EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

July 30, 2008
(House)

STATEMENT OF ADMINISTRATION POLICY

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

(Rep. Waxman (D) CA and 233 cosponsors)

The Administration supports efforts to encourage adults who smoke to choose to quit and to prevent children from ever using tobacco products. Tobacco use remains one of the leading causes of death in the U.S. and is a factor in numerous serious health conditions and diseases. In FY 2008, the Federal government will spend nearly $700 million to reduce smoking, improve tobacco cessation treatments, and support prevention programs.

However, the Administration has serious concerns with H.R. 1108. In seeking to limit the harm imposed by tobacco on the American public, the bill will unfortunately undermine one of the Nation's premier public health and regulatory institutions and potentially lead the public to mistakenly conclude some tobacco products are safe. The bill would mandate significant added responsibilities for the Food and Drug Administration (FDA) that conflict with FDA's mission of ensuring the safety and effectiveness of drugs, biologics, and medical devices. Significantly, it also would create a new tax that would be paid disproportionately by low-income individuals. Therefore, if H.R. 1108 were presented to the President, his senior advisors would recommend that he veto the bill.

FDA regulates drugs and devices by approving products after weighing the benefits against the risks of a product. In contrast, there is no such thing as a cigarette in which the benefits outweigh the risks. The use of tobacco products is inherently unsafe. Requiring FDA to oversee the regulation of tobacco products would not only distract the agency from its oversight of food, pharmaceuticals, and medical products but could be perceived by the public as an endorsement that these products are safe, resulting in more people smoking. A regulatory determination regarding an acceptable level of nicotine or other "reduced risk" product by FDA could have the perverse and unintended consequence of lowering the perceived risk of tobacco use among the public and result in an increase in tobacco use rather than a reduction.

To implement H.R. 1108, FDA would be required to develop and establish an entirely new center for tobacco control. Establishing the center would require a huge staffing effort and infrastructure development to support requirements of the legislation. FDA does not have the expertise needed to regulate tobacco products and the legislation would require FDA to investigate cigarette smuggling and perform other functions clearly beyond the scope of the Agency's mission and expertise. This would put an enormous burden on the FDA, diverting from its core mission priorities, including an array of new and enhanced initiatives to strengthen food safety and oversight of FDA regulated imports.

The bill pays for FDA's expanded regulatory responsibilities by making the regulated tobacco industry essentially responsible for all of the funding of the regulating center. Moreover, this

regressive tax will be borne disproportionately by lower-income individuals. The Administration strongly opposes tax increases to expand the size and scope of government.

In addition, the bill may spend more than it raises in revenues. This could result in diverting personnel and resources from current programs within the FDA, with the potential to seriously undermine the public health.

H.R. 1108 provides HHS with new authorities for prevention of illicit trade in tobacco products that are duplicative of authorities and responsibilities currently administered effectively by the Departments of the Treasury and Justice. The existing authority already addresses which tobacco products can lawfully appear in the domestic market, and the record-keeping requirements and inspection rights pertaining to those involved in tobacco-related transactions. H.R. 1108 includes definitions of tobacco products that are internally inconsistent and conflict with current Internal Revenue Code provisions.

Additionally, our trading partners may argue that by banning the sale of clove cigarettes but not prohibiting the sale of menthol cigarettes, the bill raises questions under U.S. international trade obligations.

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