



FDA Regulation of Tobacco Products: A Common-Sense Plan to Protect Kids and Save Lives

The Congress has approved and President Obama has signed into law truly historic legislation to grant the U.S. Food and Drug Administration the authority to regulate tobacco products. On June 22, 2009, President Obama signed the bill, H.R. 1256/S. 982, known as the Family Smoking Prevention and Tobacco Control Act, into law. On June 11, 2009, the U.S. Senate voted 79 to 17 to approve the bill and on June 12, 2009, the U.S. House of Representatives voted 307 to 97 to approve the identical bill. The bill was sponsored by U.S. Reps. Henry Waxman (R-CA) and Todd Platts (R-PA) and Senator Edward Kennedy (D-MA).

Why This Bill Is Needed

Tobacco use is the leading preventable cause of death in the United States, killing more than 400,000 Americans and resulting in \$96 billion in health care costs every year. Every day, approximately 3,500 kids will try a cigarette for the first time, and another 1,000 will become new, regular daily smokers. One-third of these kids will eventually die prematurely as a result of their addiction.

Despite tobacco's huge societal costs, tobacco products are the most unregulated consumer products on the market today; they are exempt from important and basic consumer protections, such as ingredient disclosure, product testing and restrictions on marketing to children.

What This Bill Will Do

The "Family Smoking Prevention and Tobacco Control Act" amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to grant the FDA authority to regulate the manufacturing, marketing and sale of tobacco products.

The bill adds a new chapter to the FFDCA to regulate tobacco products. Tobacco products will not be 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."

This legislation will:

- 1. Restrict tobacco marketing and sales to youth** – The legislation 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 will become effective no later than 15 months after enactment. 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,
- Limit advertising in publications with significant teen readership as well as outdoor and point-of-sale advertising, except in adult-only facilities, to black-and-white text only,
- Ban outdoor advertising near schools and playgrounds after further FDA review,
- 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. Grant FDA authority to further restrict tobacco marketing – The Secretary of Health and Human Services (HHS) will have the authority to develop regulations that impose restrictions on the advertising and promotion of a tobacco product 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. Require detailed disclosure of ingredients, nicotine and harmful smoke constituents – Tobacco companies will be 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 will be 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. Allow FDA to require changes to tobacco products to protect the public health – FDA will have authority to require changes in current and future tobacco products, such as the reduction or elimination of harmful ingredients, additives and constituents, if it decided that these changes will protect public health. FDA will be granted authority to change nicotine yields; Congress will maintain the authority to ban nicotine completely.

5. Regulate “reduced harm” claims about tobacco products to prevent inaccurate and misleading claims – This legislation 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 they market any tobacco product as presenting a “modified risk.” FDA will have 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. Require bigger, graphic health warnings –The legislation requires graphic warning labels that cover the top 50% of the front and rear panels of the cigarette pack. The FDA will have authority to revise labeling requirements and the same warning labels would be required in advertising and must comprise at least 20% of the advertisement’s area. The authority to revise the labels will allow the agency to require labels based on the best available evidence of effectiveness without new action by Congress.

7. Fully fund FDA regulation of tobacco products through a user fee on manufacturers of cigarettes, cigarette tobacco and smokeless tobacco – The legislation 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. Preserve state and local authority -- The legislation 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 will be free to adopt measures related to the sale, distribution and possession, exposure to, or access to tobacco products. State and local governments will gain new authority to restrict the time, place and manner of cigarette advertising, consistent with the First Amendment.

Who Supports the “Family Smoking Prevention and Tobacco Control Act”?

This legislation is supported by more than 1,000 public health, faith and other organizations around the country. Supporting organizations include the American Cancer Society Cancer Action Network, American Heart Association, American Lung Association and the Campaign for Tobacco-Free Kids. Recent surveys have found that 70 percent of voters support this legislation.

Both the President’s Cancer Panel and the Institute of Medicine support Congress giving the FDA the authority to regulate the manufacture and marketing of tobacco products. In its groundbreaking 2007 report, *Ending the Tobacco Epidemic: A Blueprint for the Nation*, the Institute of Medicine argued, “...product regulation by the FDA will advance tobacco control efforts in the United States and around the world. The proposed tobacco control legislation embodies the principles that should govern the regulation of tobacco products in the coming years.”