"At first people refuse to believe that a strange new thing can be done, then they begin to hope it can be done—then it is done and all the world wonders why it was not done centuries ago."
"A Secret Garden", Frances Hodgson Burnett

III Moving Forward – Creating a Safe Environment for Discussion and Dialogue

In researching and writing the two earlier white papers I made it a point to read, listen and learn as much as I could about the pros and cons of harm reduction strategies. I concluded that it was so not much whether harm reduction needed to be discussed, debated and considered but more importantly **if and how** it could be incorporated into the tobacco control agenda in a way that did not allow the tobacco industry to manipulate or control the outcomes. Dean Kenneth Warner noted in an article appearing in the New York Times Sunday Magazine in June, 2005:

> On the one hand the optimists say, we're on the verge of the era of these low-risk products. On the other, the pessimist says we're on the verge of another light cigarette fiasco. But the thing is, nobody knows. It's the most complicated thing I've ever encountered in 30 years of working on tobacco policy. It's the single most difficult issue in terms of trying to predict where it will go or where it can go.

Even many of those who raise (and have raised) questions about harm reduction as a tobacco control strategy often do so from the stand point of concerns about the unintended consequences.

After posturing and dancing around the issue for almost ten years, I believe the time has arrived to have some transparent and civil discussions about the subject, discussions that are driven by facts, challenges and opportunities and not by rhetoric. I say, to answer Ken Warner, "Let's find out !"

I keep coming back to the Institute of Medicine's landmark report, **Clearing the Smoke,** that stated that ***"harm reduction is a feasible and justifiable public health policy if it is implemented carefully".*** The report noted that the following objectives should be given high priority:

- Manufacturers 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 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.

In writing the two earlier papers, I strove to identify and pull together the various elements that needed to be considered with respect to **how** harm reduction issues could be discussed, evaluated, implemented, and monitored. I relied on the practical experience that I had in participating in a process and dialogue conducted through the Southern Tobacco Communities Project, a project funded by the Robert Wood Johnson Foundation that had brought public health advocates and tobacco producers together. That dialogue gave me a sense of both the challenges but more importantly the opportunities that can emerge from such a civilly constructed engagement.

In both papers it was suggested that stakeholders needed to 'get out of their silos' and look at the realities of the tobacco nicotine environment and to consider additional options and avenues for reducing the disease and death caused by the use of tobacco..

In this most recent stage, I have sought the input of a spectrum of people who for diverse reasons have indicated an interest in harm reduction and finding a way to pursue a long over due dialogue. I wanted their views on the practicality of moving forward and I got them!

This effort has not been about finding definitive answers about a host of complex issues pertaining to tobacco and nicotine harm reduction but rather about <u>establishing a process</u> to confront those issues and where dialogue can take place in a safe haven. Nor, as I have said repeatedly, should harm reduction be seen as a substitute to other tobacco control efforts currently being employed. It is as some have described it, the fourth pillar of tobacco control.

What follows are my recommendations about moving forward.

<u>Conclusions</u>

The overriding conclusion is that there is a need for an <u>independent</u> center/ forum (for the evaluation of tobacco and nicotine products and policies) where there can be a facilitated civil and transparent dialogue about a spectrum of complex overlapping issues. <u>Dialogue works</u> and though it may not resolve or solve all problems its does create new avenues for possibilities and understanding. Dialogue provides us with the opportunity to:

- Engage and enter into discussions 'outside the beltway' that focuses on substance rather than the politics of Capitol Hill.

It provides:

- A neutral forum and safe haven for discussing medical, scientific, social, economic, ethical, agricultural and technological issues surrounding the manufacture, sale, distribution, labeling and marketing of tobacco, tobacco and nicotine products.

- An opportunity for participants to "listen and learn" and to challenge, clarify and confirm positions and views.

- A forum to identify and provide new ideas and recommendations for removing barriers to change as well as more importantly identifying opportunities.

- An opportunity for finding common ground and to develop principles that can shape both short term and long term policy reforms and establish a more permanent and independent process through which engagement can continue.

The questionnaire/ survey clearly demonstrated that when people are provided the opportunity to express their views they can do so *constructively* and that others can benefit from their views even when disagreements and differences of opinion exist. While I approached this as a "don't ask don't tell' endeavor, it only confirmed for me what could be achieved through dialogue and discussion in a neutral and safe haven. There was no vindictiveness or hidden agendas in the answers and comments that were given and it was clear that for many filling out the questionnaire/survey actually stimulated new thinking. No individual has all the answers and no individual can get their way. But individually and collectively those who responded were extremely helpful in shaping ideas and concepts about how to move forward. They reaffirmed that some of the 'short term' and 'long term' answers and solutions will have to be worked out as part of the on going process. It would have been interesting to see how all those responding to the questionnaire would have 'engaged' in a session where they were talking face- to-face in a facilitated dialogue. Hopefully such face-to-face encounters are just around the corner.

Building on the two earlier white papers and the results of the survey the following are my additional conclusions and recommendations.

- The Center/ Forum must be and remain ***independent*** at all costs. It should be a 'safe haven' for all participants where egos and organizational hats can be checked at the door and where no 'interest' controls the agenda. It cannot be a membership organization nor should it be operated under or through the control of an organization or interest that would serve to benefit from the Center/Forum's work.

- The Center/Forum could be private sector based, university based, or even quasi governmental based so long as its independence is maintained, defended and protected. One suggestion is to have either a private based or university based entity complimented by the establishment of a quasi-government center (office) within the Food and Drug Administration. Such parallel complimentary public/private structures would enhance the dialogue even further, give parties better access to the FDA and more effectively assist the regulatory body in carrying out its responsibilities. There are numerous existing organizations and universities that have the capabilities for taking this effort on. Several that I have come across include Search for Common Ground, the conflict resolution center at George Mason University, the Institute for Environmental Negotiation (which was involved in the Southern Tobacco Communities Project) and Resolve. Obviously there many others as well as other models to consider.

- The mission of the Center/Forum should be something along the following lines of: ***To serve as an independent convener and facilitator of stakeholders, experts and other appropriate interests for discussing and making science-based policy recommendations for tobacco and nicotine strategies designed to reduced disease and death caused by the use of tobacco.***

- The Center/Forum must have the *flexibility* to be able to deal with a spectrum of issues, challenges, and opportunities as they arise. While the issue of "smokefree" noncombustible tobacco and nicotine should be a priority, the Center / Forum should be willing and able to discuss other issues as well and to not limit itself. Understanding the broader issues will enhance the ability of the Center/Forum to more effectively carry out its mission.

- The Center/Forum's Board should be composed of persons of the highest integrity and willing and able to guide the Center, setting its course and in maintaining its independence. Board members could be a combination of those that have worked directly on the tobacco issue as well as those who are recognized for other professional skills and expertise (i.e. conflict resolution and mediation, management, venture capitalists, ethics, etc.) A certain percentage (such as 1/3) of the Board could be required to have public health and/or scientific backgrounds and expertise. While it is important t to try and avoid 'conflicts of interest' it may (or may not) be difficult to find people of the right caliber who aren't some how involved directly in tobacco. I would say however, that in looking at the suggestions of names (that I have chosen not to divulge) provided by the survey respondents it could be possible to find such people. A 'search team' could be convened to identify people and set parameters for Board membership (with the proviso that no one on the search team could be considered).

- The Center/ Forum should have the authority and ability to convene conferences, debates, and roundtable discussions in carrying out its stated mission. It should employ the use of independent facilitators and moderators when necessary in order to maintain its independence and maintain its integrity.

- The Center/Forum should not function as a 'lobbying' organization (defined in the strict sense of the word) although it must be able to engage and serve to actively educate and make recommendations to stakeholders and policy makers in order to shape, guide and influence policy decisions. Thus meeting with policy makers, testifying before Governmental Committees etc. would be appropriate functions.

- While initially focusing on the United States, the Center/ Forum must also be cognizant of the international aspects of its work and efforts and to make that work product available to international NGO's, international organizations such as the World Health Organization, the World Bank , the UN as well as other international governmental policy makers etc. The Center/Forum's involvement in global tobacco initiatives could have a significant and potential impact on how tobacco and nicotine are products and policies are developed and implemented.

- The Center/Forum should identify a list of issues (such as those suggested in the questionnaire/survey and which were generally accepted) that need addressing but it should set priorities through its Board, Executive staff and other structures. It should have the ability and flexibility to adjust its priorities as needed. The Center/Forum could also consider any recommendations and suggestions from interested parties, stakeholders and experts.

- The Center/Forum should be able to tap into experts and other interested parties and stakeholders who might enhance and influence outcomes related to the Center's mission. This could include experts in the areas as toxicology and pharmacology, agronomy and plant technology, labeling and marketing, surveillance, corporate ethics, illicit trade, economics, and governmental regulation (ie. FDA, USDA, EPA, FTC, CDC etc.)

- The Center/Forum's efforts should rely on and use *fact- based and science- based* information as a core element for its discussions, dialogues and in the development recommendations.

- Funding for the Center/Forum must be as unrestricted and as 'hands off' as possible. Initially, funding should come from organizations, entities and individuals that are not directly associated with the tobacco industry. While many of respondents in the survey indcated that it *might be* acceptable for the Center/Forum to receive corporate and even tobacco company money they also felt strongly that it must be done with *extreme caution*. Decisions on how corporate contributions could be accepted could be given to the Center's Board to establish the criteria and parameters for the acceptance of such funds once the Center/Forum is up and running. A transparent discussion on how (or even if such funding) funding could or should be received should be an open one. Models and

experiences from other organizations that do mediation and dialogues and who accept corporate funding could be useful.

- Funding and contributions should not 'entitle' any funder to any special privileges, such as a seat at the table or the right to influence decision making in any way. Any 'special projects' should be carefully reviewed by the Center/Forum Board and Executive staff in order to ensure that there is no conflict of interest and that such a project meets the goals and objectives of the Center/Forum. All decision –making on special projects that receive funding for a particular source should be transparent and subject to scrutiny by outside sources.