EXECUTIVE SUMMARY

Tobacco use, and in particular the use of combustible cigarettes, continues to cause over 400,000 premature deaths in the United States each year. Globally that figure jumps to 5 million deaths annually. We are indeed in the middle of an epidemic that requires not only expanding on what already works in tobacco control but which also requires consideration of new ideas and approaches (See IOM (Institute of Medicine) 2007. *Ending the tobacco problem: A blueprint for the nation.* Washington, DC: The National Academies Press.). Greater attention needs to be given to how we can reduce the harms caused by the current products on the market and to encourage the development of noncombustible *tobacco and nicotine products* that can be used as consumer acceptable science-based alternatives to the use of highly toxic cigarettes. This paper refers to these noncombustible forms of tobacco and nicotine as "smokefree" products – products which "are tobacco based or nicotine based and which are used or taken in a noncombustible form for recreational or therapeutic uses". We can no longer rely on the simplistic view that all tobacco products are equally harmful. There are significant differences in the risks and relative risks between many tobacco and nicotine products. Even the term smokeless tobacco has outlived its usefulness as a term for describing the many very diverse noncombustible tobacco-based products currently on the market or in the process of development.

There is an urgent need for transparent, in- depth discussion about how we can restructure the way in which we define and look at these products; how we can and should regulate them; and how we make available a wider range of products that are significantly lower in risk than the toxic cigarette. What many fail to realize is that it is not so much the 'tobacco' that is the major purveyor of harm but rather how the tobacco is produced, cured, processed, treated, manufactured and used (i.e. combusted or non combusted). A significant number of the smokeless products (both traditional and novel) currently on the market are as much as 90% plus lower in risk than cigarettes (some are considered potentially even lower in risk). Nicotine replacement therapies (from which the nicotine is derived from tobacco) are even lower in risk- so low as to be, according to many researchers, of only a slight risk. Some of the products, such as the nicotine replacement therapies that are the lowest in risk, are the most heavily regulated while the traditional and novel smokeless products are only moderately regulated. The highly toxic cigarette falls way short of how it should be regulated when compared to both smoke-free tobacco and nicotine products. The number and types of products that are on or expected to be on the market are diverse and there is a need to move towards a more coherent, rationale and more flexible tobacco and nicotine policy that will deal with a dynamically changing environment.

The purpose of this paper is to lay out a process by which we can not only discuss issues in a neutral, independent environment but that will allow for the development and suggestions of policy recommendations for both the public and private sectors. Failure to move forward with these important discussions is a disservice to the public health and to the millions of users of deadly cigarettes worldwide. A recent landmark report from the Royal College of Physicians put it this way:

> ***Harm reduction is a fundamental component of many aspects of medicine and, indeed, everyday life, yet for some reason effective harm reduction principles have not been applied to tobacco smoking. This report makes the case for radical reform of the way that nicotine products are regulated and used in society. The ideas we present are controversial, and challenge many current and entrenched views in medicine and public health. They also have the potential to save millions of lives. They deserve serious consideration.***

Issues needing to be addressed

Although many issues have been identified as important for the consideration in the discussion and implementation of harm reduction strategies there has been very little in the way of substantive and organized discussion on issues or the steps that need to be pursued towards implementation. A number of topics that come to mind when considering how best to consider the future role of smokefree products as part of harm reduction strategies include:

Science and Technology

What is the state of the science with respect to the risks and relative risks of the 'category' (smokefree tobacco and nicotine products) when compared with combustible cigarettes? What is the state of the science with respect to the risks and relative risk of the various products within the smokefree category? What kind of short term and long term research priorities should be set? How can cutting edge technologies be applied to the development of new products as well as reduce the risks of products currently on the market? Who should be doing the research and who should be funding it? How can the science and research be made more readily available?

Labeling

How should the spectrum of smokefree products be labeled so that consumers understand the risks and relative risks between not only categories of products (i.e. combustible versus smokefree) but also between specific products within the category? How can other models that are used in the food, pharmaceutical and dietary supplement industries be used in helping design labeling schemes that ensure that consumers are not misled about the risks and relative risks of products? Who (in addition to a governmental regulatory authority) should be involved in developing effective models and recommendations for how smokefree products should be labeled?

Standard Setting for Both Agriculture Production and Manufacturing

What kind of benchmarks and standards should be set for how tobacco is produced, cured, processed and marketed? What kind of benchmarks and standards should be set for how smokefree tobacco and nicotine products are manufactured? Who should be involved in discussions about how the standards in these areas might best be developed and implemented? What are the best governmental agencies suited to oversee and set regulations for the development of such standards?

Marketing and Promotion

What are the marketing and promotional restrictions (and allowances) that should be imposed on smokefree tobacco and nicotine products, especially when compared to the marketing and promotion restrictions that should be applied to cigarettes? What kinds of marketing and promotional allowances should be made for smokefree products that are considered the 'lowest' in risk? What is the experience for other products, such as in the food, pharmaceutical and dietary supplement industries?

Surveillance

How do we set up an effective and workable surveillance system that allows for the monitoring of how smokefree products (as well as all tobacco and nicotine products) are being marketed and used by consumers? Who should be involved in discussing how best to set up such a system and what governmental agencies would need to be involved?

Incentives

What kind of incentives can be provided to producers and manufacturers (broadly speaking) of both tobacco leaf and other tobacco and nicotine products that will encourage producers and manufacturers to move towards the development of the lower risk tobacco and smokefree tobacco and nicotine products?

Consumer Acceptability

How do we move towards encouraging (and allowing) the development of science -based smokefree products that will be consumer acceptable? Should there be standards and/or allowances for the use of flavorings for products that are low in risk (smokefree tobacco and nicotine products) as compared with products that are significantly higher in risk (i.e. cigarettes)?

The need for an integrated regulatory framework

There is now almost universal acceptance that the tobacco industry needs to be brought under a regulatory scheme such as that of the Food and Drug Administration. The question that needs to be considered is: What should that authority entail and what other agencies should be involved in other aspects of overseeing and regulating tobacco production and manufacturing? This paper suggests that all tobacco and nicotine products should be brought under the same regulatory umbrella (i.e.

establishment of a new Center for Tobacco and Nicotine at the Food and Drug Administration.) and that various categories (combustible, noncombustible, NRT) and the products within those categories be regulated based upon the risks and relative risks of those products. In addition to the FDA it is important that the USDA be actively involved in overseeing the production side. This includes monitoring where tobacco is grown, how it is produced and cured, as well as tested for quality, health and safety specifications. Other agencies that will need to be involved include the Centers for Disease Control, the Federal Trade Commission, and the National Institutes of Health. Better and more effective measures for ensuring greater coordination within the government should be complemented with better and more effective measures for actively working within the private sector.

The need for a process for openly discussing issues

There has been a tendency to over-rely on the legislative route (i.e. enactment of FDA legislation) as the primary mechanism by and through which we can effectively change the behaviors of the tobacco industry and the products they produce. There is no question that legislation to oversee the tobacco industry (through an agency like the Food and Drug Administration) is critical and long overdue. But it is equally important that there be 'engagement' and discussion of issues that can shape, guide and influence policy-related decisions both in the public and private sectors. While there have been limited efforts at engagement in the tobacco arena, where it has been used it has paid dividends and resulted not only in a better understanding of the complex issues and differing opinions involved but also in finding common ground that serves as a basis for substantive change. The experience and process that was used that brought the public health community and the tobacco producing communities together through the Southern Tobacco Communities Project is a case in point. The type of dialogue I am referring to is not one that is focused on 'negotiations' but rather that of a facilitator-based dialogue of experts and interests that focuses on issues rather than on crafting a piece of legislation.

A proposed Road Map for dealing with 'smokefree' tobacco and nicotine products

We have a unique opportunity to make a paradigm shift in how we deal with the growing diversification of tobacco and nicotine products in the market place, a shift that, as noted above, could save millions of lives. The question is no longer whether we need to be pursuing new avenues but rather how we move forward. Building on the past experiences where dialogue and discussion has occurred and been productive, this paper recommends the establishment of a Center for the Evaluation of Smokefree Tobacco and Nicotine Products. This Center would be independent and would focus on the discussion of substantive issues pertaining to how tobacco and smokefree tobacco and nicotine products should be produced, cured, processed, tested, distributed, labeled, and marketed. The Center would not be a place for 'negotiations', although its efforts would significantly influence negotiations in other venues. The Center would have the ability to hold conferences, meetings and round table discussions using independent facilitators and experts—thereby bringing the dialogue and debate to a civilized level free from rhetoric and personal and institutional bias. Using other models and experiences both within and outside the tobacco control movement, funding would be accepted from any legitimate entity. However, any contributions from any entity would be made with no strings attached and based upon a very detailed and rigid set of criteria. Funding contributions would not entitle any contributor to a seat at the table or give such contributor any role in determining or setting the Center's agenda.