CHAPTER VI

A ROADMAP FOR DIALOGUE AND DISCUSSION OF SMOKE-FREE TOBACCO AND NICOTINE ISSUES

"At first people refuse to believe that a strange new thing can be done, then they begin to hope it can be done, then they see 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*

In the last chapter of the August 2006 paper "Tobacco and Tobacco Products at a Crossroads in the 21st Century", I outlined what I believed might be the next steps for establishing a process and structure for stakeholders and other experts to engage in dialogue and debate about a range of issues surrounding tobacco and tobacco products. I suggested the formation of a Tobacco Policy Research Center either to be free standing or as part of an academic institution, and I laid out the criteria and parameters under which such a Center should function. I maintain that in the long run such a Center is going to be essential and that we should continue to work towards the establishment of such an entity that will provide some stability and focus to the ongoing chaos and adversarial approaches that have dominated the tobacco environment.

In the meantime, there are opportunities for convening experts and stakeholders in a more narrowly focused area not unlike what was done between the public health community and tobacco growers almost 15 years ago as part of the Southern Tobacco Communities Project. I have provided both a rational and a set of specific topics that should be considered in starting discussions related to smokefree tobacco and nicotine products. What will be addressed in this last chapter will be the nuts and bolts of how to move forward with this effort even in the face of opposition and resistance from many.

Organizing stakeholders and other experts to sit down and discuss issues in a neutral safe setting is not new or unique to tobacco. Parties often come to such discussions with great trepidation and an initial unwillingness to address or talk about issues and problems in an open way. Yet, if done correctly and with the expertise of facilitators, it is possible to sweep away biases and preconceived positions and get to the heart of an issue. Resolution or agreement is not always possible but dialogue can often open up new avenues of discussion and result in new approaches to dealing with complex and controversial issues.

It has now been well over 10 years since tobacco producers and public health advocates first sat down to begin a dialogue about whether there might be any common ground between the interests of the tobacco producing communities and the public health community. Both sides were wary of each others' motives and objectives, and it was only through engagement through the auspices of a neutral third party that much common ground and understanding was found and achieved. It is time that we apply such an approach to an area where there are both hopes and fears and see what may be possible and feasible in finding common ground and understanding about the possible role that smokefree tobacco and nicotine products might play in reducing the incidence of disease and death caused by tobacco use and in particular cigarettes.

Center for the Evaluation of Smokefree Tobacco and Nicotine Products

What I am proposing is the establishment of an independent Center that would have as its mandate the creation of a process by which in-depth discussion and even debate could take place in a safe and neutral environment on issues related to the potential role that smokefree tobacco and nicotine products can play as part of a harm reduction strategy – replacing rhetoric and public relations efforts with substantive discussions between and with experts. Such a Center would not be used for "negotiations"; although it might be used in instances where further negotiations might take place on issues that have been discussed within the Center mandate. The Center would be a "think tank" on these issues – its work being used by a range of interests, including the public health community, researchers, policymakers, growers, industry (broadly speaking), etc. The Center would in some ways serve in a role not unlike that of the Iraq Study Group, performing objective

evaluations, doing fact finding, meeting with a spectrum of interests, fostering dialogue, etc. The Center would have the authorities to:

- Convene hearings, meetings, conferences and round table discussions on a variety of issues
- Foster open debates and discussions
- Issue reports, recommendations and guidance related to the goals and objective of the Center
- Establish expert advisory panels
- Interface with federal agencies such as Congress, FDA, FTC, EPA, USDA, etc.
- Interface with state and local governmental agencies
- Interface and partner with academic institutions
- Interface with private sector entities including NGOs, corporations, etc.
- Provide oversight and guidance on issues related to corpo rate accountability and transparency
- Use trained facilitators and other outside experts to assist

in carry out the Center's mandate

Among other things the Center would:

- Monitor and evaluate scientific studies related to the development, manufacture, distribution, marketing and use of smokefree tobacco and nicotine products
- Make recommendations for further scientific studies
- Compile a listing of all smokefree tobacco and nicotine products in both the U.S. and abroad.
- Provide recommendations for establishing standardized testing methods, benchmarks, etc., for all smokefree tobacco and nicotine products
- Assist in the development of ideas for how smokefree tobacco and nicotine products should be labeled and marketed
- Provide a neutral forum for the presentation of information related to the production, processing, manufacture, sale, distribution, labeling and marketing of smokefree tobacco and nicotine products
- Support efforts (not through direct lobbying activities) for policy changes that ensure that all tobacco and nicotine products fall under the same regulatory umbrella so that the labeling, advertising and marketing of such products is based on the risks and relative risks of such products
- Develop recommendations and methods for surveillance (including pre-marketing and post-marketing surveillance) for smokefree tobacco and nicotine products and in particular how such products are used
- Make recommendations concerning the best methods for the labeling, advertising and marketing of smokefree tobacco and nicotine products to ensure that the public and users of such products understand the risks and relatives of such products, especially when compared to using cigarettes or quitting tobacco and nicotine use altogether
- Review advertising and marketing practices of tobacco and nicotine manufacturers to determine if such advertising and marketing is misleading or deceptive and to recommend advertising and marketing parameters (consistent with the First Amendment) for such products
- Make recommendations concerning good manufacturing practices (GMPs) for the manufacture of smokefree tobacco and nicotine products
- Make recommendations concerning agricultural production practices for the growing, curing, processing and testing of tobacco used in smokefree tobacco and nicotine products
- Make recommendations on how agricultural production can be restructured and "incentivized" to assist growers (and manufacturers) in producing standardized and tested raw leaf for use in smokefree tobacco and nicotine products
- Make recommendations on how tobacco, pharmaceutical, biotech and other manufacturers can be incentivized to develop science-based smokefree tobacco and nicotine products that are significantly lower in risk than cigarettes and are consumer acceptable
- Make recommendations concerning public education campaigns designed to ensure that the public and users of tobacco and nicotine products fully understand the risks and relative risks of those products.

The Center should be composed of a Board of Directors which is recognized in various fields related to science and technology, public health, agriculture, harm reduction, business, conflict resolution, etc. No member of the Board should serve on the Board as a representative of any corporation, public health organization or entity that has a vested interest in the outcomes of the Center's work. The Center will not be a membership organization but will remain independent and serve

to represent a process for debate and dialogue and making recommendations and providing guidance on issues concerning smokefree tobacco and nicotine products. In addition, the Center would seek to retain the necessary staff and funding to carry out is mandate.

Funding

The Center must remain independent, transparent and objective. The issue of funding, therefore, is of critical importance. In particular, the questions arise about how and even if corporate money can or should be accepted. I take the position that it is feasible to develop a funding mechanism that will allow the Center to obtain funding from a variety of sources. But there needs to be strict parameters, guidelines, rules and conditions established.

It is well known that there are divisions within public health community as to whether any institution or individual should accept "tobacco money". Many people will always take the position that under no circumstances should any money be taken no matter what the parameters or conditions are. Others believe that tobacco industry money must be made available but only under conditions which ensure no involvement or control over the money by the industry itself. I have provided a more thorough discussion of some of these issues in Tobacco and *Tobacco Products at a Crossroads in the 21st Century,* Chapter IX.

What I would like to do here is suggest that we consider the parameters under which funding could be received by the Center to ensure the retention of complete transparency and independence. While the issue of tobacco industry funding is controversial, the parameters for funding of the Center must also equally apply to other foundations, other corporate interests (such as the pharmaceutical industry), tobacco cooperatives, biotech interests, nonprofit public health organizations, academic institutions, and individuals.

- First, funding should and could be accepted from any of the above entities (and others).

- Second, funding must be made as unrestricted contributions.

- Third, there must be no intention or effort on the part of the funder to try to influence the Center's setting of its goals, objectives or priorities. Any funder who attempts to influence the Center in this area should have its funding returned immediately.

- Fourth, funding cannot be earmarked for a specific topic or project at the request of the funder. Those decisions must be made by the Center through its Board, Executive Director, Staff, and/or independent advisors.

- Fifth, funding cannot be used a means to gain access to or as an entitlement for participation in the Center's activities. Participation in roundtable discussions, meetings, etc. is a decision that must remain the prerogative of the Center.

- If possible, funding should go into an account or trust in which all funding is co-mingled and becomes an unrestricted account available to the Center to carry out its mandate.

As many know, the American Legacy Foundation was established and is being funded primarily with "tobacco money" as part of the Master Settlement Agreement (MSA). The Foundation has been able to function quite well and with legitimacy even though most of its close to one billion dollars is tobacco industry money. Many of ALF's grant recipients are known for having very strong positions against taking tobacco money but have reconciled that position with the manner in which the foundation has obtained it funds and provides those grants.

Side Note: In addition to the language specifying that the tobacco industry has no say on how the money to be used, I found that some of the language used in the Master Settlement Agreement (Title VI- Establishment of a National Foundation) is extremely useful in helping identify how the Center could be structured.

A World Health Organization study group on tobacco product regulation noted in a recent report that:

> *It is essential that adequate funding is secured in order to establish and maintain laboratories that conduct the independent and credible research and testing for tobacco product regulation. There is little question that simply*

establishing the capacity for developing performance standards and objective tests could cost a few million US dollars each, in addition to the several million US dollars that would be required to cover start-up costs. But this cost represents an insignificant fraction of the value of the global tobacco market, which is estimated to be in the region US $ 300-400 billion. However in absolute terms the cost of developing laboratory capacity and operations represents a significant financial commitment which is not likely to be readily undertaken by individual nations. It may therefore become essential that tobacco companies be required to finance laboratory capacity and testing. (Emphasis added.)

There are many challenges to establishing a funding strategy. For example, in developing approaches for obtaining and distributing funds from the tobacco industry, account needs to be taken of the risk of financing laboratories with funds from industry could compromise the transparency, independence and integrity of those laboratories, especially if the expertise developed by the tobacco industry were needed to establish such laboratories.

(*WHO Study Group on Tobacco Product Regulation*: Guiding Principles for the Development of Tobacco Product Research and Testing Capacity and Proposed Protocols *for the Initiation of Tobacco Product Testing, page 6)*

I am also aware of a number of university-based academics and researchers who are highly respected in their fields who have made decisions to accept tobacco industry funding but only under conditions in which the companies have no control or influence.
Therefore, I believe that what is being suggested for the Center can be accomplished, particularly if it is being done with great transparency and under rules, parameters and guidelines that are both clear and enforceable. Will it satisfy criticism from everyone? Probably not.

We must also remember (despite the tobacco industry's disreputable image) that some of the same concerns about funding would apply to the pharmaceutical industry, the oil and gas industry, the food industry and many others who often fund projects or enter into partnerships expecting "returns" on their "contributions". Organizations working in some of these other areas may be able to provide important guidance in how to best craft rules, regulations and parameters for receiving private sector funding for the smokefree tobacco and nicotine Center.

Other Activities and Avenues To Enhance Dialogue and Transparency on Important Tobacco Issues

In addition to the establishment of the Center for the Evaluation of Smokefree Tobacco and Nicotine Products, there are other avenues that can be pursued that will complement the activities of the Center (as well as FDA oversight of tobacco and nicotine products) that will promote and stimulate discussions.

1. "Smokefree" Tobacco and Nicotine Companies

For decades, the tobacco companies have been perceived and viewed as "secretive", not only to the public at large but among themselves. Yet I sense a potential for change. If managed in a truly transparent manner, a new process could force some segments of the industry more into the open and give them an avenue to seriously demonstrate their ability to change their behaviors. This is partially the result of the Master Settlement Agreement (MSA); the continued and aggressive pursuit of the industry by the tobacco control community; changes in science and technology; the entry into the market of new competitors willing to do things differently; and increased competition not only between tobacco companies but with pharmaceutical and biotech companies. For those smokefree companies that have a serious interest and will make a serious commitment to changing the way they manufacture, label, market and distribute their products domestically and globally, they may want to consider the following:

- First, commit to the establishment of fair but effective regulatory oversight of their products by an agency like the Food and Drug Administration that will oversee the manner in which tobacco and nicotine products are manufactured, distributed, sold, labeled and marketed.

- Second, commit to fair but effective oversight of tobacco agriculture production, including the monitoring, tracking and testing of all tobacco leaf in the U.S. and abroad. Accept that the leaf used in manufactured products (both tobacco and nicotine based products) would need to meet specific standards for quality, health and safety.

- Third, commit to developing a mission statement with core goals and objectives that recognize the development and responsible marketing of smokefree products as key elements for reducing disease and death caused by tobacco (in particular cigarettes).

- Fourth, establish an independent advisory group that evaluates and reviews substantive recommendations from outside interests and sources (i.e., public health, growers, consumers, etc.) and that makes recommendations to the corporation for consideration as the corporation establishes its goals and objectives.

- Fifth, consider (as has been suggested by Phil Hilts in his book, *Protecting America's Health, the FDA, Business and One Hundred Years of Regulation*) putting public health and consumer representation on the Board of Directors.

- Sixth, establish serious, meaningful, measurable and enforceable corporate social responsibility goals and objectives that can be evaluated by independent entities; these would not be used for public relations purposes to undercut public health goals or to give the public the perception of a level of unjustified credibility.

Note: While the above suggestions are focused primarily on the tobacco companies, the pharmaceutical companies might want to consider similar actions.

2. The Scientific, Public Health and Tobacco Control Communities

There will always be a segment of the public health and tobacco control communities that will decide that there should be no engagement or discussion with what they view as the "enemy". In a previous section, I noted that deciding who the so-called "enemy" is no longer is a black and white issue, and that we need to start thinking more in terms of the who, what, why, where and how such engagement might take place. I also noted that discussion with the industry has been going on directly and indirectly for many years and the time might be appropriate to become more transparent about those "engagements" – whether it's with traditional Big Tobacco companies, newer visionary companies, pharmaceutical companies or biotech companies. For those in the scientific, public health and tobacco control communities (and without lessening any other tobacco control efforts), I would suggest consideration of the following:

- First, recognize that there are a range of tobacco and nicotine products (all tobacco-based or derived from tobacco) that present varying degrees of risk and relative risk, some of significant magnitude.

- Second, commit to objectively separating out issues related to science and technology from public advocacy and public relations efforts (not an easy thing to do as science is often used and often misused to advocate a policy position).

- Third, broaden the focus of the tobacco control environment to include the making of better and more thorough efforts to understand agricultural and agronomy issues; changes in science and technology; the consideration of incentives to be given to manufacturers (tobacco, pharmaceutical, biotech, etc.) to develop and eventually market lower risk products; and the tapping of experts from outside the traditional tobacco control community to assist in finding new and creative solutions for dealing with tobacco and nicotine issues.

- Fourth, recognize that confrontational, adversarial approaches to dealing with tobacco are not the sole, or in some cases, the most effective or efficient ways of obtaining significant and meaningful change in product modification.

- Fifth, recognize that in the tobacco control, public health and scientific communities there are diverse opinions on what strategies should be undertaken to most effectively (but also realistically) deal with the harm caused by tobacco products.

3. Tobacco Cooperatives

For many years, the tobacco cooperatives played the primary role of representing the interests of tobacco growers. Following the tobacco "buyout", the tobacco cooperatives are in a process of reassessing the roles they will play in the post-buyout environment. This process, like much of the rest of the tobacco

environment, is one of constant change, uncertainties and opportunities. There are several things that the cooperatives might want to consider that will serve their interests in the domestic and global arenas:

- First, they might consider establishing core business goals and objectives that clearly recognize the issue of public health and a commitment to producing tobacco that meets quality and health and safety standards.

- Second, they may want to actively advocate, support and assist in the establishment of a system that will monitor, track and test the production of tobacco in the U.S. (as well as advocating the testing of all foreign tobacco).

- Third, they may want to consider forming a U.S. Tobacco Growers Association that would represent their broader interest at the state, national and international levels. This would not be a substitute for the continuation of the cooperatives as separate entities but would rather enhance U.S. growers' abilities to shape policy decisions domestically and globally. Issues related to public health and the development of lower-risk tobacco leaf and products would be an important component of a national organization and the individual cooperatives.

- Fourth, they may want to be more active in supporting (and shaping) policies that would allow the FDA to regulate tobacco products and recognize that oversight of tobacco products should be the norm at the international level as well.

- Fifth, they might want to consider reconstituting their Boards or establishing advisory committees that would include a number of experts in areas such as agronomy, marketing, toxicology, genetics, public health, etc. An advisory group would serve as a means of making ongoing recommendations on how the cooperatives might better meet business goals, taking into account the dynamically changing tobacco environment.

4. The Role of Tobacco Commissions/ Foundations etc.

As part of the Master Settlement Agreement (MSA), many states established commissions and foundations and other entities designed to deal with not only the public health concerns associated with tobacco but also with respect to dealing with a changing culture of tobacco production and manufacture. As we look to the future and in consideration of the objectives of this paper, we need to consider how those commissions and foundations can participate and play a role – both in terms of funding and leadership. These entities could provided an important role in helping to fund research and training that will be necessary for accomplishing many of the goals and objectives noted in this paper. Some these commissions and foundations include:

- The Virginia Tobacco Indemnification and Community Revi talization Commission
- The Golden Leaf Foundation
- The Kentucky Agriculture Development Fund

Greater Dialogue, Discussion, and Debate at Tobacco Control, Scientific Conferences and Meetings

To date, there has been a lack of cross-fertilization in dialogue and debate on the part of various stakeholders at numerous meetings and conferences where important issues are being presented and discussed. The notion that "we don't talk to the industry" has in many ways outlived its usefulness, except as a public relations tool. While many wish to deny it, the dialogue, debate and engagement with industry has been occurring both directly and indirectly at some levels for many years. The public health community is constantly sending message to the tobacco industry in the form of press releases, statements to the press, testimony and in journal articles telling the industry what they should and should not do. This type of "dialogue" at a distance might be a safe way of talking with the industry, but it may also be losing its effectiveness as many in the media and the public at large often respond with, "Okay, I already know all that, what next?" One reporter who

has followed the FDA issue for years told me that it is becoming increasingly difficult to justify writing stories because not much has really changed.

I have been asking the question "what is and who is the tobacco industry?" Are we talking about traditional players of Big Tobacco such as Philip Morris and Reynolds American? Are we talking about tobacco growers, distributors wholesalers, and even convenience stores and other outlets that sell tobacco? Are we talking about technology and biotech companies who are doing research on tobacco? Are we talking about pharmaceutical companies who are in the nicotine business and whose nicotine is derived from tobacco? Do we include researchers who are independent or a part of an academic institution doing important work but who accept independent grants from tobacco, biotech companies and even pharmaceutical companies? My view is that all of the above constitute a part of what we should consider the tobacco and nicotine business.

As I mentioned in the foreword of this paper, we are in desperate need of a major paradigm shift and need to redefine what it is we are talking about, and what our goals and objectives should be. We need to realize that goals and objectives may be varied depending on what the issue is and who is involved. In a presentation I made at the tobacco and health world conference in 2006, I suggested that we might want to consider the "who, what, why, when and how" we talk to or engage with the tobacco industry, rather than flatly saying "we never talk to them".

As we ask the question "who is the tobacco industry" and seek to redefine it, and as we seek to refine the conditions by which we might engage, we also have to ask ourselves who is the public health and tobacco control community? Is it a role reserved to the CTFK and its partners? Or does it include other researchers, scientists, and public health entities at the international, federal, state and local levels? Who is qualified to be part of the discussions and who is not? And who makes the decisions to exclude certain players from taking part in those discussions? I believe that there are multiple roles and levels where dialogue and discussion can, should and must take place. It should not be a top-down dictatorial system. A scientist who is working on important research should be able to engage in discussion with an industry scientist without having to incur criticism from those who see themselves as the self-appointed gatekeepers of tobacco control. Those who oppose engagement or subscribe to engagement only on their terms should be careful not to criticize or condemn those who believe that there are important and viable alternative routes that should be explored or considered. This is not an either/or scenario and for those who truly and sincerely believe in exploring viable well-intentioned options, they should be able to do so in an environment free of personal attacks.

I believe that the tobacco control community and the scientific research community would be better served if it took the time to attend some of the tobacco research meetings and to carefully listen to and gather information about the industry. Years ago, at the suggestion of my colleague and friend Dr. Slade, I went to one of the tobacco science meetings with great fear and trepidation. But I must say that it was extremely enlightening to listen and learn. On that first occasion, for example, I heard extensive information about the prospects for the development of GMO tobacco for not only developing potentially lower-risk products but also for developing new medicines and industrial enzymes. The Society for Research on Nicotine and Tobacco (SRNT) meetings, the Tobacco Research Science Conference (TRSC) and the national tobacco control conferences are meetings where there might be some interesting but carefully controlled debates and discussions. If Congress can hold hearings and bring in the industry to question them and ask tough questions, why should we be so reluctant to do so in the private sector? Government sponsored meetings may also be a place where topics can be debated and discussed in an open and transparent fashion, not unlike what has been done in the food and pharmaceutical arenas.

Next Steps

So how can we proceed with further discussions about the establishment of the Center and how do we begin to determine the specifics of how the Center should be structured, funded and operated? Here is what I propose happen:

1. Through the auspices of the Alliance on Health Economic and Agriculture Development (AHEAD), which grew out of the Southern Tobacco Communities Project, establish a working group of 6-10 individuals who:

- Have demonstrated a sincere commitment towards the development of new strategies and policies related to the use of noncombustible tobacco and nicotine products for purposes of reducing risks associated with the use of

highly toxic combustible cigarettes.
- Have expertise in establishing independent entities and organizations including how such entities should be funded.
- Have expertise in conflict resolution and facilitation practices.

Members of the AHEAD Steering Committee would serve as *ex officio* members.

2. Task this group, working off the suggestions contained in this paper, to do a situation analysis and to map out a detailed work plan that includes the Center's structure and functions, goals and objectives, funding, etc.

3. Use the findings and recommendations of this group to then begin to actually move to establish the Center.