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TOBACCO BILL Q & A

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The House may soon be faced with a vote on a measure (H.R. 1108) to include tobacco products under the regulatory authority of the Food and Drug Administration (FDA). The RSC has prepared the following analysis providing background information on the legislation, as passed by the House Energy and Commerce Committee on April 2, 2008.

What is the purpose of the provisions of H.R. 1108 regulating tobacco products?

Both the stated purpose and expansive scope of the proposed FDA regulation of tobacco under H.R. 1108 can be observed in Title I of the bill: "The Secretary [of Health and Human Services] may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health." Under the bill, the definition of the public health is extended to both users and non-users of tobacco products.

Some conservatives may note that this language is a significant modification from the original justification for tobacco regulation—namely, the need to protect children from gaining access to tobacco products. In fact, while children are mentioned several times in the findings section of H.R. 1108, the word "children" appears only four times in the remaining 176 pages of the bill. Some conservatives may be concerned that this new focus on a more expansive goal of protecting the public health may divert energy away from efforts to combat underage consumption of tobacco products.

Does H.R. 1108 contain a tax increase?

Many conservatives may be concerned that it does. The bill includes assessments on tobacco companies, ostensibly termed "user fees," to finance the FDA's work regulating tobacco products. However, the Congressional Budget Office estimates that tobacco regulation will reduce the number of smokers—thus decreasing the amount of revenue derived to the federal government from tobacco taxes.

While the version of H.R. 1108 reported from full Committee attempted to address this matter by including a finding that the bill's scope was not intended to intrude upon any authority under the Internal Revenue Code, the House Ways and Means Committee has requested a referral on the grounds that the fee ultimately constitutes a tax. As Ways and Means Chairman Rangel wrote to Speaker Pelosi on April 3, 2008:

> The amount of money raised by the assessment of the user fee is more than the amount of money being made available to the Secretary of Health and Human Services (HHS) for the regulation of tobacco….Since the bill forbids the funds from being spent on anything other than tobacco regulation, [the funds] would in fact revert back to the general fund of the U.S. Treasury. The Committee on Energy and Commerce would then be financing the costs of government generally, which is clearly the jurisdiction of the Committee on Ways and Means.

Therefore, many conservatives may be concerned that, following Chairman Rangel's own logic, the "user fee" in H.R. 1108 in fact constitutes a tax increase on tobacco companies.

Under what standard would tobacco be regulated under H.R. 1108?

The bill would re-institute standards first proposed in 1996 to regulate tobacco as a medical device. However, it remains unclear how these standards can be reconciled with the inherent nature of tobacco products. For instance, Title I of H.R. 1108 deems a tobacco product as "adulterated" if "it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health." Based on this description, it is unclear how any tobacco product would fail to qualify as "adulterated," raising questions as to how the standards can be appropriately applied.

Will H.R. 1108 impede the introduction of reduced-risk tobacco products?

H.R. 1108 places stringent restrictions on the introduction and marketing of new products that would reduce or modify the inherent risks associated with the consumption of tobacco. The bill states that a reduced risk product may be marketed only if the product will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users" and also will "benefit the population as a whole," including persons who do not consume tobacco products. Other reduced risk products may be approved for distribution, but will be subjected to further marketing restrictions, post-market surveillance, and potential revocation of the distribution license after a five-year period. Some conservatives may be concerned that such onerous restrictions on the introduction of new reduced risk tobacco products could have the effect of inhibiting the introduction of products that could reduce the risks associated with tobacco consumption while potentially serving as a barrier to entry for new market competitors.

How would tobacco advertising be regulated under H.R. 1108?

In addition to codifying federal restrictions, which tobacco companies agreed to in their 1998 settlement with state Attorneys General, H.R. 1108 places additional federal restrictions on tobacco advertising, while simultaneously eliminating federal pre-emption by allowing states to enact legislation "imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion" of tobacco products. Some of the federal restrictions on advertising content in H.R. 1108 include the following specifications for the size of warning labels on tobacco products:

> The text of such label statements shall be in a typeface *pro rata* to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement.

Some conservatives may be concerned that the highly prescriptive restrictions described above, and elsewhere in H.R. 1108, constitute an undue intrusion on companies' constitutional free speech rights to advertise a product that most Americans already know is unhealthy.

What implications might consumers draw from FDA's proposed role in regulating tobacco?

As FDA Commissioner Andrew von Eschenbach testified before the House Energy and Commerce Committee in October 2007, the FDA has heretofore been structured as an agency to promote and protect the public health. In the Commissioner's opinion, requiring FDA to "approve" tobacco products as a result of H.R. 1108 would dramatically change the agency's focus: "Associating any agency whose mission is to promote public health with the approval of inherently dangerous products would undermine its mission and likely have perverse incentive effects."

Is FDA competent to regulate tobacco products?

The statements of several Congressional Democrats—who have criticized the agency's handling of food and drug safety, particularly with regard to imported products—raise questions as to why they would support granting new and broad authority to FDA with regard to tobacco regulation. For instance, Energy and Commerce Oversight Subcommittee Chairman Bart Stupak (D-MI), in holding a hearing on FDA's decision to approve an antibiotic despite receiving false clinical trial data, called the incident "a microcosm of the failure by all FDA stakeholders—FDA, pharmaceutical sponsors, and third-party monitors—to ensure the integrity of clinical trials used to support the safety and approval of new drug applications." On top of questions which Democrats themselves have raised regarding FDA's competence, some conservatives may question whether the food safety concerns that have arisen in recent months make now an appropriate time significantly to expand the agency's regulatory remit and mission.

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