



H.R. 1108 – Family Smoking Prevention and Tobacco Control Act

FLOOR SITUATION

H.R. 1108 is being considered on the floor under suspension of the rules and will require a two-thirds majority vote for passage. This legislation was introduced by Representative Henry Waxman (D-CA) on February 15, 2007. The bill was reported as amended by the Committee on Energy and Commerce on July 17, 2008, by a vote of 38 to 12.

H.R. 1108 is expected to be considered on the floor of the House on July 30, 2008.

BACKGROUND

The Food, Drug, and Cosmetics Act (FDCA) was passed by Congress in 1938 and established the Food and Drug Administration (FDA). The FDA has the authority to regulate food, drugs, devices, and cosmetics.

In the 1990's, the FDA claimed authority under the FDCA to regulate cigarettes and smokeless tobacco products as delivery devices for nicotine. The Supreme Court invalidated the tobacco regulation in March 2000 and concluded that Congress had intended to preclude FDA from regulating tobacco products. Because the FDCA prohibits the marketing of products that have not been found to be safe and effective, the Court found that the statute would have forced the FDA to ban cigarettes and smokeless tobacco if the agency had jurisdiction over them.

**Note: The Supreme Court's decision only addressed the jurisdictional issue of whether the FDA had the authority to regulate tobacco products, but did not address potential First Amendment violations in the regulation.*

On November 23, 1998, 46 states, the District of Columbia, and five U.S. territories signed the Master Settlement Agreement with four major cigarette companies. The four companies, Philip Morris Inc., R.J. Reynolds Tobacco Company, Brown & Williamson Tobacco Corp., and Lorillard Tobacco Company, agreed to make annual payments in perpetuity to the states as reimbursement for past tobacco related medical expenses.

The Master Settlement Agreement required the companies to pay nearly \$206 billion over the first 25 years. In testimony before the Senate Committee on Health, Education, Labor, and Pensions on February 27, 2007, the Government Accountability Office (GAO) testified that states used 30 percent of their Master Settlement Agreement payments on health care and less than 3.5 percent on tobacco control programs that focus on prevention, including youth education, enforcement, and smoking cessation services.

**Note: According to the Energy and Commerce Report's Dissenting Views, "many members of the Committee would have supported further steps to require states to use more of their Master Settlement Agreement funds to combat underage smoking and promote smoking cessation while also strengthening the Synar Amendment on the underage purchasing of cigarettes.*

SUMMARY

H.R. 1108 authorizes the Food and Drug Administration (FDA) to regulate tobacco products, including modified risk tobacco products.

Center for Tobacco Products: The bill establishes a Center for Tobacco Products within the FDA that will be responsible for the implementation of this legislation. Within this Center, it creates an office to assist small tobacco product manufacturers in complying with the requirements in this act.



Registration of Tobacco Manufacturers: The bill requires owners and operators engaged in the manufacturing, preparation, compounding, or processing of tobacco products to register annually with the FDA, including foreign establishments. It also requires the FDA to conduct biennial inspections of registered establishments.

Submission of Health Information: Tobacco manufacturers are required to provide the Secretary of HHS within six months of the date of enactment with a listing of all ingredients, substances, compounds, and additives that are added to the tobacco, paper, filter, or other part of a tobacco product by brand and by quantity in each brand and subbrand. The tobacco manufacturers are further required to provide a description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine.

Restrictions: The Secretary may restrict the sale and distribution of a tobacco product if the Secretary determines that the regulation would be appropriate for the protection of the public health. In determining whether a restriction protects the public health, the Secretary would weigh the risks and benefits to the population as a whole, taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products and the increased or decreased likelihood that those who do not use tobacco products will start using such products. The Secretary may by regulation 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. The bill explicitly states that the FDA cannot prohibit the sale of any tobacco product or establish a minimum age of sale for tobacco products above the age of 18.

Flavored Tobaccos: The bill requires that within three months of the date of enactment that cigarettes or any of its component parts are prohibited from containing an additive, artificial flavor, or natural flavor, or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee. Cigarettes may continue to contain tobacco and menthol.

Tobacco Product Standards: Under this legislation, the Secretary may adopt tobacco product standards if it is determined to be appropriate for the protection of public health. The standard must include provisions for nicotine levels, for the reduction or elimination of other harmful components of the product. The bill prohibits the Secretary from banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products, or reducing the nicotine levels of a tobacco product to zero.

Adverse Event Reporting: The bill requires tobacco manufacturers to report significant adverse tobacco product experiences to the FDA. In addition, it requires manufacturers to report on the corrective action taken or removal from the market of a tobacco product to reduce health risk posed by the product.

Modified Risk Tobacco Products: A modified risk tobacco product is defined as any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products, this category does not include smoking cessation products. The bill places conditions on the marketing of modified risk tobacco products and requires the Secretary to consider the health benefits of these products when considering the application from a manufacturer to issue new products.

**Note: According to the Dissenting Views, "If enacted, this legislation significantly curtails, if not entirely eliminates, incentives to develop and market products that reduce exposure to tobacco toxicants. In order to obtain approval of a modified-risk product, an applicant must demonstrate that the marketing and labeling of the product is or has been demonstrated to be less harmful."*



Further, it has to be demonstrated that the product reduces risk for both the individual and for the population as a whole. It is unlikely that such a standard could ever be proven."

Judicial Review: The bill allows for persons adversely affected by a regulation that establishes, amends, or revokes a tobacco product standard, or is denied an application for approval of a new tobacco product, the ability to file a petition for judicial review.

Equal Treatment of Retail Outlets: The bill requires the Secretary to issue regulations that will make retail establishments that primarily sell tobacco products comply with advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

State and Local Authority: Nothing in this bill limits the authority of a Federal agency, a State or political subdivision of a state, or the government of an Indian tribe to enact, adopt, promulgate, or enforce any tobacco regulations that is in addition to, or more stringent than requirements in this bill. State law is preempted with respect to tobacco requirements relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, manufacturing standards, or modified risk tobacco products.

Tobacco Products Scientific Advisory Committee: The bill requires the Secretary to establish the Tobacco Products Scientific Advisory Committee within one year of the date of enactment of this legislation. The twelve member committee will be made up of seven individuals who are physicians, dentists, scientists, or health care professionals, one person who is an officer or employee of a State or local government or the Federal government, a representative of the general public, a representative of the tobacco manufacturing industry, a representative of the small business tobacco manufacturing industry, and a representative of the interest of the tobacco growers. The Advisory Committee will provide advice and recommendations to the Secretary about the effects of the alteration of nicotine levels in tobacco products, the existence of a nicotine threshold level that does not induce dependence, and its review of other safety, dependence, or health issues relating to tobacco products.

Smoking Cessation Products: H.R. 1108 allows the Secretary to fast track research and approval processes for smoking cessation products and to consider approving the extended use of nicotine replacement products for the treatment of tobacco dependence. In addition, the Secretary is required to report to Congress within three years on how to best regulate, promote, and encourage the development of innovative smoking cessation products.

User Fee: The bill imposes a quarterly user fee upon each manufacturer and importer of tobacco products. The user fees would be used to pay for the costs incurred by the FDA regulating tobacco products. Each manufacturer or importer of tobacco products can determine the amount of their fee each quarter by multiplying their percentage share (based on the kind of tobacco product) by the portion of the user fee amount for the current quarter that will be assessed on all manufacturers and importers.

**Note: According to the Dissenting Views of the Committee Report, "We are also opposed to the annual tax assessments placed on the manufacturers during the markup. Manufacturers will be assessed \$754.72 million by 2018, yet FDA will only be allowed to spend \$712 million directly on tobacco regulation. Claiming that a tax is a user fee does not change the fact that it is a tax. The remaining \$42.72 million is required to eliminate the "pay-go" problem that will result from lower tax collections in other areas once this bill is enacted."*

Final Rule: The Secretary is required by H.R. 1108 to publish a final rule regarding cigarettes and smokeless tobacco that includes regulations regarding the distribution of samples of cigarettes and smokeless tobacco to adults in adult-only facilities. Samples of tobacco products are prohibited from being distributed at sporting or entertainment events. The final rule must be identical, with a few



exceptions, to the final rule issued in 1996 which was before the Master Settlement Agreement. The dissenting views of the Committee note that the final rule may not withstand judicial scrutiny. Additionally, under the legislation the final rule will not be subject to the Congressional Review Act.

Cigarette Label and Advertising Warnings: The bill requires warning labels to be placed on the upper portion of the front and back panels of a cigarette package and make up 30 percent of the front and rear panels of the packaging. In addition, a warning must be placed in advertisements for tobacco products and the size of the warning is dependent on the size of the advertisement. The bill requires similar warnings to be placed on smokeless tobacco packaging.

Cross-Border Trade in Tobacco Products: The Comptroller General is required to conduct a study of cross-border trade in tobacco product, including illicit trade and trade of counterfeit products. In addition, the Comptroller General is to collect data on cross-border advertising of tobacco products and make recommendations to eliminate cross-border advertising. A report must be provided to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce within 18 months of the enactment of the act.

COST

According to the Congressional Budget Office, "CBO estimates that: enacting H.R. 1108 would reduce direct spending, on net, by \$0.3 billion over the 2009-2013 period and by \$0.5 billion over the 2009-2018 period; Federal revenues would decline by \$0.1 billion over the 2009-2013 period and by \$0.4 billion over the 2009-2018 period; considering both the revenue and direct spending effects, enacting the bill would reduce budget deficits (or increase surpluses) by a total of \$0.2 billion over the 2009-2013 period and \$31 million over the 2009-2018 period; in addition, CBO estimates that implementing the bill would increase spending subject to appropriation by about \$3 million over the 2009-2013 period, assuming the availability of the necessary funds." ([CBO Cost Estimate](#))

ADDITIONAL VIEWS

Energy and Commerce Dissenting Views from the Committee Report: "Forcing the FDA to regulate tobacco products – products that will never qualify as "safe and effective" – could have significant negative impacts on all Americans. This Congress, and specifically this Committee, has spent a great deal of time investigating the ways in which the FDA has been unable to fulfill its core mission. Therefore, we are concerned that burdening the FDA with added responsibilities outside of the agency's expertise and core missions at this time will have dire consequences for the American people and the FDA's ability to ensure the safety and efficacy of our nation's food, drugs, and medical devices."

STAFF CONTACT

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