Independent science-based decisions by 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 also create *fair* standards and will provide *predictability* to farmers and to industry.

Presidential Commission Report, Tobacco at a Crossroad, May 2001

Specific Suggestions, Comments, and Modifications For Discussion Concerning S. 625 and HR 1108 Legislation to Give FDA Authority over Tobacco Products

AHEAD
The Alliance for Health Economic and Agriculture Development

MAY 2007

About the Alliance:

The Alliance is an informal organization whose purpose is to educate, stimulate and facilitate discussion with and between public health advocates, growers, the scientific community, tobacco manufacturers, consumers, pharmaceutical and biotech interests about a spectrum of issues pertaining 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 with 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 2001. The Steering committee members serve as individuals, each of whom has significant and unique experience in dealing with tobacco related issues.

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Additional Comments and Suggestions for Discussion from AHEAD on S. 625 and HR 1108 – Legislation to give FDA jurisdiction for the oversight of tobacco products

On February 27th the Alliance for Health Economic and Agriculture Development submitted some constructive comments to the Senate Committee on Health Education Labor and Pensions (HELP) on S. 625 and the "Need for FDA Regulation of Tobacco Products"

In those comments we addressed several areas and made several suggestions in the following areas:

1. The need for a Separate Chapter under the FDCA that includes both tobacco and other nicotine products.
2. An expanded role for a Tobacco and Nicotine Scientific and Surveillance Advisory Committee.
3. The allocation of a portion of the tobacco *user fee* to fund tobacco and nicotine research.
4. Providing incentives to industry (and producers) to develop lower risk products.
5. Issues related to tobacco agriculture that need to be addressed by Congress.

In addition to those constructive suggestions, 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 will be regulated in the coming years.** We want to also reiterate that AHEAD has a longstanding commitment to enactment of legislation designed to give the FDA regulatory authority over manufactured tobacco products. We also believe that FDA legislation must be considered in light of other national tobacco policy reforms and recommendations including those highlighted in several of the Alliance's white papers. For copies of those white papers, as well as a copy of the Senate testimony, email: ScDBa@aol.com or call 202 686-8898.

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 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).

* * * * *

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

As we suggested in our earlier comments to the Senate HELP Committee we encourage 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)