A H E A D
Alliance for Health Economic and Agriculture Development*

"The monopoly on good ideas does not belong
to a single party. If it's a good idea, we will consider it"
President –elect Barak Obama
January 6, 2009

Essential Elements and Principles for Food and Drug Administration Oversight of Tobacco and Nicotine Products (and related issues) 111th Congress (2009)

Congress has been considering regulation of tobacco products by the Food and Drug Administration for almost 20 years, and while many of the elements and recommendations remain the same, much has also changed. Currently there is little disagreement that FDA is the most appropriate agency to over see tobacco products. As Congress once again looks at FDA/Tobacco legislation in the 111th Congress it needs to ensure that hearings are held that will allow for all interested parties to have their views heard and considered. We need an open, transparent and inclusive process for the consideration of this important legislation, not a closed one. The tobacco companies in particular need to be brought before Congress, something that has rarely happened since the infamous nicotine hearings involving the seven CEO's back in the mid-1990's. But Congress must also be willing to listen to and consider other *constructive* ideas and views-- some of which are noted below, so that effective, workable and fair legislation is enacted.

- The title of the legislation should be changed to better reflect the purposes of the Act. Suggested new title: "**The Tobacco and Nicotine Full Disclosure, Consumer Protection and Product Accountability Act".**

- **All** tobacco and nicotine products should be brought under the same regulatory umbrella in a newly established **Center *for Tobacco and Nicotine*** at the FDA.

FDA authorities over tobacco and nicotine products should include and cover misbranding (including claims); adulteration, labeling, good manufacturing practices, standard setting, regulation of ingredients and additives; advertising and marketing, sales and distribution etc.

- **All** tobacco and nicotine products should be regulated ***based on the risks and relative risks*** associated with the products. This should include both the categories under which these products fall (combustible, non-combustible, and therapeutic) as well as between products within each category. Products that are **scientifically** established to be lower in risk should be regulated less stringently. Products that are higher in risk should be regulated more stringently.

- To assist in dealing with and setting standards and regulations based on the risks and relative risks of the products, the Food and Drug Administration should establish three tobacco and nicotine classification panels – one dealing with combustible products; one dealing with noncombustible tobacco and nicotine products; and a third dealing with products that make therapeutic health claims. Each panel should be composed of experts from various fields needed to effectively consider a spectrum of issues.

- There should be established within the Center an ***Office for Evaluation of New Tobacco and Nicotine Products*** that would serve to review applications for the sale and marketing of reduced risk products- products for which there is a reasonable expectation that the product will, when used as intended and based on the totality of information provided by the applicant, reduce significant levels of risk (See IoM recommendations, Clearing the Smoke). The Office would have the authority and responsibility to bring stakeholders together including researchers and scientists, public health, industry (tobacco, pharmaceutical, biotech, etc), producers, consumers, other governmental agencies and other experts to discuss and evaluate these products including how they should be labeled and marketed, as well as what kind of surveillance protocols and requirements are necessary etc. Recommendations would then be referred to one or more of the three Classification panels for final review and approval. The FDA should have full authority to require corrective action over the labeling and marketing of such products (including immediate removal of the product) if the manufacture fails to adhere to agreed upon requirements and protocols or if the product is determined not to be meeting its intended expectations.

- An FDA Scientific and Regulatory Advisory Committee (expanded version of what was contained in the legislation in the 110th Congress) should be established that includes a broader spectrum of experts and interests qualified to advise and review actions and activities of the agency in carrying out its duties to oversee tobacco and nicotine product including product development, the manufacture, sale distribution and marketing of such products. In addition to those already listed in the legislation considered in the 110th Congress, such experts should

include: an expert in agronomy and tobacco plant technology; an expert in labeling, advertising and marketing; and an expert in harm reduction.

- As the FDA does in others areas that it oversees (such as foods, over the counter drugs, pharmaceuticals etc) the FDA should have the authority to hold public meetings and forums that include public health experts, scientists, industry, consumers, growers, etc. This is in addition to the functions of the Office for the Evaluation of New Tobacco and Nicotine Products.

- The Food and Drug Administration should establish better ties and work closely and collaboratively with other agencies including the CDC, the USDA, the NIH, the FTC, the EPA, ATF, and the Department of Homeland Security. This could be accomplished through the establishment of an upgraded **Tobacco and Nicotine Interagency Coordinating Committee** that would not only serve the interests of the FDA but other agencies as well.

- Costs associated with oversight and regulation should be paid for through **users fees** assessed on manufacturers. A small percentage of the user fee should be allocated to carrying out research in areas relative to issues necessary for assisting the Food and Drug Administration in making regulatory decisions and for conducting a public educational campaign to assist consumers in better understanding the risks and relative risks of the spectrum of tobacco and nicotine products.

- Manufacturers (tobacco, pharmaceutical, biotech etc.), and producers (via USDA) should be provided *incentives* for developing products that are scientifically intended to significantly lower the risks of tobacco products (See for example the recommendations of the IoM, Clearing the Smoke). Incentives coupled with regulation and competition can serve to promote the development of responsible science-based lower risk products.

- Update the 'Findings' referenced in the current FDA tobacco legislation (110th Congress) to not only reflect concerns of past abuses by the tobacco industry, but also that reflect the advancement in science and technologies in a variety of areas (both with respect to tobacco and nicotine) that could have a significant impact on reducing disease and death caused by the use of tobacco.

* The Alliance for Health Economic and Agriculture Development (AHEAD) is an informal organization whose purpose is to educate, stimulate, and facilitate discussions with and between public health advocates, growers, the scientific community, tobacco manufacturers, consumers, policy makers, pharmaceutical and biotech interests, and economists about a spectrum of issues related to the production processing, manufacture, sale, distribution, labeling, marketing and use of tobacco, tobacco (and nicotine) products. The Alliance is an outgrowth of the Southern Tobacco Communities Project established in the mid-1990's through a grant from the Robert Wood Johnson Foundation that brought the public health community and

growers together to engage in a civil dialogue about tobacco. That dialogue led to the issuance of a set of **Core Principles** in 1998 and the presidential commission report **Tobacco at a Crossroads** in 2001. The Steering committee members serve as individuals, each of whom has significant and unique experiences in dealing with tobacco related issues. (For more information go to : www.tobaccoatacrossroads.com or call 202 686-8898)