



CRITICAL ELEMENTS OF LEGISLATION TO GRANT FDA AUTHORITY TO REGULATE TOBACCO PRODUCTS

Tobacco is the leading preventable cause of death in the United States, killing more than 400,000 Americans every year and costing our nation nearly \$100 billion in health care costs every year. Every day, another 1,200 Americans die of tobacco use and 1,000 children become new regular smokers. Despite tobacco's huge societal costs, tobacco products are among 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.

The need for legislation to grant the U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products is a result of the March 2000 Supreme Court decision that held that, under current law, the FDA does not have authority to regulate tobacco products. As a result, it is now up to Congress to grant the FDA the authority it needs to regulate tobacco products to protect the public health.

The legislation pending before Congress would grant the FDA broad authority to regulate the manufacturing, marketing, and sale of tobacco products. The critical elements of this legislation are summarized below.

Authority to Restrict Youth Access and Marketing. 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 legislation requires that six months after enactment, FDA reinstate the 1996 regulations which restricts marketing that influences children and youth access to tobacco products. These regulations include bans on outdoor advertising within one thousand feet of schools and limiting all remaining outdoor and point-of-sale tobacco advertising to black-and-white text only. The regulations would become effective no later than one year after enactment.

After the regulations go into effect, the legislation gives the Secretary of the Department of Health and Human Services (HHS) the authority to amend these regulations through a standard rulemaking process, which will provide for public discussion about the necessity of any changes to the regulations.

Health Information Disclosure. The legislation requires 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, as well as all documents developed after enactment that relate to health, toxicological, behavioral, or physiological effects of current or future tobacco products. Small manufacturers are given more time to comply with this provision.

FDA legislation also allows the Secretary of HHS to require the tobacco companies to submit information on all research related to reduced risk products and marketing research, as well as information about whether technology exists to reduce the harm caused by their products.

“Public Health” Standard. The legislation creates a new “public health” standard for evaluating tobacco products, their marketing and related claims. The “public health” standard is different from FDA’s traditional standard of determining whether a particular drug or medical device is “safe and effective.” A different standard is necessary for tobacco products because there is no such thing as a safe tobacco product. Under the proposed legislation, the Secretary may adopt standards or issue regulations that are “appropriate for the protection of public health.” The “public health” standard requires consideration of whether a product change would reduce the overall harm caused by tobacco use, including the harm caused to individual tobacco users and the impact on the population as a whole.

Health Warnings. The legislation requires larger, more effective health warnings on tobacco products and advertising and grants FDA the authority to adjust the format, type size and text of any health warning. Under the bill that passed the House in 2008, health warnings must cover the top 30 percent of the front and rear panels of the package and FDA could increase the required label to cover 50 percent of the front and rear panels of the package or require graphic warning labels. The 2007 Senate Committee on Health, Education, Labor and Pensions-passed bill would require warning labels to cover the top 50 percent of the front and rear panels of the package and require FDA to issue regulations two years after enactment to create graphic warning labels.

Authority to Establish Product Standards. The legislation provides FDA with the authority to require changes to tobacco products to protect the public health. Such changes could include the reduction or elimination of ingredients, additives, constituents, including smoke constituents or reduction in nicotine yields. Product standards are the primary way in which FDA could require meaningful changes to tobacco products to be made less harmful.

Modified Risk Products. FDA legislation prohibits any person or company from labeling, advertising or taking any other action directed to consumers that states or implies that the product is less hazardous than other tobacco products or that there is reduced exposure to a substance without two criteria being met. First, a person or company must have sought FDA review according to the standards set forth in the legislation and second, FDA must have issued an order that the product may be introduced into interstate commerce. The legislation also prohibits the use of descriptors, such as “light,” “mild” and “low” which have misled consumers about the health consequences of these products.

FDA authority over “reduced risk” claims is increasingly important as tobacco companies continue to develop new products that make implicit or explicit claims of reduced harm, such as “All of the taste...Less of the toxins” and “Reduced Carcinogens. Premium Taste.” Under the proposed FDA legislation, FDA would be able to prohibit these claims unless the manufacturer demonstrates to the FDA that the product will actually reduce harm.

The legislation requires that the Secretary only issue an order to allow a reduced risk product into interstate commerce 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.

The legislation would also set out criteria for products the manufacturer asserts contain a reduced level of a substance, or presents a reduced exposure to a substance. The Secretary may only approve an application for such a product if the Secretary has found that scientific evidence is not available and has concluded that the available evidence demonstrates that a substantial reduction in morbidity or mortality is anticipated. FDA legislation would restrict approval of such a product to no more than five years at a time, and require the manufacturer conduct post-market surveillance studies annually. FDA legislation would allow the Secretary to approve such products only if the Secretary also determines that the manufacturer has demonstrated that the product would be appropriate to promote the public health, is expected to benefit the public as a whole, and will not mislead customers into believing that the product is less harmful than other products.

State and Local Authority. FDA legislation does not preempt state and local governments from enacting other tobacco control laws, including fire-safe cigarettes and smoke-free laws. States would be free to adopt measures related to the sale, distribution, and possession, exposure to, or access to tobacco products. State and local governments could also restrict the time, place and manner of cigarette marketing, consistent with the First Amendment.

The legislation would prohibit state and local governments from establishing requirements that are different from, or in addition to, requirements of FDA regarding tobacco product standards, pre-market approval, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk products.

Adequate Funding. FDA legislation includes adequate funding through a user fee on tobacco manufacturers.

FDA Authority over Tobacco Farms or Tobacco Growers. FDA legislation limits the scope of FDA's regulatory authority to tobacco manufacturers and does not give FDA authority over the growing of tobacco.

March 2009