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Tobacco-Settlement: Wyden Commission

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wyden commission

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 31 1998

The Honorable Ron Wyden
U.S. Senate
Washington, DC 20510

Dear Senator Wyden:

Thank you for your hard work on the vital issue of protecting our children from the diseases and death caused by tobacco use. This has been a long fight for you, and that is why I must bring to your attention what I know must be the unintended consequences of the proposed Title II, Section 224 of the committee amendment to S. 1415. Rather than bringing additional responsibility to the tobacco industry, this provision will likely absolve the companies of any accountability to meet youth tobacco use reductions. Let me share with you our concerns.

This provision actually gives the industry a "trap door" to protect the companies from losing liability protections even if they fail to meet youth tobacco use reductions required in the "lookback" sections of the Act.

If companies follow or do not follow recommendations of this panel, that evidence will have to be considered in determining if the companies made reasonable efforts to meet the targets; such consideration may well be used by the companies as a defense for failure to meet these targets.

In addition, the panel will have the affirmative responsibility to determine if the industry is likely to fail to meet any of its targets, based on a vague standard of "clear and present danger," and once informed by the panel, the FDA Commissioner then will have the affirmative responsibility, using the heavy burden of "clear and convincing evidence," to take action with regard to the companies' liability caps.

This process shifts the responsibility and obligation to meet public health goals from the industry to the Department of Health and Human Services.

Furthermore, the role of the FDA Commissioner under this provision raises questions of whether this process will interfere with the Agency's traditional rule-making. This uncertainty may actually restrict FDA's flexibility to exercise its jurisdiction over tobacco products. For instance, will these recommendations require FDA to engage in rule-making, and if the Agency engages in rule-making based on these recommendations, is it then subject to APA challenges that the panel process has pre-determined the rule-making?

Finally, this provision creates a whole new bureaucracy in the Department and confuses the authorities being given to various HHS agencies in other provisions of this legislation. To make an annual, detailed report to Congress on companies' compliance both with all provisions of this legislation and with their own annual plans, as well as reporting if the companies will meet their targets and what additional steps companies should undertake to meet the targets, will require an extensive compliance apparatus. Much of this may already be the responsibility of FDA, SAMHSA, or even non-HHS agencies with which we cooperate closely. In addition, the provision would impose new responsibilities on the FDA, diverting attention and resources away from its regulatory responsibilities under the Act.

Knowing how important this issue is to you, I wanted to make you personally aware of how this provision will undermine the vital public health protections you have labored so long to achieve.

Sincerely,

Donna E. Shalala