

A H E A D

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FDA Tobacco Legislation and the Commission Report – *Tobacco at a Crossroads*

In May of 2001, the presidential commission report Tobacco at a Crossroad, signed by leaders of the public health community and tobacco producers, was released. The opening paragraph of the report noted that “Tobacco Farmers and their communities are in the midst of an unprecedented economic crisis. At the same time, public concern over the health hazards of using tobacco products is at an all time high. Resolving these two crises will require *new, visionary tobacco policy* in this country.” (Emphasis added). While tobacco producers did obtain the tobacco buyout, many of the issues, challenges, and opportunities outlined in the commission report remain the same. This document will focus on FDA and the understanding and agreements that were reached on that important area (although other areas such as the role of tobacco agriculture will also have to be addressed by Congress sometime in the near future). We believe that the current legislation in Congress should be measured against both the spirit and specifics of what are contained in the commission report and we have made our suggestions both in the form of testimony to the Senate HELP Committee and in a document recommending some very specific changes in the legislation for stakeholders to consider. *We believe our recommendations will enhance the legislation, bring fairness and predictability to growers, encourage the promotion of lower risk science-based products, while protecting the public health.* Copies of those documents can be obtained by contacting AHEAD at 202 686-8898 or by email at ScDBa@aol.com. What follows are various excerpts from the Commission report.

- In the long run effective regulation by the FDA benefits everyone including farmers. (page 42)
- Independent science based decisions by FDA designed to protect the public health by taking all *reasonable steps* to reduce the harm of tobacco now being sold and *promote the introduction of less harmful* products will also create *fair standards* and will provide *predictability to farmers* and to industry. Farmer may benefit directly. (pages 42-43 emphasis added).
- This proposal will provide an **opportunity** for America’s farmers as well as well as responsible manufacturers to distinguish themselves from foreign competitors in producing crops in an environment in which health concerns are important. (Page 42, emphasis added)

- The technology already exists to remove many of the components of manufactured tobacco products that are known to cause harm. FDA should have the authority to evaluate scientifically and then through notice and comment rulemaking, the standard process to decide whether to reduce or where **appropriate** eliminate the harmful and or addictive components of manufactured tobacco products in order to protect public health. **This process will give farmers, public health representatives, manufacturers, consumers and other stakeholders an opportunity to bring to the attention of the agency the impact of any specific proposal on their particular needs and concerns.** This authority should not be limited to ingredients added by the tobacco manufacturer where the technology exists to reduce or eliminate a harmful constituent of the product or its smoke. This authority should focus on health considerations and **not seek to reduce tobacco use by requiring the addition of an added ingredient simply because it negatively impacts on the product's taste.** (page 45, emphasis added).
- A benefit to farmers, responsible manufacturers and public health representatives of this authority residing in FDA is that the FDA's rules provide for input from any interested party and organization and require FDA to review and take into consideration the comments it receives. The creation of the Tobacco Grower Advisory Board will further ensure that **farmer concerns are aired and considered prior to the rule-making process. Thus FDA authority provides predictability and an opportunity for farmers, the public health community and others to be heard when FDA is considering the adoption of a rule setting a standard for manufactured tobacco products that farmers believe may impact them.** It specifically means that farmers will have an **opportunity to bring the impact of any proposed action on America's tobacco farmers to the attention of the agency prior to the adoption of such a rule and that obligation imposed by the agency to reduce harm will be imposed only after careful consideration of all relevant factors brought to the agency's attention, including those raised by farmers.** (pages 45-46, emphasis added)
- It is not the intention of this Commission or public health advocates in granting the FDA such authority to legally prohibit the use of tobacco products by adults. (page 42)
- The legislation should recognize that it is the **USDA and not the FDA that has authority over tobacco farms or tobacco growing.**(page 46, emphasis added)