FDA REGULATION OF TOBACCO PRODUCTS: A COMMON SENSE LAW TO PROTECT KIDS AND SAVE LIVES

On June 22, 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act, which gives the U.S. Food and Drug Administration the authority to regulate the manufacturing, marketing and sale of tobacco products. This landmark law ended the special protection from regulation that the tobacco industry enjoyed for decades and represents a milestone in protecting America's children and health from the devastating consequences of tobacco use.

On June 11, 2009, the U.S. Senate voted 79-17 to approve the bill, H.R. 1256/S. 982. On June 12, 2009, the U.S. House of Representatives voted 307 to 97 to approve the identical bill. The legislation was sponsored by U.S. Reps. Henry Waxman (D-CA) and Todd Platts (R-PA) and the late U.S. Senator Edward Kennedy (D-MA).

Why This Law Is Important

Tobacco use is the leading preventable cause of death in the United States, killing more than 480,000 Americans and resulting in $170 billion in health care costs every year. Every day, about 2,300 kids try a cigarette for the first time, and about 350 other kids become daily smokers. One-third of these kids will eventually die prematurely as a result of their addiction.

Until the law was enacted, tobacco products had escaped regulation despite their devastating toll in health, lives and dollars. They were exempt from basic consumer protections, such as ingredient disclosure, product testing and restrictions on marketing to children.

What the Law Does

The Family Smoking Prevention and Tobacco Control Act grants the FDA authority to regulate the manufacturing, marketing and sale of tobacco products.

Tobacco products are not regulated under the "safe and effective" standard currently used for other products under the agency's purview, but under a new standard – "appropriate for the protection of the public health."

The law:

1. Restricts tobacco marketing and sales to youth – The law includes specific restrictions on youth access and marketing and grants FDA authority to take additional actions in the future to protect the public health. The regulations are effective on June 22, 2010. These regulations:

- Ban all remaining tobacco-brand sponsorships of sports and entertainment events,
- Ban free giveaways of any non-tobacco items with the purchase of a tobacco product or in exchange for coupons or proof of purchase,
- Ban outdoor advertising near schools and playgrounds after further FDA review,[1]
- Restrict vending machines and self-service displays to adult-only facilities, and
- Require retailers to verify age for all over-the-counter sales and provide for federal enforcement and penalties against retailers who sell to minors.

2. Grants the FDA authority to further restrict tobacco marketing – The Secretary of Health and Human Services (HHS) has the authority to develop regulations that impose restrictions on the advertising and promotion of tobacco products consistent with and to the full extent permitted by the First Amendment to the Constitution. These regulations would be based on whether they are appropriate for the protection of the public health. This authority gives the agency the flexibility to respond to inevitable tobacco industry attempts to circumvent specific restrictions.

3. Requires detailed disclosure of ingredients, nicotine and harmful smoke constituents – Tobacco companies are now required to provide the FDA with information about their products. This information will allow the agency to determine how best to reduce the harm they cause and to better educate the public about the health effects of tobacco use and the dozens of toxic substances in tobacco products. For example, tobacco companies are required to disclose to the FDA the ingredients in each existing tobacco product by brand and by quantity in each brand, including all smoke constituents. They must also inform the FDA of any changes to the product.

4. Allows FDA to require changes to tobacco products to protect the public health – The FDA has the authority to require changes in current and future tobacco products, such as the reduction or elimination of harmful ingredients, additives and constituents, if it determines that these changes will protect public health. FDA has the authority to change nicotine yields; Congress maintains the authority to ban nicotine completely.

5. Regulates "reduced harm" claims about tobacco products to prevent inaccurate and misleading claims – The law prohibits the use of descriptors, such as "light," "mild" and "low," to characterize a product on labels or in advertising. In addition, a manufacturer must first file an application and receive an order before marketing any tobacco product as presenting a "modified risk." FDA has the authority to review the marketing of such products and determine if the applicant demonstrates that the product, as actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole – taking into account both users of tobacco products and persons who do not currently use tobacco products.

6. Requires bigger, bolder health warnings – Beginning on June 22, 2010, the law requires large text warning labels for smokeless tobacco products that take up at least 30 percent of each principal display panel of the package and at least 20 percent of the face of advertisements. The law also requires FDA to implement large, graphic cigarette warning labels that cover the top 50 percent of the front and rear panels of the cigarette pack and at least 20 percent of the area of advertisements. However, in 2012, the federal appeals court in the District of Columbia struck down the specific graphic warnings proposed by FDA, finding they would violate the companies' First Amendment rights. FDA has indicated it intends to develop new graphic warnings that will survive constitutional challenge.

7. Fully funds FDA regulation of tobacco products through a user fee on manufacturers of cigarettes, cigarette tobacco and smokeless tobacco – The law allocates payment of all tobacco product-related FDA costs among the manufacturers of cigarettes, cigarette tobacco and smokeless tobacco products sold in the United States, based on the manufacturers' respective shares of the entire U.S. tobacco product market.

8. Preserves state and local authority – The law does not preempt state and local governments from enacting other tobacco control measures, including tobacco taxes, smoke-free workplace laws and fire-safety standards for cigarettes. States are free to adopt measures related to the sale, distribution and possession, exposure to, or access to tobacco products.

State and local governments have new authority to restrict the time, place and manner of cigarette advertising, consistent with the First Amendment.

April 25, 2016

[1] Section 897.30(b) of the FDA's initial Final Rule called for a total ban on any outdoor cigarette or smokeless ads within 1000 feet of schools or playgrounds. But the new law directed FDA to make changes to this provision prior to the publication of the Final Rule if FDA determined that any modifications were appropriate in light of governing case law regarding the First Amendment and permissible restrictions on commercial speech. On March 19, 2010, FDA published the Final Rule without any provision relating to outdoor ads near schools or playgrounds, at all, but issued a related notice and request for comments on that same topic. See http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/RegsRestrictingSale/default.htm.