



## THE PUBLIC HEALTH COMMUNITY PETITIONS THE FDA TO REGULATE ALL TOBACCO PRODUCTS

### Citizen Petition Highlights

The Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act) grants the U.S. Food and Drug Administration (FDA) the authority to regulate all tobacco products, including all tobacco products currently marketed in the United States. However, in its charge to the FDA, Congress only required the FDA to regulate cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco. For all other products, the FDA is required to take an affirmative step and promulgate a rule that asserts jurisdiction over those products. In the four years since the passage of the Tobacco Control Act, the FDA has repeatedly stated its intention to regulate other products but it has yet to attempt to do so. This petition asks the FDA to assert jurisdiction over and regulate all tobacco products as stringently as it regulates cigarettes and smokeless tobacco.

While this void in FDA regulation of tobacco products continues to exist, state and local governments are trying to address the harms these products pose to the public's health. The differential treatment afforded to certain products at the federal level creates confusion regarding enforcement at all levels of government. In addition, FDA's failure to regulate some products can also lead consumers to think that the unregulated products are safer than other products because they are manufactured, advertised, marketed, sold and distributed in ways that cigarettes and smokeless tobacco are not.

This problem is exacerbated by the tobacco industry's efforts to develop new products that exploit regulatory loopholes and to acquire established businesses that manufacture and distribute novel products. As the tobacco industry diversifies its product lines, it continues to design and market its products to create and sustain nicotine addiction.

It is not a coincidence that as the rate of cigarette smoking decreases, the rate of using other tobacco products increases. This is troubling based on the known harms of many of these products and the potential health consequences of other tobacco products, both to individual users and at the population level.

The petition compiles data on four classes of products that are unregulated by the FDA: cigars, dissolvable tobacco products, e-cigarettes and hookah. However, the petition asks the FDA to regulate all products that meet the Tobacco Control Act's broad definition of tobacco products

and only focuses on these particular products by way of example. Below is a small sample of the data presented in the petition.

### **Cigars**

- Between 2000 and 2011, cigar sales increased 123 percent, while cigarette sales decreased by 32.8 percent.
- While cigar smoking in the United States was historically a behavior of older men, cigar smoking is now a behavior that skews younger, with young adults (age 18-24) smoking cigars at a significantly higher rate (15.9%) than adults age 25-44 (7.2%), age 45-64 (4.9%), and age 65 or older (1.8%).
- Experimentation with cigars is widespread in the U.S. among young adults, especially men. Among Hispanic, non-Hispanic Black, and non-Hispanic White men age 18-34, ever use of cigars ranges from 26.1% to 46.4%. Among women age 18-34, ever use of cigars ranges from 20.7 to 25.8%.
- Approximately 13.1 percent of high school students are current cigar smokers, while 6.6 percent of adults regularly use cigars.
- Regular cigar use causes cancers of the lungs, larynx, oral cavity, and esophagus.
- Cigar smokers who smoke regularly and those who inhale deeply are at increased risk of coronary heart disease and chronic obstructive pulmonary disease.
- Cigars can be more harmful than cigarettes because of higher levels of tobacco-specific *N*-nitrosamines inhaled by users and bystanders.
- The tar, carbon monoxide, and ammonia levels in cigars are higher than those found in cigarettes as well, and the tar found in cigars contains a type of hydrocarbon linked to an increased capability of producing tumors.
- The disease-free life-years lost due to cigar smoking have been estimated at 5.2 years.

### **Smokeless Tobacco**

- The most recent Youth Risk Behavior Surveillance Report reveals that 7.7 percent of high school students currently use smokeless tobacco, with rates particularly high among 11<sup>th</sup>- and 12<sup>th</sup>-grade males: about 15 percent of all 11th and 12th grade males use smokeless tobacco.
- The prevalence of use of smokeless tobacco has increased sharply among white males in grades 9-12.
- From 2005 to 2011, total consumption of cigarettes declined 23%, while convenience store unit sales of smokeless tobacco increased by 56.8% over the same time period. This increase was driven in large part by the increasing popularity of moist snuff products, which comprised at least 90% of the smokeless tobacco market each year and increased in sales by 65.6% from 2005 to 2011.
- Sales of pouched moist snuff increased an incredible 333.8% while flavored moist snuff sales increased 72.1%, in convenience store sales between 2005 and 2011.
- As recently as 2007, snus comprised only 0.1% of the smokeless tobacco market; by 2011, snus comprised 3.7% of the market.

- Two nationally representative cross-sectional surveys, the 2010 Social Climate Survey of Tobacco Control and the 2009 Consumer Styles Survey, both found that over 5% of surveyed adults reported trying snus. Reported use of snus is even higher among surveyed daily smokers (12.9%) and all younger adults (8.0% of 18- to 24-year-olds).
- Use of smokeless tobacco is linked to periodontal disease and tooth decay.
- Smokeless tobacco creates nicotine addiction.
- At least 28 chemicals found in smokeless tobacco are known to cause cancer.
- The Surgeon General, the Centers for Disease Control and Prevention, and the National Institutes for Health agree: smokeless tobacco use causes cancer.

## Hookah

- Results obtained by the 2008-2009 National College Health Assessment survey indicate that 8.4% of college students (10%, if limited to 18-24 year olds) reported current use of hookah while 30.5% of college students reported ever use.
- The Legacy Young Adult Cohort Study found that ever use of hookah by men age 18-34 was 19.2% among U.S.-born Hispanics, 13.7% among non-Hispanic Blacks, and 21.5% among non-Hispanic Whites. Ever use by women age 18-34 was 26.5% among U.S.-born Hispanics, 10.7% among non-Hispanic Blacks, and 18.4% among non-Hispanic Whites.
- Hookah is linked to increased risk of cardiovascular disease, clogged arteries and lung, oral, lip and bladder cancer.
- Studies comparing the effect of a single cigarette to 45 minutes of hookah use suggest that hookah smokers double their carbon monoxide exposure and triple their nicotine exposure, thereby intensifying the negative health effects of the smoke.
- Shared mouthpieces and the moist smoke associated with hookah smoking allow not only for the spread of common viruses like the cold, flu, or herpes simplex, but also deadly diseases including tuberculosis and hepatitis.

## E-cigarettes

- Data from the 2009 and 2010 national Consumer Styles Surveys found that awareness of e-cigarettes by U.S. adults doubled from 16.4% in 2009 to 32.2% in 2010. Ever use of e-cigarettes increased over the same period, from 0.6% in 2009 to 2.7% in 2010.
- National survey data also indicate an increase in awareness from 2010 to 2011 (40.9% to 57.9%), as well as ever use (3.3% to 6.2%).
- The Legacy Young Adult Cohort Study found that ever use of e-cigarettes among men age 18-34 was reported by 16.4% of U.S.-born Hispanics, 4.8% of non-Hispanic Blacks, and 8.8% of non-Hispanic Whites; current use was 5.3%, 3.5%, and 1.7%, respectively. Ever use of e-cigarettes among 18-34 year old women was 5.1% for U.S.-born Hispanics, 5.3% for non-Hispanic Blacks, and 8.0% for non-Hispanic Whites; current use was 1.6%, 4.0%, and 1.8%, respectively.
- While there is some evidence that e-cigarette vapor contains lower levels of cigarette-associated toxins than cigarette smoke, the mixture of chemicals in e-cigarette vapor has not been well studied and there is evidence that other toxic chemicals may be present in these products.

- There is also evidence that the liquid found in e-cigarettes contains amounts of nicotine that could be toxic or even lethal – especially to children – if ingested or absorbed transdermally, yet no warning labels are required on these products.

The problem is clear and the solution is simple. The FDA must assert jurisdiction over and regulate all tobacco products to protect the public health. The scientific evidence regarding the prevalence of the use of these products and the data regarding the harm that these products cause makes the case for FDA regulation. For some other products, a dearth of information is available as to their impact on both individual and population level harm. While some have taken this lack of evidence of harm as evidence of safety, the petition correctly points out that harm has not been concluded because the products are not well studied. This lack of information also underscores the need for FDA action.

This petition asks the FDA to undertake a simple and logical regulation: to bring all tobacco products under its regulatory oversight and to extend restrictions that currently apply to cigarettes and smokeless tobacco to all tobacco products. There is no reasonable justification to continue to allow so many tobacco products to go unregulated at the federal level considering the harm that they pose and the specific and broad authority possessed by the FDA.