Statement of AHEAD (Alliance for Health Economic and Agriculture Development)

Concerning FDA Regulation of Tobacco Products

Subcommittee on Health
Committee on Energy and Commerce

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The Alliance 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 about a spectrum of issues related to the production, processing, manufacture, sale, distribution, 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 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 Crossroad** in May of 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: see www.tobaccoatacrossroads.com or call 202 686-8898)

Statement of AHEAD (Alliance for Health Economic and Agriculture Development) Concerning the Need for FDA Regulatory Oversight of Tobacco

On behalf of the Alliance on Health Economic and Agriculture Development (AHEAD), I am pleased to provide this testimony to the Subcommittee on Health concerning the need for FDA regulation and oversight of tobacco products.

This is an issue that has languished in Congress for far too long. It is now over 15 years since I had the privilege of working with two members of this Subcommittee, Congressman Mike Synar (D-OK) and Congressman Bob Whittaker (R-KS) in introducing what was the first legislation in Congress to give FDA regulatory oversight over tobacco products. And I also want to express my deep appreciation to Congressman Waxman for his years of work on not only this issue but many other tobacco issues that came before this Subcommittee when he was Chairman.

Today while the goals and objectives of FDA oversight remain much the same as they were in the early 1990's, at the same time much has changed in the tobacco environment which needs to be considered in crafting any legislation. The legislation being discussed today is virtually identical to legislation introduced in the last three Congresses, and not much different than the McCain legislation of almost 10 years ago.

The Alliance would like to provide the Subcommittee with some broad and specific recommendations and suggestions on how this legislation can be improved upon and made more workable.

First and foremost, the Alliance has taken the position that the FDA is the appropriate and must logical agency for overseeing the manufacture, sale, distribution, labeling and marketing of tobacco products. Several of the Alliance's 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, as well as via the legislative route. The views and positions of the Alliance have been guided by the work of the Southern Tobacco Communities Project (funded through a grant from the Robert Wood Johnson Foundation) , a set of core principles issued and adopted by the public health community and tobacco growers (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 foreign, comparable to regulations

> established for other products regulated by the FDA. Such regulations should have as their goal the protection of public health and assurances 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 Crossroads** 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 public health by taking all *reasonable steps* to reduce the harm of tobacco products now being sold and *promote* the introduction of less harmful products will create *fair* standards and will provide *predictability* to farmers and industry (pages 42-43)

In the spirit of civil and transparent dialogue, the Alliance offers constructive suggestions for restructuring and improving the legislation now pending before this Subcommittee. This testimony is provided in two parts, the first of which focuses on some broader recommendations concerning how tobacco products (and other nicotine products) should be regulated under the FDA. Part II deals specifically with specific language changes to the legislation in a number of areas.

PART I

1. **A Separate Chapter under the FD&C Act for all Tobacco and Nicotine Products**
2. **Tobacco and Nicotine Scientific and Surveillance Committee**
3. **User fees to fund tobacco and nicotine research**
4. **More effective coordination between governmental agencies**
5. **Providing incentives to develop lower risk products (tobacco and nicotine)**
6. **Tobacco Agriculture**

1. A Separate Chapter under the FD&C Act for all Tobacco and Nicotine Products

As noted above the tobacco environment has been changing and will continue to change. It is clear that we are dealing with a market place in which there is increasing competition and overlap between a spectrum of diverse tobacco based products, pharmaceutical products, as well as tobacco producers, and tobacco and pharmaceutical manufacturing interests. Many in the public health community, the research community, the tobacco industry and the pharmaceutical industry increasingly speak in terms of the need for a more ***coherent and rational tobacco and nicotine policy.*** A restructured regulatory scheme would allow the FDA to prescribe labeling and marketing requirements for all nicotine containing products based upon risks, relative risks and intended use of those

products, allowing the consumer to fully understand the risks and relative risks of products available to them – from the highly toxic combustible products (cigarettes), to significantly lower risk noncombustible tobacco based products, to even lower risk nicotine replacement therapies (NRT). Several recent studies have shown significant consumer misunderstanding about the risks and relative risk of those products – something that needs to be rectified. 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 of cigarette smoking 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 more importantly the opportunities 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 craft a coherent and workable regulatory policy that will allow these products to be regulated in a consistent manner based on their risks, relative risks and intended use.

Our first recommendation is to bring all tobacco and nicotine products under the **same regulatory umbrella** as part of a separate Center at the FDA. This Center could be named the Center for Tobacco and Nicotine. Within this framework it would make sense given the wide spectrum of risks and relative risks associated with tobacco and nicotine products, that we use a model similar to one used under the medical device section of the FD&C Act by establishing three distinct categories and panels to review, classify and recommend labeling and marketing requirements and allowances for products. (This type of model was one considered by the Institute of Medicine in its report **Clearing the Smoke**) These three categories would be:

a) Combustible products (Cigarettes, cigars, little cigars, pipes etc)
b) Noncombustible tobacco and nicotine products (for recreational use), including tobacco based products as well as nicotine based products which are not used for therapeutic purposes.
c) Noncombustible tobacco and nicotine products for therapeutic use, including products containing nicotine derived from tobacco (i.e. patches, gums, lozenges, inhalers), and tobacco based products that would be used for therapeutic purposes (no products currently on the market).

The panels would be composed of a spectrum of ‘experts’ in the fields of public health, pharmacology, addiction, biotechnology, advertising and marketing, good manufacturing practices, agronomy etc. Any interested party would be allowed to petition a panel for the reclassification of a product, a variance on the regulatory requirements for a product or even removal of a product not meeting regulatory specifications. New products would be subjected to pre-market approval. Regulations for both categories and individual products would be based on the ‘risk’ profile of the category and of the product.

2. Tobacco and Nicotine Scientific and Surveillance Committee

To assist the FDA and the Tobacco and Nicotine Classification Panel(s), we suggest that provisions in the currently proposed Tobacco and Scientific Advisory Committee (sec. 918) be expanded and also include surveillance functions. These two areas in particular have and will continue to have significant ramifications on the ability of the agency to do its job in not only reviewing products but also in 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 will continue to change. Major changes in curing techniques and biotechnology impacting on tobacco and nicotine products is already on here or just over the horizon.

Surveillance is a crtical component of any tobacco and nicotine regulatory effort. In addition to making sound scientific 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 fully understand the risks and relative risks of those products.

Having a ‘high level ‘ advisory committee in place, with representation from a broad spectrum of experts, 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 scientific and surveillance data.

3. User Fees to Fund Tobacco and Nicotine Research

There has been some growing discussion within the public health and scientific communities as to how the tobacco industry could participate and/or be required to fund research that will have short term and long term 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 have opposed 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 priorities and allocate funding to such agencies as the NIH and CDC in carrying out both research and surveillance efforts.

4. 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 any one agency or even one department. The current legislation does recognize this to a certain extent but 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 as well. We would recommend that these functions 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 already exist it has not be used as effectively as it could or should be. The proposed Interagency Tobacco and Nicotine Coordinating Committee should include representation from such Departments and agencies as **HHS** (FDC,CDC,NIH,CMS etc.), **USDA, EPA,FTC,ATF,USTR, and DHS**.

5. Providing Incentives to Develop Lower Risk Products and Medications

Both the Institute of Medicine (IOM) and several organizations within the public health community (as well as the presidential commission report) have called for incentives and the encouragement of industry (broadly speaking) to develop scientifically based lower risk products. Yet there are no provisions in the legislation for using competitive 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 be given to 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, and no or a minimal tax on medicinal and therapeutic products. Other 'incentives' could come in the form of 'tax credits" or expedited review (and greater leeway in marketing) for new products that have a science based expectation to lower risks.

6. Tobacco Agriculture

Over two years ago, Congress provided growers with an industry-funded tobacco buyout. At the same time, 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 the recognized need for FDA oversight over manufactured products. All stakeholders must realize and consider that what is done (or not 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 technologies that exist to remove tobacco specific nitrosamines (TSNA's)? What pesticides and other chemicals are being used, and should we be reducing those pesticide and chemical applications? What should US producers do to move towards production standards that will have a positive effect in reducing the level of risk posed by tobacco currently on the market? Where does the nicotine in both tobacco and nicotine products come from? What role can genetically modified tobacco and geonomics 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? What system do we need to monitor tobacco production both here in the US and abroad? What kind of authorities and structures need to be restored at the USDA (such as a permanent Tobacco Advisory Board) to ensure that there is continuity and consistency between the regulation of the manufactured products by the FDA and what is needed to be done by the USDA (as well as other agencies such as EPA).

Whether one wishes to acknowledge it or not HR 1108 does have consequences on producers of tobacco and it would be prudent for Congress to carefully and fully consider these ramifications (both positive and negative) as it moves forward with the FDA legislation.(See recommendations in Part II). We would also encourage this Committee to officially request the House Agriculture Committee to hold hearings on these important issues – issues that not only impact domestic tobacco production and health issues here in the US but could have significant ramifications 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.

PART II

Specific suggestions for modifications to S. 625 and HR 1108

AHEAD also provides the following specific suggestions for modification in the legislation. **As before we hope that all parties interested in this important legislation will take the time to consider these suggestions and to work towards finding *common ground* that will most effectively and fairly establish a workable and flexible process under which tobacco and tobacco products (and nicotine products) will be regulated in the coming years.**

SUMMARY OF PROPOSED CHANGES

1. Sec. 2. Findings: Add a number of findings to the legislation that reflects a changing environment in which tobacco and nicotine products are produced, processed, manufactured, labeled and marketed.

2. Sec.3 Purpose: Add language that emphasizes that enforcement authority of the FDA be both flexible, and ***fair*** and that there should be incentives for the development of science- based lower risk products. Add a new subparagraph (8) that ensures that adult users are fully and accurately informed about the risks, relative risks, and intended uses of tobacco and nicotine products.

3. Sec.4 Scope and Effect (page 15): Although the language is designed to ensure that FDA does not infringe upon USDA's authorities, the current language references 'existing law'. Many of the provisions of the previous existing law designed to ensure integrity of tobacco were repealed -- leaving a serious void. This section needs clarification.

4. Sec. Definition (pages 16-17): Keep definition of tobacco product as defined in lines 12-18 and strike the exemptions in lines 18-23. A restrictive definition (as currently in legislation) is a *disincentive* for the development of new scientifically based tobacco based products that could lower the risks associated with other high risk tobacco products.

5. Sec. 900- Definitions (page 23): Modify the definition of a 'smokeless product' to include all tobacco based products that consist of cut, ground, powdered, compressed or leaf tobacco that are intended to be used in a noncombustible form.

6. Sec. 901 Limitation of Authorities (pages 23-24: While indicating that producers (growers) should not be subject directly to the provisions of FDA authority, the legislation provides an exception that would subject producers to the requirements of the Act if the producer is also a tobacco manufacturer or *controlled* by a manufacturer. In a post buy out environment this in effect could subject almost all growers, warehouses and cooperatives to the requirements of the Act. This sections needs careful reconsideration.

7. Sec.906(d) General Provisions.(pages 45-56): Consider striking this section as it seems to (except for a few limitations) provide the Secretary with very broad authority to regulate tobacco products with only a showing that it is in the interest of public health. At a minimum if this section is retained, added a new subparagraph (C) which would further clarify what must be taken into consideration. The limitations (906(d)3) concerning face-to-face transactions, minimum age of sale and matchbooks could be moved elsewhere in the Act.

8. Sec. 907(a)(3) Tobacco Product Standards (pages 54 and 59): Add a new subparagraph (C) on page 54 that requires consideration of *consumer acceptability* and that tobacco users will use such products as alternatives to higher risk products. Also, revise and add new sub-paragraphs (2) and (3) under the section, Consideration by Secretary (page 59) to require consideration of the impact of standards on tobacco producers, processors and other small businesses and to again require consideration of *consumer acceptability* of the products required to meet the performance standard.

9. Sec. 911 Modified risk Tobacco Products pages 85-100): Revises requirements to be more consistent with the language and intent of the IOM report Clearing the Smoke and the presidential commission report Tobacco at a Crossroad. Allows the Secretary to promulgate rules and regulations for tobacco product *categories* (in addition to individual products for which an application has been filed) that will allow users of tobacco to differentiate between the risks and relative risks of such categories. Under Sec.911(l) amend to use IOM language specifying the criteria to be used by the Secretary in establishing guidance and standards (including involvement of tobacco manufacturers.)

10. Sec.918 Tobacco Products Scientific Advisory Committee (pages 109-11): Add three additional voting members including an expert in agronomy and tobacco plant technologies; an expert in labeling, marketing and consumers affairs; an expert in harm reduction. (Note: Failing to add an expert in agronomy and tobacco plant technology we suggest making the grower representative a voting member).

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1. Sec. 2 FINDINGS (pages 2-13)

We encourage the Subcommittee to conduct a careful review of the findings that will more adequately reflect the current environment surrounding the production, manufacture, sale, distribution, labeling and marketing of tobacco and nicotine products.

We also suggest adding the following findings:

New technologies are available (and are being developed) that will allow tobacco and tobacco products to be developed that are lower in risk.

Tobacco manufacturers should be given incentives and encouraged to develop and market products that can be reasonably expected to reduce the risk of disease compared with many of the tobacco products currently on the market.

Tobacco producers should be given incentives to produce, cure, and process tobacco that is lower in tobacco specific nitrosamines, toxins and pesticides and that can reasonably be expected to reduce the risk of disease.

The Congress should enact and the USDA should implement tobacco agriculture policies that will compliment FDA oversight that will ensure that

both domestic and foreign tobacco meet minimum health and safety standards, and that product standards don't create competitive disadvantages for American tobacco producers.

Stakeholders, including scientists, public health organizations, tobacco manufacturers, pharmaceutical and biotech companies, tobacco producers, governmental agencies and others should be encouraged to engage in transparent, open debate and dialogue about issues pertaining to the production, manufacture, sale, labeling and marketing of tobacco and tobacco products.

It is in the interest of users of tobacco and nicotine products that the Congress establish a more coherent tobacco and nicotine policy that will allow consumers to understand the risks, relative risks and intended uses of all tobacco and nicotine products.

2. Sec. 3 PURPOSE (pages 13-15)

On page 14 line 3-6 revise to read:

(4) to provide new, flexible, and fair enforcement authority to ensure that there is effective oversight of , and incentives for, the tobacco industry's efforts to develop, introduce and promote less harmful tobacco and nicotine products.

On page 14 insert a new subparagraph (8) (and re-designate all paragraphs thereafter)

(8) to ensure that adult users are fully, accurately and truthfully informed about the risks, relative risks and intended uses of all tobacco and nicotine products.

On Page 15 lines 12-17 the current legislation reads:

(b) AGRICULTURAL ACTIVITES. – The provisions of this Act (or amendment made by this Act) which authorizes the Secretary to take certain actions with regard to tobacco and tobacco products shall not be construed to

affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

Comment: The current provisions of the legislation would and do allow the FDA to have influences indirectly over tobacco production through such things as performance standards and modified risk requirements. In addition because the Congress repealed important tracking, monitoring and testing provisions that were part of the 'tobacco program' when the buyout was passed, there is virtually **no** "existing law regarding the growing, cultivation, or curing of raw tobacco". This could give the FDA the green light to have even more authority and the ability to indirectly or directly affect requirements at the production level. This section therefore needs to be carefully written to ensure that FDA does not have excessive and undue influence over tobacco production. Authorities should be restored to the USDA and FDA, USDA (and other agencies) should work cooperatively. Growers should be part of the process not victims of the process.

3. Title I - Authority of the FDA - Sec. 101 pages 16-17 (Definition of Tobacco Products)

On page 16, strike lines 18-23.

Comment:

In our testimony submitted to the HELP Committee we suggested that the definitions of tobacco (and nicotine) products be revised as part of our broader suggestion that all tobacco and nicotine products be brought under a single regulatory umbrella at the FDA (under a separate chapter) that will allow for a more coherent tobacco and nicotine policy to be implemented.

The Institute of Medicine, many in the public health community and the presidential commission report have all called for the development of new lower risk tobacco products. (See for example, the Principle Recommendations, of the IOM report which states that **Manufacturers have the necessary incentive to develop and market products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco related disease**.) Yet this legislation, by selectively restricting what is and what is not a tobacco product (even when the product is composed of tobacco) prevents the development of many new and potentially lower risk tobacco based products --- products that could help reduce the disease caused by the use of more toxic products. Competition (with incentives) to develop new products (coupled with fair and effective regulations) may be in the best interests of the public health, tobacco and nicotine users, manufactures and even producers. It should be up to

the FDA to determine if a tobacco product meets the regulatory requirements of the Act.

If Congress chooses to continue to keep tobacco and therapeutic nicotine products under separate sections of the FDCA, then **at a minimum** we suggest that subparagraph (2) , lines 18-23 be stricken from the legislation. This will encourage tobacco companies , biotech companies and even pharmaceutical companies to develop tobacco- based consumer products (not therapeutic) for which there is a reasonable expectation (based on scientific evidence) that such products will reduce risks.

4. "CHAPTER IX- TOBACCO PRODUCTS

Section 900 – Definitions:

On page 21 lines 14-18, amend the definition of smokeless tobacco *Section 900 (16)* to read:

"(16) SMOKELESS TOBACCO. – The term smokeless tobacco means any tobacco based product that consists of cut, ground, powdered, compressed or leaf tobacco that is intended to be used in a noncombustible form.

Section 901 FDA Authority Over tobacco Products (Scope)

Comment:

Page 23 (line 24) - 24 (lines 1-23) "Limitations of Authority" intends that the provisions of the Act "shall not apply to tobacco leaf that is not in the possession of the manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producers of tobacco leaf without written consent".

Under the "Exception" (B) line 11 , if a tobacco producer of tobacco leaf who is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer".

In a post buyout environment where there will undoubtedly be more realignment of producers and industry such that the lines between them will increasingly become blurred, it is feasible that all tobacco producers, warehouses, or cooperatives who enter into any kind of a contractual relationship with a manufacture could/will be subject to the provisions of the ACT.

"Subparagraph (C) – Rule of Construction" line 17 also indicates that "nothing in this Chapter shall be construed to grant the Secretary authority to promulgate regulations of any matter that involves the production of tobacco leaf or a producer, thereof, *other than activities by a manufacturer affecting production*". Again, while well intended, the post buy environment will more than likely see increased contractual and business relationships between producers and manufacturers such that all tobacco producers could be subject to the requirements of the Act. This is also a likely scenario given that the FDA will be establishing performances standards, good manufacturing practices, and setting regulations governing reduced risk products that through the manufacturer or by other means will affect (directly or indirectly) all tobacco producers in the US.

These provisions must be carefully reconsidered and rewritten to ensure that the tobacco producers does not find him or herself subject to direct or indirect authority of the Act unless it is accomplished in a fair and equitable manner and under conditions which producers are directly and actively involved in the setting of standards and requirements. For example, the Act should clearly state that any regulations which would indirectly require growers to change the leaf that they produce should be done with both the involvement of growers and in consultation with the USDA.

Sec. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS ----Section 906(d) RESTRCTIONS. (page 45, line 20-24, page 46 lines 1-17).

Comment:

This section, 906(d) RESTRICTIONS (pages 45 and 46), would give the Secretary almost opened ended, unlimited authority to establish regulations and restrictions *"on the sale and distribution of a tobacco products, including restrictions on access to, and the advertising and promotion of the tobacco product, if the Secretary determines that such regulations would be appropriate for the protection of the public health*".

While the Secretary does have to make a finding of the risks and benefits to the population as a whole, including users and non-users of tobacco products taking into account; the increased or decreased likelihood that those will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products, it would seem that given the public health risks of tobacco the Secretary could effectively impose such restrictions on all tobacco products (including products that might be considered lower in risk) that would make access to all tobacco products even to adults excessively restrictive.

In addition, this section talks about restrictions on the sale distribution, access to and advertising of tobacco products' in general terms, not in terms of children and adolescents but in terms of the adult populations as well.

Does this subsection (with the exception two limitations on face- to- face transactions and minimum age of sale) in effect given the Secretary such broad authority as to allow the Secretary the ability to supercede many of the other provisions of the Act?

Given the extensive requirements concerning the manufacture, sale, labeling and marketing of tobacco products covered under many sections of the legislation this section could and should be eliminated. The 'limitations' noted under 906(d)3, could be moved elsewhere in the legislation.

At a minimum, the public health standard used for making a "finding as to whether a regulation would be appropriate for the protection of public health" should also require the following new subparagraph (C)

(C) the risks, relative risks and intended uses of the spectrum of tobacco products from those using the most harmful tobacco products (combustible products) to those who would use lower risk products (including noncombustible smokeless tobacco products and pharmaceutical nicotine)

Section 907. TOBACCO PRODUCT STANDARDS.(Pages 53-64)

Comment:

One of the reasons that tobacco growers and public health organizations joined together in support of FDA oversight over tobacco products has been the potential for producers to work under a system under which there are fair and realistic standards established that would give US producers a more competitive role in producing tobacco leaf (as well as the final manufactured product) that has fewer toxins, pesticides, and meets other health and safety standards when compared with leaf that is produced overseas. While standard setting in the legislation is in terms of the manufactured tobacco product, there is no question that there is an indirect (if not direct) effect on US producers. For that reason and others we therefore suggest the following modifications to Section 907.

907(a)(3) TOBACCO PRODUCT STANDARDS (Page 54)

After subparagraph (B), (lines 21-23) add the following:

(C) the increased or decreased likelihood that the product will be consumer acceptable and that an existing user of tobacco will use such products as alternatives to other higher risk products on the market.

Revise subparagraph (E) CONSIDERATION BY THE SECRETARY.- page 59 as follows:

(E) Consideration by Secretary.--
The Secretary shall consider all information submitted in connection with a proposed standard including information concerning the:

(1) Countervailing effects of the tobacco product standards on the health of adolescent users; adult tobacco users, or non-tobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter

(2) The direct and indirect impact of the standards on tobacco producers, processors and other small businesses to be able to comply with the standard.

(3) The consumer acceptability of the product or products for which the tobacco standard is required.

Section 911. MODIFIED RISK TOBACCO PRODUCTS (Pages 85-100)

Comment:

Another reason that many growers have joined with the public health community in supporting FDA regulatory oversight of tobacco products has been the prospects for the development of lower risks tobacco products. This section of the legislation is therefore of particular interest and concern, both from the standpoint of public health and how US producers can effectively play a positive role. The provisions of this section seem to be more determined to keep lower risk products off the market rather than in giving industry ***incentives and encouragement*** to develop lower risk products especially given the significant dangers associated with products currently on the market. This includes the 'standards' that must be met in order to bring a product onto the market.

Section 911(b)(2) SOLD OR DISTRIBUTED (pages 85-86)-- establishes what the term 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products' entails. Several issues here should be noted. While the banning of such descriptors such as 'light' , mild (Subparagraph ii, page 86) etc is essential does this also mean that truthful meaningful statements such as "this is a smoke free tobacco product", or 'this is a smokeless tobacco product' will also be prohibited? How would such restrictions be considered under the First amendment and in particular how would recent decisions made with respect to health claims on food products impact on the circumstances under which claims on tobacco product would be allowed or disallowed? Descriptors which are

misleading and deceptive should be prohibited --- and already are by the Act's 'misbranding' section (903) --- but those that are accurate, truthful and non-misleading should be allowed under controlled circumstances, even if requiring explanatory, clarifying labeling and disclosures.

More problematic is subparagraph (iii) page 86-87 which would conclude that a tobacco product is a reduced risk product even in situations in which 'the tobacco manufacturer has taken any action directed to consumers *through the media or otherwise*, other than by means of the tobacco product's label, labeling, or advertising that would be reasonable be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances. This provision would seem to suppress any and all discussion, debate, dialogue and publication of scientific findings, studies etc.

Subsection 911(d) FILING. (pages 87-88)

This section lays out some of the requirements for the filling of an application for a modified risk tobacco product. Revise (d)6 to read:

> **"(6) data and information on who the targeted potential users of the product are and how consumers are expected to use such product.**

Comment: As with several other sections, the concern is that there seems to be a required showing on how consumers actually use the product even before the product is put into the market place. The focus should be, as we noted above,on the *expected* intended use of the product. The surveillance requirement that will involve industry, FDA etc should provide the data to determine if the target audience and the messages contained in the labeling and marketing of the product are having their intended effect as contained in the application.

Subsections 911 (g) and (h) (page 89-96 lines)

Comment:

These sections establish the basis and criteria on which the Secretary can approve an application for a modified risk tobacco product when the applicant has demonstrated that such product, as it "*actually* used by consumers will--- (A) *significantly* reduce harm and the risk of tobacco related disease to individual users; and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do no currently use tobacco products". The legislation as drafted is problematic in

that it requires a showing of an outcome that can't be evaluated unless and until such products are allowed on the market (putting the cart before the horse). As we noted above, issues pertaining to 'actual use' should be part of the surveillance provisions under the legislation. It also sets the standards for allowing a harm reduction product on the market so high as to be unfeasible and contrary to the views expressed in the IOM report, the presidential commission report and other statements from some of the public health community. It may also have the unintended consequence of perpetuating the use of higher toxic products. We also think that the Secretary should have the authority to establish labeling and marketing standards based upon the risks, relative risk, and intended uses between product categories.

We propose that in consideration of the IOM report, several statements of the public health community, and recommendations of the presidential tobacco commission that the current sections (g) and (h) be deleted and the following new (g) and (h) be substituted:

(g) APPROVAL. ---

(1) MODIFIED RISK PRODUCTS.—

The Secretary shall approve an application for a modified risk tobacco product if the Secretary finds that that the applicant has demonstrated that, as intended to be used by consumers ---

(A) The product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects to an individual as compared with whatever benchmark product or products the Secretary may establish*

(B) The product substantially reduces the exposure to one or more tobacco toxicants based upon whatever benchmark product or products the Secretary may establish.*

(C) The product has the reasonable expectation based upon a consensus of the available scientific evidence (both evidence submitted by the applicant and evidence available through other sources) to benefit the individual and the population as a whole, taking into account:

- **i) the risks and relative risk to individuals of the tobacco product that is the subject of the application especially when compared to other categories and products on the market.**
- **ii) the increased or decreased likelihood that existing users of tobacco products who might otherwise quit might switch to the tobacco product which is the subject of the application.**
- **iii) the increased or decreased likelihood that persons who do not use tobacco might start using the tobacco product that is the subject of the application.**

iv) the risks and benefits to persons from the use of the tobacco product that is the subject of the application compared to the use of other higher toxic tobacco products.

v) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation to treat nicotine dependence.

(D) That the product as intended to be used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the anticipated overall impact of use of the product meets the other requirements required as part of the application.

(E) That the labeling and advertising for the modified risk products will enable the user of such products, as well as the public, to comprehend information concerning the modified risk and to understand the risks and relative risks and significance of such information in the context of total health.

* This language is derived from the Regulatory Principles (regulatory Principle # 4) contained in the IOM Report, Clearing the Smoke.

(h) ADDITIONAL AUTHORIES AND CONDITIONS.—

(1)The Secretary may require that a product that is the subject of the Application also:

(A) Disclose on the label or through other means such as package inserts, other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or may increase the risk of other diseases or health related conditions associated with the use of the tobacco product.

(B) Disclose on the label or through other means such as package inserts other information that will ensure that consumers are fully and accurately informed of the known, likely, and potential consequences of using the tobacco product.**

(C) Label the product detailing the conditions of use of the tobacco product if the tobacco product may affect the risk of the product to human health.

(D) Meet protocols and specified criteria for the allowance or disallowance of comparative claims of the product, taking into

consideration how such comparative claims will be understood by the users of the tobacco product in comparison with other products on the market.

(2) Absent the submission of an application for a specific modified risk product, the Secretary may also establish generic labeling and marketing standards for product categories that will allow users of tobacco products to understand the risks, relative risks and intended uses of and between such categories. Such generic labeling and marketing standards shall compare the risks, relative risks and intended use between:

(A) combustible tobacco products with noncombustible tobacco products and nicotine replacement therapies;
(B) noncombustible tobacco products with combustible tobacco products and nicotine replacement therapies;
(C)nicotine replacement therapies with noncombustible and combustible tobacco products.

In developing such generic labeling and marketing standards for product categories the Secretary shall consider the effects of such regulations on the individual and the population as a whole taking into consideration:

(A) the increased or decreased likelihood that a tobacco user who might otherwise quit using tobacco might continue to use a tobacco product;
(B) the increased or decreased likelihood that a user of a higher risk tobacco product will switch to a lower risk tobacco and or nicotine product;
(C) the increase or decreased likelihood that nonuser of a tobacco product will start using a product within one of the tobacco and nicotine categories;
(D) the critical first amendment requirement that the public is entitled to truthful, accurate, non- misleading information about the products they choose to use.

In developing such generic labeling and marketing standards for product categories, the Secretary shall not be precluded from permitting truthful, non-misleading statements to be made about a particular category even if different products within such category have, as among themselves, different degrees of relative risk, so long as such statement accurately apply to the category as a whole and are based on sound science.

Subsection 911(i) Postmarket Surveillance Studies

We suggest revising 911(i)1 concerning post market surveillance and studies to include provisions ensuring authorities of the Secretary to conduct survey and studies and to read as follows:

(i) POST MARKET SURVEILLANCE AND STUDIES.-

(1) IN GENERAL.- Applications approved by the Secretary under (g) (1) shall require the applicant's agreement to conduct post-market surveillance and studies for the tobacco product and to submit to the Secretary the results of such surveillance and studies to enable the Secretary to determine the impact of the application approval on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations, to enable the Secretary to review the accuracy of the determinations upon which the approval was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product.
(B) The results of such post-market surveillance and studies required under paragraph (A) shall be submitted annually.
(C) Nothing in this section shall limit the authority of the Secretary to conduct independent studies and surveys of consumer perception, and behavior relating to reduced risk products or the tobacco product which is the subject of the application..**

** This language is derived from the IOM report **Clearing the Smoke**, Regulatory Principle 5.

Section 911(l) Implementing regulation or guidance.—(Pages 99(lines 13-24)-100 (lines 1-25)

We suggest revising (l)(1) and (2) as follows:

(l)IMPLMENTING REGULATIONS OR GUIDANCE.—

(1) SCIENTIFIC EVIDENCE.--- Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall ---

(A) establish criteria for scientific studies needed prior to approval to show that there is a reasonable expectation that the product will reduce the risk of one or more specific diseases or other adverse health effects , as compared with whatever bench mark product the Secretary requires;***

(B) establish criteria for scientific studies needed prior to approval to show that the product substantially reduces exposure to one or more tobacco toxicant;***

(C) establish appropriate guidance and standards on the use of biomarkers, intermediate clinical endpoints, and other feasible outcome measures;

(D) provide guidance and standards for post market surveillance related to consumer perceptions, behavior and health outcomes;

(2) CONSULTATION.- The regulations or guidance issued under paragraph (1) shall be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance. The Secretary shall as appropriate and necessary also consult with tobacco manufacturers to ensure that the necessary data and information is made available that will allow the Secretary to develop the appropriate standards and guidance. ****

*** These are (again) based on the language contained in the IOM report, **Clearing the Smoke**, Regulatory Principle # 4.

**** The provision allowing the Secretary to consult with tobacco manufacturers is consistent not only with other requirements of the legislation (submission of data) but also with the recommendations of the IOM report and the presidential commission report.

We also suggest deleting subparagraph (E) (page 100 of S.625, lines 16-19) as the legislation already requires that the applicant submit the results of post-market surveillance and studies on an annual basis.

Section 918. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE Pages 109-110)

Comment:

It would seem that given that the Scientific Advisory Committee is charged with a number of functions under the legislation including reviewing such things as applications for modified risk products, setting performance standards etc. that its composition should

include several members who have other critical expertise and training. We suggest the following additional voting members:

(iii) 1 individual who is an expert in agronomy and tobacco plant technologies;
(iv) 1 individual who is an expert in labeling, marketing, and consumer affairs;
(v) 1 individual who is an expert in harm reduction

(Note: re-designate the current subparagraphs (iii), (iv), and (v) accordingly)

Respectfully Submitted on Behalf of AHEAD,

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