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

"The monopoly of ideas does not belong
to a singe party. Of it's a good idea we will consider it"
President-elect Barak Obama

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MAKING SCIENCE-BASED REDUCED RISK TOBACCO PRODUCTS A PART OF EFFORTS TO REDUCE DISEASE AND DEATH FROM TOBACCO

CONSTRUCTIVE AND RATIONAL MODIFICATIONS TO THE FINDINGS AND SECTION 911 OF HR 1108 (110th Congress)

The Alliance for Health Economic and Agriculture Development (AHEAD) has recently (January 2009) issued a statement on what we suggest are the essential elements and principles for FDA regulatory oversight over tobacco and nicotine products and that should be used for guiding consideration of legislation in the new 111th Congress. (go to: www.tobaccoatacroassroads.com) .

This document focuses on the modification and amendment to the legislation as passed in the 110th Congress focusing on the 'Findings' and in particular section 911 (reduced risk section) of the legislation and does not entail our broader recommendations

While the issue of modified risk products (harm reduction) has gained a great deal of public attention over the last several years, substantive dialogue and discussion has actually been taking place for many years. It is unfortunate that this dialogue was precluded from taking place during consideration of HR 1108 in the 110th Congress.

Because of what is often referred to as the "low tar/light" cigarette fiasco, there has been an historic and justifiable tendency to look at the issue of "reduced risk" products as fraught with ***negative*** public health ramifications. For many in the public health community it has been the tobacco industry's abuses and more importantly the 'lack of FDA regulatory oversight" that has driven their opposition, concern and heightened

resistance to products that might be potentially lower in risk and reduce the incidence of disease.

But when the FDA (or a similar independent third party regulatory body) is provided authority to oversee tobacco and nicotine products, this *negative* view should shift to giving greater attention and serious consideration to how such products can potentially **benefit *public health.***

The gradual but clearly discernable shift by many, away from viewing "reduced risk" products as nothing but attempts by the tobacco industry to mislead and deceive the public, to viewing these products as having the *potential* to help reduce disease and death caused by smoking (if implemented under a regulatory scheme) has been recognized for more than ten years. From an important conference held at Georgetown University in 1998 (*Tobacco Dependence: Innovative Regulatory Approaches to Reduce Death and Disease*), to the FDA commissioned Institute of Medicine report Clearing the Smoke-Assessing the Science Base for Tobacco Harm Reduction (2001), to a presidential commission report Tobacco at a Crossroad (2001), to a recent landmark report from the Royal College of Physicians (2007), the subject of tobacco harm reduction as a public health strategy has gained increasing legitimacy.

Such legitimacy warrants the new 111th Congress (and with a new Administration committed to open, transparent and inclusive governing) to pause and to give consideration as to how the modified risk sections (as well as the Findings) of HR 1108 (S.625) could be drafted to better reflect the significant and growing body of evidence and recommendations in this area and in particular the recommendations of the Institute of Medicine. The Institute of Medicine has stated that harm reduction ***is a feasible and justifiable public health policy if it is implemented carefully*** and includes achieving the following objectives:

- Manufactures have the necessary *incentive* to develop and market products that reduce exposure of toxicants and that have a reasonable prospect of reducing the risk of tobacco-related disease;

- Consumers are fully and accurately *informed* of all the known likely, and potential consequences of using these products;

- Health and behavioral effects of using PREPS (potentially reduced exposure products) are *monitored* on a continuing basis;

- Basic, clinical, and epidemiological *research* is conducted to establish their potential for harm reduction for individuals and populations; and

- Harm reduction is implemented as a *component* of a comprehensive national tobacco control program that emphasizes abstinence-oriented prevention and treatment.

(Institute of Medicine, *Principal Recommendations*, Clearing the Smoke, page 7)

The legislation as passed in the 110th Congress neither encourages nor provides incentives for the development of these science- based (regulated) products.

Keeping the tobacco industry from misleading and deceiving the public about so-called 'reduced risk' products is essential, but making sure that the public understands the risks and relative risks of the spectrum of products on the market and 'encouraging' the development of truly science based lower risk products is equally important. Product innovation by tobacco and pharmaceutical companies in a regulated environment is something that should, as the IOM has suggested, be **'encouraged'** not discouraged. This was also the recommendation contained in the presidential commission report, **Tobacco at a Crossroad** (May 2001), comprised of public health organizations (including CTFK, ACS, AHA) and tobacco producers, and eventually supported by well over 100 other organizations.

As currently drafted, both the 'Findings' of the legislation and the statutory requirements of section 911 do not recognize or provide the ***balance*** that will keep unsafe products that make unsubstantiated claims off the market, while providing incentives and encouragement for the development of science based lower risk products that are shown to reduce risk. The requirements of the legislation raise the bar so high as to be a 'disincentive' for any researcher or company (especially new innovative companies) from working towards developing new alternative products. The Royal College of Physicians in commenting on HR 1108 and S 625 has noted that "…**there are concerns that the bar for reduced risk products entering the market is so high as to make it very difficult for the industry to introduce a reduce-risk product to the US market.** For example, claims of reduced risk would need to be proven at both the individual level and population level, and doing so would require comprehensive studies of non-smokers, ex-smokers, and smokers, of adults and children, carried out over several decades. This would be impossible in practice before bringing a product to market". (**Harm Reduction in Nicotine Addiction**, Royal College of Physicians 2007, page 182)

When the House Energy and Commerce Committee reported HR 1108 in early April (2008) the Committee rightly considered suggestions for improving the legislation in an number of areas but for some reason 'resisted' any legitimate discussions about how the 'reduced risk" section of the legislation (Section 911) could be improved or even clarified that would better reflect the recommendation of such respected entities as the Institute of Medicine and the Royal College of Physicians. Such important reports should not be ignored but should be used to assist in shaping policy decisions.

What follows are suggestions as to how the *Findings* and Section 911 could be modified to better reflect both the state of the science with respect to 'reduced risk products" and how best to regulate them in such a way that consumers are fully informed about the risks and relative of all tobacco and nicotine containing products.

I FINDINGS

Many of the "Findings" in the legislation as they relate to "reduced risk products" are warranted, especially given the tobacco industry's history, but they represent only half of what needs to be stated. Clearly no health claim statements should be allowed in an environment in which there is no FDA oversight and clearly there needs to be a clear scientific basis for allowing these products onto the market. But to provide a more balanced approach and one that better reflects the recommendations of a number of well respected public health authorities it is suggested that the following changes be incorporated into the Findings.

Modify the following Findings:

1. Finding # 36 by revising "It is essential that manufacturers prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria and will benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." to read:

It is essential that manufacturers prior to marketing such products be required to demonstrate that the products will meet a series of rigorous criteria and that there is a reasonable expectation that the product will benefit the populations a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Rationale: The way the *Finding* is currently written there must be a showing that the product **will** accomplish certain objectives prior to being introduced into the market. This might either be an impossibility or something that might take years to demonstrate. The far more *balanced* approached (and one that can be monitored through surveillance and reporting) and the one which is more consistent with the IOM recommendations is that **the manufacturers be required to show as part of the application process that there is a *reasonable expectation*** that the product will achieve certain results.

2. Finding # 40 by revising " The dangers of products sold or distributed as modified risk tobacco products that in fact do not reduce risk are so high that there is a compelling governmental interest in insuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product" to read:

There is a compelling governmental interest that the labeling, and marketing for all tobacco and nicotine products be complete, accurate, and truthful so that the public and users of such products fully understand the risks, relative risks and intended uses of such products.

Rationale: It is important that in giving consumers complete and accurate information about a modified risk product that they understand the risk in the context of how that product's risks compare to other products on the market (cigarettes, smokeless, nicotine replacement therapies, complete cessation of both tobacco and nicotine use etc. .)

Add: the following new Findings:

1. New Finding**: The Institute of Medicine in the landmark report, Clearing the Smoke concluded that harm reduction is a feasible and justifiable public health policy if it is implemented carefully.**

Rationale: It seems odd that in using references to the NCI and FTC in the modified risk Findings, the legislation does not even mention the most comprehensive review and recommendations contained in the Institute of Medicine Report, Clearing the Smoke. Recognizing some of the IOM's recommendations will provide a more appropriate *balance* to the findings currently contained in the legislation.

2. New Finding: **Many users of tobacco and nicotine products are currently unable to evaluate the spectrum of tobacco and nicotine products based on their risks and relatives- often believing that nicotine replacement therapies and noncombustible tobacco products are as dangerous or more dangerous than highly toxic cigarettes**.

Rationale: One of most important objectives of FDA oversight (and supported by the recommendations of the IOM) is to ensure that users of tobacco and nicotine products are provided full and complete information fully that will allow them to understand what tobacco and nicotine products are on the market and what the risks and relative risks of those products are. A number of studies have shown that there is a great deal of confusion and misunderstanding about the risk and relative risk of these products.

3. New Finding: **New technological advancements at both the agricultural level and at the manufacturing level are making it possible to reduce levels of known toxicants such as TSNA's, pesticides, and other chemicals that present risks to users of tobacco products.**

Rationale: The ability to develop science based modified risk product will depend on the evolving technological advances. It is now possible to significantly reduce many toxic substances in tobacco and tobacco products. Further developments such as the use of genetically modified tobacco will further allow the toxicity in products to be reduced.

4. New Finding: **While no tobacco product can be considered "safe" there are significant differences in risk between a growing spectrum of tobacco and nicotine**

products on the market. These products should be regulated, labeled, and marketed according to their risks and relative risks.

Rationale: In order for users of tobacco (and the general public) to fully understand the risks of tobacco and nicotine products on the market these products need to be regulated (labeling, marketing etc) based on their risks and relative risks and intended uses. (ie greater regulation on products such as cigarettes, less regulation on noncombustible tobacco products and even less regulation on nicotine based products).

II Modifications to Section 911 – Modified risk Tobacco Products

1. Revise section (d)6 , "data and information on how consumers use actually use the tobacco product ; and;" to read:

"data and information on how consumers are intended to use the tobacco product; and

Rationale: Because we are dealing with 'new' products or 'new uses' of products, it is impossible to provide information and data on 'actual use'. An evaluation of the product can be made on its "intended use" supplemented by information and data from both the applicant and other sources that will allow the Secretary to make an informed determination that the product will meet certain expectations. The surveillance provisions of the legislation will become critical in being able to monitor and evaluate if such expectations are being met.

2.. In subsection 9(g) of Section 911 revise subparagraph one ---"(1) MODIFIED RISK PRODUCTS.- Except as provided in paragraph (2), the Secretary shall approve an application for a modified risk tobacco product filed under this section only if the Secretary determines that the applicant has demonstrated that such product as it is 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 not currently use tobacco" to read as follows:

"(1) MODIFIED RISK PRODUCTS -- Except as provided in paragraph (2), the Secretary shall approve an application for a modified risk tobacco product filed under this section if the Secretary determines that based upon the scientific evidence there is a reasonable expectation that the product, as intended to be used by consumers, and based upon the totality of information provided to the Secretary by the applicant and other sources that ---

(A)The product will substantially reduce exposure to one or more tobacco toxicants in that such reduction would be sufficiently large that measurable reduction in morbidity and/or mortality (in subsequent clinical or epidemiological trials) would be anticipated as judged by independent scientific experts.
(B)If any reduced risk claims are made, that the product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects, as compared with whatever bench mark product the agency requires to be stated in the labeling.
(C)The labeling, advertising, and promotion of all tobacco related products with exposure reduction or reduced risk claims will be carefully regulated under a "not false or misleading" standard with the burden of proof on the manufacturer.
(D) consideration (as specified under paragraph (g)4) has been given to the effects that the availability and use of the product may have on the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

NOTE: Subparagraphs A), B) and C) are taken directly out of the *Regulatory Principles* contained in the Institute of Medicine's Clearing the Smoke (page 10)

Rationale: As noted in the above suggested changes to 9d)6, the Secretary is only allowed to approve an application for a modified risk product if the product as 'actually used' by a consumer meets certain objectives. Because we are dealing with new products, it is impossible to provide data on actual use. An evaluation of the product based on its 'intended use' coupled with the consideration of data submitted by the applicant as well as other sources, would make the approval of the application far more thorough while recognizing at the same time that there are some "unknowns" that can only be evaluated over time. Again the surveillance and reporting provisions of the legislation will be critical components in monitoring how these products may *actually* be used. The Institute of Medicine noted for example that "The effect on public health will depend upon the biological harm caused by these products and the individual and community behaviors with respect to their use. Regulation cannot assure that the availability of risk-reducing PREPs will lead to reduced tobacco related harm in the population as a whole. However, a regulatory agency can assure that data are gathered that would permit the population effects to be monitored. If tobacco use increases or tobacco-related disease increase, these data would serve as a basis for developing and implementing appropriate public health interventions" (page 6)

III Amend Paragraph g(4) – BENEFIT TO HEALTH OF INDIVIDUALS AND POPULATION AS A WHOLE by re-designating (E) as (G) and adding the following new (E) and (F):

(E) the risks and relative risk to individual users of the tobacco product that is the subject of the applications especially when compared to other categories and products on the market;

(F) 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.

IV Other Suggested Changes as They Relate to Modified Risk Products

Science Advisory Committee

Under Section 911(f) applications for an approval of a modified risk product will be submitted to the Science Advisory Committee for review and recommendations. Because of this it is important that the Science Advisory Committee represent and have the necessary expertise that will allow for careful consideration and deliberation of the application. We therefore suggest that the composition of the Committee be expanded (or modified) to include:

- One expert in agronomy and tobacco plant technology (voting)
- One expert in labeling, advertising and marketing (voting)
- One expert in harm reduction (nonvoting/advisory)

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The Alliance for Health Economic and Agriculture Development (AHEAD) is an informal organization whose purpose is **to educate, stimulate and facilitate and encourage discussions** with and between health advocates, growers, the scientific community, tobacco manufacturers, consumers, policy makers, pharmaceutical and biotech interests, and economists about a spectrum of issues related to the production, processing, manufacture, sale, distribution, labeling, marketing and use of tobacco and tobacco (and nicotine) products. The Alliance is an outgrowth of the Southern Tobacco Communities Project established in the mid-1990's through a grant from the Robert Wood Johnson Foundation that brought the public health community and growers 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**, May 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, background and discussion about issues pertaining to tobacco harm reduction and other issues, visit: www.tobaccoatacrossroads.com , or contact AHEAD at 202 686-8898