"Do I not destroy my enemies
when I make them my friends?"
Abraham Lincoln

FOREWORD AND INTRODUCTION

For the last several years, the Alliance for Health Economic and Agriculture Development (AHEAD)* has worked diligently to encourage open, transparent and civil dialogue among the tobacco control community, the scientific community, tobacco producers, policy makers, tobacco and nicotine manufacturers, consumers and other experts. Reversing decades of mistrust and animosity has not been and is not easily accomplished. AHEAD has produced a number of white papers that have been distributed and read by a broad spectrum of interests both in the United States and abroad. It has testified before Congress calling for a more open process for consideration of tobacco legislation as well as for comprehensive oversight hearings. It has made specific suggestions to improve legislative proposals in Congress including legislation to give FDA authority to oversee and regulate the tobacco industry and its products, and it has encouraged stakeholders, Members of Congress of both parties and from tobacco and non-tobacco states, to work cooperatively.

Years of entrenchment and polarizing tactics by various special interests and their inability to step back and consider how issues might be more civilly approached has made what we are suggesting that much more difficult to achieve. Yet when it comes to discussing the feasibility of incorporating harm reduction as a part of our efforts to reduce disease and death from tobacco, the time may be right for "change."

In 2006, I wrote an extensive paper entitled, **Tobacco and Tobacco Products at a Crossroads in the 21st Century--- Seeking Civil Solutions in an Uncivil Environment**.** It wasn't a typical tobacco control paper. The purpose of the paper was designed to look at number of key elements that needed to be considered if the debate on tobacco harm reduction, regulation of the industry and other issues was to move forward and what kind of a process might be used to achieve those goals and objectives. It meant looking at and considering issues and constituencies that are often if not always overlooked and ignored by the tobacco control community and the industry. It meant *partially* discarding the antagonistic, polarizing 'warfare' of the 1980's and 1990's and putting in place a process that was more workable, transparent and subject to accountability --- something that needed to be applied to all stakeholders and interests. Changing decades of entrenchment by interest groups, whether they be Big Tobacco or the mainstream or not- so- mainstream tobacco control community is not easy. There is not only a great deal of monetary power and clout involved but also emotional, competitive, and egotistical factors that make for a mix of factors that are not easily altered.

Amongst some of the elements I raised that needed to be considered were:

- What is tobacco and what makes tobacco harmful?
- Who and what are the issues, players, challenges and opportunities?
- How do we ensure transparency and accountability and avoid unintended consequences?
- How do we better understand the risks and relative risks between the various tobacco (and other nicotine) products on the market?
- Why oversight of tobacco and the tobacco industry is both necessary and inevitable.
- Where do we go from here? A process for future engagement.

Given the severe economic crisis that is not only gripping this country but the rest of the world as well, I want to add to that list the necessity of at least taking into ***consideration*** the economic impact that policy decisions could have on many individuals and businesses who unfortunately find themselves connected (directly or indirectly) in some way with the tobacco industry. Many associated directly or indirectly with the tobacco industry, like so many others in industries such as, Wall Street, the auto industry, and the banking industry etc. find themselves in the middle of a situation over which they have little control and which can be significantly disruptive to themselves, their families, and communities. It makes it even more important that we at least talk about solutions that can minimize these risks and effects but at the same time without compromising public health objectives. At a minimum we need to consider making these people a part of the solution for change rather than seeing them as a part of the problem.

For the last several years I and an increasing number of others have come to believe that like many other pressing issues confronting this nation (and the world), we have to *partially* tone down the "tobacco wars" as we know them and begin structuring ways by which we could move the public health agenda forward through a more rational and civil dialogue. The 'toning down' should be *selective*, as in the case of discussing tobacco and nicotine product innovation and development. And it is essential that an independent neutral body be involved. I am, therefore, not suggesting that the tobacco control community let up its criticism on the industry when such criticism is justly deserved. I am suggesting that when we have complex issues such as harm reduction that we manage the issues through a much more independent and civil dialogue and process in order to find answers.

In the second paper, **"Smokefree" Tobacco and Nicotine Products- Reducing the Risks of Tobacco Related Disease: A Constructive and Practical "Road Map" Towards a Civil Dialogue to Influence Public and Private Sector Policy Decisions **,** I suggested that rather than trying to bite off more than we could chew that we should begin by focusing efforts to initiate a dialogue on what has come to be referred to as "smokefree" tobacco and nicotine products. Although a contentious area where there are many differing opinions and concerns, there are also areas of agreement from which to generate a substantive dialogue.

In that paper I focused on:

- What are 'smokefree' products and why they could be helpful as part of a public health strategy;
- Issues for discussion, including: Science and Technology, Labeling, Marketing, Production and manufacturing standards, Consumer acceptability, Surveillance, and Incentives for change;
- The need for an integrated regulatory framework;
- The need for a process for openly discussing and debating issues;
- A proposed "Road Map" for change (The establishment of an independent Center for the Evaluation of *Smokefree* Tobacco and Nicotine Products and Policy).

In this, what might be considered the 'third part' of my discussion on harm reduction and the changing tobacco and nicotine environment, I sought the views of a spectrum of individuals through the use of a survey/questionnaire. After completing the above two papers, a number of people asked me "what's next, how can and how do we move forward?" When that question started coming from such a broad spectrum of people, I decided that the next step would be to get some of their views and ideas. I sent the questionnaire out to approximately 70 people all of whom had either expressed an interest and/or support for harm reduction and dialogue or who had experience in areas such as conflict resolution, fund raising, research etc. The list included individuals who work in the tobacco arena and those who do not. Eliciting some fresh insights was important. Questionnaire recipients included not just those in the US but a number of people from abroad as well.

At the suggestion of several people (prior to sending the questionnaire out) I decided that each person would be assigned a number (rather than using names) so that their views could be revealed in and with the confidence that what they might say would not be broadcast. It is very unfortunate that there continues to be intimidation on the part of some that discourages and in some cases prevents people from expressing their views. I also decided that I would not formally publish the results but rather use the answers and comments to help shape a plan on how we could move forward. There will be some who will say they didn't receive the questionnaire and who will attempt to both ridicule and downplay it. Those individuals are often the ones who lack transparency and a willingness to listen or learn from the differing views of others. They represent exactly what this exercise is not about.

The idea of employing *harm reduction* strategies for reducing the disease and death caused by the use of tobacco in various forms, and the process by which people can have a dialogue to discuss contentious issues are not mine but have been germinated and generated from a number of people and sources. One such source (and one with a successful outcome) was the Southern Tobacco Communities Project that is discussed and detailed in my earlier white papers. The ideas and concepts of harm reduction are also not unique to tobacco. *Harm reduction* plays an important role in our every day lives, whether in the food, pharmaceutical, auto safety, drug, or environmental arenas to

give just a few examples. The role that tobacco harm reduction can play in reducing disease and death deserves serious consideration and discussion. It demands an abandonment of the rhetoric and polarizing efforts that plague our ability to move forward. We have to get beyond knee-jerk reactions of 'unintended consequences' every-time something is proposed and suggested. If we as a society took that position on everything we face, we would have made little progress as a nation.

Tobacco is also in many ways a 'microcosm' of what is wrong with how Washington has done business in the past. It is adversarial and polarizing, it is dominated by special interests, it lacks transparency, it lacks a process by and through which controversial issues can be discussed and debated in an open and civil environment.

Many organizations have become so institutionalized, so introverted, so bureaucratic, so polarizing, and so adversarial that they have partially lost their focus and their ability to think ***creatively*** and 'outside the box'. One international control expert described this mentality as "it's either my way or no way." What is it that prevents us from considering doing things differently? Is it the need to have power and control? Is it the need to be seen as the only route for negotiating or talking with adversaries? Is it an effort to preserve an organization's funding and a purpose of 'raison d'etre'? Probably a little of all of these. *Change* is something that is difficult in all walks of life. Resistance to 'change' is often both internal and external in nature—a resistance to reorienting or changing an organization's internal agenda as well as an inability to reorient to a changing world outside that organization.

As this paper is being written we are also witnessing long over due debates and discussions about saving Wall Street, the pros and cons of protecting the auto industry. In some ways both are suffering because they and those who needed to be involved did not want to deal with the reality of the underlying issues as well as with inevitable 'change'. The tobacco industry is not the tobacco industry of the past and with that come challenges and opportunities. Does 'Big Tobacco' have the ability to be able to change and put themselves on a road where the products they manufacture, market and sell are regulated, modified or even phased out? Should we be looking to drive the Big Tobacco companies, who won't change, out of the market place and replacing them with companies (that are more pharmaceutical like) that are more transparent, accountable and focused on developing science based products that are significantly lower in risk? Will the tobacco control advocates recognize that this is not the 1990's any more and that many of the approaches that served us well in the past may today result in their loss of power and influence? Are we going to see new leadership and risk- taking that reflects changes in the tobacco and nicotine arena, or will we see efforts to preserve the 'status quo' and resist and deny opportunities for 'change'?

A Comment on the FDA Legislation

Just after the November 2008 presidential election, I emailed a large number people a very short commentary on what I thought the election and the commitment to 'change' in Washington would and should have on the FDA/tobacco legislation. I indicated that consideration of that legislation could serve as a test case example—an example that would call for the expeditious enactment of that the legislation, but more importantly would have the Congress and the Administration commit to an open, transparent, and inclusive process and that would reflect the kind of 'change' that Americans are yearning for from their government. It seems that the message of using the FDA/tobacco issue as a means to help set the tone for the 111th Congress was picked up but the Campaign for Tobacco Free Kids as well as papers like the Washington Post (editorial, January 2, 2009).

Without harping on it, the process by which the FDA legislation (which I have actively supported my entire professional life) was introduced and considered in the last Congress (as well as those before) represents the exact 'undemocratic process' by and through which discussions of the legislation should not have taken place. It represents and reflects the old school of politics in Washington- one that President-elect Obama has committed to changing. An outdated bill was (re) introduced as a pre-made deal. Hearings in both the Senate and House were for the most part pro forma. Efforts to gain co- sponsorship were given high priority to demonstrate that the legislation was uniformly supported even though many who supported the general concept of FDA regulation were unfamiliar with the details of the legislation. What was and has been selectively ignored were the specifics of the legislation. It really doesn't (and shouldn't) take much anymore to convince Members (especially in an election year as occurred in the 110th Congress) that "Big Bad Tobacco" needed to be regulated. That is and was a 'no-brainer'. Work on FDA tobacco regulation has been on the agenda of the public health community for more than 20 years !!!! This is something that very few (including most in industry) would now disagree with. **BUT……**

Important issues deserving of discussion were intentionally and selectively left off the table. Decision-making was reserved to a few individuals. Many who had views and might be directly or indirectly impacted were selectively excluded from the hearings and discussions. Even the FDA, the entity that would have to implement the statutory requirements, never appeared at the hearings. You can't bring people to the center, find common ground, or improve legislation when the process is one of exclusion and alienation. When suggestions to improve the legislation including the accuracy and clarity of language were made, the answer on most occasions was "you will get nothing unless you endorse the legislation". This kind approach in a democratic society must change.

Let's clear the slate and do this right this time. Let's step back and look at the legislation, have an open process of discussion and craft something that actually might work more effectively and fairly. The current form of the legislation is 150 pages long and I have found no one who has said that the legislation is 'perfect', including some of its most

ardent supporters. Let's make policy decisions based on facts and a spirit of cooperation to achieve defined **goals** rather than having such decisions concentrated in the hands of a few. With respect to the specific area of harm reduction a topic of great importance to public health, hearings in the new 111th Congress should include:

- Consideration of the best and most effective structure for overseeing the regulation of tobacco and nicotine products in a more consistent way--- one that actually benefits the public and the consumer and provides them consistent and reliable information about the risks and relative risks of all tobacco and nicotine products.
- Looking at technological advances and opportunities that have the potential for significantly lowering the risks of tobacco use and will improve health.
- Evaluating and understanding the risks and relative risks of all tobacco and nicotine products, and how these products should be differentially labeled and marketed.
- Questioning the tobacco industry on what they are doing to develop and use technologies to significantly lower the risks of products on the market, including consideration of removing the higher toxic products from the market place altogether.
- Understanding how tobacco agriculture (where pesticides, nitrosamines and other toxins can be addressed) needs to be incorporated into a regulatory structure and scheme that oversees the manufactured product.
- Understanding how FDA would work more closely with other agencies in the federal government such as USDA, FTC, CDC, NIH, DHS, ATF etc.
- Understanding what incentives might be given to manufacturers of tobacco and nicotine products (IOM recommendations) that will move them away from the manufacture of the highly toxic products and into producing products that are *scientifically* established as lower in risk and regulated.

We **can** create an open process by and through which important and legitimate issues can be discussed, not just as it pertains to Congress and legislation, <u>but in the private sector as well</u>. A commitment by the incoming Administration and a commitment by leadership in the House and Senate to **real change** presents a unique opportunity to employ these new approaches and processes that can not only shape legislation and policy but regulation as well. It can help set new directions for how the private sector can and should interact. It can be a stimulus for changing the tobacco industry in substantive and fundamental ways not only in the United States but globally as well. It can be a mechanism by and through which the public health community can also change – abandoning some its ways of the past and replacing them with mechanisms by which we can find and implement solutions more efficiently and effectively, with less polarization and with less animosity.

*****The Alliance for Health Economic and Agriculture Development (AHEAD) was established in order to educate, stimulate and facilitate discussions and dialogue between public health advocates, growers, the scientific community, tobacco manufacturers, consumers, policy makers, economists, pharmaceutical and biotech interests 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 that brought the public health community and tobacco producers together to discuss the tobacco issue in a civil and safe environment.

****** Tobacco and Tobacco Products at a Crossroads in the 21st Century- Promoting Civil Dialogue in an Uncivil Environment, and "SMOKEFREE" TOBACCO AND NICOTINE PRODUCTS – A Constructive and Practical "Road Map" Towards a Civil Dialogue To Influence Public and Private Sector Policy Decisions, can be found at: www.tobaccoatacrossroads.com