications/prod_regulation/waterpipesecondedition/en/, 2015.

⁴⁶ FDA Guidance for Industry and FDA Staff, “General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2) (“FDA Guidance on Characterizing Flavors”), at 2.

⁴⁷ *Id.*

Like other tobacco products, there is evidence that flavored waterpipe tobacco appeals to youth and may play an important role in initiation of waterpipe tobacco use. The government-sponsored 2013-2014 Population Assessment on Tobacco and Health (PATH) survey found that 88.7 percent of 12-17 year olds who had ever used waterpipe tobacco used flavored tobacco the first time they tried the product, and 89.0 percent of current users used flavored tobacco in the last month.⁴⁸ Use of flavored tobacco is higher for users of waterpipe tobacco than for any other tobacco product, and more than three-quarters (78.9%) of youth waterpipe tobacco users reported that they use it because it comes in appealing flavors. As noted above, the soothing sensation produced by flavored waterpipe tobacco may make it easier for inexperienced users to inhale the smoke and thus may make the product more attractive to new users.⁴⁹

The current state of the science, and the experience with other flavored tobacco products, support a product standard prohibiting characterizing flavors (other than tobacco) in waterpipe tobacco.

E. FDA SHOULD DEVELOP RULES PROHIBITING INTERNET SALES OF WATERPIPE TOBACCO

Given the large and growing number of young people who purchase tobacco products on the internet as well as the fact that large numbers of young people use waterpipe tobacco, it is likely that many of those seeking to purchase this product through internet transactions are minors. Thus, addressing the issue of internet sales is particularly important for this product.

FDA's proposed rule asserting jurisdiction over hookah would prohibit the sale of hookah over the internet to those under eighteen. Such a prohibition is necessary and important. Although most sellers already purport not to sell tobacco products such as hookah to minors, studies show that the vast majority of internet sellers of other tobacco products do not impose meaningful age verification procedures, with the result that these products are readily available for purchase on the internet by minors.

The comments filed in Docket No. FDA-2014-N-1089, the docket in which FDA proposed to extend its jurisdiction to other tobacco products contained a detailed analysis of the problems posed by requiring age verification in internet sales. These comments are incorporated by reference. After presenting this analysis, we concluded that unless and until FDA develops age verification requirements sufficient to block cigarette and e-cigarette sales to underage buyers on the internet, it should prohibit internet sales entirely. We continue to believe that such

⁴⁸ Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015

⁴⁹ The evidence cited by FDA in its review of the use of menthol in cigarettes is pertinent in this regard. FDA, "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes," <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/UCM361598.pdf>, 2013. See also FDA Tobacco Product Scientific Advisory Committee (TPSAC), "Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations," <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>, 2011.

a policy is warranted and believe that it is particularly appropriate for waterpipe tobacco. A recent study surveyed a large number of websites selling e-cigarettes and concluded that virtually none of them required effective age verification.⁵⁰ There is no reason to believe the situation is any different with regard to the sale of waterpipe tobacco on the internet.

Respectfully submitted,

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco – Free Kids

Truth Initiative

⁵⁰ Nikitin, D, et al., “Is the E-Liquid Industry Regulating Itself? A Look at E-Liquid Internet Vendors in the United States,” *Nicotine & Tobacco Research*, published online first April 1, 2016.