



## CRITICAL ELEMENTS OF THE KENNEDY-CORNYN/WAXMAN-DAVIS (S. 625/H.R. 1108) LEGISLATION TO GRANT FDA AUTHORITY TO REGULATE TOBACCO PRODUCTS

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

Below is a short summary of how the Kennedy-Cornyn and Waxman-Davis bills (S. 625/H.R. 1108) deal with the issues that have been considered critical in any FDA bill.

**Youth Access and Marketing.** S. 625/H.R. 1108 grant FDA the same broad authority regarding the sale and distribution of tobacco products, including access, advertising and promotion, that FDA asserted in 1996. This would allow FDA to restrict advertising and promotion, including advertising that impacts children or misleads consumers, beyond the restrictions of the 1996 FDA regulations, to the extent permitted under the First Amendment. The FDA could also take further action to ensure that tobacco products are not illegally sold to children.

**Reinstate Youth Access and Marketing Restrictions of the 1996 Rule to Help Reduce Youth Tobacco Use.** S. 625/H.R. 1108 require that one month after enactment, FDA republish the 1996 regulations, which restrict marketing that targets 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, which will be identical to the regulations promulgated by the FDA in 1996, would become effective no later than one year after enactment.

After the regulations have gone into effect, the bills give 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.** S. 625/H.R. 1108 require 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, as well as all documents developed after enactment that relate to health, toxicological, behavioral, or physiological effects of current or future tobacco products.

The Secretary of HHS may also require the tobacco companies to submit information on all research related to health, behavioral or physiologic effects of these products and their marketing, as well as information about whether technology exists to reduce the harm caused by their products.

**“Public Health” Standard.** The existing FDA standard for approving drugs and devices is whether there is a “reasonable assurance that a product is safe and effective.” A different standard is necessary for tobacco products because there is no such thing as a safe tobacco product. Under S. 625/H.R. 1108, the FDA would determine whether an action regarding a tobacco product will “protect the public health.” This standard would require 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.** S. 625/H.R. 1108 revise the health warnings on both cigarettes and smokeless tobacco products and grant FDA the authority to further revise and add health warnings and to alter their format, including, but not limited to, changing their size, location and color. S. 625/H.R. 1108 require health warnings to cover at least 30% of the front and back of cigarette packs and strengthen the warning’s content.

**Authority to Establish Performance Standards.** S. 625/H.R. 1108 provide FDA with the authority to require changes to tobacco products to protect the public health by issuing performance standards. Such changes would include the reduction or elimination of ingredients, additives, constituents, including smoke constituents or reduction in nicotine yields. Performance standards would be the primary way in which FDA would require tobacco products to be made less harmful.

These bills allow FDA to require meaningful changes to tobacco products and to require the reduction of nicotine.

**Modified Risk Products.** FDA authority over new products that the tobacco industry wants to portray as less harmful is increasingly important as new products are marketed with such slogans as, “All of the taste...Less of the toxins” and “Reduced Carcinogens. Premium Taste.” Under S. 625/H.R. 1108, FDA would be able to prohibit these claims unless the manufacturer demonstrates to the FDA that the product will actually reduce harm.

The bills prohibit any person 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 reduces exposure to substances in tobacco products without first having sought and obtained FDA approval according to the standards set forth in the legislation. The bills also prohibit the use of descriptors, such as “light”, “mild” and “low” to characterize the level of a substance in a product.

Under S. 625/H.R. 1108, the Secretary shall only approve an application for a modified tobacco product 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 bills 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. The bills 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. The bills 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.** S. 625/H.R. 1108 expand state authority over tobacco marketing. Today, states have no right to regulate cigarette marketing. At a minimum, state and local governments would be free to adopt measures related to the sale, distribution, possession, exposure to, access to, use of tobacco products, or fire safety standards for tobacco products.

FDA would maintain exclusive authority in such areas as tobacco product standards, pre-market approval, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk products. States could not establish requirements in these areas.

**Adequate Funding.** S. 625/H.R. 1108 include adequate funding through a user fee on tobacco manufacturers.

**FDA Authority over Tobacco Farms or Tobacco Growers.** S. 625/H.R. 1108 do not give FDA authority over the growing of tobacco.