# EXECUTIVE REVIEW AND SUMMARY

"Tobacco Harm Reduction" seems to be on the lips of everyone who is associated with tobacco, public health, industry, growers, biotech companies and consumers. Some think it's a good idea that holds promise for reducing disease and death caused by the use of tobacco. Others think it poses great risks. And still others retain an 'abstinence only' view. The goals of this paper are to lay out a series of issues that I believe must be considered as part of the harm reduction debate and dialogue if 'harm reduction' is to move forward; to stimulate discussion and to find potential new avenues towards achieving goals. Harm reduction is not as 'black and white' as many like to think it is. What is possible and what is not possible, what will work and what will not work will depend on how the various stakeholders and other experts choose to be involved or not be involved. This paper contains some essential elements that I suggest must be a part of any harm reduction efforts and discussions. These elements are intricately intertwined and overlapping and each cannot be dealt with in a vacuum. This paper attempts to provide some suggested guidance as well as recommendations for both a short and longer term process to deal with harm reduction. The rapidly changing tobacco environment demands new leadership from all of the stakeholders. It demands transparency to engage in meaningful dialogue when appropriate. We should be talking and considering **how** to move forward rather than hanging on to the past and finding reasons why nothing should be done.

## What is Tobacco Harm Reduction ?

We first have to more clearly define what we are talking about. Tobacco harm reduction, for the purposes of this paper, deals primary with *lowering risks* associated with tobacco and tobacco containing products both for the individual as well as for the population as a whole. It is not a substitute for other tobacco control efforts that are currently underway both here in the United States and globally but an important component of those strategies. However, unlike many of the other tobacco control strategies, it involves a broader spectrum of interests including the scientific community, the tobacco industry, the public health community, tobacco producers, biotech companies, agronomists, growers, and most importantly consumers of tobacco. Tobacco harm reduction involves 'meeting users of tobacco products where they are' and giving them options and guidance for taking control of their own health needs and goals, whether it involves total cessation of all tobacco and nicotine products or using products that may be substantially lower in risks.

## What is Tobacco and What Makes it Harmful?

Many people think that all tobacco products are equally harmful – something that is far from being an accurate statement. Many think that it's the nicotine that causes cancer. and that so-called light cigarettes are 'safer'. They are not. Some people think that a cigarette containing American blend tobacco is made from US tobacco. It is not always so. Many people believe that tobacco has no positive attributes. That is no longer a valid statement. Tobacco is grown and produced throughout the world and the leaf, quality and safety of the tobacco varies significantly. There are many different types of tobacco products some of which are smoked other's which are taken and used in noncombustible form (smokeless tobacco). Pesticides, chemicals, flavorings and other additives are applied to tobacco and tobacco products as are various types of filters, and other technologies. Curing techniques can affect the levels of toxicity in the tobacco plant. Genetic manipulation of tobacco holds promise for being able to reduce toxins in tobacco and to develop medicines and other products using the tobacco leaf. All of these things have the potential for both increasing and lowering the risks and relative risks of the tobacco and tobacco product. While we know much about tobacco there is a great deal more that we can and must learn if harm reduction strategies are to be successful. We cannot meet the needs of consumers or truly educate the public about the risks and relative risks of products under the current state of affairs. The current chaos must be replaced with an orderly discussion of the issues and the implementation of a process and system that will clearly provide us with meaningful information. Neither the tobacco industry, the public health community, nor even the pharmaceutical industry should be able to 'misuse' or distort science for the achievement of public policy objectives. Science should guide policy – not the other way around. If harm reduction is to be an effective viable strategy for reducing disease and death then we need to do much more in understanding both the tobacco and tobacco products currently on the market and those expected to be introduced into the market in the future.

## Issues, Players, Challenges and Opportunities

There is a strong tendency to look at harm reduction as a 'debate' between public health advocates and the tobacco industry. While it is convenient to frame it in such terms to perpetuate the view that this is a 'war' between good and evil, it is not. Serious and meaningful modification of tobacco and tobacco products will need to involve a number of other important stakeholders experts and disciplines. These include:

1. Science and Technology. First and foremost is the role of the scientific community from both within and outside the tobacco industry. Currently, in spite of the fact that some argue that the industry should fund and conduct scientific research, there is also a deep historic distrust of the industry's research as well as any attempts in their past to fund academic institutions and independent researchers. This divide must be bridged in a way that protects the integrity of science and the research community while at the same time 'forcing' the industry to the table to conduct and fund research in a responsible and accountable manner. We need to develop scientific research priorities and to find scientific answers rather than playing a protracted public relations game that leads no-where. Changes in science and technology will continue to provide new opportunities for understanding the tobacco plant as well as how tobacco causes harm. Uniform standards to assess and test tobacco products are urgently needed and must be developed in a way that involves both industry and non-industry scientists and academics. Industry research, research from academic institutions, pharmaceutical companies, and biotech companies must be shared and integrated.

2. Tobacco Agriculture. Tobacco agriculture and the role of tobacco producers must be recognized as playing an important part in the discussions, debates and outcomes related to tobacco harm reduction. Some of what determines the harm caused by tobacco can be addressed beginning at the production level. The removal of TSNA's, the use of pesticides and other chemicals on tobacco, the manner in which the plant is harvested and cured, all can effect and impact toxicity. Genetic research on both the tobacco seed and the tobacco plant hold potential promises for developing new forms of tobacco that could be potentially lower in risk and which could also be used in developing new medicines and industrial enzymes using the tobacco leaf. And there will undoubtedly be other technologies that will bring other positive changes on the production of the tobacco plant. Therefore, for harm reduction strategies to move forward, we will need to involve the grower community, agronomists and other scientific experts in the discussion process.

3. Competition and Incentives. Competition (coupled with 'incentives') is often ignored by the public health community as a way of challenging and changing the behaviors and products of the tobacco industry and others involved in the production of tobacco and tobacco products. Competition has the ability for the tobacco industry, biotech companies and other entrepreneurs to develop truly science-based products that can reduce risks. Giving incentives to companies, innovators, and even producers to expend research dollars in efforts for the development of new technologies and products can only have a positive impact on changing both the industry and the spectrum of products on the market. In addition, competition coupled with effective regulation can have a positive effect in driving out the 'bad actors' whose goals are to make profits even if it is at the expense of the public's health. This is not unlike the scenarios that the 'drug' and 'food' industries faced in the early part of the 20th century.

4. Consumers /Individual rights. While both the industry and public health talk about the importance of users/consumers of tobacco in their efforts, both seem to do little to really involve consumers or users of tobacco in their decision making. The industry's goal has been merely to 'sell' products that consumers will buy. The public health community generally takes the position that 'we know what's best for you and will tell you what we want you to know'. The issue of consumer and individual rights needs to be given a much higher priority in any discussions related to harm reduction–particularly in a democratic society. Because harm reduction involves attempting to meet the needs of consumers and users of tobacco products 'where they are', there is going to have to be far more attention paid to what consumers want, what can be made available to them, and how products and information are provided to them.

## Transparency, Accountability, Unintended Consequences

The last four (4) decades might best be described as a period of deep distrust- a period of perpetual 'war' between industry and the public health community. While this state of

war has done much to bring attention to the dismal history of the industry's activities, in today's environment the idea of 'war for the sake of war' may also be impeding opportunities. This may be the case for the area of harm reduction. The critical element, and one that cuts across the spectrum of issues raised in this paper is the need for real 'transparency' amongst all of the stakeholders and to find a way to engage that provides a 'safe haven for dialogue'.

1. Tobacco Manufacturers. Since the late 1950's the tobacco manufacturers have promised ad nausea that they would put the interests of public health above all other corporate interest. They did not and they have not. Industry documents have shown decades of deceit and cover-ups that have resulted in extensive litigation against them. They have used their economic and political influences to prevent enactment of meaningful and fair legislation by the US Congress that would have governed how they manufactured, sold, labeled and marketed their products. Today the environment is forcing changes on the 'tobacco industry': the industry is changing, innovators and biotech companies are coming to the forefront. The industry seems very divided in their views on the future. The question remains as to whether such change will really impact their behaviors or lead us down the path reminiscent of past deceptions. Are their efforts to promote and talk about Corporate Social Responsibility (CSR) real or are they, as they have been in the past, 'wolves in sheep's clothing'?. The industry's actions will determine if in fact they are really changing. While there are signs of it, they must be far more transparent and accountable in their activities and actions – especially when it comes to the development and marketing of new products.

2. The Public Health Community. While the tobacco industry has been the least transparent of any of the stakeholders and for a longer period of time, it concerns me that we are seeing similar traits in many of the other stakeholders, including the public health community. The rapidly changing tobacco environment is also forcing the public health community to deal with issues that can no longer be seen as black and white. Over the course of 25 years that I have been involved in tobacco, I have never seen as much infighting as has occurred over the last five years. There is more 'competition' for dollars; there is turf protection. Those who express views that are outside the 'norm' are chastised. Ideas and views should be encouraged and not suppressed. The public health community needs to be willing to lay its cards on the table and provide the transparency needed to understand why certain views and positions may be taken or not taken and who is funding who and what. While the tobacco industry is routinely and severely chastised for funding research or attempting to open up dialogues with other stakeholders, the pharmaceutical industry routinely and extensively funds and supports both research and the public health community. This may have positive effects but it must be transparent. In addition the notion that "we don't talk to the industry" is and has been a 'myth' for a some time. The time may be ripe to shine a little sunlight on these efforts and to more openly acknowledge that engagement with the industry has taken place.

3. The Pharmaceutical Industry. While the tobacco industry remains the primary focus in the development of harm reduction products, the pharmaceutical industry must also be considered in the scheme of discussions. They are an increasingly influential corporate power in the tobacco arena. The principles of 'transparency' should extend to the pharmaceutical industry just as rigorously as they are applied to the tobacco companies. Significant amounts of money from the pharmaceutical industry go to researchers and public health organizations. There have been concerns raised by many (both inside and outside the tobacco arena) that some researchers and public health organizations have become too dependent on pharmaceutical moneys that may affect decision making. The time may have arrived to take a closer look at all corporate influences in the tobacco arena and to try and ascertain what types of standards might be developed that apply to any and all corporate funding going into the tobacco control movement.

4. Policy Makers. The recent Washington/K street scandals involving influences of money and special interests are not isolated incidents but are indicative of a deeper set of concerns going to the very heart of our democratic system. For years, tobacco policy in the United States Congress has been held hostage to the interests of the tobacco industry and its allies. Few, if any, real substantive hearings have been held on tobacco in spite of the overwhelming impact that tobacco has on the health of the nation including expenditures for health care costs. If Congress is serious about cleaning house and reforming itself, and finding workable and meaningful solutions, it must hold a series of hearings to assess what changes are needed to reform this nation's antiquated tobacco policies. It needs to be willing to listen to legitimate views and recommendations, provide real leadership and move forward.

5. Unintended Consequences. Consideration of unintended consequences is an important exercise in decision making. This process is obviously not a perfect science because the environment can change and in turn alter the consequences and outcomes. If a decision is made to move forward it then becomes important are the consequences to determine how best to monitor outcomes, to minimize the unintended consequences and to consider possible safeguards and alternatives. Not only does one have to consider the consequences of taking an action, but equally important for not taking an action. Unfortunately, 'unintended consequences' has increasingly not been used as a means to move cautiously forward but rather for stymieing discussion and preventing any resolution on a subject. Today it seems that the use of 'unintended consequences' often has self-serving motivations. This trend, first begun and brilliantly executed by the tobacco industry and now used by others, is troubling in that it prevents transparency and reinforces the 'status quo'.

## The Relative Risk Reduction Continuum

In order for harm reduction to be implemented effectively, consumers of tobacco (and NRT products) will need to understand the risks and relative risks of products on the market. Currently consumers are confronted with a marketplace of chaos. Not all tobacco products carry 'equal harm' and as science and technology continues to develop there will be an ever increasing number of new tobacco and tobacco-containing products on the market. Much focus has been on deciding how and when to call a product a PREP (Potentially Reduced Exposure Product). I believe that we eventually need to move away from classifying products as PREPs and begin talking in terms of the *risks and relative risks* of products (both those currently on the market and new ones yet to be introduced). What might be a PREP today may be not be a PREP in five years and may become a product that carries relatively higher risks. There are significant health risk differences between combustible, noncombustible tobacco products, and nicotine replacement therapies (NRT). Within each of those categories there are products that carry differing levels of risks. A consumer of tobacco (and NRT) should be able to fully understand where the various products fall on the risk and relative risk continuum- to be able to recognize the differences between what is a 'cessation' product and one that is a harm-reducing product. To accomplish this effectively will (as noted below) require a governmental agency that can ensure a level playing field and also assist in the development and use of uniform testing methods for these products. Regulation of the various products should be commensurate with the 'risk profile' associated with the product. The higher the risk, the greater the regulatory oversight and restriction. In addition, it will be important that coordinated surveillance efforts be conducted involving government, industry, and public health, that can monitor how these products are being used and if there are any unintended consequences taking place so that adjustments can be made in the labeling and marketing of such products.

## Why Governmental Oversight of Tobacco and Tobacco Products is Necessary and Inevitable

In order for users of tobacco products ( and NRT products) to be able to ascertain where products fall on relative risk reduction continuum it will be essential that there be an independent third party that can evaluate all products and to, using uniform scientific standards, determine how such products should be labeled and marketed. There has been a growing recognition within, not only the public health community but in industry and with Wall Street analysts, that there needs to be an agency like the FDA that will provide a level playing field for overseeing the manufacture, labeling and marketing of tobacco products including newer products. It is ironic that such a system (while not perfect) is recognized as essential for other consumer products such as foods and drugs –a system that benefits consumers and public health and involves the participation of manufacturers. What is very clear is that we cannot and should not accept 'voluntary approaches' or 'self-regulation' as a way of achieving goals. Not only do voluntary approaches not serve public health but they also destabilize the tobacco production and manufacturing sectors. For many years there have been arguments made (mostly by industry) that oversight of tobacco products might be better dealt with by the Federal Trade Commission or the Centers for Disease Control and Prevention. While each of these agencies has a role to play, neither is suited to regulate the complexities of the tobacco product. There will however, need to be greater coordination with the FDA , including coordination with the FTC, EPA, ATF, NIH, CDC and even DHS. Most importantly, from the standpoint of harm reduction there will need to be coordination with the USDA, and agency that must regain its authorities to oversee the production, and inspection of both domestic and foreign tobacco. Without effective, meaningful but fair oversight we are doomed to repeat the mistakes of the past. The FDA is clearly the best suited and most logical agency for overseeing the tobacco industry and its manufactured products.

## Where Do We Go From Here?: An Independent Tobacco Policy Research Center

What has been clearly lacking over the years is a meaningful and civil way to, as Dr John Slade has said, engage in an 'orderly discussion' about issues related to harm reduction, as well as other tobacco related issues. The prospects for Congressional action on FDA oversight do not look promising for this year and even if Congress were to enact legislation today, it would be several years before we would see regulations issued. So what can be done? This paper suggests that there is a critical and crucial need for the establishment of a totally independent, transparent Tobacco Policy Research Center, that can begin and continue the work necessary to move forward with effective harm reduction discussions and strategies. The work that the Center undertakes could also be a catalyst in moving Congress forward with legislative objectives as well as assisting the FDA (and other agencies such as USDA) with its activities once the agency obtains jurisdiction. There are critical and important issues that must be discussed and dealt with and no existing organization, corporation, or other entity is up for the job. The process (while much more extensive and permanent) would be similar to the process used that brought the public health community and growers together and which eventually resulted in the release of a set of *Core Principles* and recommendations contained in the presidential commission report, Tobacco at a Crossroad.