Statement of AHEAD
The Alliance for Health Economic and Agriculture Development

Concerning
The Need for FDA Regulation of Tobacco Products

Before the
Senate Committee On Health, Education, Labor and Pensions

February 27, 2007

About the Alliance:

The Alliance is an informal organization whose purpose it to educate, stimulate, and facilitate discussions with and between public health advocates, growers, the scientific community, tobacco manufacturers, consumers, pharmaceutical and biotech interests about a spectrum of issues related to the production, processing, manufacture, distribution, sale, labeling, marketing and use of tobacco and tobacco products. The Alliance is an outgrowth of the Southern Tobacco Communities Project established in the mid-1990's 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 Crossroad* in May, 2001. The Steering Committee members serve as individuals, each of whom has significant and unique experience in dealing with tobacco related issues.

The Alliance for Health Economic and Agriculture Development (AHEAD) appreciates this opportunity to submit these comments to the Senate Committee on Health, Education, Labor, and Pensions concerning "The Need for FDA Regulation of Tobacco Products".

There are several members of the HELP Committee who have been true leaders on the FDA/ tobacco issue going back to the early 1990's, including Chairman Kennedy. We want to thank all of them for their past and current support for this long over due legislation.

As the 110th Congress convened in early January, we were pleased to hear a commitment from both Parties in the House and Senate to restore democratic principles to the legislative process, and to provide transparency, cooperation and civility in consideration of this nation's legislative agenda.

It is with that in mind and that we hope that our views, along with the views of many others, will be given serious consideration in reviewing this legislation. The bill has many critical and essential elements but we believe that this good bill can be made even better.

There undoubtedly be those who will oppose **any** changes to the legislation or any discussions for improvement, or even clarification. Because of the ground work that has been laid by many over the last 10- plus years, there are very few who question the general importance of this legislation. But given the fact that there have been no hearings on this legislation in either House in the past; that there are significant changes occurring in the tobacco environment, including technological changes, production and manufacturing changes; and because the legislation is in the same form as has been introduced in previous Congresses, it seems only right and fair for this new Congress to hold open transparent and substantive hearings, including bringing in the industry to be asked the tough questions that need to be asked.

The Alliance firmly believes that the FDA is the appropriate agency for overseeing the manufacture, sale, distribution, labeling, and marketing of tobacco and other nicotine products. Several of the Alliance Steering Committee members have been involved and worked on this issue for more than 15 years, both via the administrative route by petitioning the FDA and working within the FDA, and also via the legislative route. The views of the Alliance have been guided by the work of the Southern Tobacco Communities Project, a set of **Core Principles** issued by both the public health community and the tobacco grower community (1998) and the presidential commission report, **Tobacco at a Crossroad** (May 2001). On the issue of FDA for example the *Core Principles Statement* noted:

> That it is in the best interests of the public health community and the tobacco producer community that FDA should have authority to establish *fair and equitable* regulatory controls over the manufacture, sale, distribution, labeling (including country of origin) and marketing of tobacco

> products, both domestic and imported, comparable to regulations established for other products regulated by the FDA. Such regulations should have as their goal the protection of public health and the assurance that users of tobacco products are provided with full and complete information about the products they are using.

The presidential commission report **Tobacco at a Crossroad** noted:

> In the long run, effective regulation by the FDA benefits everyone, including farmers. It will save lives. Independent science based decisions by the FDA designed to protect the public health by taking all *reasonable* steps to reduce the harm of tobacco products now being sold and *promote* the introduction of less harm products will also create fair standards and will provide predictability to farmers and to the industry (pages 42-43)

In the spirit of a civil dialogue, the Alliance offers the following constructive suggestions for restructuring and improving the effectiveness of the legislation.

I. A Separate Chapter under the FDC Act for "Tobacco and Nicotine Products"
II. Tobacco and Nicotine Scientific and Surveillance Advisory Committee
III. Using User Fees to Fund Tobacco and Nicotine Research
IV. More Effective Coordination Between Governmental Agencies
V. Providing Incentives to Industry to Develop Lower Risk Products
VI. Tobacco Agriculture

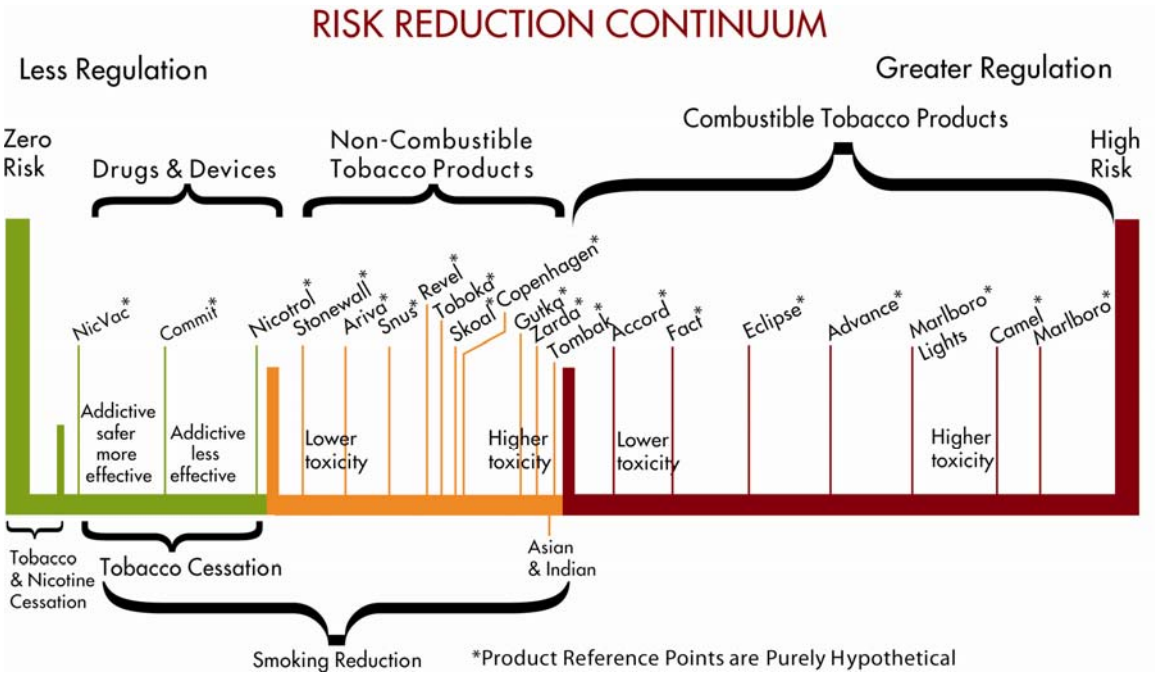
I. A Separate Chapter Under the FDC Act for "Tobacco and Nicotine Products"

As we noted above, the tobacco 'environment' has been changing and will continue to change rapidly. It is clear that we are dealing with a marketplace in which there is increasing competition and overlap between a spectrum of tobacco, pharmaceutical, grower and manufacturing interests. Many in the public health community, the research community, the tobacco industry, and the pharmaceutical industry speak in terms of the need for a more ***coherent tobacco and nicotine policy***. A restructured regulatory scheme would allow the FDA to prescribe labeling and marketing requirements for nicotine containing products based upon the risks, relative risks, and intended use of those products, allowing the consumer to fully understand the risks and relative risks of the products available to them --- from the highly toxic combustible products, to significantly lower-risk noncombustible products to even lower risk nicotine products designed for cessation. For a long time it has been convenient to look at all tobacco products as being equally harmful –clearly a supposition that is not supported by the science or even common sense. There has also been a tendency to separate tobacco from other nicotine products used for cessation even though most (if not all) of the products on the market today have one thing in common – **they contain nicotine derived from tobacco.**

The challenge and the opportunity that we face whether as health advocates, scientists, policy makers, producers, manufacturers (broadly speaking) or consumers is to consider the most effective way in which to take **all** of these products and to craft a *coherent and workable* policy that will allow these products to be regulated in a consistent manner based on their risks and relative risks and intended use.

The Comparative Risk Reduction Continuum Chart

The following chart is a hypothetical representation of the relative risks presented by a spectrum of products – from those that are highly toxic in the form of combusted tobacco, to those at the other end of the continuum, where risks are very small or even negligible. In each case, the regulation of the product would be based on risk. The higher the risk the more regulation (labeling, warnings, marketing restrictions, taxation etc.). The lower the risk the less regulation. If we can begin to develop better and more consistent methods for testing and evaluating products, we can in fact plot where we would expect products to fall on the continuum.



Definition of Products

It might be useful to revisit how products (tobacco and nicotine) are defined. Clarifying these definitions (including making distinctions between recreational and therapeutic products) would go a long way in determining the labeling and marketing requirements for not only various categories of products (e.g. combustible, noncombustible, therapeutic) but also for specific products within each category.

Tobacco and Nicotine Product Categories

Within our suggested framework, it makes sense that given the wide spectrum of risks and relative risks associated with tobacco and nicotine containing products, we use a model similar to that used under the medical device section of the FDC Act by establishing three distinct categories and panels to review, classify and recommend labeling and marketing requirements for products. The goal would be to ensure that consumers are provided with accurate and non-misleading information about a spectrum of products on the market so they can readily understand the risks and relative risks of those products.

Legislation should not be too proscriptive but should establish the appropriate parameters under which the scientific panels (see below) could conduct their work. Many of the requirements spelled out and mandated in great detail under current proposals could be refined to require the scientific panels to make appropriate science- based decisions. All of the essential elements that would be necessary to allow the panels to do their work would obviously be retained (submission of data, registration requirements, the establishment of performance standards, good manufacturing practices, payment of users fees etc).

The three categories that we suggest Congress and the various stakeholders consider are:

Category I – Combustible Products (cigarettes, cigars, pipe tobacco etc.)

Category II – Noncombustible Tobacco and Nicotine Products (for recreational use)

- Noncombustible products containing tobacco (traditional smokeless products, new novel non-combustible tobacco based products)
- Noncombustible products containing nicotine derived from tobacco (new products that are not tobacco based but are not drugs or intended for therapeutic purposes)

Category III – Noncombustible Tobacco and Nicotine Products for Therapeutic Use

- Tobacco based products that are used for therapeutic/cessation uses (no products are currently on the market)

- Products containing nicotine derived from tobacco (patches, lozenges, inhalers, gums etc)
- Products that contain synthetically manufactured nicotine (no products are currently on the market)

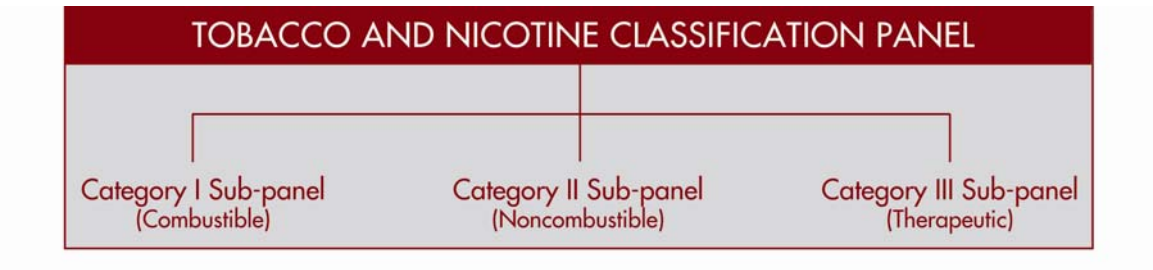
(Side Note: There is also good evidence that genetically modified tobacco may, over the next 5-10 years, not only be used in the development of tobacco and nicotine products but also in the manufacture of pharmaceuticals, industrial enzymes etc. Thus, it might be useful to consider the eventual establishment of a category for tobacco and nicotine products that might be derived from GMO tobacco.)

Tobacco and Nicotine Classification Panel (and Sub-panels)

A Tobacco and Nicotine Classification Panel (TNCP) should be established within the FDA to be composed of three sub-panels organized along the basis of the ***categories*** noted above. The panel (TNCP) would be charged with overseeing the spectrum of regulatory issues (manufacturing, sales, distribution, labeling, marketing, GMP's performance standards etc.) for all tobacco and nicotine containing products. The panel would be composed of "persons who are qualified by training and experience" to evaluate issues and make recommendations. Such persons might include experts in:

- Public health
- Pharmacology
- Toxicology
- Addiction
- Biotechnology
- Advertising, marketing, and promotion
- Production and agronomy
- Labeling
- Good manufacturing g practices
- Consumer affairs
- First amendment

The Panel and sub-panels would be structured as follows:



Each of the three sub-panels would do the majority of work into looking at the science related to a particular category and the products in that category. Each panel would develop proposed labeling, marketing requirements performance standards etc. for not only the category, but for individual products within the category. The panels would have the authority to convene hearings and call witnesses to assist them in their duties. Classification panels would make recommendations to the larger panel and would then, on behalf of or through the Commissioner publish proposed rules and issue final regulations. New products which do not meet substantially equivalent requirements would require pre-market review and approval.

Any interested party would be allowed to petition the panel for reclassification of a product, a variance on the regulatory requirements for the product or even removal of a product not meeting regulatory specifications.

In addition, each panel might include nonvoting members representing the interests of consumers, tobacco manufacturers, pharmaceutical companies, and producers.

The classification panels would also draw on the expertise of the proposed restructured *Tobacco and Nicotine Scientific and Surveillance Advisory Committee* noted below.

II. Tobacco and Nicotine Scientific and Surveillance Committee

To assist the Food and Drug Ad ministration and the Tobacco Nicotine Classification Panel with its work (as well as with other agencies), we suggest that provisions in the currently proposed Tobacco and Scientific Advisory Committee (Section 918) and the surveillance functions of the legislation be combined and expanded to include not only science but surveillance. These two areas have and will continue to have, significant ramifications on the ability of the agency to do its job in not only the review of products but also determining how the public (both the individual consumer and the population as a whole) may be using such products. There is no doubt that the science pertaining to the production, manufacture and marketing of tobacco and nicotine products is changing and changing very rapidly.

Surveillance is a critical component of any tobacco and nicotine regulatory effort. In addition to making sound science-based policy and regulatory decisions, we regard surveillance as one of the top two or three functions that will be needed to be carried out, and one that will play an important role in deciding how the spectrum of tobacco and nicotine products should be labeled and marketed to ensure that any users of these products are interpreting the information in a way that allows them to make a fully informed choice.

Having a "high level" advisory committee in place to assist FDA (and other agencies) in their efforts will go a long way towards ensuring that policy is being made with the most up to date science and surveillance data.

We suggest that the Advisory Committee issue an annual report to be submitted to the Secretary of HHS and to Congress.

III. Using User Fees to Fund Tobacco and Nicotine Research

There has been some ongoing discussion within the public health and scientific communities as to **how** the tobacco industry could participate and fund research that will have a short term and long effects on the reduction of disease and death caused by the use of tobacco products. Many are concerned about the misuse of science by the industry and therefore oppose any measure that would leave the industry in charge of research funding decisions. It might therefore be useful to consider using a portion of the *user fee* to fund tobacco and nicotine research. An "Office on Tobacco and Nicotine Research' established in the Office of the Secretary could be used to set research priorities and allocate research funding to such agencies as the NIH the CDC etc.

IV. More Effective Coordination Between Governmental Agencies

One of the things that is often ignored or forgotten is that oversight and control over the manufacture, sale, distribution, labeling and marketing of tobacco and tobacco products does not and cannot rest within one agency or even within one department. The current legislation does recognize this to a certain extent (see for example the section on "Involvement of other agencies, informed persons"). We believe the interagency functions should be strengthened. Strengthening these functions would not only benefit the FDA, but would benefit other departments and agencies that deal with tobacco. We would recommend that these interagency efforts be strengthened by establishing a broader and more comprehensive Interagency Tobacco and Nicotine Coordinating Committee within the government that ensures ongoing cooperation, communication and integration on a variety of issues. While an interagency committee currently exists in the Department of HHS, it has not been used as effectively as it could or should be. The proposed Interagency Tobacco and Nicotine Coordinating Committee should include representation from the following Departments and agencies:

The Department of Health and Human Services (HHS)

- Food and Drug Administration (FDA)
- Centers for Disease Control and Prevention(CDC)
- National Institutes of Health (NIH)
- Centers for Medicare and Medicaid Services (CMS)

The United States Department of Agriculture (USDA)

The Environmental Protection Agency (EPA)

The Federal Trade Commission (FTC)

Alcohol Tobacco and Fire Arms (ATF)

Department of Homeland Security (DHS)

US Trade Representative (USTR)

Department of Commerce

V. Providing Incentives to Industry to Develop Lower Risk Products and Medications

Both the Institute of Medicine (IOM) and several organizations within the public health community have called for incentives and the encouragement for industry (broadly speaking) to develop scientifically based lower risk products. Yet there are no provisions in the legislation for using competitive market forces (**in a regulated environment**) for stimulating change in the tobacco industry, the pharmaceutical industry, biotech industry etc. and the products they manufacture. Consideration should therefore be given to either incorporating incentives into the legislation or in committee report language suggesting ways that such efforts could be achieved. One obvious and often cited example is to tax products based upon their risks and relative risks: higher taxes for combustible products, lower taxes for noncombustible products, no or minimal tax on medicinal/therapeutic products.

VI. Tobacco Agriculture

A little over two years ago, Congress provided tobacco growers with an industry-funded tobacco *buyout*. At the same time, the Congress intentionally or unintentionally repealed most of the tobacco program, leaving domestic and foreign tobacco virtually unregulated. In an environment in which tobacco is considered an inherently dangerous product, such action makes little sense, especially when considered against the recognized need for FDA oversight over manufactured products. All stakeholders must realize that what is

done at the production level has significant impacts on the health and safety of the final product.

For example: How do different growing technologies and curing processes impact the nicotine levels and other characteristics of the plant? What are the technologies that exist to remove tobacco- specific nitrosamines (TSNA's)? What pesticides and other chemicals are being used, and should we be reducing those pesticides and chemicals? What should US producers be doing to move towards production standards that will have a positive effect in reducing the level of risk posed by tobacco products currently on the market? Where does the tobacco (and nicotine derived form tobacco) in both tobacco and pharmaceutical products come from? What role can genetically modified tobacco play in not only reducing risks associated with tobacco products but also in the development of medicines and industrial enzymes? What incentives and training should be given to producers to begin changing their methods of production to meet the challenges of the 21st century (both here in the US and abroad)? What system do we need to monitor tobacco production in the US as well as abroad? What kind of structures need to be restored and expanded at the USDA (such as a permanent Tobacco Advisory Board) to ensure that there is continuity and consistency between the regulation of manufactured products by the FDA and what is needed to be done by USDA?

While we recognize that the Senate HELP Committee does **not** have jurisdiction over the agricultural issues pertaining to tobacco, we encourage the committee to take these issues into account and officially request the Senate Agriculture Committee to hold hearings on these important issues – issues that not only impact domestic tobacco production and health issues but globally as well. While other agricultural commodities have integrated regulated strategies between USDA, FDA and EPA, tobacco does not. It's time that is changed.

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