

Fact Sheet 2

Tobacco Product Standards

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

S. 625/H.R. 1108

Introduction

The U.S. Food and Drug Administration legislation would give the FDA authority to establish and periodically re-evaluate and revise tobacco product standards for both existing and new tobacco products, and to order changes in cigarettes and other existing tobacco products to meet those new product standards. Such tobacco product standards are to be based on available medical, scientific and other technological evidence as appropriate for the protection of the public health. “Appropriate for the protection of the public health” is to be determined with respect to the risks and benefits to the population as a whole, including users and non-users of tobacco products, taking into account the increased or decreased likelihood that existing users of tobacco products will stop and that nonusers will start because of the new product standards.

The legislation does not allow the FDA to use its new product standard authority to reduce nicotine yields of a tobacco product to zero. The legislation does give the FDA authority to determine whether nicotine can be reduced to levels that do not cause or sustain addiction, and to reduce nicotine yields to those levels, if it chooses to do so. The legislation’s product standard section also directly prohibits any cigarettes with a characterizing flavor other than tobacco or menthol.

The legislation does not allow the FDA to use its new product standard authority unilaterally to order a complete ban of tobacco products or of any specific type of existing tobacco product (i.e., the FDA could not ban all cigarettes, all small cigars, all big cigars, all smokeless tobacco products, all pipe tobacco or all roll-your-own tobacco). The legislation does authorize the FDA to ban any brand new type of tobacco product from being sold in the United States. The agency also could use its product standard authority to eliminate such tobacco products as all cigarettes containing menthol, all cigars or smokeless tobacco containing flavors that are attractive to youth or all tobacco products containing certain additives or constituents. The legislation does not interfere with the right of Congress to ban any tobacco products or with states’ right to ban any tobacco products within their borders.

If the FDA were to determine that an additive or a constituent—in either the tobacco product or the smoke emitted by the product—was harmful and should be removed, the burden would be on a party challenging the proposed standard to prove that the proposed change would not reduce or eliminate the risk of illness or injury.

New Tobacco Products

The legislation would place requirements and restrictions on new tobacco products that might be offered for sale in the United States. Before introducing any new tobacco product into the market, the legislation requires that the manufacturer disclose to the FDA information regarding the ingredients, constituents and nicotine level, as well as any documents relating to the health effects of the product or its





ingredients and constituents (i.e., the same information all existing tobacco products must provide pursuant to the legislation). In addition, for any new tobacco product that is similar to existing tobacco products, the legislation requires that the manufacturer show the FDA that the product is substantially equivalent to a tobacco product already on the market and meets all related product standards for that type of product.

Before introducing any brand new tobacco product that is not similar to existing tobacco products, the legislation requires additional premarket review by the FDA based on the manufacturer's submission of, among other things, samples of the product and its proposed labeling; information on the tobacco product's ingredients, properties and principles of operation; available information on the health risks of the product; and information on how the product complies with existing tobacco product standards. Based on the goal of protecting overall public health, the FDA may permit the product to be sold, forbid its sale, or allow its sale subject to restrictions on its sale, distribution, and marketing.

Reduced Risk Tobacco Products

Any tobacco products for which manufacturers make explicit health claims are subject to FDA authority under existing law, but the FDA has not applied this authority to reduced-risk claims. The legislation would not change the FDA's authority in relation to tobacco products that are intended to be used for the treatment of tobacco dependence or for smoking cessation, or in relation to tobacco products claiming other health benefits separate from tobacco use risk reduction. But all tobacco products that manufacturers advertise or market, explicitly or implicitly, as offering a reduced risk of harm or disease compared to other tobacco products would fall under the new provisions of the legislation relating to "modified risk tobacco products."

The legislation defines modified risk tobacco products as tobacco products sold or distributed to reduce harm or the risk of disease compared to other tobacco products, including, among other things, any product whose labeling or advertising explicitly or implicitly presents it as being less harmful than other commercially available tobacco products or having lower levels (or being free) of a specific substance.

Manufacturers would be required to obtain premarket approval before marketing or selling modified risk tobacco products by providing the FDA with the information required of proposed brand new tobacco products, plus more extensive information on the product's effect on tobacco-related diseases and health and its ability to reduce risk. The legislation would authorize the FDA to approve a proposed modified risk tobacco product based on the submission of thoroughly substantiated information regarding the benefit of the product to overall public health.

For approved products, the legislation would require the FDA to ensure that the advertising and labeling of such products would enable the public to understand the modified risk characteristics of the product and its relative significance in relation to total health and all of the health harms associated with tobacco use. The FDA also could impose restrictions and requirements on the product's labeling and advertising and marketing to educate consumers or to protect public health.

Approval as a modified risk tobacco product would last for five years. The legislation would require manufacturers to conduct and annually report to the FDA post-market



surveillance of such reduced risk product's actual usage. If that surveillance, or any other evidence, showed that the availability of the product was not promoting overall public health gains, the FDA could rescind or not renew the approval.

Related Provisions

The legislation requires tobacco product manufacturers to disclose to the agency detailed information regarding ingredients, additives, nicotine, and harmful product and smoke constituents. This would provide the FDA with information that it would be authorized to use to order changes to tobacco products for purposes of reducing the harm they cause and to educate the public about the chemicals in tobacco products and health effects of tobacco use.

The legislation would establish a Tobacco Products Scientific Advisory Committee to help guide the FDA on the effects of alterations in the nicotine yields of tobacco products and on whether there exists a threshold level below which nicotine does not cause addiction in the case of a given tobacco product. The committee also would provide its review of "other safety, dependence, or health issues relating to tobacco products" when requested by the FDA. The committee would consist of 11 members. Voting members would include seven scientists or health professionals, one government official and one representative of the general public. Non-voting members would include one representative of the tobacco industry and one representative of tobacco growers. The Senate version of the legislation would establish additional protections against conflicts of interest —disallowing certain tobacco industry ties among voting members—and would prohibit non-voting members from chairing the Advisory Committee.

Adulterated and Misbranded Tobacco Products

Adulterated and misbranded products are prohibited by the Food, Drug, and Cosmetic Act (FDCA). Most of the provisions in the FDA legislation are part of a new tobacco product section that would be added to the FDCA, including definitions of what constitutes prohibited adulterated and misbranded tobacco products. Under the legislation, a tobacco product would be regarded as adulterated if, among other things, it were contaminated by any added poisonous or deleterious substance, its manufacturing facilities were not sanitary or failed to satisfy applicable product standards or it did not have required premarket approval. The legislation further defines prohibited misbranded tobacco products to include, among other things, any tobacco product with packaging that fails to meet the specified packaging and labeling requirements or was not manufactured in a facility duly registered under the Act. Ordinary cigarettes and other tobacco products would not be considered adulterated or misbranded.

