HHS Public Access

Author manuscript

Tob Control. Author manuscript; available in PMC 2018 May 01.

Published in final edited form as:

Tob Control. 2018 May ; 27(3): 347–351. doi:10.1136/tobaccocontrol-2017-053634.

Implications and challenges for implementation of the FDA's final deeming rule for waterpipe tobacco

Erin L Sutfin[1], **Eric K Soule**[2], **Karma McKelvey**[3], and **Desmond Jenson**[4]

[1]Department of Social Sciences and Health Policy, Wake Forest School of Medicine, Winston-Salem, NC, USA

[2]Department of Psychology, Virginia Commonwealth University, Richmond, VA, USA

[3]Center for Tobacco Control Research and Education, University of California San Francisco, San Francisco, CA, USA

[4]Tobacco Control Legal Consortium, a program of the Public Health Law Center, Mitchell Hamline School of Law, St Paul, MN, USA

Abstract

For the first time, the Food and Drug Administration's (FDAs) Center for Tobacco Products now has regulatory authority over all tobacco products, including waterpipe tobacco. In the rule expanding its authority to cover all tobacco products, the FDA uses largely a one-size-fits-all approach. However, several aspects of waterpipe tobacco smoking make it unique from other tobacco products, which may require more specific, tailored rules. This paper describes the distinct features of waterpipe tobacco products and accessories, and identifies unique challenges to the current regulation posed by this form of tobacco use. Additionally, we highlight the need for further research-generated evidence to support additional rulemaking.

Waterpipe tobacco smoking (WTS) is an ancient practice known by different names across the world, including hookah, narghile and hubble-bubble.[1] WTS involves the passage of air, often heated by charcoal, through the tobacco then through water prior to inhalation. The introduction of flavoured waterpipe tobacco in the 1990s, known as shisha or *ma'assel*, a mixture of shredded tobacco with honey or molasses and dried fruit and flavourings, escalated the spread of WTS worldwide.[2,3]

WTS in the USA is common, especially among young adults — even among those who do not smoke cigarettes.[4–6] Data from the 2013–2014 National Adult Tobacco Survey show that young adults, ages 18–24, have the highest prevalence of WTS (20.2%), representing 55%

Correspondence to Dr Erin L Sutfin, Department, of Social Sciences and Health, Policy, Division of Public Health, Sciences, Wake Forest School, of Medicine, Medical Center, Boulevard, Winston-Salem 27157, NC, USA; esutfin@wakehealth.edu.

Contributors ELS and EKS developed the concept for this paper. All authors contributed substantially to the writing and revising of this paper. All authors approved the final version of the manuscript.

Disclaimer The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH, the FDA or the Robert Wood Johnson Foundation.

Competing interests None declared.

Provenance and peer review Not commissioned; externally peer reviewed.

of adult current users.[7] Data from the 2015 National Youth Tobacco Survey show WTS was the fourth most commonly used tobacco product by high school students, behind e-cigarettes, cigarettes and cigars, with 7.2% reporting past month use.[8]

Similar to cigarette smoking, WTS is associated with significant health risks, including exposure to nicotine, which introduces the potential for addiction.[9,10] Recent systematic reviews concluded chronic obstructive pulmonary disease, cardiovascular disease, low birth weight, lung cancer, oral cancer and oesophageal cancer are all associated with WTS.[11,12] Adverse health effects are attributed to inhalation of large volumes of smoke during WTS[10,13,14] that contain considerable amounts of carcinogens, hydrocarbons and heavy metals.[15,16]

Adolescents and young adults have limited understanding of WTS health risks. Most perceive WTS to be less harmful and less addictive than cigarette smoking, particularly those reporting having ever-smoked waterpipe tobacco.[17–21] Adolescents and young adults perceive WTS as less harmful partly because they believe the water filters toxins from the smoke.[22–26] Misperceptions of reduced harm also stem from the belief that they do not smoke frequently enough to cause negative health effects, or can quit before becoming addicted to nicotine.[17,22,27] This underestimation of health risks is also positively associated with current use of waterpipe tobacco.[6,28,29]

WTS has several unique features that may create challenges for regulation. Below we describe these challenges and propose regulatory solutions and highlight the need for additional research to inform the rulemaking process.

OVERVIEW OF FSPTCA AND FINAL DEEMING RULE

In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (FSPTCA) delegating regulatory power over tobacco products to the US Food and Drug Administration (FDA).[30] While the FSPTCA provides comprehensive authority for the agency to regulate all tobacco products, at the time of its passage, the law only obligated the FDA to regulate cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco. In order to regulate all other products, the agency was required to take an affirmative step and ‘deem’ products to be subject to its regulatory authority. While the FDA was aware of the importance of comprehensive tobacco product regulation for several years, the agency did not take the first step towards ‘deeming’ all products to be subject to the FSPTCA until 24 April 2014. The agency issued a notice of proposed rulemaking outlining its plans to regulate e-cigarettes, cigars, waterpipe tobacco, dissolvable tobacco, nicotine gels and all other products made or derived from tobacco.[31] The FDA received over 135 000 comments to its proposal, and after considering all comments issued its final rule on 10 May 2016.[32]

While there is little question that comprehensive FDA regulation of all tobacco products will eventually yield significant public health benefits, the agency, like the public, has focused the most attention on the rule’s impact on e-cigarettes and to a slightly lesser extent, cigars. Although the statutory scheme established in the FSPTCA creates a one-size-fits-all approach to the regulation of tobacco products, the FDA is free to adapt its own rules to

ensure that the statutory scheme is implemented in a way that accounts for all of the differences in the ways each type of tobacco product is manufactured, marketed and consumed. The FDA has made these sorts of modifications for e-cigarettes and cigars, discussed below, but has not done the same for waterpipe tobacco. FDA regulation of waterpipe tobacco will usher in many public health benefits. However, in examining the FDA's action, it is clear there are still many opportunities to improve the regulation to ensure maximum public health benefits.

UNIQUE CHALLENGES FOR WATERPIPE TOBACCO

Modified-risk claims

Beginning 8 August 2017 with a 30-day sell-off period for existing stock, packagers and advertisers of waterpipe tobacco will be prohibited from making unsubstantiated or misleading modified-risk claims that imply decreased harm, such as '0% tar', and use of words like 'light', 'mild' or 'low'. Research on waterpipe tobacco packaging found that 77% of the 74 waterpipe packages studied indicated zero tar in their product.[33] However, this is misleading because tar is a smoke constituent defined as 'nicotine free, dry particulate matter'[34] and not a component of the actual tobacco. The deeming rule will require elimination of all labelling, labels and advertising that include such modified-risk claims. Some of these will be clearly identifiable, while others may be more difficult to recognise. For example, words like 'light', 'mild' and 'low' that were displayed commonly on cigarette packaging before the FSPTCA have been identified as being misleading to consumers and will be prohibited on waterpipe packaging. However, waterpipe tobacco packages often use other words or images that could be misleading consumers to believe these products are safer. Examples include 'natural', 'mist', 'freeze', and images such as fruits and desserts that may affect harm perception and product appeal. These types of messages and/or images could convey reduced harm to consumers, but are not explicitly prohibited by the FSPTCA, and thus in order to take an enforcement action, the FDA would likely have to demonstrate these types of messages do indeed convey reduced harm.

The deeming rule extends the ban of unsubstantiated modified-risk claims beyond just product packaging to other advertising as well, including manufacturer and retailer internet websites and displays in tobacco shops or WTS cafés. A qualitative assessment of websites promoting WTS cafés in the USA found that 16% of the reviewed sites stated or implied that WTS is safer than cigarette smoking.[35] Additionally, 22% of websites promoted the mildness of WTS, using terms such as 'all-natural' and 'pure'. The FDA recently issued warning letters to three tobacco manufacturers for product labelling including 'additive-free' and 'natural' on cigarette packaging.[36] The FDA determined that these companies were making unsubstantiated modified-risks claims. This suggests that similar claims on waterpipe packaging and websites will also be considered unsubstantiated modified-risks claims and will require FDA action. Given the distinct terms used for waterpipe tobacco, the FDA will need research evidence to determine whether such descriptors convey reduced harm messages to consumers and if regulatory action is warranted.

Retailer versus manufacturer for waterpipe cafés/bars

The deeming rule makes clear that waterpipe cafés that sell only prepackaged shisha will be considered pure retailers. However, if cafés create custom tobacco blends by mixing together shisha and/or adding flavour enhancers, they will also be considered manufacturers. Under the law, cafés that mix their own tobacco blends would fit squarely in the definition of 'manufacturer' and thus be subject to the new tobacco product premarket review requirements for each blend of tobacco they create. As required by law, waterpipe tobacco must go through the same new product review process as other new tobacco products (eg, new cigarette brands) before introduction into the marketplace. Cafés that do not comply with this requirement will see their products rendered adulterated and misbranded and may be subject to seizure by the FDA and could be subject to civil monetary penalties or a no-tobacco-sale order.

The FDA speculates with regard to e-cigarette stores/vape shops, '… most vape shops will continue to operate but those that have not already switched to pure retailing will likely do so'.[32] Similarly, we expect that most waterpipe tobacco cafés that are creating their own blends of shisha will choose to stop doing so and sell only prepackaged products to avoid the potentially costly premarket review process. However, one possible challenge to the implementation of this section of the rule is that waterpipe tobacco café owners and employees may not be fully aware of these new legal requirements. While there are organised groups of retailers and manufacturers for both the e-cigarette and cigar industries, the same is not true of waterpipe tobacco. The FDA has provided materials on its website, but has yet to announce any retailer training where the agency will directly engage waterpipe retailers. The FDA should be aware of the current practices in waterpipe cafés and compliance actions need to include these specialised retailers in enforcement activities.

Quality control

The final deeming rule provides little to no guidance on responsible manufacturing and preparation practices of waterpipe tobacco products. With regard to e-cigarettes, the final deeming rule addressed several comments related to quality control, including avoiding accidental exposures to nicotine liquids (eg, child safety packaging, exposure warnings) and lack of quality controls in place for mixing e-liquids. The FDA acknowledged the need for quality control measures and indicated that the agency has such authority to issue tobacco product manufacturing regulations under section 906€ of the Federal Food, Drug, and Cosmetic (FD&C) Act. However, the final deeming rule does not address quality control for waterpipe tobacco. Water-pipe cafés prepare the tobacco and waterpipe for customers, including packing the tobacco into the head and often getting it 'started' by puffing on the mouthpiece before providing it to the customer. The same hoses are frequently used for multiple customers without requirements for cleaning. Without established quality control requirements, the waterpipe tobacco preparation and serving process may not be sanitary. Indeed, bacterial contaminations that are associated with health risks have been reported from samples taken from components of waterpipes provided in cafés.[37]

Waterpipe tobacco components

WTS is quite different from other forms of tobacco in that it involves three distinct parts: waterpipe tobacco, the heating source and the device. The device itself also contains multiple components, such as the hose, mouthpiece, base and liquid. This complexity creates unique regulatory challenges. Section 101 of the FSPTCA defines a 'tobacco product' to include 'any component, part, or accessory' of that product. The finalised deeming rule covers all new tobacco products, including components and parts, but excludes accessories of the newly deemed products. The following is a non-exhaustive list of examples of components and parts used with waterpipe tobacco directly from the final rule: 'flavor enhancers and the vials in which they are contained; hose cooling attachments; water filtration base additives (including those which are flavored); flavored waterpipe tobacco charcoals and the wrappers or boxes that contain the charcoals; and bowls, valves, hoses, and heads'.[32] Under this definition, the liquids that some waterpipe smokers fill the base of the waterpipe with such as juice, alcohol or energy drinks[38] could be considered a water filtration base additive and therefore a tobacco product component. Thus, if a café sold a particular type of shisha with wine in the base, for example, this combination could be considered a 'new tobacco product' and could be subject to premarket review. As described in the previous section, café owners may choose to no longer sell these kinds of products. This presents a unique challenge for the FDA, again requiring retailer education and compliance activities.

Waterpipe tobacco

The tobacco itself also creates unique challenges. Absent regulation, shisha has been marketed aggressively in a wide variety of flavours known to be appealing to youth (eg, fruit, candy, dessert), resulting in rapid and increasing uptake and continued use.[39] Further, flavourings are often added to the already sweetened and flavoured shisha by employees in waterpipe cafés.[38] This is of great concern as nearly two-thirds of youth waterpipe smokers report using flavoured tobacco.[40] Data from the 2013–2014 Population Assessment of Tobacco and Health reveal that among adolescent (ages 12–17) past 30-day waterpipe smokers, 78.9% reported liking the flavours available as a reason for use, which was the most endorsed reason.[41] Despite the FDA's announced intention to prohibit characterising flavours in cigars with the exception of tobacco and menthol,[32] the FDA has not indicated characterising flavours will be prohibited in waterpipe tobacco.

An additional challenge for the FDA is the use of herbal shisha for WTS, which claims to be tobacco-free and nicotine-free. If the shisha is indeed tobacco-free, then it may not be considered a tobacco product under the FSPTCA and the FDA may or may not have regulatory authority. However, research has found that package labelling information about nicotine content is not always accurate.[42] The FDA may need to consider testing the shisha purporting to be tobacco-free in order to confirm that it is not a covered tobacco product.

Health warnings

Health warnings on tobacco products can be an effective communication tool, and cigarette smokers report receiving information about smoking risks from cigarette packs more than any other source, except television.[43] While the deeming rule requires, for the first time, a

health warning on waterpipe tobacco packaging and advertisements, there are several challenges specific to WTS that may undermine the effectiveness of this requirement. First, one mechanism through which package warnings are thought to be effective is their broad reach (seen by product users and non-users) and their frequency of exposure, including at the critical times of purchase and use.[44] Because much of WTS occurs in commercial waterpipe cafés and bars, where employees prepare the waterpipe for customers, customers may rarely be exposed to the packaging.[4546] Similarly, waterpipes at parties or other social settings may be prepared by an experienced user, leaving most without exposure to the waterpipe tobacco packaging.

A second challenge to the deeming rule's health warning requirement for waterpipe tobacco product packaging and advertising is related to the required content of the message. The deeming rule only requires that a single text message (WARNING: This product contains nicotine. Nicotine is an addictive chemical.) be displayed on waterpipe tobacco product packaging and advertising. A single text warning, focused only on nicotine content and addiction, is unlikely to result in increased understanding of the full range of known health harms associated with WTS. Additionally, a single warning could result in message staleness over time. The FDA acknowledges this concern and 'intends to conduct research to keep abreast of scientific developments regarding the efficacy of the final health warnings and the ways in which their efficacy could be improved'.[32] As with cigarettes, cigars and smokeless tobacco, mandated warnings for WTS should cover a broad range of health effects, including addictiveness, general and specific health effects, second-hand exposures and relative risk.

Finally, the text-only nature of the newly required warning will likely limit its effectiveness. A recent meta-analysis of 48 independent samples reported that pictorial warnings were more effective than text-only for 12 out of 17 effectiveness outcomes.[47] Specifically, compared with text-only warnings, pictorial warnings better elicited and held attention, resulted in stronger cognitive and emotional reactions, elicited more negative attitudes towards the pack and smoking, and increased intentions to quit smoking. Additionally, results from a recent randomised controlled trial showed that participants who carried cigarette packs labelled with pictorial warnings, compared with those with text-only warnings, were more likely to quit or attempt to quit smoking during the trial, had greater intentions to quit, had more negative emotional reactions and conversations about quitting, and thought more about the harms of smoking.[48] There is growing evidence that compared with text-only warnings, pictorial warnings are more effective in conveying the harms of tobacco product use, are more noticeable and result in more quitting behaviours.[4748] Therefore, the impact of the required warning will likely be suboptimal and the FDA should consider ways to strengthen waterpipe warnings, including adding images.

RESEARCH NEEDS AND FUTURE DIRECTIONS

While the deeming rule is a critical step forward towards the FDA's goal of reducing tobacco use, there are many ways in which the rule may not adequately cover WTS. In order to address the unique needs associated with waterpipe tobacco, additional research is needed. Little is known about the types of modified-risk claims being made for waterpipe tobacco and how they are perceived by customers. Only a handful of studies have addressed

waterpipe tobacco advertising, including websites, and to our knowledge no studies have been conducted on product labelling in the USA. While research has shown that words used commonly on cigarette packaging, including ‘light’, ‘mild’ and ‘low’, are associated with inaccurate perceptions of reduced harm,[49] research assessing whether the descriptors and imagery used on waterpipe tobacco packaging are associated with risk perceptions has yet to be conducted. In order for the FDA to take regulatory action addressing waterpipe tobacco pack descriptors and images, a better understanding of how waterpipe tobacco packaging influences consumer perceptions is necessary.

Clarity of the practices of commercial WTS establishments is also needed to inform enforcement practices and retailer education needs. For example, it will be critical to the success of the deeming rule to ensure cafés that are creating custom blends are registered as manufacturers and have completed the premarket review process. Additionally, understanding whether and how often commercial WTS establishments incorporate substances other than water into the base, rendering that substance a component of a tobacco product potentially subject to regulation, is unclear. This practice may cease as enforcement of the deeming rule takes effect, but retailer education will be critical to ensure it does not continue. While much attention has focused on the impact of the deeming rule on vape shops, the FDA needs to ensure that WTS cafés are not operating as manufacturers without complying with federal regulations specific to tobacco product manufacturers.

The FDA has the authority to require WTS warnings in locations other than on tobacco packaging and in advertising. In fact, the deeming rule requires an 8.5×11 inch sign/display of mandated health warnings at the point of sale where unpackaged, single cigars are sold. Adjustments were also made for tobacco products in small packages such as e-liquid for e-cigarettes. In the deeming rule, the FDA responded to a comment suggesting that warnings be required on components and parts of waterpipe tobacco, not just the tobacco. In the response, the FDA disagreed, indicating that consumers cannot use a component without the tobacco, implying that consumers would have to be exposed to the tobacco packaging warnings. However, as described above, this is often not the case. Research is needed to better understand how many waterpipe tobacco smokers are exposed to the product packaging and to determine the optimal placement for waterpipe warnings to maximise exposure among both users and non-users alike. Research is also needed on exposure to waterpipe advertising and the effects of adding the required health warning to advertisements.

An additional aspect of WTS that was not addressed in the deeming rule is the availability of waterpipe tobacco in a wide range of flavours. Given that WTS carries many of the same risks as cigarette smoking and does not help people quit smoking, there is no compelling reason to continue to allow waterpipe tobacco to be sold as a flavoured product. Because the great majority of research conducted to date on flavours has been done with cigarettes, the FDA may need to build a strong scientific foundation on WTS-specific research to support any additional rulemaking with respect to flavoured waterpipe tobacco, including how flavours impact product appeal and harm perceptions.

The USA is not alone in lacking much-needed WTS-specific regulations. In fact, few countries have developed such regulations. The Framework Convention on Tobacco Control (FCTC) guides policy implementation for 180 member countries around the world. Several FCTC parties include waterpipe tobacco in their definitions of 'tobacco products', but only a few have laws specific to WTS. For example, only Israel, Lebanon and Turkey have health warning laws for WTS.[46] However, only Lebanon requires warnings that are focused on evidence-based health effects of WTS, the others require warnings about *tobacco* generally but applied to waterpipe tobacco. Much like the FDA's regulation of tobacco, the FCTC is meant to address all types of tobacco products; however, WTS-specific regulations are critically needed.

CONCLUSIONS

Given the continued high rate of WTS among adolescents and young adults and the considerable health risks associated with use, strong regulation is needed to decrease use and improve public health. The deeming rule is a critical first step that gives the FDA authority to regulate waterpipe tobacco and set forth particular rules to begin to decrease use. However, the unique nature of WTS, including the device (ie, waterpipe), the tobacco and the environment in which it is typically consumed, may require some WTS-specific adaptations of the rules to maximise their intended benefits. As described above, research evidence is needed to support both FDA action to enforce current rules and provide a foundation for any additional rulemaking.

Acknowledgments

Funding EKS was supported by the National Institutes of Health under Grant Number P50DA036105 from the National Institute on Drug Abuse and the Center for Tobacco Products of the US Food and Drug Administration. KM was supported by NIH/NCI Grant No. T32 CA113710-11. DJ was supported by the Robert Wood Johnson Foundation.

References

1. Maziak W, Eissenberg T, Ward KD. Patterns of waterpipe use and dependence: implications for intervention development. Pharmacol Biochem Behav. 2005; 80:173–9. [PubMed: 15652393]
2. Maziak W, Ward KD, Afifi Soweid RA, et al. Tobacco smoking using a waterpipe: a re-emerging strain in a global epidemic. Tob Control. 2004; 13:327–33. [PubMed: 15564614]
3. Rastam S, Ward KD, Eissenberg T, et al. Estimating the beginning of the waterpipe epidemic in Syria. BMC Public Health. 2004; 4:32. [PubMed: 15294023]
4. Maziak W. The global epidemic of waterpipe smoking. Addict Behav. 2011; 36:1–5. [PubMed: 20888700]
5. Maziak W. The waterpipe: an emerging global risk for Cancer. Cancer Epidemiol. 2013; 37:1–4. [PubMed: 23196170]
6. Sutfin EL, McCoy TP, Reboussin BA, et al. Prevalence and correlates of waterpipe tobacco smoking by college students in North Carolina. Drug Alcohol Depend. 2011; 115:131–6. [PubMed: 21353750]
7. Hu SS, Neff L, Agaku IT, et al. Tobacco Product Use among adults - United States, 2013–2014. MMWR Morb Mortal Wkly Rep. 2016; 65:685–91. [PubMed: 27416365]
8. Singh T, Arrazola RA, Corey CG, et al. Tobacco use among Middle and High School students–United States, 2011–2015. MMWR Morb Mortal Wkly Rep. 2016; 65:361–7. [PubMed: 27077789]

9. Akl EA, Gaddam S, Gunukula SK, et al. The effects of waterpipe tobacco smoking on health outcomes: a systematic review. Int J Epidemiol. 2010; 39:834–57. [PubMed: 20207606]
10. Eissenberg T, Shihadeh A. Waterpipe tobacco and cigarette smoking: direct comparison of toxicant exposure. Am J Prev Med. 2009; 37:518–23. [PubMed: 19944918]
11. Montazeri Z, Nyiraneza C, El-Katerji H, et al. Waterpipe smoking and Cancer: systematic review and meta-analysis. Tob Control. 2017; 26
12. Waziry R, Jawad M, Ballout RA, et al. The effects of waterpipe tobacco smoking on health outcomes: an updated systematic review and meta-analysis. Int J Epidemiol. 2016 dyw021.
13. Blank MD, Cobb CO, Kilgalen B, et al. Acute effects of waterpipe tobacco smoking: a double-blind, placebo-control study. Drug Alcohol Depend. 2011; 116(1–3):102–9. [PubMed: 21277706]
14. Cobb CO, Khader Y, Nasim A, et al. A multiyear survey of waterpipe and cigarette smoking on a US university campus. J Am Coll Health. 2012; 60:521–7. [PubMed: 23002800]
15. Jacob P, Abu Raddaha AH, Dempsey D, et al. Comparison of nicotine and carcinogen exposure with water pipe and cigarette smoking. Cancer Epidemiol Biomarkers Prev. 2013; 22:765–72. [PubMed: 23462922]
16. Primack BA, Carroll MV, Weiss PM, et al. Systematic review and Meta-Analysis of inhaled toxicants from Waterpipe and Cigarette Smoking. Public Health Rep. 2016; 131:76–85. [PubMed: 26843673]
17. Akl EA, Ward KD, Bteddini D, et al. The allure of the waterpipe: a narrative review of factors affecting the epidemic rise in waterpipe smoking among young persons globally. Tob Control. 2015; 24:i13–i21. [PubMed: 25618895]
18. Akl EA, Jawad M, Lam WY, et al. Motives, beliefs and attitudes towards waterpipe tobacco smoking: a systematic review. Harm Reduct J. 2013; 10:12. [PubMed: 23816366]
19. Aljarrah K, Ababneh ZQ, Al-Delaimy WK. Perceptions of hookah smoking harmfulness: predictors and characteristics among current hookah users. Tob Induc Dis. 2009; 5:16. [PubMed: 20021672]
20. Smith-Simone S, Maziak W, Ward KD, et al. Waterpipe tobacco smoking: knowledge, attitudes, beliefs, and behavior in two U.S. samples Nicotine Tob Res. 2008; 10:393–8. [PubMed: 18236304]
21. Wackowski OA, Delnevo CD. Young adults' Risk perceptions of various tobacco Products relative to Cigarettes: results from the National Young adult Health Survey. Health Educ Behav. 2016; 43:328–36. [PubMed: 26304709]
22. Cornacchione J, Wagoner KG, Wiseman KD, et al. Adolescent and young adult perceptions of Hookah and Little Cigars/Cigarillos: implications for risk messages. J Health Commun. 2016; 21:818–25. [PubMed: 27337629]
23. Jawad M, Jawad S, Mehdi A, et al. A qualitative analysis among regular waterpipe tobacco smokers in London universities. Int J Tuberc Lung Dis. 2013; 17:1364–9. [PubMed: 24025391]
24. Richter PA, Pederson LL, O'Hegarty MM. Young adult smoker risk perceptions of traditional cigarettes and nontraditional tobacco products. Am J Health Behav. 2006; 30:302–12. [PubMed: 16712444]
25. Roskin J, Aveyard P, Canadian AP. Canadian and English students' beliefs about waterpipe smoking: a qualitative study. BMC Public Health. 2009; 9:10. [PubMed: 19134220]
26. Wray RJ, Jupka K, Berman S, et al. Young adults' perceptions about established and emerging tobacco products: results from eight focus groups. Nicotine Tob Res. 2012; 14:184–90. [PubMed: 22110049]
27. Murphy-Hoefer R, Alder S, Higbee C. Perceptions about cigarette smoking and risks among college students. Nicotine Tob Res. 2004; (6 Suppl 3):S371–S374. [PubMed: 15799600]
28. Cavazos-Rehg PA, Krauss MJ, Kim Y, et al. Risk factors associated with Hookah Use. Nicotine Tob Res. 2015; 17:1482–90. [PubMed: 25646349]
29. Primack BA, Sidani J, Agarwal AA, et al. Prevalence of and associations with waterpipe tobacco smoking among U.S. university students Ann Behav Med. 2008; 36:81–6. [PubMed: 18719977]
30. Family Smoking Prevention and Tobacco Control Act Pub. L. 111-31, 123 Stat. 1776, 2009. (codified at 21 U.S.C § 387 et seq.

31. US Food and Drug Administration. Deeming Tobacco Products to be subject to the Federal Food, Drug, and Cosmetic act, as amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Proposed Rule, 79. Fed Reg. 23:142. (proposed April 25, 2014).
32. US Food and Drug Administration. Deeming Tobacco Products to be subject to the Federal Food, Drug, and Cosmetic act, as amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final rule, 81. Fed Reg. 28:974. (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100 1140 and 1143).
33. Nakkash R, Khalil J. Health warning labelling practices on Narghile (shisha, hookah) waterpipe tobacco products and related accessories. Tob Control. 2010; 19:235–9. [PubMed: 20501497]
34. International Organization of Standardization. Cigarettes – determination of nicotine-free dry particulate matter and nicotine in sidestream smoke. 2013. http://www.iso.org/iso/catalogue_detail.htm?csnumber=59227, (accessed 5 Jan 2017)
35. Primack BA, Rice KR, Shensa A, et al. U.S hookah tobacco smoking establishments advertised on the internet. Am J Prev Med. 2012; 42:150–6. [PubMed: 22261211]
36. Food and Drug Administration. FDA takes Action against three tobacco manufacturers for making “additive-Free” And/Or “natural” Claims on Cigarette Labeling. 2015. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm459840.htm
37. Safizadeh H, Moradi M, Rad MR, et al. Bacterial contamination of different components of the waterpipe. Int J Tuberc Lung Dis. 2014; 18:988–91. [PubMed: 25199017]
38. Griffiths MA, Harmon TR, Gilly MC. Hubble Bubble trouble: the need for Education about and regulation of Hookah Smoking. Journal of Public Policy & Marketing. 2011; 30:119–32.
39. Feirman SP, Lock D, Cohen JE, et al. Flavored tobacco Products in the United States: a systematic review assessing use and attitudes. Nicotine Tob Res. 2016; 18
40. Corey CG, Ambrose BK, Apelberg BJ, et al. Flavored tobacco Product Use among Middle and High School students–United States, 2014. MMWR Morb Mortal Wkly Rep. 2015; 64:1066–70. [PubMed: 26421418]
41. Ambrose BK, Day HR, Rostron B, et al. Flavored tobacco Product Use among US Youth aged 12–17 years, 2013–2014. JAMA. 2015; 314:1871–3. [PubMed: 26502219]
42. Vansickel AR, Shihadeh A, Eissenberg T. Waterpipe tobacco products: nicotine labelling versus nicotine delivery. Tob Control. 2012; 21:377–9. [PubMed: 21636612]
43. Hammond D, Fong GT, McNeill A, et al. Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four country survey. Tob Control. 2006; 15:iii19–iii25. [PubMed: 16754942]
44. Slade J. The pack as advertisement. Tob Control. 1997; 6:169–70. [PubMed: 9396096]
45. Salloum RG, Asfar T, Maziak W. Toward a regulatory framework for the Waterpipe. Am J Public Health. 2016; 106:1773–7. [PubMed: 27552262]
46. Jawad M, El Kadi L, Mugharbil S, et al. Waterpipe tobacco smoking legislation and policy enactment: a global analysis. Tob Control. 2015; 24:i60–i65. [PubMed: 25550418]
47. Noar SM, Hall MG, Francis DB, et al. Pictorial cigarette pack warnings: a meta-analysis of experimental studies. Tob Control. 2016; 25:341–54. [PubMed: 25948713]
48. Brewer NT, Hall MG, Noar SM, et al. Effect of Pictorial Cigarette pack warnings on changes in smoking behavior: a Randomized clinical trial. JAMA Intern Med. 2016; 176:905–12. [PubMed: 27273839]
49. Elton-Marshall T, Fong GT, Zanna MP, et al. Beliefs about the relative harm of “light” and “low tar” cigarettes: findings from the International Tobacco Control (ITC) China Survey. Tob Control. 2010; 19:i54–i62. [PubMed: 20935197]

What this paper adds

- Waterpipe tobacco smoking (WTS) in the USA continues to be a significant threat to public health.
- The FDA's final deeming rule does not address many of the unique challenges associated with WTS, potentially limiting its ability to reduce the public health impact of WTS.
- Regulations that address the specific challenges associated with this unique form of tobacco use are greatly needed.