

Fact Sheet 1

An Overview

Proposed Regulation of Tobacco Products by the U.S. Food and Drug Administration

S. 625/H.R. 1108

Background

Tobacco products have long been largely exempt from regulation under the nation's federal health and safety laws, including the Food, Drug, and Cosmetic Act. The U.S. Food and Drug Administration (FDA) is authorized to regulate food, drugs and cosmetics, but not tobacco products, unless their manufacturers make explicit health claims related to a tobacco product's marketing and sale, which very rarely occurs.

In an effort to remedy this gap, on February 15, 2007, U.S. Senators Edward Kennedy (D-MA) and John Cornyn (R-TX) and U.S. Representatives Henry Waxman (D-CA) and Tom Davis (R-VA) introduced identical bills, S. 625 and H.R. 1108, to grant the FDA authority to regulate tobacco products. As of July 20, 2007, the Senate bill had 53 sponsors and cosponsors (including 39 Democrats, 12 Republicans, and 2 Independents) and the House bill had 192 sponsors and cosponsors (including 161 Democrats and 31 Republicans). The Senate approved similar legislation in 2004, but that legislation did not receive a vote in the House and did not become law.

Key Provisions

The legislation would add a new chapter to the Food, Drug, and Cosmetic Act, establishing and governing the regulation of tobacco products. The new chapter, titled the "Family Smoking Prevention and Tobacco Control Act," would vest the FDA with jurisdiction to regulate both current and new tobacco products and restrict tobacco product marketing, while also directly implementing provisions that would, among other things, restrict tobacco product marketing and advertising, strengthen cigarette and smokeless tobacco warning labels, reduce federal preemption of certain state cigarette advertising restrictions, and increase nationwide efforts to block tobacco product sales to youth.

The legislation would vest the FDA with extensive authority to regulate tobacco products and to regulate and restrict tobacco product marketing, including the following:

- Restrict tobacco advertising and promotion in order to promote overall public health, within the constraints of the First Amendment (the U.S. Supreme Court likely would be asked to adjudicate whether any of the legislated advertising restrictions unconstitutionally interfered with commercial speech)
- Stop illegal sales of tobacco products to minors
- Ban the use of all tobacco product flavorings, including fruit and candy flavors, if the FDA determined that doing so would have the net effect of promoting the public health (the legislation would immediately ban all cigarettes that have a characterizing flavor other than tobacco or menthol)





- Require changes in tobacco products, such as the removal of harmful ingredients or the reduction of nicotine to non-addictive levels if the FDA finds that such levels exist and that the reduction would promote overall improvements to public health
- Prohibit health claims about purported reduced-risk products, where such claims are not scientifically proven or would cause net public health harms (e.g., by discouraging current tobacco users from quitting or encouraging new users to start)
- Require tobacco companies to disclose the contents of tobacco products, changes to their products and research about the health effects of their products
- Require larger, more informative health warning labels, including color and graphics, on tobacco product packages and advertisements
- Prohibit terms such as “light,” “mild” and “low-tar” on tobacco product packages and advertisements that mislead consumers into believing that cigarettes marketed with such terms cause fewer health problems than other cigarettes, while authorizing the FDA to restrict additional terms in the future

The legislation would also impose certain limits on the FDA’s new authority. Most notably, it would prohibit the FDA from banning conventional tobacco products, such as cigarettes and smokeless tobacco, or requiring the total elimination of nicotine in tobacco products. However, the FDA would be authorized to order the reduction of nicotine to non-addictive levels in some or all tobacco products in order to promote overall public health, and the agency conversely could order an increase in nicotine levels in some or all tobacco products if it found that doing so would promote overall public health. In addition, states would remain free to ban all or some tobacco products or the sale of tobacco products containing nicotine.

The bill also would prohibit the FDA from using its new authority to increase the new federal minimum age of 18 to a higher level, require prescriptions for the purchase of tobacco products, ban tobacco product sales in any particular type of sales outlet or regulate tobacco farming directly. In all of these areas, the FDA could ask Congress to either take these actions or provide the agency with new authority to do them.

The legislation also would mandate that the FDA’s tobacco regulations, adopted in 1996 but nullified by the Supreme Court in 2000, take effect within one year of enactment. The FDA rule, as codified by the legislation, would:

- Ban all outdoor tobacco advertising within 1,000 feet of schools and playgrounds
- 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 free samples and the sale of cigarettes in packages that contain fewer than 20 cigarettes
- Limit any outdoor and all point-of-sale tobacco advertising, except in adult-only facilities, to black-and-white text only



- Limit advertising in publications with significant teen readership to black text on white background only
- Limit all audio-visual advertising (e.g., at point of purchase or on the Internet), except in adult-only facilities, to black text on white background visuals and spoken words (no music, images or moving images)
- Restrict vending machines and self-service displays to adult-only facilities
- Establish 18 as a federal nationwide minimum age for legal tobacco product sales with strong federal penalties, including the loss of the right to sell tobacco products for chronic, repeat offenders (with no preemption of existing state laws or penalties, and preserving state authority to impose higher minimum age laws)
- Require retailers to verify age for all over-the-counter sales by checking a photographic ID, and provide for federal enforcement and penalties against retailers who sell to minors

The FDA tobacco legislation also includes a number of other provisions that would immediately establish new law, including the following:

- Limits the current federal preemption against state regulation of cigarette advertising under the Federal Cigarette Labeling and Advertising Act, by allowing states to restrict the location, color, size, number and placement of cigarette advertisements
- Grants the FDA exclusive authority in such areas as tobacco product standards, pre-market approval, adulteration, misbranding, labeling, registration, manufacturing standards and modified-risk products, thereby preempting existing state authority in these areas—but states would continue to have authority to regulate the ignition propensity of tobacco products through so-called fire-safe cigarette laws
- Requires the tobacco companies to submit, within six months of the legislation's enactment, a listing of all tobacco ingredients and additives to tobacco, paper and filters by brand and by quantity in each brand, a description of the content, delivery and form of nicotine in each product, and all documents developed after enactment that relate to the health, toxicological, behavioral or physiological effects of current or future tobacco products
- Revises and strengthens the content of health warnings on both cigarette and smokeless tobacco products. The House version requires the health warnings to cover at least 30 percent of the front and back of most cigarette and all smokeless tobacco product packages; the Senate version requires the warnings to cover at least 50 percent of the front and back of all packages
- The House version (which has not yet been modified) authorizes the FDA to block tobacco companies from making any statements explicitly or implicitly claiming that the FDA has approved or certified any tobacco product. The Senate version has been revised so that it explicitly forbids tobacco product manufacturers and others from claiming that tobacco products have been approved or certified by the FDA in their advertising or other public communications

The new FDA regulation of tobacco products and their marketing would be funded through a new user fee imposed on all tobacco product manufacturers active in the United States, allocated by market share. The fee would grow to \$450 million per year (Senate legislation) or \$300 million per year (House legislation), and then be adjusted annually for inflation. This funding measure is meant to ensure that no existing FDA resources would need to be reduced or diverted to support the FDA's new tobacco control activities.

