



WHY THE FDA SHOULD 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 specific authority to regulate tobacco products so that tobacco products are treated like other products we consume.

The need for action is clear:

- Since 1998, when Congress attempted to pass legislation granting authority to the FDA to regulate tobacco products,¹ nearly six million children have become daily smokers, nearly two million of whom will die prematurely of tobacco-related illnesses.²
- The Centers for Disease Control and Prevention estimates that tobacco causes over \$96 billion in annual health care expenditures. This includes over \$30 billion in total annual Medicaid costs (state and federal), or 14 percent of all Medicaid costs. The federal share of Medicaid costs exceeds \$17 billion annually.³ Another study estimates the smoking-caused Medicare expenditures exceed \$20 billion annually.⁴

The authority that such legislation would grant the FDA would not lead to a ban on tobacco products or even constitute special regulation of tobacco – it would simply be comparable to the FDA's existing authority over other consumer products.

Effective regulation would provide more information to consumers, protect kids and the public health, and assure that decisions are based on sound science.

Below is a short summary of how the Kennedy-Cornyn (S. 625) and Waxman-Davis (H.R. 1108) bills 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 it asserted in 1996 regarding the sale and distribution of tobacco products, including access, advertising and promotion. 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. The republished regulations would

become effective one year after enactment. These regulations include a ban on outdoor advertising within one thousand feet of schools and limit all remaining outdoor and point-of-sale tobacco advertising to black-and-white text only.

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.

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 regarding 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 determines 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 warning 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. The bills would immediately strengthen the content of health warnings; H.R. 1108 requires health warnings to cover at least 30% of the front and back of cigarette packs while S. 625, as amended in Committee, would require health warnings to cover 50% of the front and rear panels of the package and require the FDA to issue regulations two years after enactment to create graphic warning labels.

Authority to Establish Performance Standards. S. 625/H.R. 1108 provide FDA the authority to require changes to tobacco products to protect the public health through the issuance of 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.

While the bills allow FDA to require changes to the product, the bill reserves to Congress the narrow and specifically tailored authority to ban “all cigarettes”, or “all smokeless tobacco products”, or “all little cigars”, or “all cigars other than little cigars”. While FDA can require the reduction of nicotine, even to very low levels, the bill also reserves to Congress the right to require the reduction of nicotine yields of a tobacco product to

zero. These reservations of authority to Congress will not prevent the FDA from requiring meaningful changes to tobacco products.

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 can demonstrate to the FDA that the product will actually reduce harm.

S. 625/H.R. 1108 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 bills. The bills would also prohibit the use of descriptors, such as “light”, “mild” and “low” to characterize the level of a substance in a product.

Under the bills, 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.

S. 625/H.R. 1108 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 evidence that is available demonstrates that a substantial reduction in morbidity or mortality is anticipated. These bills restrict approval of such a product to no more than five years at a time and would require the manufacturer to conduct post-market surveillance studies annually. These 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. Under the bills, states and localities can impose bans or restrictions on the time, place and manner, but not content of the advertising or promotion of any cigarettes. State and local governments also are free to regulate the sale, distribution, and possession of tobacco products, pass smoke-free workplace laws, restrict youth access to tobacco products and pass measures relating to 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 provide adequate funding for FDA to effectively carry out the requirements outlined 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.

¹ On June 17, 1998 the Senate defeated the Universal Tobacco Settlement Act (S. 1415), sponsored by Senator John McCain of Arizona.

² Substance Abuse and Mental Health Services Administration, U.S. Dept of Health and Human Services (HHS), *National Survey on Drug Use and Health* (formerly the *National Household Survey on Drug Abuse*), 1998-2005. <http://www.oas.samhsa.gov/nsduh.htm> [estimates assume that youth initiation remained the same in 2006 as it was in 2005, the last year with actual data]. Youth deaths: Approximately one-third of regular youth smokers will ultimately dying prematurely from smoking. U.S. Centers for Disease Control (CDC), *State Highlights 2002: Impact and Opportunity, April 2002*, [updating CDC, "Projected Smoking Deaths Among Youth – United States," *Morbidity and Mortality Weekly Report (MMWR)* 45(44): 971-9740, November 8, 1996, <http://www2.cdc.gov/mmwr/>], www.cdc.gov/tobacco/StateHighlights.htm.

³ CDC, *Sustaining State Programs for Tobacco Control: Data Highlights 2006* [and underlying CDC data and estimates], <http://www.cdc.gov/tobacco/datahighlights/index.htm>.; Centers for Disease Control and Prevention, "Annual Smoking-Attributable Mortality, Years of Potential Life Lose, and Economic Costs -- United States 1995-1999," *MMWR*, April 11, 2002, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5114a2.htm>; L. Miller et al, "State Estimates of Total Medical Expenditures Attributable to Cigarette Smoking, 1993" *Public Health Reports* 113.

⁴ Zhang, X., et al., "Cost of Smoking to the Medicare Program, 1993," *Health Care Financing Review* 20(4): 1-19 (Summer 1999).