FACT SHEET: FDA Takes Significant Steps to Protect Americans from Dangers of Tobacco Use

Tobacco Use Remains a Significant Public Health Threat

According to the Centers for Disease Control and Prevention (CDC), smoking is the leading cause of preventable death in the United States and is responsible for 480,000 deaths per year in the U.S. Additionally, more than 16 million Americans live with a smoking-related disease, and treating these tobacco-related illnesses costs more than $170 billion annually.

For decades, the federal government and the public health community have fought to protect people from the dangers of smoking. Since the first Surgeon General's report on Smoking and Health in 1964, which warned Americans about the risks associated with tobacco use, we have made significant progress and reduced smoking rates among Americans.

The 2014 Surgeon General's report on the Health Consequences of Smoking indicates that tobacco prevention and control efforts have saved at least 8 million lives in the last 50 years. Nearly one-third of the increase in life expectancy that has occurred over the past half century is due to tobacco prevention and control efforts.

However, we're not doing all we need to do to protect Americans from the harmful effects of tobacco use, particularly our nation's youth and young adults.

Alarming Youth Use of Tobacco Products

While there has been a decline in the use of traditional cigarettes among youth over the past decade, their use of other tobacco products continues to climb. A survey supported by the FDA and CDC shows that, in 2015, one in four high school students and one in 13 middle school students reported being tobacco users (using one or more tobacco products in the previous 30 days) – that's 4.7 million youth tobacco users. About 2.3 million also reported being current users of two or more types of tobacco products.

The survey also indicates current e-cigarette use among high school students skyrocketed from 1.5 percent in 2011 to 16 percent in 2015 (an over 900 percent increase) and hookah use has risen significantly from 4.1 percent to 7.2 percent during that same time. In 2015, 3 million middle and high school students currently used e-cigarettes, 1.4 million currently used cigars and 1.2 million currently used hookah. And data show high school boys smoked cigars at about the same rate as cigarettes.

Additionally, a joint study by the FDA and the National Institutes of Health (NIH) shows that in 2013-2014, nearly 80 percent of current youth tobacco users reported using a flavored tobacco product in the past 30 days – with the availability of appealing flavors as the most commonly cited reason for use.

Data also show that of the middle school and high school students who smoke cigars, more than 63 percent of them use flavored cigars, including cigarillos and little cigars. Research also has shown that premium cigars are also used by youth and young adults. All cigars pose serious

negative health risks and contain harmful and potentially harmful chemicals, including nicotine, an addictive substance.

Nicotine is dangerous and highly addictive, whether it comes from an e-cigarette, hookah, cigarette or cigar. Research has clearly demonstrated that exposure to nicotine at a young age increases the chance that kids will become addicted. In addition to nicotine exposure, there are numerous other chemicals present in tobacco products that can cause disease.

Final Rule Addresses Public Health Concerns Focusing on Youth

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), passed by Congress on a bipartisan basis and signed by the President in 2009, gave the FDA tools to protect the public from the harms of tobacco use. Since June 2009, the FDA has regulated cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products under its tobacco control authority. The law also gave the FDA the ability, through rulemaking, to regulate additional products that meet the legal definition of a tobacco product.

This new rule brings *all* tobacco products under FDA oversight, including e-cigarettes, cigars, hookah tobacco and pipe tobacco, among others. This historic step will help improve public health and protect future generations from the risks of tobacco use by putting additional restrictions in place that make it illegal to sell tobacco products to minors.

Before this rule, there was no federal law prohibiting stores and websites from selling e-cigarettes, hookah tobacco, and cigars to minors. The new rule aims to deter youth initiation through restricting youth access to these products by:

- Not allowing products to be sold to persons under the age of 18 years;
- Requiring age verification by photo ID;
- Not allowing the selling of tobacco products in vending machines (unless in an adult-only facility); and
- Not allowing the distribution of free samples.

The rule also serves as the foundation for future FDA actions related to tobacco, including where scientific data supports regulatory action, addressing flavors in combustible products.

Extending the FDA's Authority is a Milestone in Public Health and Consumer Protection

Going forward, the FDA will be able to review all new tobacco products not yet on the market. The actions being taken also will help the FDA prevent misleading claims and provide consumers with better information about the risks of tobacco use. The rule also will allow the FDA to evaluate the ingredients of tobacco products, how those products are made, and their potential dangers.

The rule will subject all manufacturers, importers and/or retailers of newly-regulated tobacco products to any applicable provisions, bringing them in line with other tobacco products the FDA has regulated under the TCA since 2009.

These requirements include:

- Registering manufacturing establishments and providing product listings to the FDA;
- Reporting ingredients, and harmful and potentially harmful constituents;
- Requiring premarket review and authorization of new tobacco products by the FDA;
- Placing health warnings on product packages and advertisements; and
- Not selling modified risk tobacco products (including those described as "light," "low," or "mild") unless authorized by the FDA.

Manufacturers of newly-regulated products must show that the products meet the applicable public health standard set forth in the law and receive authorization from the FDA, unless the product was on the market as of February 15, 2007. The review process gives the agency the ability to evaluate important factors such as ingredients, product design and health risks, as well as their appeal to youth and non-users.

Under staggered timelines, FDA does not intend to enforce the premarket review requirements for up to three years while manufacturers submit – and the FDA reviews – a new tobacco product application. FDA will issue an order granting marketing authorization where appropriate; otherwise the product will be subject to enforcement.

To assist the newly-regulated tobacco industry in complying with the requirements being announced today, the FDA is also publishing several other regulatory documents that provide additional clarity, instructions and/or the FDA's current thinking on issues specific to the newly-regulated products.

For More Information

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For more information:

- Final Rule: [FR LINK]
- Deeming – Extending Authorities to All Tobacco Products: [LINK]
- FDA takes significant steps to protect Americans from dangers of tobacco through new regulation [LINK]