



CIGARS SHOULD NOT BE EXEMPTED FROM REGULATION BY THE FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration (FDA) has announced that it intends to assert authority over all tobacco products. While the Family Smoking Prevention and Tobacco Control Act specifically directs the FDA to regulate cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco, it also authorizes the agency to extend its authority to other categories of tobacco products and to determine which of the statute's provisions and regulations should apply to each of the other tobacco product categories, including cigars.

FDA's authority to assert jurisdiction over cigars is clear. Cigars fall within the definition of "tobacco products" laid out in the Tobacco Control Act (i.e., "any product made or derived from tobacco that is intended for human consumption..."), and cigars are specifically mentioned in its sections on tobacco product standards (Sec. 907) and user fees (Sec. 919).

No tobacco product was excluded from FDA jurisdiction under the Tobacco Control Act so that FDA could evaluate the science and public health considerations of every product. However, legislation has been introduced in the House and Senate (H.R. 1639 and S. 1461) that would exempt certain types of cigars from FDA oversight. Congress should not impede the science-based process created by the Tobacco Control Act by legislating an exemption from regulation for certain tobacco products.

Cigar Smoking Is a Public Health Concern

Consumption of cigars is rising. Although cigarette smoking has been slowly declining, total consumption of cigars (i.e., large cigars, cigarillos, and small cigars) in the United States has increased dramatically since 1993, reversing a decline in consumption that had persisted for most of the twentieth century.¹ Between 2000 and 2011, for example, cigar consumption increased by 123 percent while cigarette consumption declined by 32.5 percent.²

Young people are using cigars. Cigar smoking is the second most common form of tobacco use among youth. Results from the 2011 Youth Risk Behavior Survey show that more than one in six (17.8%) high school boys currently smoke cigars.³ Each day, almost 3,000 kids under 18 years old try cigar smoking for the first time.⁴

In some states, cigar smoking among some populations is even more popular than cigarette smoking. In Montana, 18.1 percent of high school boys currently smoke cigarettes, but 22.1 percent smoke cigars.⁵ The 2010 Maryland Youth Tobacco Survey found that high school cigar use had increased while high school cigarette use had declined over the past 10 years; cigar smoking rates in Maryland were nearly equal to cigarette smoking rates in 2010.⁶ Similarly, a study in Ohio found cigars to be the most popular tobacco product among high school students.⁷ One reason youth cigar smoking rates are high is because cigars are being marketed in a range of kid-attracting flavors, such as candy, fruit and chocolate.⁸

Cigar smoking harms health. While the health risk of cigar smoking are not the same as cigarette smoking, cigar smoke is composed of the same toxic and carcinogenic constituents found in cigarette smoke. Some cigar smokers inhale – albeit less than cigarette smokers – while others may not, but any cigar use increases health risks compared to those who do not use tobacco at all. Cigar smoking causes cancer of the oral cavity, larynx, esophagus and lung. Daily cigar smokers, particularly those who inhale, have an increased risk of heart disease and chronic obstructive pulmonary disease (COPD). Cigar smokers are also at increased risk for an aortic aneurysm.⁹

All cigar smokers, whether they inhale or not, expose their lips, tongue and throat to smoke and its toxic and cancer-causing chemicals.¹⁰ Cigar smokers who inhale absorb smoke into their lungs and bloodstream, and deposit tobacco smoke particles in their lungs as well as their stomachs and digestive tract.¹¹ Moreover, many youth and adult users are now smoking cigars, especially smaller ones, with full inhalation, just like cigarettes.

H.R. 1639 and S. 1461 Would Exempt Many Cigars from Regulation

H.R. 1639 and S. 1461 would exempt certain cigars from regulation by FDA. The bills would prohibit FDA from issuing regulations “on any matter that involves traditional large and premium cigars,” which H.R. 1639 defines as any roll of tobacco that is wrapped in tobacco leaf, does not contain a filter, and weighs at least six pounds per 1,000 units. Cigarettes and little cigars are specifically excluded from the exemption.

The bills undercut a science-based regulatory process. The Tobacco Control Act gives FDA considerable flexibility to determine how cigars should be regulated. Using a science-based process, FDA can determine which of its regulatory authorities should apply to cigars and promulgate regulations that are reasonably related to the health risk of the product. FDA has not yet proposed how it would regulate cigars. Once it issues a proposed rule, all interested parties, including cigar manufacturers and retailers, would have an opportunity to comment on FDA’s proposal. FDA would have to consider these comments before issuing a final rule. H.R. 1639 or S. 1461 would prevent a science-based regulatory process from determining how to regulate cigars.

The bills block any regulation of certain types of cigars. The exemption provided in the bills is broad. H.R. 1639 and S. 1461 would prohibit FDA from issuing any regulation of certain cigars no matter how much the benefit to public health or how little the cost to industry. FDA regulates many products (e.g., drugs, medical devices, and food) but, if H.R. 1639 and S. 1461 were enacted, the agency would be prohibited from issuing any regulation for a product that can cause a variety of cancers and increase the risk of heart and chronic obstructive pulmonary disease.

The bills could exempt more than premium cigars. The definition of “traditional large and premium cigar” used in H.R. 1639 and S. 1461 could invite manufacturers of non-premium cigars, such as some cigarillos and blunts, to assert that their products are covered by the exemption from regulation. Neither bill, for example, specifies that an exempt cigar must be rolled by hand even though “hand rolled” is a defining characteristic of a premium cigar. Neither bill defines “leaf tobacco.” Many of the cheap, kid-friendly cigars are rolled in a brown paper that is not “whole leaf” but contains some form of reconstituted or homogenized “leaf tobacco.” This may allow these products to claim they are exempt. Both bills create incentives for manufacturers to modify their products to become exempt, for example by changing how much they weigh or what they are wrapped in. These loopholes can be used by tobacco companies to widen the proposed exemption far beyond premium cigars.

Swisher Sweets blunts and cigarillos, which come in flavors such as chocolate and strawberry, or Phillies Sugarillo Cigarillos, which have been advertised with the tagline, “when sweet isn’t enough,” both weigh more than six pounds per 1,000 cigars and could argue that they meet the definition. These products are cheaper than premium cigars and often come in flavors that appeal to youth. Data from the National Survey on Drug Use and Health show that Phillies and Swisher Sweets are among the most popular cigar brands among youth age 12-17.¹²

Here are a few examples of large cigars that are not traditional, premium cigars, but weigh over six pounds per 1,000 units and contain no filter:

	Weight per cigar (ounces)	Weight per 1,000 cigars (pounds)
Phillies Cigarillo – Double Apple 	0.1 oz	6.6 lbs
Dutch Masters Cigarillo – Chocolate 	0.1 oz	6.6 lbs
White Owl Cigarillo – White Grape 	0.1 oz	6.6 lbs
Zig Zag Cigarillo – Peach 	0.1 oz	6.6 lbs
Bluntville Cigar – Vanilla 	0.14 oz	8.8 lbs

	Weight per cigar (ounces)	Weight per 1,000 cigars (pounds)
Phillies Cigarillo – Grape 	0.1 oz	6.25 lbs
Optimo Blunt – Peach 	0.2 oz	12.5 lbs
Swisher Sweets Sweet Chocolate Blunt 	0.2 oz	12.5 lbs
White Owl Blunts Xtra – Peach 	0.2 oz	12.5 lbs

User Fee Payments Would Amount to Only a Fraction of a Penny Per Cigar

The Tobacco Control Act established a system for assessing and collecting user fees to provide all necessary funding for the FDA to implement its new responsibilities. The user fees are paid by each manufacturer and importer of a tobacco product that is regulated by FDA. If as expected FDA asserts authority over cigars, the user fees will be allocated among cigar manufacturers based on each manufacturer's percentage share of all excise taxes paid by cigar manufacturers during the prior fiscal year.

The table below shows the portion of the total user fees cigar manufacturers would have to pay starting in federal fiscal year (FFY) 2012, assuming five percent growth or no growth in the large cigar category. Under both scenarios, the user fee per cigar is about half of a penny, even by FFY 2019, when user fees would reach their highest level. Even if cigar sales declined 10 percent each year until 2019, the user fees would still only be about one penny per cigar.

	Total User Fee (millions)	Cigar Manufacturer's Allocation ¹³	Cigar Manufacturer's Portion of Total User Fee (millions)	5% growth ¹⁴		No growth ¹⁵	
				Estimated Large Cigar Sales ¹⁶ (millions of sticks)	User Fee Per Cigar	Estimated Large Cigar Sales ¹⁵ (millions of sticks)	User Fee Per Cigar
FY 2012	\$477	9.13%	\$43.6	13,554	0.3¢	12,909	0.3¢
FY 2013	\$505	9.13%	\$46.1	14,232	0.3¢	12,909	0.4¢
FY 2014	\$534	9.13%	\$48.8	14,944	0.3¢	12,909	0.4¢
FY 2015	\$566	9.13%	\$51.7	15,691	0.3¢	12,909	0.4¢
FY 2016	\$599	9.13%	\$54.7	16,476	0.3¢	12,909	0.4¢
FY 2017	\$635	9.13%	\$58.0	17,299	0.3¢	12,909	0.4¢
FY 2018	\$672	9.13%	\$61.4	18,164	0.3¢	12,909	0.5¢
FY 2019	\$712	9.13%	\$65.0	19,072	0.3¢	12,909	0.5¢

¹ National Cancer Institute (NCI), *Cigars: Health Effects and Trends*, Smoking and Tobacco Control Monograph No. 9, 1998. Economic Research Service, U.S. Department of Agriculture. U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), Tobacco Statistics.

² TTB, Tobacco Statistics.

³ U.S. Centers for Disease Control & Prevention (CDC), "Youth Risk Behavior Surveillance—United States, 2011," *Morbidity and Mortality Weekly Report (MMWR)* 61(SS-4), June 8, 2012.

⁴ SAMHSA, *Results from the 2010 National Survey on Drug Use and Health: Detailed Tables*, 2011 <http://oas.samhsa.gov/NSDUH/2k10NSDUH/tabs/Sect4peTabs10to11.pdf>

⁵ CDC, *MMWR* 61(SS-4), June 8, 2012.

⁶ Maryland Department of Health and Mental Hygiene, 2010 Maryland Youth Tobacco Survey, *Monitoring Changing Tobacco Use Behaviors 2000-2010, Legislative Report*, November 2011, <http://fha.dhmh.maryland.gov/ohpetup/docs/HG13-1004d-FHA-BiennialTobaccoReport.pdf>.

⁷ Brooks, A, et al., "Cigars, Cigarettes, and Adolescents," *American Journal of Health Behavior* 32(6):640-649, 2008.

⁸ See, e.g., Lewis, M, et al., "Dealing with an Innovative Industry: A Look at Flavored Cigarettes Promoted by Mainstream Brands," *American Journal of Public Health* 96(2), February 2006.

⁹ NCI, *Cigars: Health Effects and Trends*, 1998.

¹⁰ NCI, *Cigars: Health Effects and Trends*, 1998.

¹¹ See, e.g., Rodriguez, J, et al., "The Association of Pipe and Cigar Use with Cotinine Levels, Lung Function, and Airflow Obstruction: A Cross-sectional Study," *Annals of Internal Medicine* 152:201-210, 2010; McDonald, LJ, et al, "Deposition of Cigar Smoke Particles in the Lung: Evaluation with Ventilation Scan Using ^{99m}Tc-Labeled Sulfur Colloid Particles," *Journal of Nuclear Medicine* 43:1591-1595, 2002.

¹² SAMHSA, Analysis of data from the 2010 *National Survey on Drug Use and Health*, 2011.

¹³ Percentage apportioned to the large cigar category determined by the USDA's Farm Service Agency's class allocation for FY 2012, as directed by the FSPTCA. See http://www.fsa.usda.gov/Internet/FSA_File/class_allocations_12.xls.

¹⁴ These calculations assume a five percent growth in the cigar category over the years, which is the average growth in the large cigar category in the 2 years before the federal excise tax increase and the federal ban on flavored cigarettes in 2009. If growth in the large cigar category is higher than 5% per year, then the user fee per cigar will be even less in the out years.

¹⁵ These calculations assume no growth in the cigar category.

¹⁶ U.S. Alcohol and Tobacco Tax and Trade Bureau, Tobacco Statistics (taxed and imported sales of large cigar sticks for FFY 2010-2011).