



August 8, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-0189, RIN 0910-AG38, Proposed Rule on Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

Dear Dr. Hamburg:

The American Cancer Society Cancer Action Network (ACS CAN) strongly supports the U.S. Food and Drug Administration (FDA) proposed rule to deem all tobacco products subject to its authority with additional recommendations to further protect public health. ACS CAN is the nonprofit, nonpartisan advocacy affiliate organization of the American Cancer Society dedicated to eliminating cancer as a major health problem by supporting legislative, regulatory, and policy efforts that will make cancer a top national priority. ACS CAN appreciates the opportunity to provide comments on the proposed rule. We have also submitted comments as part of a coalition of health and public organizations (can be found on the docket as “Campaign for Tobacco -Free Kids, joined by 23 healthcare and public health organizations”).

Our comment letter reiterates the recommendations in the coalition’s comments with two further recommendations:

- FDA should consider additional warning labels on the health effects, beyond addiction, for proposed deemed products that combust tobacco, specifically waterpipe and pipe tobacco. These risks are well-documented in the scientific literature and would be appropriate as warning labels to protect public health.
- Sales of components, parts, or accessories of a tobacco product that are “part of a finished tobacco product or intended or expected for consumer use in the consumption of a tobacco product” should be restricted from children under the age of 18.

Introduction

While the tobacco industry has spent the last 50 years vehemently denying and misleading the American public about the dangers of tobacco use and marketing its products to youth, the American Cancer Society has documented the lethal consequences of smoking and its detrimental effects on almost every organ of the body; and ACS CAN is advocating for

comprehensive public policies to effectively reduce the death and disease from tobacco use and exposure to secondhand smoke. In fact, the reductions in overall cancer mortality the nation has experienced over the past few years can be partially attributed to our work in tobacco prevention and control to prevent youth from ever starting to use tobacco products and helping current users quit.

Despite our efforts, tobacco use remains the number one preventable cause of death in the United States, responsible for more than 480,000 deaths each year.¹ Increasing the risk of at least 12 types of cancer, tobacco use is responsible for 30 percent of all cancer deaths, including 87 percent of lung cancer deaths among men and 70 percent among women.² ACS CAN has established and is pursuing aggressive goals to reduce cancer incidence and mortality in cooperation and collaboration with the public, private, and nonprofit sectors.

To achieve the goals for reduction of tobacco-related cancer incidence and mortality, ACS CAN strongly supports the full implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) and believes that the public health benefit from regulating the manufacture, marketing, sale, and distribution of tobacco products can only be realized when the FDA has and uses its authority to regulate *all tobacco products*. It is imperative that the final rule is issued no later than one year after publication of the proposed rule.

ACS CAN respectfully offers the following recommendations.

I. Extension of FDA’s Authority to All Tobacco Products

All tobacco products, including so-called “premium” cigars, must be regulated by FDA (proposed Option 1). ACS CAN opposes proposed Option 2, which would exempt these so-called “premium” cigars from regulatory authority. Additionally, all tobacco product components, parts, and accessories that are “part of a finished tobacco product or intended or expected for consumer use in the consumption of a tobacco product” must be regulated by the FDA. ACS CAN opposes the exemption for accessories.

As the proposed rule correctly states “all cigars are harmful and potentially addictive (including small cigars, cigarillos, large cigars, and premium cigars).” Cigar smoke has higher levels of cancer-causing substances and there is no safe level of exposure to cigar smoke for users or nonusers. Regular cigar smoking is associated with increased risk of cancers of the lung, oral cavity, larynx, esophagus, and probably pancreas. Cigar smokers have a 4 to 10 times greater risk of dying from laryngeal, oral, or esophageal cancer compared to nonsmokers.³ Additionally,

¹ U.S. Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Printed with corrections, January 2014.

² American Cancer Society. *Cancer Facts & Figures 2014*. Atlanta: American Cancer Society; 2014.

³Shanks TG, Burns DM. Disease consequences of cigar smoking. National Cancer Institute, Smoking and Tobacco Control, Monograph 9: Cigars – Health Effects and Trends. Washington, DC: National Institutes of Health; 1998.

regardless of whether they inhale, cigar smokers directly expose their lips, mouth, tongue, throat, and larynx to cigar smoke.⁴ Moreover, a long-term study of over 130,000 men found that even cigar smokers who reported that they did not inhale were approximately three times more likely to die from lung cancer than those who never smoked.⁵

The causal connection between secondhand cigarette smoke and lung cancer and heart disease is now beyond dispute.⁶ Given that the amount of toxicants and pollutants emitted by cigar smoking typically exceeds that emitted by cigarette smoking, it is reasonable for FDA to assume that secondhand cigar smoke creates similar, if not greater, risks of disease than cigarette smoke.⁷

Exempting any tobacco product or accessory from regulation creates an opportunity for industry to develop a new market for the unregulated product. Without regulation, a manufacturer would not have to meet basic good manufacturing and labeling practices, list harmful or potentially harmful ingredients, or be subject to product standards that could reduce the harmfulness of its products. Furthermore, an unregulated product could make unsubstantiated health claims and have virtually unrestricted access to market its product to all consumers.

For additional information on the lack of justification for exempting any cigars or tobacco product accessory from FDA regulation, see the Tobacco Control Partners' Joint Comment Letter (can be found on the docket as "Campaign for Tobacco -Free Kids, joined by 23 healthcare and public health organizations," p.11).

II. Protecting Youth

a. Restrictions on sales to minors and prohibition of free samples

ACS CAN supports FDA's proposal to prohibit all sales to minors and to only permit vending machine sales in places not accessible by youth. Additionally, some of the proposed deemed tobacco products may have components, parts, or accessories that are "part of a finished tobacco product or intended for consumer use in the consumption of a tobacco product" but may be sold separately as described in the preamble of this proposed rule. If the only purpose of these components, parts, or accessories is for use as a finished tobacco product, there is no justification for enabling youth to have access, therefore tobacco product components, parts,

⁴ Shanks TG, Burns DM. Disease consequences of cigar smoking. National Cancer Institute, Smoking and Tobacco Control, Monograph 9: Cigars – Health Effects and Trends. Washington, DC: National Institutes of Health; 1998.

⁵ Shapiro, JA, et al., "Cigar Smoking in Men and Risk of Death from Tobacco-Related Disease," *Journal of the National Cancer Institute*, 92(4):333-337, 2000, at 334.

⁶ See generally, U.S. Department of Health and Human Services (HHS), *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General*, 2006.

⁷ See generally, U.S. Department of Health and Human Services (HHS), *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General*, 2006
http://www.cdc.gov/tobacco/data_statistics/sgr/2006/index.htm.

and accessories should be included in the prohibition of sales to minors and vending machine sales.

Finally, because of the ready availability of the deemed products to young people through the internet, and the inherent difficulty of enforcing effective age verification for on-line sales, FDA should prohibit internet sales of the deemed products. If the agency decides to permit internet sales, it should at least impose age verification procedures on internet sellers of the deemed products analogous to the procedures mandated for internet cigarette sales by the Prevent All-Cigarette Trafficking Act of 2009.

For additional information recommending the provisions of FDA's 2010 Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents that should be applied to the proposed deemed products, see Tobacco Control Partners' Joint Comment Letter (can be found on the docket as "Campaign for Tobacco -Free Kids, joined by 23 healthcare and public health organizations," p.20).

b. Application of all provisions of the 2010 Regulation restricting the sale and distribution of cigarettes and smokeless tobacco to proposed deemed products

The proposed rule does not go far enough to protect youth from the aggressive – and effective – marketing of proposed deemed tobacco products. All the provisions of the 2010 Regulations Restricting the Sale of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents should be applied to the proposed deemed products, including the prohibition on self-service displays, the use of tobacco brand names on non-tobacco merchandise, and tobacco brand name sponsorship of events.

Manufacturers of proposed deemed tobacco products are using the same marketing strategies that the cigarette and smokeless tobacco manufacturers have long used to attract youth including advertising on television and radio, sponsoring music and sports events, celebrity endorsements, and images of their products as cool, sexy, and rebellious.⁸ In response, youth are increasingly using these products. E-cigarette use among youth has doubled and the decline in cigar use has slowed.⁹ No tobacco product should be exempt from marketing restrictions to prevent the targeting of youth by tobacco product manufacturers.

The importance and effectiveness of tobacco marketing restrictions to protect youth was recognized by Congress in the findings of the Tobacco Control Act. The findings state that the marketing restrictions "will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and

⁸ A Gateway to Addiction? A survey of popular electronic cigarette manufacturers and targeted marketing to youth. April 2014. http://www.durbin.senate.gov/public/index.cfm/files/serve/?File_id=81d14ff7-f2f6-4856-af9d-c20c0b138f8f

⁹ CDC. Notes from the Field: Electronic Cigarette Use Among Middle and High School Students – United States 2011-2012. *MMWR* 2013; 62(No.35): 729-730. Kann, L et al. Youth Risk Behavior Surveillance – United States 2013. *MMWR* 2014; 63(No.4): 1-170.

smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use.¹⁰”

In addition, the findings of the Tobacco Control Act state:

“An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18.¹¹”

“Tobacco advertising and promotion play a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.¹²”

For additional information recommending the provisions of FDA’s 2010 Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents that should be applied to the proposed deemed products, see Tobacco Control Partners’ Joint Comment Letter (can be found on the docket as “Campaign for Tobacco -Free Kids, joined by 23 healthcare and public health organizations,” p.20).

c. Prohibition of characterizing flavors

Recognizing the success of the use of flavors in cigarettes to attract and addict youth users, Congress outright prohibited the use of characterizing flavors, other than tobacco and menthol, in cigarettes in the Tobacco Control Act. FDA must extend the prohibition of the use of characterizing flavors to all other tobacco products, including currently regulated and proposed deemed tobacco products, and use its enforcement authority to remove flavored so-called little cigars from the market.

In addition to its advertising strategies, tobacco manufacturers have targeted youth with the use of new products, ingredients, and product design. Altering tobacco product ingredients and design can improve the ease of use of a product by masking harsh effects, facilitating nicotine uptake, and increasing a product’s overall appeal.¹³ Candy and fruit flavorings in tobacco products are a promotional tool to lure new, young smokers, and aggressively marketed with creative campaigns by tobacco companies.¹⁴ The use of any flavored tobacco product among

¹⁰ The Family Smoking Prevention and Tobacco Control Act, (Pub.L. 111–31, H.R. 1256)

¹¹ The Family Smoking Prevention and Tobacco Control Act, (Pub.L. 111–31, H.R. 1256)

¹² The Family Smoking Prevention and Tobacco Control Act, (Pub.L. 111–31, H.R. 1256)

¹³ 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.

¹⁴ Delnevo, C, et al., “Preference for flavoured cigar brands among youth, young adults and adults in the USA,” Tobacco Control, epub ahead of print, April 10, 2014. King, BA, et al., “Flavored-Little-Cigar and Flavored-

youth is concerning because it exposes them to a lifetime of nicotine addiction and increases the danger that youth move from these other tobacco products to cigarette smoking.

Smokeless tobacco companies have a long history of using flavorings, such as cherry, apple, and honey, and other product manipulation to gradually to get new, young users addicted to “starter” products, keep them using and even move them on to more potent products. So-called little cigars have the look and feel of a cigarette, yet are often sold individually and are available in a variety of flavors. Because of the flavorings often used in waterpipe tobacco, the sweet aromas, and use of water, users misperceive this practice as less harmful than cigarette smoking.¹⁵ The use of characterizing flavors in e-cigarettes has exploded on the market. These products have benefited by being exempt from the prohibition on characterizing flavors that applies to cigarettes.

The FDA must extend the prohibition of flavorings in cigarettes to all other tobacco products, including little cigars, smokeless tobacco products, loose tobacco, hookah tobacco, and e-cigarettes for the same reason the law outright banned flavorings in cigarettes – they are used to appeal to young smokers, mask the harshness of using tobacco, and ease them into a lifetime of addiction.

ACS CAN believes that FDA can prohibit the use of characterizing flavors in all tobacco products using its enforcement discretion immediately upon finalization of the deeming regulation. Such enforcement action can be done without additional rulemaking, can use the existing scientific evidence that is well-established regarding the use of flavors in marketing to youth, and would allow FDA to respond appropriately to protect public health.

The proposed deeming regulation acknowledges FDA’s broad discretion in determining how and if tobacco products can remain on the market after they are deemed tobacco products under the agency’s authority. Using its enforcement discretion, FDA can permit tobacco products to remain in the marketplace if their marketing is only targeted at adults. That would allow FDA to require the withdrawal of all e-cigarettes with characterizing flavors other than tobacco. FDA can also make the same requirement of little cigars

Additionally, cigarette manufacturers have skirted the characterizing flavor prohibition by rebranding their cigarettes as cigars. FDA should take immediate enforcement action on any tobacco product that meets the definition of a cigarette that is using a characterizing flavor.

Cigarette Use Among U.S. Middle and High School Students,” *Journal of Adolescent Health* 54(1):40-6, January 2014.

¹⁵ Morris DS, Fiala SC, Pawlak R. Opportunities for Policy Interventions to Reduce Youth Hookah Smoking in the United States. *Prev Chronic Dis* 2012;9:120082. Akl EA, Gaddam S, Gunukula SK, Honeine R, Jaoude PA, Irani J. The Effects of Waterpipe Tobacco Smoking on Health Outcomes: A Systematic Review [External Web Site Icon](#). *International Journal of Epidemiology* 2010;39:834–57. Smith JR, Edland SD, Novotny TE, et al. Increasing hookah use in California. *Am J Public Health*. Oct 2011;101(10):1876-1879.

For additional information recommending the prohibition of characterizing flavors in all tobacco products, see Tobacco Control Partners' Joint Comment Letter (can be found on the docket as "Campaign for Tobacco -Free Kids, joined by 23 healthcare and public health organizations," p.40).

d. Tobacco Product Packaging

The FDA must mandate child resistant containers for liquid nicotine products and e-cigarettes as they have proven to be a direct and immediate threat to children. The Centers for Disease Control and Prevention reports the number of calls to poison control centers involving child poisonings from e-cigarettes and liquid nicotine products has increased dramatically, with reports of poisonings leading to vomiting and seizures.¹⁶

In addition to reducing the risk of poisoning, tobacco product packaging, and minimum packaging requirements specifically, can reduce youth access to these products. Smaller pack sizes and tobacco products sold individually allow these products to be sold at lower prices, making them much more appealing to youth who are more price sensitive than adults. The FDA should consider requiring minimum packaging requirements for tobacco products, to reduce youth access to these products.

For additional information recommending child resistant containers for nicotine liquid products, see Tobacco Control Partners' Joint Comment Letter (can be found on the docket as "Campaign for Tobacco -Free Kids, joined by 23 healthcare and public health organizations," p.49).

III. Providing Information to Consumers

ACS CAN supports the FDA's proposal for warning labels for cigars and a warning on the addictiveness for all tobacco products. The scientific literature supports the use of all of the five cigar warning labels, as well as specific warnings for waterpipe and pipe tobacco products. Equally important is that the FDA update and frequently rotate the warnings to sustain their effectiveness.

a. Warnings for cigars

All five warnings for cigars, including the warning on reproductive effects, already required under the 2000 Federal Trade Commission (FTC) consent orders involving the seven largest cigar manufacturers, are strongly supported by the scientific evidence, are appropriate for the protection of public health, and should be required for all cigars.

¹⁶ Centers for Disease Control and Prevention. Calls to Poison Control Centers for Exposure to Electronic Cigarettes – United States, September 2010-February 2014. *MMWR* 63(13): 292-293.

For additional information recommending strong health warnings on the dangers of cigar smoking, see Tobacco Control Partners' Joint Comment Letter (can be found on the docket as "Campaign for Tobacco -Free Kids, joined by 23 healthcare and public health organizations," p.50).

b. Addictiveness warning for all tobacco products

The proposed warning label for all tobacco products on the addictiveness of nicotine is appropriate for the protection of public health as it is supported by the scientific evidence. However, ACS CAN is concerned that the word derived would not be well understood by the majority of Americans. As such, ACS CAN recommends amending the warning to read: "WARNING: This product contains nicotine from tobacco. Nicotine is an addictive chemical."

For additional information recommending strong health warnings on the addictiveness of nicotine, see Tobacco Control Partners' Joint Comment Letter (can be found on the docket as "Campaign for Tobacco -Free Kids, joined by 23 healthcare and public health organizations," p.50).

c. Warnings for waterpipe and pipe tobacco products

FDA should consider additional warning labels for proposed deemed products that combust tobacco, specifically waterpipe and pipe tobacco. The health consequences of pipe smoking, beyond the risk for addiction, including lung disease and several types of cancer, have been established in the scientific literature. In addition, secondhand tobacco smoke from pipes and waterpipes can result in significant exposure to toxicants and carcinogens. Warning labels for waterpipe and pipe tobacco about risks of lung disease, cancer, and the harms of secondhand smoke are therefore appropriate for the protection of public health.

Evidence Supporting Warnings for Waterpipe (Hookah/Shisha/Narghile) Smoking:

Despite a limited number of epidemiologic studies to date, waterpipe smoking is known to be associated with higher risk of lung cancer, and possibly esophageal cancer, as well as low birth weight and periodontal disease.¹⁷ Waterpipe smoking results in significant exposure to toxicants, including many carcinogens such as tar, aldehydes, and polycyclic aromatic hydrocarbons.¹⁸ Smoke inhaled during a typical session of waterpipe smoking contains similar or higher amounts of many toxicants and carcinogens than smoke inhaled during the smoking of a cigarette.¹⁹ Waterpipe smoking also results in substantial nicotine intake, considered

¹⁷ Akl EA. The effects of waterpipe tobacco smoking on health outcomes: a systematic review. *International Journal of Epidemiology* 2010;39: 834–857.

¹⁸ Maziak, W. The waterpipe: An emerging global risk for cancer. *Cancer Epidemiology*. 2013;37: 1–4.

¹⁹ Eissenberg, T, Shihadeh, A. Waterpipe Tobacco and Cigarette Smoking Direct Comparison of Toxicant Exposure. *Am J Prev Med*. 2009 December ; 37(6): 518–523. Maziak, W. The waterpipe: An emerging global risk for cancer. *Cancer Epidemiology*. 2013;37: 1–4.

sufficient to sustain nicotine addiction.²⁰ With respect to secondhand smoke, a session of waterpipe smoking can generate amounts of ambient toxicants and carcinogens several times higher than those generated from the smoking of a cigarette.²¹ These findings concerning both toxicity and addiction potential indicate that additional warning labels addressing the harms of waterpipe smoking, beyond addiction, are appropriate for the protection of public health.

Evidence Supporting Warnings for Pipe Smoking:

Pipe smoking also exposes users to tobacco carcinogens. A comprehensive review by the International Agency for Research on Cancer (IARC) in 2004 concluded that pipe smoking (as well as cigar smoking) was “strongly related to cancers of the oral cavity, oropharynx, hypopharynx, larynx and oesophagus, the magnitude of risk being similar to that from cigarette smoking” and also concluded that pipe smoking is causally associated with lung cancer.²² Further evidence was provided by analyses from a cohort of 138,307 U.S. men enrolled in an American Cancer Society prospective cohort study (the Cancer Prevention Study II) which found that exclusive pipe smoking, compared with never use of tobacco, was associated with significantly increased risk of death from cancers of the lung, oropharynx, esophagus, colon and rectum, pancreas, and larynx, and from coronary heart disease, cerebrovascular disease, and chronic obstructive pulmonary disease.²³ Importantly, the “relative risks of lung cancer showed statistically significant increases with number of pipes smoked per day, years of smoking, and depth of inhalation, and decreases with years since quitting.” These results were consistent with prior prospective and case-control studies that have found positive associations between exclusive pipe smoking and tobacco-related diseases. Additional warning labels, beyond addiction, for pipe tobacco therefore would be appropriate for the protection of public health.

d. Sustaining the effectiveness of all warnings

Warning labels must be replaced often enough to remain fresh and effective, and must be updated as new scientific evidence on the health effects of specific products emerge. The science literature makes evident that the effect of specific warnings is likely to deteriorate over time.²⁴ The statute provides for substitution of new warning labels. In order to ensure that warning labels remain as effective as possible, FDA should establish a target schedule for

²⁰ Eissenberg, T, Shihadeh, A. Waterpipe Tobacco and Cigarette Smoking Direct Comparison of Toxicant Exposure. *Am J Prev Med.* 2009 December ; 37(6): 518–523. Jacob, P et al. Comparison of Nicotine and Carcinogen Exposure with Water Pipe and Cigarette Smoking. *Cancer Epidemiol Biomarkers Prev* 2013;22:765-772.

²¹ Daher, N et al. Comparison of carcinogen, carbon monoxide, and ultrafine particle emissions from narghile waterpipe and cigarette smoking: Sidestream smoke measurements and assessment of second-hand smoke emission factors. *Atmos Environ.* 2010 January 1; 44(1): 8–14.

²² World Health Organization. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Tobacco Smoke and Involuntary Smoking. Vol 83. International Agency for Research on Cancer, Lyon 2004.

²³ Henley SJ, Thun MJ, Chao A, Calle EE. Association between exclusive pipe smoking and mortality from cancer and other diseases. *J Natl Cancer Inst.* 2004;96(11):853-861.

²⁴ Hammond, D., et al., “Measures to evaluate the effectiveness of tobacco product labeling policies. In: *IARC Handbook II: Evaluating the Effectiveness of Population Based Tobacco Control.* International Agency for Research on Cancer, 2007. Institute of Medicine, *Ending the Tobacco Epidemic, A Blueprint for the Nation* (2007). Ference R, Hammond G, Fong D, Warning Labels, C-3.

reconsideration and revision of the warnings in the light of evidence developed from evaluation of the warnings promulgated pursuant to this regulation. Such a schedule should call for ongoing consumer research and re-examination of the adequacy of existing warning labels at no more than a one-year interval. There should be a presumption that new labels will be required at no more than a two-year interval. Introduction of new labels may also be required to convey newly available information about the dangers of a tobacco product or as a result of additional research indicating that certain warnings are particularly effective.

IV. Implementing Tobacco Product Review

a. Conditions for use of FDA's enforcement discretion for tobacco product review

FDA's proposed use of its enforcement discretion to create a grace period for tobacco products that would otherwise be illegal, according to the statute, and allow these products to remain on the market should only apply if certain conditions are met. These conditions are:

- The grace period should not be longer than 12 months after the publication of the final rule, which allows for the time necessary to permit manufacturers to submit applications for marketing orders.
- The grace period should only be permitted for proposed deemed products if they are in compliance with all other provisions of the Tobacco Control Act, and are adhering to marketing practices that do not appeal to youth.
- Appropriate provisions are in place to ensure that proposed deemed products are not permitted to remain on the market for unreasonably long periods of time pending FDA review of their application. Provisions can include the denial and subsequent removal from the market of products whose applications are incomplete or unmeritorious.

One of the key components of the Tobacco Control Act is that premarket review is required of all new or modified tobacco products. This is to prevent the marketing of products unless the manufacturer has submitted scientific information that the product would be "appropriate for the protection of the public health," and only after the FDA has issued an order permitting its marketing. In proposing the grace period for proposed deemed products, the FDA recognizes that because of statutorily required application dates, premarket review would be required for some of the proposed deemed products, rendering these products illegal on the market until FDA issues an order permitting them to be on the market.

The proposed grace period represents an extraordinary departure from the statutory requirements applicable to cigarettes and smokeless tobacco products. If no conditions are placed on the marketing of these products during this period, manufacturers will be free to continue to market these products in ways that appeal to youth and to manipulate the content of these products in wholly uncontrolled ways for an indefinite period. In light of the irresponsible marketing of these products and the growth in their sales between the time FDA

announced its intent to assert jurisdiction and the date on which FDA announced its proposed rule, it would be inconsistent with FDA's public health mandate to allow these otherwise illegal products to continue to be marketed without any constraints on their marketing and with no controls over their content.

For additional information recommending tightening the premarket review provisions for new products and substantially equivalent products, see Tobacco Control Partners' Joint Comment Letter (can be found on the docket as "Campaign for Tobacco -Free Kids, joined by 23 healthcare and public health organizations," p.58).

V. Ensuring Compliance with the Law

As FDA begins to exert its new authority over the proposed deemed tobacco products it must make enforcement as a priority. The FDA must ensure that resources are sufficient to effectively monitor compliance with the law and provide a swift response to violations, and establish collaborations with other federal agencies, states and local governments, and non-governmental organizations when appropriate, to ensure regulation has maximum effectiveness. State and local governments and the public need to know when new regulations have been issued, when they have the authority to enforce the regulation, and to have a process for reporting to the FDA when a regulation has been ignored or violated.

Additionally, the nongovernmental tobacco control community has been exceptionally successful at implementing effective tobacco control policies, monitoring the industry and providing scientific expertise when needed over the last several decades. By engaging the tobacco control community on enforcement and other regulatory issues, the FDA would be able to act more quickly to address likely evasive and innovative tobacco industry activities that will arise as a result of new regulations and restrictions.

VI. FDA's Regulatory Impact Assessment

The Regulatory Impact Assessment ("RIA") accompanying the proposed rule massively underestimates the net welfare gain resulting from the proposed rule and should be corrected.

For additional information regarding how the RIA significantly underestimates the benefits of the proposed rule, see Tobacco Control Partners' Joint Comment Letter (can be found on the docket as "Campaign for Tobacco -Free Kids, joined by 23 healthcare and public health organizations," p74).

Conclusion

It is critically important for the protection of public health that a final rule is issued no later than one year after the publication of the proposed rule. The full benefit of regulation of the manufacture, marketing, sale, and distribution of tobacco products requires that *all tobacco products* be subject to these regulations.

ACS CAN strongly encourages the FDA to proceed with implementation of the Tobacco Control Act in a swift and transparent way that allows opportunity for input from organizations who have been working in tobacco control for decades. As the FDA regulates the manufacture, marketing, sale, and distribution of tobacco products, ACS CAN urges the FDA to rigorously enforce the tobacco control standard for the protection of public health, including actions that would reduce youth initiation of all tobacco products, addiction and health disparities, and the morbidity and mortality caused by tobacco use. ACS CAN is ready to assist the FDA in using its regulatory authority assertively and aggressively to truly end the enormous toll tobacco takes on our nation.

If you have any questions please feel free to contact either Gregg Haifley at Gregg.Haifley@cancer.org or Katie McMahon at Katie.McMahon@cancer.org. Thank you.

The American Cancer Society Cancer Action Network (ACS CAN) is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society and has 1 million volunteers who come from every state and congressional district in the country. ACS CAN works in support of evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem.