

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

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Cigars are not currently regulated by the Food and Drug Administration (FDA). Under the Family Smoking Prevention and Tobacco Control Act, Congress immediately applied FDA's new regulatory authority to cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco and gave FDA the authority to assert jurisdiction over all other tobacco products.

Congress did not exclude any tobacco product from potential regulation under the Tobacco Control Act so that FDA could evaluate the science and public health considerations of every tobacco product. Cigars clearly 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 the statute (see Sec. 907 and Sec. 919).

The Tobacco Control Act gives FDA considerable flexibility to determine how to apply its regulatory authority to cigars and other tobacco products that were not immediately under FDA's jurisdiction. FDA is not required to regulate all tobacco products like cigarettes and is not required to regulate all cigars in the same way.

### **Cigar Smoking Is a Public Health Concern**

**Consumption of cigars is rising.** Sales of cigars (i.e., large cigars, cigarillos, and small cigars) more than doubled between 2000 and 2013 from 6 billion cigars to more than 13 billion cigars.<sup>1</sup> Cigar sales began to increase in 1993, reversing a decline in consumption that had persisted for most of the twentieth century,<sup>2</sup> and has been increasing at a time when cigarette smoking has been slowly declining. Between 2000 and 2013, for example, cigar consumption increased by 114 percent while cigarette consumption declined by 37 percent.<sup>3</sup> Much of the growth in cigar sales can be attributable to smaller cigars.

**Young people are using cigars.** While cigar smoking conjures images of middle-age and older men, today's cigar smoker is more likely to be a youth or young adult. Cigar smoking is the second most common form of tobacco use among youth. Results from the 2013 Youth Risk Behavior Survey show that high school boys now smoke cigars at the same rate as cigarettes (16.5 percent for cigars and 16.4 percent for cigarettes). Among all high school students, 12.6 percent were current (past-month) cigar smokers in 2013, and although cigarette use has declined significantly in recent years, there has been little change in cigar use.<sup>4</sup> Each day, more than 2,700 kids under 18 years old try cigar smoking for the first time.<sup>5</sup>

Nationally, 12<sup>th</sup> grade boys smoke cigars at a higher rate than cigarettes (23% compared to 19.6%).<sup>6</sup> Cigar smoking by high school boys equals or surpasses cigarette smoking in more than 20 states.<sup>7,8</sup> Results from the 2013 Youth Risk Behavior Survey show that among African American high school students, cigar use exceeds cigarette smoking (11.7% current cigar use vs. 8.2% current cigarette use).<sup>9</sup>

One reason youth cigar smoking rates are high among certain demographics is because cigars are being marketed in a range of kid-attracting flavors, such as candy, fruit, and chocolate.<sup>10</sup> "Candy-flavored" is an appropriate descriptor, given a recent chemical analysis showing that the same flavor chemicals used in sweet-flavored cigars of various sizes are also used in popular candy and drink products such as LifeSavers, Jolly Ranchers, and Kool-Aid.<sup>11</sup>

Youth and young adults prefer cigar brands that come in a variety of flavors, and preference decreases significantly with age (95% of 12-17 year old cigar smokers report use of a usual brand that makes flavored cigars compared with 63% of cigar smokers aged 35 and older).<sup>12</sup> Nationally, more than one-third of middle and high school cigar smokers have reported using flavored cigars.<sup>13</sup> The majority of high school cigar smokers in Florida use flavored cigars (68.8%). In fact, one out of seven high school students in Florida has tried a flavored cigar.<sup>14</sup> Similarly, in Maryland, nearly three-quarters of high school cigar smokers used flavored cigars.<sup>15</sup>

A survey of adult tobacco users found that young adults (e.g., 15.9% of 18-24 year olds) are much more likely to be cigar smokers than older adults (e.g., 4.9% of 45-64 year olds).<sup>16</sup> Data suggest that flavored cigar products are driving cigar use among adults. With few exceptions, use of flavored cigars among adult cigar smokers is highest among those groups with the highest overall cigar use rates, including young adults aged 18-24 (57.1%), income below \$20,000 (51.7%), and non-Hispanic others (62.4%).<sup>17</sup>

***Cigar smoking harms health.*** While the health risks of cigar smoking are not the same as for 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.<sup>18</sup>

All cigar smokers, whether they inhale or not, expose their lips, tongue and throat to smoke and its toxic and cancer-causing chemicals.<sup>19</sup> 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.<sup>20</sup> Moreover, many youth and adult users are now smoking cigars, especially smaller ones, with full inhalation, just like cigarettes.

### **FDA Should Regulate All Types of Cigars**

In April 2014, FDA released a proposed rule to assert jurisdiction over tobacco products not currently regulated by FDA. The proposal is seeking public comment on two options: 1) FDA would assert jurisdiction over all tobacco products, including all cigars or 2) FDA would assert jurisdiction over all tobacco products except cigars designated as “premium” cigars.

All tobacco products, including all types of cigars, should be regulated by the FDA. Consumption of cigars has increased; kids and young adults are smoking cigars at higher rates than older adults; and manufacturers are targeting kids with cheap, sweet-flavored cigars. As FDA’s own proposed rule states, “all cigars are harmful and potentially addictive.”

If FDA were to exempt premium cigars from its oversight, the agency would have no authority to implement even basic public health protections for these products. FDA requires food manufacturers under its authority to disclose ingredients, adhere to good manufacturing processes, and follow rules for making health claims and using additives. Yet FDA would not be able to issue similar regulations for premium cigars -- a product that causes a variety of cancers and other serious medical problems – unless it asserts jurisdiction over them.

When FDA releases its final rule asserting jurisdiction over currently unregulated tobacco products, it should include oversight of premium cigars. Even if FDA were to conclude that some requirements applicable to other tobacco products should not be imposed on premium cigars, FDA could fashion an appropriate set of applicable requirements without completely exempting them from regulation.

### **H.R. 792 and S. 772 Could Exempt Some Machine-Made and Flavored Cigars from Regulation**

Some cigar manufacturers and retailers are asking Congress to exempt many cigars from FDA oversight. H.R. 792 and S. 772 would prohibit FDA from issuing regulations “on any matter that involves traditional large and premium cigars.”

***The bills undercut a science-based regulatory process.*** The Tobacco Control Act, which Congress approved on a bipartisan basis in 2009, gives FDA considerable flexibility to determine how cigars, including different types of cigars, should be regulated. FDA can determine the rules that should apply to cigars using evidence-based criteria such as the health risk of the product, the type of user, and how the product is marketed. The proposed rule that FDA has issued seeks comment on whether FDA should regulate premium cigars. If enacted, H.R. 792 and S. 772 would interfere with the current rulemaking

process that FDA has initiated and block an open, 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. 792 and S. 772 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 would be prohibited from implementing even basic public health protections such as requiring disclosure of ingredients and measures to reduce youth access to these products.

**The bills could exempt many cigars.** While supporters of H.R. 792 and S. 772 may intend to exempt only “traditional large and premium cigars” from FDA oversight, the bills define premium cigars differently than the FDA has proposed to do, which raises concern that these bills could exempt a broader array of cigars. H.R. 792 and S. 772 would not only exempt traditional hand-made cigars but also would specifically exempt some machine-made cigars, which tend to be cheaper and more affordable for young people than hand-made cigars. Moreover, despite concerns raised by public health organizations that similar legislation introduced last Congress could have exempted flavored cigars that are attractive to kids, the current bills still do not prohibit strawberry, grape, cherry or other flavored cigars from qualifying for an exemption.

The number of cigars covered under the exemption in H.R. 792 and S. 772 would likely increase over time as cigar manufacturers modify their products or change their manufacturing processes to qualify for the exemption. Tobacco manufacturers have a history of modifying their products to avoid regulations or attain lower tax rates. In the 1960s and 1970s, “little cigars” that look like cigarettes were developed to avoid the ban on broadcast advertising of cigarettes and higher cigarette taxes.<sup>21</sup> More recently, tobacco manufacturers have modified their products to be classified as cigars rather than cigarettes in order to avoid FDA regulations of cigarettes such as prohibiting the use of certain characterizing flavors and the use of misleading descriptors such as “light” and “low.” The definition of “traditional large and premium cigar” in these bills creates the same opportunity for product modification that manufacturers have previously engaged in to evade regulations and higher taxes.

Campaign for Tobacco-Free Kids – Research Department – June 17, 2014

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<sup>1</sup> U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), Tobacco Statistics.

<sup>2</sup> 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. TTB, Tobacco Statistics.

<sup>3</sup> TTB, Tobacco Statistics.

<sup>4</sup> U.S. Centers for Disease Control & Prevention (CDC), “Youth Risk Behavior Surveillance—United States, 2013,” *Morbidity and Mortality Weekly Report (MMWR)* 63(4), June 12, 2014.

<sup>5</sup> Substance Abuse and Mental Health Services Administration (SAMHSA), *Results from the 2012 National Survey on Drug Use and Health: Detailed Tables*, 2013.

<http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect4peTabs1to16-2012.htm#Tab4.10A>.

<sup>6</sup> CDC, *MMWR* 63(4), June 12, 2014.

<sup>7</sup> The 21 states are: Arkansas, Georgia, Illinois, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Montana, Nebraska, Nevada, New Hampshire, New York, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, and Wyoming. CDC, *MMWR* 63(4), June 12, 2014.

<sup>8</sup> 2013 Florida Youth Tobacco Survey. <http://www.floridahealth.gov/reports-and-data/survey-data/fl-youth-tobacco-survey/reports/2013-state/index.html>.

<sup>9</sup> CDC, *MMWR* 63(4), June 12, 2014.

<sup>10</sup> 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.

<sup>11</sup> Brown, JE, et al., “Candy Flavorings in Tobacco,” *New England Journal of Medicine*, DOI: 10.1056/NEJMc1403015, May 7, 2014, <http://www.nejm.org/doi/full/10.1056/NEJMc1403015>.

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- <sup>12</sup> 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.
- <sup>13</sup> King, BA, et al., "Flavored-Little-Cigar and Flavored-Cigarette Use Among U.S. Middle and High School Students," *Journal of Adolescent Health* 54(1):40-6, January 2014.
- <sup>14</sup> 2013 Florida Youth Tobacco Survey, <http://www.floridahealth.gov/reports-and-data/survey-data/fl-youth-tobacco-survey/reports/2013-state/index.html> .
- <sup>15</sup> 2013 Maryland Tobacco and Risk Behavior Survey, in Moncrief, D, Maryland Statewide Youth Tobacco Initiatives, MDQuit 8<sup>th</sup> Best Practices Conference, January 23, 2014, [http://mdquit.org/sites/default/files/pdf\\_files/Moncrief.pdf](http://mdquit.org/sites/default/files/pdf_files/Moncrief.pdf).
- <sup>16</sup> King, BA, et al., "Current Tobacco Use Among Adults in the United States: Findings from the National Adult Tobacco Survey," *American Journal of Public Health*, September 20, 2012.
- <sup>17</sup> King, BA, Dube, SR, & Tynan, MA, "Flavored Cigar Smoking Among U.S. Adults: Findings From the 2009–2010 National Adult Tobacco Survey," *Nicotine & Tobacco Research*, August 27, 2012.
- <sup>18</sup> NCI, *Cigars: Health Effects and Trends*, 1998.
- <sup>19</sup> NCI, *Cigars: Health Effects and Trends*, 1998.
- <sup>20</sup> 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 <sup>99m</sup>Tc-Labeled Sulfur Colloid Particles," *Journal of Nuclear Medicine* 43:1591-1595, 2002.
- <sup>21</sup> Delnevo, CD & Hrywna, M, "A Whole 'Nother Smoke' or a Cigarette in Disguise: How RJ Reynolds Reframed the Image of Little Cigars," *American Journal of Public Health* 97(8):1368-75, August 2007.