

*Within the context of wrenching and rapid social changes that today's societies are undergoing, can the voices of reason and maturity prevail against the extreme oversimplification and polarizations that have characterized so many of the largely ineffectual approaches for treating drug problems and other risk behaviors? Is our society secure and mature enough to allow for shades of gray that reflect the reality of how to approach individual, collective, and policy recommendations for the 21<sup>st</sup> Century and beyond?*

D. Abrahms, PhD, D. Lewis, from the introduction of  
Harm Reduction: Pragmatic Strategies for Managing  
High Risk Behaviors, G. Alan Marlett, 1998

## Establishing an Open, Transparent and Civil Dialogue On Tobacco and Nicotine Products and Policies

### Refining Ideas and Views for the Establishment of An Independent Center/ Forum for the Evaluation of Tobacco and Nicotine Products and Policies

### New Thinking and Ideas in an era of “Societal Change”

## Part III

Events are overtaking *the orderly discussion* of harm reduction for tobacco in the range of novel products and marketing strategies that anticipate new emphasis on less toxic products. These products and marketing approaches are coming years in advance of any possible regulatory structure.

John Slade, MD (May 2001)

## **ABOUT THE AUTHOR**

Scott D. Ballin has spent close to 30 years involved in issues related to tobacco and public health. He has worked on a spectrum of issues ranging from labeling reforms on cigarettes and smokeless tobacco products, FDA regulation of tobacco, excise tax increases, clean indoor air laws, and tobacco agriculture reforms. For more than 10 years he served as the American Heart Association's Vice President and Legislative Counsel, a Steering Committee Member and two-time Chairman of the Coalition on Smoking OR Health (AHA,ACS,ALA) which was the first truly active national coalition in the tobacco control movement. He has provided advice and consulting services to the American Lung Association, the Campaign for Tobacco Free Kids and Star Scientific, Inc. Most recently he has served and continues to serve on the Steering Committee of the Alliance for Health Economic and Agriculture Development (AHEAD), an informal organization formed to bring parties together to work for the enactment of the Presidential Commission Report, Tobacco at a Crossroad. He remains a strong advocate for bringing parties and experts together in neutral forums, for having open and transparent dialogues, and for finding common ground.

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## **Acknowledgement and Dedication**

This paper is dedicated to all of those who have had the courage to listen and learn and to provide thoughtful suggestions and ideas for meaningful 'change' often in the face of adversity and criticism.

*“ Politics like science, depends on our ability to persuade each other of common aims based on a common reality. Moreover, politics, unlike science involves compromise, the art of the possible.”*

Barack Obama, The Audacity of Hope

## **TABLE OF CONTENTS**

I. Foreword and Introduction

II. Evaluation of ideas and views concerning the establishment of an independent Center for the Evaluation of Smokefree Tobacco and Nicotine Products and Policies

III. Moving Forward - Creating a Safe Environment for Discussion and Dialogue

IV. Miscellaneous quotes and statements

*“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 21<sup>st</sup> 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 111<sup>th</sup> 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 110<sup>th</sup> 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 111<sup>th</sup> 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, but in the private sector as well. 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 21<sup>st</sup> 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](http://www.tobaccoatacrossroads.com)

## **II Evaluation of ideas and views concerning the establishment of an independent Center for the Evaluation of Smokefree Tobacco and Nicotine Products and Policies**

In an effort to gain ideas and views from a spectrum of people and interests about the possibility and feasibility of establishing an independent **Center for the Evaluation of Smokefree Tobacco and Nicotine Products and Policies**, I developed a questionnaire that was sent to approximately 70 people. As of this writing, more than 60% of those contacted have responded. All of the people contacted had an interest and some level of support for the idea of harm reduction being incorporated into tobacco control strategies or had other expertise such as conflict resolution and mediation expertise, actual experience in being involved in similar types of dialogues, or had some knowledge of issues related to fund raising (particularly related to corporate fund raising).

The survey was not intended and is not being formally published but rather is being used as a resource for moving (or not moving) us one step closer to making such an independent safe haven a reality. The survey participants were asked to provide their personal views based on their own experiences. Each person was assigned a number rather than having to disclose their names. This was something that was suggested by several people who wanted to express their views but some of whom were concerned about ‘fallout’, criticism or even alienation by their colleagues. I want to say up front that I was both surprised and pleased by the extent to which a large number of those responding took the time to provide their thoughtful ideas and views. The honesty with which the answers and comments were made was refreshing, appreciated, and informative. In many ways the survey represents and is indicative of what can happen when people are given an avenue to express their views and ideas in a safe environment - exactly what the Center is intended to provide!

The questionnaire was broken down into 4 sections: General Questions; Issues; Structure and Duties; and Funding.

What follows are the various questions that were asked and some general discussion about the answers and thoughts provided.

### **Section I – General Questions**

**Question 1. Do you believe that there is a need to have broader, transparent, multifaceted and more in-depth discussions about the role that smokefree tobacco and nicotine could play in reducing disease by the use of highly toxic combustible products?**

### General findings and observations:

All of the respondents indicated support for having such a dialogue. Clearly people recognize the important role that such dialogue can play.

### Respondent Comments:

- Easy to say, difficult to achieve. This discussion would require that commentators at both ends of the spectrum tone down the rhetoric and make their arguments based on science, not emotions or attacks and sarcasm.
- Such discussions are long overdue and essential to the credibility of the tobacco control community.
- We also need more honesty in any discussions. We also need to overcome some of the mainstream dogma if we are to succeed.
- PAST TIME !!!
- This is essential because 1) there is alarming levels of ignorance regarding the difference between smoke and nicotine and 2) millions of people are dying because harm reduction policies, strategies and products have not been given recognition and place it deserves in global public health & tobacco control. I prefer another term than 'Center' because this implies more of a think tank institution. Perhaps consideration should be given of the term 'Forum' which is politically softer and provides greater flexibility of engagement and action.
- These discussions must occur in every newspaper and other media, at every tobacco conference, health conference and in meetings of government funded health agencies.
- Public health seems to have moved on to obesity, yet this is a really important set of issues.
- We need to get out of a circle whereby people are attacked for wanting to open a dialogue and to support scientific studies on these products.
- Given the tenacity of nicotine addiction, it only seems fair to recognize that absolutist abolitionist policies are unworkable and abusive to people who are suffering from the use of cigarettes.
- Absolutely imperative even though it includes industry participation.
- Perhaps not an absolute "need" in the strictest sense-as these products are far from a panacea and cannot undo the harms (or appeal) of combustibles—But certainly a "benefit" to more open dialogue.

**Question 2. This survey advocates the establishment of a truly independent Center where issues related to smokefree tobacco and nicotine can be discussed in a *neutral and safe haven*. Do you think the establishment of such a Center (if done carefully) is a good idea?**

### General findings and assessment:

All of the respondents indicated support for the concept of a center or forum. But in this question a larger number of people began to ask probing questions and make suggestions about how to avoid pitfalls, deal with or remove barriers etc.

### Respondent comments:

- Currently there is no ‘safe ground’ to discuss the issues outlined in question 1. The more it is discussed the better. The “center” can only be of help, can’t see it being a hindrance to public health goals.
- It can’t be worse than the ‘status quo’, but creating an independent center won’t resolve these problems unless harm reduction opponents are willing to engage in discussions.
- Of late the tobacco control agenda has switched to more of an anti-corporate slant than an anti-health impact. A non-political neutral environment is key.
- Am concerned that if not handled properly it is possible that the Center will become ‘territorial’ and want to own the topic.
- There must be a platform where all stakeholders can convene in an open and nonjudgmental atmosphere.
- It’s not a good idea, it’s a great idea!! It would be a landmark event.
- Provides a forum for objective review and recommendations.
- I would especially like to see unbiased research done with respect to American consumers so that we better know their attitudes, beliefs and likely reaction to these products.
- Makes sense to concentrate resources (ever scarce) and research in such a Center—perhaps it would be prudent to have a national center then several regional satellite centers- thereby preserving a local favor, kind of like the Fed. Reserve system.
- In principle, I agree. In practice, it will be a significant challenge to est. a center that, say 90% of the tobacco control community (however defined) could accept as objective.
- Needs to be open/credible/ reported in peer-reviewed journals.

**Question 3. If you believe that such a Center merits consideration, should the Center be a private based entity with its own governing structure, or should it be part of a university, or even a quasi-governmental entity?**

General findings and assessment:

Approximately a third (33%) of the respondents suggested that the Center should be university based. Another third (33%) said that they believed the Center should be private based. One sixth of the respondents said that they supported a quasi –governmental entity and one sixth indicated they were comfortable with all three options.

Respondent Comments:

- A university setting would ensure credibility and objectivity.
- Needs credibility of academia.
- I would hope that if it were private-based it would be less susceptible to political (in all senses of the word) influence.
- I strongly feel that University or quasi-governmental carries some baggage.
- The Center should be privately based with its own governing structure to avoid inherent biases of academic and quasi-governmental entities already active in the tobacco and health debate.
- What seems appropriate is a university center with support from private, government funding and research support from NIH.
- A government agency is the best place for oversight. However, an external center mandated and funded by government would be useful. The definition of independent would mean excluding those entities who profit from the sale of nicotine products.
- It needs to have appropriate safeguards but could be possible at any of these three.
- I think it could be any of three but private would be best.
- Whilst it might need private funding it would be more advisable if it was seen as truly independent of private commercial interests.
- The key will be a Center that at least 90% of TC community would accept as objective. Quasi-governmental most often has that sense of objectivity.
- Should be a private based which operates transparently.
- I believe that the only way for research outcomes to have credibility is if it is at least quasi-governmental.
- All of the above. Ultimately it's up to government to act, however it would be useful to have a quasi-governmental entity whose role it would be to collect up relevant information to share with government regulators. The agency would not be constrained by politics and could question actions (or lack of action) taken by regulators
- I don't think it matters as long as the entity meets the criteria in question 2 (independent center where issues can be discussed in a neutral and safe haven).
- At first I thought anything but private based. But housed at a foundation or stand alone may in fact be best.

**Question 4. Which of the following would represent the most accurate and best “mission statement” for the Center? If you wish to make your own suggestions for a “mission statement” please do so in the space provided (D).**

- A. \_\_\_ To discuss, develop and provide science-based recommendations and guidance with respect to the production, manufacture, sale, distribution, labeling and marketing of *smokefree* tobacco and nicotine products.**

- B. \_\_\_\_ To serve as an independent convener and facilitator of stakeholders, experts and other appropriate interests for discussing and making recommendations for *smokefree* tobacco and nicotine strategies designed to reduce disease and death caused by the use of tobacco.**
- C. \_\_\_\_ To provide a ‘safe haven’ and neutral forum for a civil discussion, debate, and dialogue of public health strategies and goals related to the production, manufacture, sale, distribution, labeling and marketing of *smokefree* tobacco and nicotine products.**
- D. \_\_\_\_ -----

General findings and assessment: Respondents favored (B), but only by a small margin (40%), followed closely by both (A) with 30% and (C) with 20%. About 10% of the respondents wrote their own suggestions often combining various aspects of (A), (B), and (C). In a number of instances, respondents added changes to the “mission statement” they favored (see below). Several people indicated that the words “strategies designed to reduce disease and death” in recommendation (B) were important no matter what the “mission statement”. Several who favored (B) also suggested including the words ‘science and policy’.

#### Respondent Comments:

- All of the above or a combination of them works for me.
- Some combination of the three...To provide a neutral forum to discuss, develop and provide science-based recommendations and guidance...to serve as an independent convener and facilitator ...etc.
- B & C are similar. A combination of A and B/C; self initiating and serving as “host”. I would also include in the scope, consideration of all tobacco products since core objective is reduction of death and disease from tobacco use.
- I think that parts of all three should be included with (A) as main focus.
- ‘A’ is simple, clear and inclusive but think that would be useful to have this message (reduce disease and death caused by the use of tobacco) in the mission statement.
- What is really needed is funded organization dedicated to informing the public about the relative/comparable risks of different tobacco products...health organizations and governmental agencies should not mislead the public. That way these discussions will be forced to occur in the news media and in many other public forums.
- All three appear to be intrinsic to the mission with some stating how recommendations would be achieved and/or delivered to a wider audience; others stating what would result from the work.

- If the ‘reduction of tobacco-caused disease and death’ is not part of the mission statement it is a non-starter---this is the purpose after all !!
- I think that it could be useful having all three of these but emphasis should be on objective assessment of the science base as opposed to the wishful thinking displayed by many anti-tobacco groups. Option (A) however would probably need more headcount and thus more funding.
- The “mission statement” should be a combination of B+C---option A is too passive in my view and option C by itself is too “neutral”.
- Seems to me that a national center ought to embrace all three of the above.... with a web of affiliated regional centers. The above three items would unfold as directed by the national effort.
- I like B but would add “science based, objective” following the word ‘making’ in line 2.
- Add ‘science and policy’ after the word ‘discussing’ (mission statement (B), line 2)

**Question 5. It is being suggested that one of the roles of the Center would be to shape and influence policy and regulatory decisions (such as with Congress, agencies like the FDA, USDA, CDC, NIH, FTC, EPA etc). In addition to providing guidance to these and other agencies, do you think the Center should take on a proactive lobbying role?**

General findings and assessment: A majority of the respondents felt that the Center should not take on a proactive lobbying role (60%) while 40% said that it should be proactive. A number of the comments however indicated that even though they opposed having the Center being proactive in lobbying they did support it serving in an educational capacity with policy makers in helping shape and make policy decisions.

Respondent Comments:

- Lobbying activities should be open and transparent and open to public scrutiny.
- No. It must be one thing or the other e.g. research and policy or lobbying. I suggest research and policy.
- No. Lobbying is not consistent with “neutral forum” concept.
- Lobbying should not be permitted if the entity is funded via the government or is non-profit as it should be.
- No. It should function as a scientific base of excellence.



- Not lobbying per se but provide information to policy makers.
- Yes. Provided the mission statement stays true. To the extent resources can bear, policy change should be sought.
- No. I believe it needs to be a facilitator of fact-based research and science and convey its findings to the groups listed.
- No. It is better I think that the entity be independent of politics. Of course it would hopefully influence politics by producing good info, etc.
- No. That is something that should evolve, after the value and objectivity of the Center is established.
- Center should certainly share its views, recommendations whenever public policy relating to tobacco use is at issue. That doesn't mean that it has to emulate the often counter-productive partisan warfare carried on by some.
- Yes. However, the Center should anticipate that other stakeholders may decline to participate in the Center as a result.
- No. I guess an independent Center can't be too proactive or pushy.
- Yes. Dream ticket would be accredited observer on WHO/FCTC. Lobbying should be educational rather than political. The lack of understanding of lawmakers of tobacco issues continues to amaze me.
- No. If it is truly going to be a neutral haven what would it lobby for. Lobbying suggests partisanship – let others do this.
- Yes and No. Only as an expert witness that reaches out to legislators and government personnel by distributing results from its work, inviting government to meetings, but not in sense of hiring lobbyists to make something happen on the hill e.g., tradeoffs on legislation etc. which is best left to stakeholders.
- Yes. The only way to effectively counter opponents of harm reduction is to proactively lobby for reasonable and responsible harm reduction policies.
- Yes...Maybe. Proactive advocacy role needs to be able to influence but not get co-opted.
- No. Especially at the beginning, a lobbying role would cause divisions, while the body of content/ evidence has not been fully established yet.
- Yes. Solutions kept in a vacuum are not solutions.
- Yes. The Center should influence policy related to those items/issues that there exists consensus among the Center participants.
- No. Remain neutral...disseminate the facts and facilitate discussion.
- No. Would support it issuing scholarly reports. Conducting seminars with policy makers—not lobby the specific laws. Add a global role related to WHO/ FCTC.

**Question 6. Given that tobacco is not only a domestic (US) issue but a global one as well, do you think the Center should also consider guidance to other nations, NGO's, and the World Health Organization?**

General findings and observations: A clear majority (85%) of the respondents favored including providing recommendations, guidance etc to other nations, the WHO, NGO's etc.? Even where some opposed the idea they did so with the qualification that the Center needed to be focused on the US first with the possibility of expanding activities at a later date.

Respondent Comments:

- Yes, but focus on US though.
- Yes, critical to include international context.
- No. Perhaps eventually but there are significant cultural, economic issues across the world that should not be the focus of the group based in the US.
- No. A global view yes, but no guidance!
- No. Not at first.
- No. Eventually but not initially.
- Yes. We are in a "world-wide" business.
- Yes!!! Of course. Although the local interpretations, regulations + products (e.g. Swedish snus) are important, the global framework is of paramount importance in a flat world.
- Yes. Tobacco issues are global, all commerce and policy have global aspects.
- Yes. Product relation needs to consider issues related to trade, source of tobacco, contraband etc.
- Yes. While taking on this issue at the national level takes significant resources and dedication, it would be helpful if some efforts could also be devoted to international policies and situations.
- Yes. In fact the Center should be located outside the US on more neutral ground.
- Yes. It is naïve to believe we can consider tobacco's impact to be isolated in any specific region. Must be considered in the global context.

- No. The Center might become too diffuse.
- Sure. This is an international problem – good ideas, from whatever source should be shared – when a consensus emerges to do so, then all such entities should present a unified front in promoting particular positions.
- Yes. No question. It’s a global issue, although each country’s regulatory system is unique. The Center could even be located abroad.
- Yes. The epidemic of cigarette- caused disease crosses borders.
- No. I believe the Center should focus on the US. Otherwise, the task is too large and daunting.
- Yes. It doesn’t cost much to share findings, and to the extent policy becomes a standard globally, multinational companies are more inclined to accept it.
- No. I think it needs to be a focused effort so it will have clear priorities.
- Yes. Without question.
- Yes. This is difficult too. US discussions on global link rarely consider India and its smokeless tobacco issues. You would need international staff and a strong governance stance to look international enough.
- Yes. I think the Center will need to take an international perspective to be truly effective – engagement with WHO will be essential.

**Question 7. In addition to serving in a role to foster dialogue, guidance, and recommendations on policy and other matters, should the Center be a forum for conducting “negotiations” between stakeholders?**

General findings and observations:

About 50% of the respondents indicated that the Center *might* take on providing “negotiating” functions depending on the circumstances involved. About 40% indicated ‘yes’ although even some giving a positive ‘yes’ often provided additional qualifying statements. Less than 10% indicated that the Center should not take on a ‘negotiating’ role.

Respondent Comments:

- Maybe. May depend of how dialogue progresses.
- Yes. As a ‘service’ with parameters.
- Maybe. Will be very difficult to bring industry and health together.

- Yes. On topics that are designated by collective with resolution made transparent (in other words with general rules).
- Yes. We need neutral ground to promote understanding.
- Maybe. Premature to determine context and possible role.
- Yes/Maybe. Clear rules and firewalls should be set, so that discussions don't turn into a free-for-all. In particular it is important to start distinguishing between anti-tobacco activists and sound public health groups. Ultimately the motives of all groups need to be examined. (That is why it is important to include saving lives, improving health in the mission).
- Maybe. Negotiations to the end of producing consensus policy or other recommendations.
- Yes/Maybe. Not sure what is meant by 'negotiations' but any policy changes that can be agreed to (to inform smokers about the comparable risks or to provide incentives to encourage smokers to substitute smokefree tobacco/nicotine alternatives) should be encouraged.
- Yes. If all stakeholders are invited to participate in crafting recommendations and this is done with full participation by a wide variety of those stakeholders, then the negotiations will be happening as a matter of course or no recommendations will ever be forthcoming. The existence of the forum itself entails sharing existing views in the hope that a consensus can be reached with no guarantees that such will result.
- I am not in favor of negotiating with the tobacco industry ever. The primary role of the Center should be to offer policy solutions to minimize harm from tobacco/nicotine products. Let the politicians and stakeholders compromise their respective positions or proposed solutions. The people need an honest reliable source of information focused on public health objectives. If you negotiate, you lose the option to criticize either the government or private stakeholders, whose interests are compromised over profits.
- Maybe. Not sure what this looks like—is probably needed in order to progress, but may be a slippery slope towards partisanship.
- Maybe. This is a tricky one as evidenced by the role of CTFK in the FDA bill. But maybe the Center could develop ground rules for dialogue. I don't however, think it (Center) should be cast as a mediator.
- Maybe. One would hope the concept of the Center would lead to dialogue and a frank exchange of views which may lead to agreement on certain issues. In light of how some would view the concept of "negotiations" (particularly with the enemy) the Center should act as a "facilitator".
- Yes. Certainly – this is a key part of the dialogue which is an essential element in moving forward to meaningful reform in a democratic society – this is far superior to the incessant long distance shelling from diverse sectors who have so often been the enemy of progress.
- Yes. Sure. I think the "negotiation" role would be an important element, but participants would need to leave their swords and sarcasm – but not their principles – at the door.
- Maybe. If that does not compromise its independence.
- Maybe. If it looks like something productive can be achieved, and can be achieved better via the Center than elsewhere.

- Maybe. I could see a role whereby the Center could be a ‘gathering place’ to hold discussions among various stakeholders.
- Yes. It seems at present that tobacco industry objectives are irreconcilable with those of public health—some negotiations will be needed where consensus cannot be achieved.

## II. ISSUES

**Question 1. Currently there is a general consensus and acceptance that “smokefree” tobacco and nicotine products are lower in risk than the more toxic combustible products such as cigarettes. It is being proposed that the primary focus of the Center should be on “smokefree” tobacco and nicotine. Do you agree?**

General findings and observations: Approximately 65% agreed that the primary focus of the Center should be on “smokefree” tobacco and nicotine. However in some cases where the respondents gave ‘yes’ / ‘no’ answer they qualified those answers.

Respondents Comments:

- This is the key issue confronting tobacco policy –making for the public health organizations/agencies as well as industry..
- Not sure honestly.
- Yes, however, combustible and heat-not-burn ‘PREPs’ will need to be brought into the Center’s purview once smokefree has progressed.
- Yes, but without losing sight of goal –reducing cigarette consumption!
- Yes, but smoke-bearing products should not be overlooked. Products containing small amounts of actual smoke have been shown to reduce certain harms. New material science advances might one day remove most/all harms from smoke.
- No. The Center should and would necessarily need to consider all tobacco/nicotine delivery products.
- No, it should deal with tobacco issues/policy and not be limited to products.

- Yes. There is a huge intellectual and policy gap.
- No But use this issue as a catalyst to foster more discussion.
- I would say focus on reducing harm caused by tobacco use which clearly includes smokefree and nicotine.
- It should be a major component, but medical advances continually occur such that truly effective applications may emerge. Be open minded not frozen in place in some static way.
- Yes, but not to the total exclusion of considering developments on the combustible scene (such as heat-not-burn products).
- I think it should be the full spectrum of harm reduction issues facing tobacco control. An initial discussion could even be consensus-building around the most acceptable terminology, i.e. “harm reduction” ok for 90% + of the TC community?
- No. The issues are too closely intertwined.
- Based on personal experience, focus groups have indicated the positioning of combustible products as “significantly more dangerous than smokefree products is significantly more credible as opposed to characterizing smokefree products as “lower in risk” than combustible which is not believed.
- No. A broad harm reduction focus including pharmaceutical solutions and other interventions – vaccine etc. is needed.
- No. I do not believe that smokefree tobacco and nicotine – though less harmful are the sole answer to the elimination of the tobacco problem.
- No. This will be a (the) major focus during the near future but the Center should be designed with a broader focus.
- No. At this point in time, I think it is difficult to separate smokeless tobacco from the broader issue of “harm reduction”.
- Some will say that FDA already covers medicinal products so what smokefree non-tobacco products are being referred to? (presumably things like the e-cigarette or Fagerstrom’s synthetic snus-like product?)
- No. the Center should address a broad range of reduced harm products.
- Not quite. It could be the prime focus but relevant issues overlap with combustibles e.g. nitrosamines.

**Question 2. Effective “smokefree” tobacco and nicotine harm reduction strategies will most certainly require consideration of a spectrum of over lapping issues which are currently viewed and considered separately. In addition to the more traditional stakeholders, the Center would thus have the ability and flexibility to tap into a broader spectrum of experts, many of whom may not be directly or in directly**

**associated with tobacco (i.e. labeling and marketing experts, toxicologists, agronomists, economists, facilitators etc.) Is it important, and should we be expanding the number of qualified participants in those discussions rather than limiting them?**

General finding and observations: Over 95% of the respondents indicated that they believed the Center should have the ability and flexibility to tap into a broader spectrum of interests.

Respondent Comments:

- Especially as an advisor to FDA on so-called reduced harm products, this additional knowledge base would be critical.
- The more folks involved in tobacco harm reduction/policy discussions, the more likely the chance for consensus development.
- Cautious expansion with specific ends in mind. Relationship building and trust have been so important in the past.
- Yes. But don't get trapped by the need for yet more data. All sources of information should be considered, but don't assume we don't already have sufficient information to act now. The illusion that we lack knowledge of how to regulate tobacco products because of the complexity of how the products are engineered and marketed is simply wrong. I would not cut off sources of data. However, neither would I allow the process of strong meaningful policy options coming to the table to be delayed under some illusion that tobacco industry interests and sources of information have not been considered. In most cases, history has taught us the information we get from industry is incomplete and confusing. I've never really found the explanations coming from industry experts to be that enlightening when voluntarily provided.
- Yes. But to appear to be a "tool" of Big Tobacco would be a problem.
- Any conclusions or recommendations made by the Center will be more robust with broader stakeholder input.
- As long as they are qualified (to be defined.... i.e not self-appointed "experts")... and don't forget the ethicists.
- Hell yes – all stakeholders need to feel that their various concerns will be considered. "narrow casting" risks normalization and endangers the likelihood that the Center will be viewed as a predictable special ???.
- Very important to tap into expertise on other areas of harm reduction.

- Start small and let things naturally progress with successful strategic accomplishments. Start with issues that have a high percentage to be successful.
- Cannot understand industry (tobacco and pharma) science without engaging them in ongoing dialogue.
- Expansion should be considered by the group of stakeholders but there could be a roster of experts devoted to that role by the group.
- Inclusivity is very important. The economic argument eventually helped the FCTC succeed, the same will be true for the 4<sup>th</sup> pillar of harm reduction (would add expertise to the list of type of people on illicit trade/counterfeiting).
- In particular, I would say health experts: toxicologists, pulmonary medicine etc.
- Yes, but without losing focus on finding the organization unable to make decisions because of participation overload.

**Question 3. Below are a number of issues and areas that the Center might wish to consider taking on as part of its mission. Do you agree that these issues and areas are important? Space is provided below to allow you to make additional comments and to suggest deletions and/or additions.**

- **Monitor and evaluate scientific studies related to the development, manufacturing, distribution, marketing and use of smokefree tobacco and nicotine products;**
- **Make recommendations for scientific studies;**
- **Assess technological advances and opportunities in the areas of production and manufacturing, and suggesting ways in which meaningful collaborations between the public health community, researchers, producers, manufacturers (broadly speaking) and government agencies might be achieved;**
- **Compile a list of all smokefree tobacco and nicotine products in both the US and abroad;**
- **Provide suggestions and recommendations for establishing standardized testing methods etc. for all smokefree tobacco and nicotine products;**
- **Provide suggestions and recommendations for the establishment of standards and practices governing the growing, curing, processing and testing of tobacco used in smokefree tobacco and nicotine products;**
- **Provide recommendations concerning the best and most effective 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 relative risks of such products, especially when compared to using cigarettes or quitting tobacco and nicotine altogether;**



- **Develop and provide recommendations and methods for the monitoring and surveillance of all smokefree tobacco and nicotine products and, in particular how such products are used;**
- **Review advertising and marketing practices of tobacco and nicotine manufacturers to determine if such advertising is misleading or deceptive and recommend advertising and marketing parameters (consistent with the First Amendment) for such practices;**
- **Make recommendations concerning good manufacturing practices (GMP's) for the manufacture of smokefree tobacco and nicotine products;**
- **Make recommendations concerning good agricultural practices (GAP) for the growing, curing and processing of tobacco leaf;**
- **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 which have consumer acceptability;**
- **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 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 these products;**
- **Make recommendations respecting corporate social responsibility (CSR) measures (including the monitoring and enforceability of such measures) for all smokefree tobacco and nicotine manufacturers.**

**Generally Agree with these recommendations \_\_\_\_**

**Generally Disagree with these recommendations \_\_\_\_**

**Generally agree (or generally disagree) and wish to add the following comments and thoughts \_\_\_\_\_**

General findings and observations:

All of the respondents (save one) indicated that they *generally agreed* with recommendations. However, a number of observations and comments were made. Some decided that they would prioritize what they thought should be the top areas of focus, particularly at the inception of the Center. Others noted that one of the first activities of the Center should be to review various recommendations and then prioritize them. In either case the clear message was that it was important that the Center not take on too much initially, that it kept its focus and then expand outwards to deal with other areas as needed.

## Respondent Comments:

- Make recommendations based on science.
- The group should focus on the tasks it is most uniquely qualified to do, and what can move the dialogue/scenario forward. Quite likely, an objective setting session at the Center's inception is needed to establish priorities – hard just to tick off a list.
- How you would prioritize among these many excellent topics is a major challenge.
- I would like to see something on how best to influence consumers to at least try noncombustible tobacco and nicotine products; other incentives may be needed than information. Make recommendations on differential taxation. I just feel that the consumer needs to be involved and incentivized rather than labouring under a guilt complex. De-normalization initiatives don't help either ! My take on this is that it encourages consumers to have bunker mentality.
- At the risk of being a broken record--- I think all of the above could be useful , but only if the scientific community, FTC, FDA, other consumers of the Center's recommendations see it as an unbiased, science-based resource and given the current state of 'harm-reduction' discussions that will be a challenge.
- STRONGLY agree.
- All recommendations must be carefully vetted to ensure that they do not impact, wherever possible competitive positioning of one company over another.
- Don't be too broad....focus on a few issues that directly address the risk factors associated with smokefree tobacco products.
- I hope the recommendations would be to government who would have the authority to create incentives to modify actions of the tobacco industry so that they would operate with the interests of the publics' health in mind.
- If the information is not provided to the public regarding the relative risks of products, then the Center would have the moral obligation to do so.
- Recommendations should be prioritized as to potential impact on the eradication of tobacco use by man (which I consider the long term goal).
- Start with establishing a base for overall policy direction; have to include consumer understanding, acceptance, rejection and resulting behavior; this list would have to be prioritized to not divert resources away from the core objective; need some sense of technical and commercial feasibility; need to consider 'consequences' including illicit trade, enforcement, and revenue implications for states.
- I think the group should develop its agenda and the Center should facilitate and not cross the line into the development of policy or recommendations..... the Center should be the space for dialogue and exploration/ not decision-making.

- Don't some overlap with the CDC and potentially the FDA?
- Some prioritization is essential. Resources may never be adequate to do all of this.
- Again, I believe being fact + science based and ideally advisor to FDA is the single most important role.

### III. STRUCTURE AND DUTIES

**Question 1. It is being suggested that the Center be composed of a Board of Directors made up of highly respected qualified individuals who would view their role as ensuring that the mission of the Center is carried out effectively. To avoid conflicts of interests or the perception of one, those serving on the Board should have no direct associations with any organization, NGO, or corporation that has a vested interest in the outcomes of the Center. Do you agree?**

General findings and observations:

About 65% of the respondents agreed with the statement. However, in many cases, many respondents raised questions about the feasibility of being able to find such completely independent Board members who would have the independence, knowledge and commitment to serve. These kinds of comments were also reflected from those who disagreed. A couple of people who did not agree also indicated that they felt that the industry (as well as public health) should be represented on the Board.

Respondent Comments:

- Just get the right people. Affiliation should be relevant but not disparitive.
- Unclear as to who this would exclude.
- Yes but this will be difficult to achieve, leaders in all areas will be unlikely to break from the positions of their organizations.
- No, it has to be a public health center and they need to control it. The industry should be able to participate but not control.
- Yes. But would this be limited to "current" direct associations or would it extend to past associations?
- No. I think the majority should be independent but I think you can have some who could be effective liaisons.

- Yes. How “direct” is direct? Since everyone depends on income from some source, it may be difficult to find people whose income source is sufficiently indirect including those in universities and government. This is tricky.
- Yes. But will the Center find other qualified/willing individuals to serve?
- No. The main criteria for conflict of interest should be profits in the marketing and manufacturing of tobacco/nicotine delivery products. Thus, any one with affiliations to the tobacco industry or pharmaceutical industry that might benefit financially from policies that favor sales of their products should be excluded. NGO’s so long as they are non-profit would be fine in my opinion.
- Yes. INDEPENDENCE IS VITAL !
- Yes. Those who have vested interests would be invited to share views and participate in the reform dialogue.
- No. I do not believe you can find people with “passion” about topic that do not have a vested interest in the outcome.
- No. Most who have enough knowledge or expertise to serve on the Board have a vested interest. Interest needs to be transparent and set aside.
- Yes. I with how to avoid a conflict of interest—but obviously with “interest” often comes passion and dedication to the issue.
- Yes. Except that it seems that excludes many who might be qualified.
- Yes. This would be ideal but given the criteria above (in the question) how many suitable Board members could be found.
- No. If Board members have to vested interest in an organization’s “outcomes” then what is their purpose.
- No. Having a vested interest can help move things along as opposed to having endless dialogue. Could a compromise be that those that do have a direct association have no vote or are ex officio.
- Yes. Better base in university to avoid all the hot air.
- Yes in principle. Almost impossible to achieve – those qualified to serve on the Board would almost certainly have a perceived conflict.
- Given the likely mission of the Center, it is important that primary stakeholders in the industry and public health have positions on the BOD

**Question 2. What are some of the qualifications that you believe Board members must have, and do you have suggestions of people in your view would be qualified?**

General Findings and observations:

As this was not a yes/no answer some of the comments (below) might best express the views of the respondents. As to names that were recommended (which I will not mention as part of this assessment), I can only conclude that it is possible to find people who have the expertise, passion and independence and who are not or no longer directly associated with an organization that has a vested interest) to serve on the Center's Board.

Respondent Comments:

- Not sure but the board should reflect the different points of views on this issue, including political, ethical, racial/ethnic etc. There should be a selection committee to pick the Board of Directors and those on the selection committee would not be considered for the Board.
- Scientific, public health, regulatory/governmental and commercial experience needs to be present across the Board membership.
- Imagination and creativity ability to imagine the future; broad credibility across various sectors; open minded not affiliated with 'factions'; dedicated to the ultimate mission of reducing tobacco related disease and death; comprised in part of members with tobacco control (or tobacco) experience and the other part "virgins".
- A mixture of scientists public health professionals, marketers and ethicists; also useful would be some elder statesman from other public policy arena--- maybe a former pragmatic Surgeon General or the ex- head of related UN organization (WHO);someone with developing world expertise would be good possibly with UN experience; what about an economist type or some ex world Bank person;
- Scientific, policy and public health expertise.
- They have a public health mission in mind. Specifically, they should be fully supportive of efforts to rapidly reduce harm caused by tobacco/nicotine products without regard to maintaining the profits of private entities.
- They have knowledge of government policy and population risk reduction.
- Ideally include the following(a) a respected medical doctor with expertise in tobacco control and health issues (b) a respected epidemiologist (c) a lawyer with expertise on these product issues (d) a marketing/labeling expert (e) someone who has worked at FDA on these issues, (g) someone with expertise on nicotine addiction/psychopharmacology, (h)someone who is familiar with production side economics and (i) some one with all-round credibility who could act as chair/spokesperson for the Board.
- Open minded people.

- They have breadth and depth of knowledge of many aspects of tobacco/nicotine product development and marketing.
- If past associations are not obstacles then..... (names deleted)
- Collegiality is crucial along with respect- avoid prima donnas; stubborn people.
- I'll use “ *name deleted*” as my e.g. – he is one of the most thoughtful and (perhaps to my own biased view) objective thinkers on this issue but I bet he would be considered out of bounds for Board Duty by many involved in this issue
- Public health, regulatory plus research.
- Recognized experts in health, agriculture, government regulation.
- A mix of public health organization reps, industry reps, grower association reps, university/research reps.
- Honesty, integrity, independence, experience, expertise.
- Must have respect for players. Must have credentials that command respect.
- Lack of bias, demonstrated competence, intelligence, ability to analyze and clearly present a point of view, willingness to commit the time and effort needed and ability to think across categorical demarcations and assimilate scientific facts.
- Depends. If the Center is small there needs to be expertise on the board. On the other hand with a bigger institute the board can be composed of distinguished persons without particular knowledge in the area.
- Pragmatism, knowledge of tobacco issues, open minded, rational/scientific rather than ‘fundamentalist’, experience or knowledge of other public health issues.
- Think you have to consider what individual will bring to the table before immediately excluding because of affiliations. If movement to consensus is a goal, don't you have to have some level of participation by those who have been “vested” in the issue?
- Mix of MD/MPH/ epi/ risk assessment/ psychology/ economics.
- Expertise in management, conflict resolution, in public policy in general.
- Scientific background, strong integrity and public track record. Regardless of discipline, must be open-minded and pragmatic (as opposed to dogmatic).
- Consumer protection and science backgrounds.
- Integrity, trustworthiness, creativity, legal, scientific or practical experience.
- I would like to see some scientific/medical background and perhaps an FDA background.
- I believe any board member should be considered an expert in his or her field. A board member should have at least 20 years experience in his or her field.
- Individuals should have degrees in areas that will be critical to the process such as toxicology, agronomy, effects of marketing etc.
- Knowledge, unbiased views, cooperation.
- Different mind set, skills, cultural – definitely public health, economics, agriculture, business and communication.

**Question 3. It is being suggested that the following are some of the general authorities and duties that the Center might need in order to effectively consider and address the kinds of issues noted in section II. Do you generally agree with these? Space is provided for you to make additional comments as to the addition or deletion of these duties and activities.**

- **Provide an atmosphere that fosters open, civil debate, dialogue and discussion;**
- **Provide a neutral forum and safe haven for the presentations and discussion of information related to the production, processing, manufacture, sale distribution, labeling and marketing of smokefree tobacco and nicotine products;**
- **Convene meetings, hearings, conferences and roundtable discussions on a variety of issues and topics;**
- **Establish expert advisory panels;**
- **Interface with private sector entities including NGO's, foundations, corporations, grower cooperatives;**
- **Interface with academic institutions and researchers;**
- **Interface with governmental agencies such as the US Congress, FDA,USDA, FTC etc.;**
- **Provide oversight and guidance on issues related to corporate accountability and transparency;**
- **Issue reports, recommendations, and guidance related to the goals and objectives of the Center;**
- **Use trained facilitators and other outside experts to assist in carrying out the Center's mandate.**

General findings and observations:

All of the respondents agree that these were functions and duties they generally agreed with. Several people made comments which follow below.

Respondent Comments:

- Very good !!
- I think the main duties would be generating and compiling research and serving as an advisory panel to Congress, FDA ,USDA, FTC etc.
- I think the "active" role of manufacturers could limit those who will join in due to the perceived conflict of interest.

- Would suggest focus on getting started and viable with a focused approach –5-6 priorities before trying to do everything else.
- STRONGLY agree !!
- Maybe all too embracing.
- If information is not provided to the public regarding relative risks of products, then the Center would have the moral obligation to fill the void.
- Establishing a conduit with UN agencies, especially the WHO would be essential for the Center to have true global reach.
- Again, all of these are reasonable but needs to be “vetted”/shaped by the actual group once in place.
- Think that establishing ‘expert advisory panels’ is quite ambitious –will become more of a think tank, rather than a forum.
- The Center has the opportunity to interface with international and non-USA national government agencies and organizations.
- These activities are all fine but what is really needed is media and legislative advocacy, grassroots organizing, and informing smokers of smokefree alternatives.

#### **IV. FUNDING**

**Because the Center must remain independent, transparent and objective, the issue of funding and the conditions and parameters under which funding is accepted is critical. Below are a series of probing questions with respect to how funding might be accepted and whether there should or should not be restrictions.**

**Question 1. Should all funding entities be required to adhere to the same set of guidelines and parameters?**

Findings and observations:

A significant majority of the respondents (over 75%) indicated that those financially contributing to the Center should follow the same guidelines and parameters. However, a number of people had questions about the question and made comments some of which appear below.



## Respondent comments:

- This I think is essential.
- This would be the prudent course to take.
- Yes in principle but it depends on whether those guidelines would exclude certain funding sources that would otherwise pass muster but can not provide funding due to some aspect of the guidelines.
- I don't know. Maybe broad parameters with the right to restrict.
- Not sure. If say a donor makes a one-off donation with no strings attached do we care if it adheres to specific guidelines?
- No. Have general principles, but keep it sensible. As long as there is disclosure it should not be limited.
- I believe, with respect to questions 1-5, the Center should ideally be funded only with government \$'s. However, realistically, it will probably require private \$ + NGO \$'s.

**Question 2. Should the Center accept funding from corporate interests if such funding is unrestricted?**

## Findings and observations:

Over 75% of the respondents indicated that they thought the Center should be allowed to accept corporate funding if the funds were unrestricted. However, there were a number of comments even from those who said yes about how and from whom that money should be accepted. Many were obviously anticipating survey questions that would consider the various differences in corporate funding.

## Respondent comments:

- Yes, but not tobacco money.
- You have two paths to take – either take unrestricted from vested interests or work it from grants/appropriations etc.
- This will be necessary to acquire adequate funding. While some criticism will be expected, with the right leadership organization, and independence this will not be an issue.

- May be necessary to get corporate support but may cause others not to participate.
- Yes. But (there is always one) the CTR may be a non-starter for many if “corporate interests” = tobacco companies. I don’t have any good suggestions for getting around this (other than the usual “impenetrable firewall”) and it could cost the CTR some valuable essential players.
- Possibly !
- Perhaps initially the Center could test the water by avoiding such money. The way WETA does ..it might be a model.
- Public/private probably offers best balance.
- Yes. Total transparency coupled with independent decision-making on how funds are used is obviously critical.
- No. Should be restricted so as not to be influenced by contributions.
- Yes. But \$’s from tobacco interest would be an issue.
- No. I think the Center should be ideally funded only by government \$. However, realistically, it will probably require private \$ and NGO \$.
- Yes. But if you accept tobacco industry funding, anti-tobacco groups probably won’t want to have anything to do with the Center.
- No. My view is that the entity should be funded from public sources which by definition should be transparent. It would be best that in my view if the government taxed tobacco producers and earmarked a percentage of these funds to support the Center.

**Question 3. If you answered ‘yes’ to the above question (should the center accept corporate funding) is it possible using other “models” such as the parameters under which the American Legacy obtains tobacco money) to therefore allow the acceptance of tobacco money if such money is unrestricted and conditions are met?**

Findings and observations:

Recognizing that approximately ¼ of the respondents did not answer this question because they felt the Center should not take corporate money, an overwhelming 95% plus of those that did, answered this question in the affirmative.

Respondents comments:

- For instance, illicit trade expertise (of tobacco industry) cannot now be utilized, to the detriment of ??? health and lives. Some form of “détente” is necessary to achieve goals of mutual concern and would ultimately lead to saved lives and better health.
- Look at the Rubicon funding model used by the Institute for Science and Health
- Yes. But of course there is the risk that non-supporters of the Center would claim efforts and results are biased.... But w/o there may not be enough funds and interest to support Center financially.
- This (this type of model) should be possible but not necessary.
- Full transparency as to sources and uses of private funds -- avoid all appearance of conflict of interest - full disclosure is the key – perhaps only 10-25% of budget could come from such sources.
- ALF doesn't seem to have a problem with their model, so something similar might fly.
- Probably not. Legacy was creation of a massive lawsuit settlement with the 46 states. I don't think anti-tobacco groups would want to collaborate with an organization that receives industry funding even if its “unrestricted” .
- Yes. Although amendments of the MSA requires everybody to agree.

**Question 4. If you believe it is feasible to establish stringent and enforceable funding parameters for accepting tobacco money, is there or should there be a distinction made between manufacturers who produce combustible products such as cigarettes and others that produce noncombustible tobacco and nicotine based products? (i.e. the Center should not accept funding from companies that manufacture and sell combustible products).**

Findings and observations:

Approximately 75% of the respondents indicated there shouldn't be a distinction made between tobacco manufacturers who produce combustible products such as cigarettes and those who produce non-combustible such as smokeless tobacco products. Interestingly, only a few (less than 5%) of the respondents decided not to answer this question --- mostly likely because of their earlier answers.

Respondent comments:

- I believe the distinction is important, because the two categories of products have vastly different safety profiles.

- Moot as eventually will be selling both products in the multi-faceted industry.
- There are companies (such as BAT and RJRT) that sell both (at least for the foreseeable future).
- There will always be overlap between the producers of these products.
- No. Should not accept funding from those who produce noncombustible products either.
- No. This would stack the funding in favor of a particular tobacco interest which could be taken over by a cigarette manufacturer at any moment.
- No. All stakeholders should be invited to participate regardless of the general view of the relative risks of their products. The need to reduce risks to combustible products exceeds that of smokeless, so who should combination product manufacturers be excluded?
- No. Splitting hairs is an invitation to endless bickering – if all (owners are invited to participate in the dialogue process, then why not permit participants to fund in a transparent fashion.?
- No. Almost all of the “Big Tobacco” companies are involved in smokeless. It would be good if they could be encouraged to get into the nicotine market. I would like to see government encourage joint ventures (Tobacco/PHRMA) but that might be too much to hope for!!
- No. Since all large cigarette companies are also marketing smokeless products, it make no sense to refuse money from cigarette companies (if it is decided to accept money from noncombustible tobacco companies).
- No. I think everyone has to play if the Center is to be useful.
- No. Soon there won't be any fine lines between manufacturers.
- Virtually all of the major combustible players are now in the non-combustible business so this is moot.
- No. If the Center accepts industry funding you will have to not differentiate.
- No. If you believe your system is able to insulate and specific interests of funders from the work of the Center there should be no need for such a distinction.

**Question 5. Is there or should there be a distinction made between those produce and manufacture traditional forms of tobacco from those who manufacturer or use tobacco in developing new alternative products, and which may contain tobacco as well as nicotine derived from tobacco?**

Findings and observations:

An overwhelming majority (over 85%) indicated that there should not be a distinction. This included a few people who had indicated in earlier questions that they did not support the idea of any corporate funding. Many felt that it would be difficult to separate

out the various forms of tobacco especially as the lines become increasingly blurred between the various products.

Respondent comments:

- Yes. The distinction between combustible tobacco products and other nicotine products should be across all sectors – production, manufacturing, labeling, distribution.
- No. Ultimately some consensus will ?? tobacco based products that are combustible. Every product category needs to be ranked on a risk/hazard continuum.
- No. It is difficult but NRT and the pharmaceuticals are very different to tobacco sellers. Addictive NRT is an issue which comes into the harm reduction debate.
- No. You are already stacking funding in favor of a particular tobacco interest, which could be taken over by a cigarette manufacturer at any moment.
- No..... a prescription for interminable wrangling and bickering.
- No. Almost all of “Big Tobacco” companies are involved in smokeless, it would be good if they could be encouraged to get into the nicotine market.
- No. All noncombustible tobacco/nicotine products sold in US are very similar relative to cigarettes. Splitting hairs over miniscule differences in risk (ie Skoal, Snus, Ariva, e-cigarette Committ and Nicorette) is silly when cigarettes are 100 times deadlier than any of those smokefree products.
- No. The issue is not who but how.
- No. Again, if you believe the system is able to insulate any special interests of funders from the work of the Center there should be no need for such a distinction.
- No. Again it depends on the use rather than the source of the money.
- No. Distinction should be made on transparency issues and integrity of business practices, not products.
- No. I believe (as indicated elsewhere) that the Center should ideally be funded only by government \$. However, realistically, it will require private \$ and NGO \$.
- No. I appreciate the controversy but the Center’s activities should consider all stakeholders.
- No. This decision would contribute to polarization.
- No. Basically all of the major tobacco companies are also pursuing these other types of products, so it is difficult/impossible to make a distinction. And it is not necessary- traditional tobacco companies should be able to foster the dialogue on an equal footing (provided the stringent controls are met).
- No. No direct funding should come from entities that stand to benefit financially from the work of the Center.

**Question 6. Should the Center accept funding from nonprofit organizations (NGO's) that have specific interests in tobacco control if such funding is unrestricted?**

Findings and Observations:

An overwhelming number of respondents answered in the affirmative. (95%). Several people did not answer the question again probably based on views that funding should come from governmental sources only. A number of people qualified their answers through comments indicating that funding should be open to all interests.

Respondent Comments:

- NGO's have much to give and gain from the Centers decision's and activities. Equal rules should apply to all funders.
- Yes. I think everyone has to play if the Center is to be useful.
- Yes. Anything to save lives --- improve health linked to smoke and nicotine should be encouraged, on condition of disclosure of funds.
- Yes. Same rules for everyone.
- Yes. Same guidelines as apply to industry.
- Yes. Above all the Center should be non-partisan in its funding model, and use this as a catalyst to break down attitudinal barriers.
- Yes. The same rules should apply to both sides.
- Yes. Do NGO's such as ACS ALA AHA have conflict of interest rules and firewalls when it comes to corporate contributions? Particularly from corporations that stand to benefit from such affiliations? Could be useful models.
- Yes. Ideally the funding should come from government. However, I see no reason why non-profit organizations that have as their mission reducing the harms caused by tobacco use could not contribute funds to support the Center.

**Question 7. Should the Center accept funding from such organizations as universities and foundations if such funding is unrestricted?**

Findings and observations:

All of the respondents answering this question gave an affirmative response (100%)  
Only two did not respond probably again because they believe that the source of funding of the Center should come from government.

Respondent comments:

- Yes. To ensure credibility and objectivity I think most if not all funding should come from this source to avoid any appearance of conflict.
- Yes. But note, most funding may be restricted.
- Yes. Anything to save lives --- improve health linked to smoke + nicotine should be encouraged, on condition of disclosure of funds.
- Yes. Same rules for everyone !
- Yes. Probably more foundations than universities. Pity that Gates/Bloomberg are on the pathway to the abstinence only track. What about Soros ?

**Question 8. The sources of funding should not be allowed to influence the Center's mission, goals or objectives. It is being suggested that those decisions must remain the prerogative of the Board, Executive staff, advisory committees etc. Do you agree?**

Findings and observations:

All respondents except one answered in the affirmative (99%) on this question. Some felt very strongly that this was a key element to the success or failure of the Center. The lone 'no' indicated that they thought that many funders would might be required to have conditions placed on their funding decisions.

## Respondent comments:

- Again, independence is key !
- Yes. The decision in general should be made clear at the original founding of the center so that backsliding isn't possible.
- Yes. But this means the Board will need to be purer than Caesar's wife, which will be difficult to achieve.
- YES !!!!!
- Yes. ++++
- Yes. Strongly
- Yes. There may be certain conflicts unforeseen, so yes the Board should use its judgment.
- No. I think most foundations, corporations, government funders "restrict".
- Yes. Absolutely, although funders would probably want to know in advance the specific research tracks that are being funded.
- Yes. Sources of funding almost always influence an organization's goals and objectives, even if claimed otherwise, as continued funding is usually a key goal and priority. But the organization should try to be as autonomous as possible.
- Yes. Of course we should not be so naïve to think that funding sources do not influence how the Center will behave. This is why the bulk of funding for such a Center should come government (the people).
- 

**Question 9. In accepting funding that is unrestricted it is further being suggested that no funding can or should be accepted based on the condition that it will be used for a particular project. Do you think such a restriction is both necessary and appropriate?**

## Findings and Observations:

Unlike the overwhelming positive response in question 8, there were differing opinions as to whether the Center should or should not accept funding that is targeted for a specific project. About 60 % indicated that there should be restrictions with the remaining saying 'no'. Many of those who said 'no' felt that with the right restrictions in place this should not be a problem. Several also suggested that maybe the Center's Board should solicit specific project funding.



## Respondent comments:

- Yes. But I think that the purpose of the funding is less important than the source. PM could provide funding specifically to solve the problem of world hunger and it would still destroy the credibility of the Center.
- Yes. But I believe the Board could solicit funds for a particular project (a fine distinction perhaps), but perceptions will be important for the Center to be successful.
- Not sure. Could go either way but probably would agree.
- By unrestricted I take this to mean that the outcome and interpretation will be ring-fenced from influence. But I don't see a problem with eliciting specific funding for specific projects.
- Need to preserve flexibility but o.k. if appropriate controls are in place.--- Centers integrity and independence are essential and funding must be zealously policed. Perhaps may need an ombudsman or an equivalent of an inspector general to ensure that the Center remains on the right path.
- I don't think it matters either way except that it might make it more difficult to obtain funding.
- Yes. The Center's Board should decide.
- No. Not always possible, so be careful for excessive restrictions for the sake of "independence". What if a certain meritorious project came along and was given specific funding (eg. Bloomberg initiative)?
- No. Certain funders will require that their funding be used for specific projects so they can measure outcome.
- No. Not necessary but would be appropriate "project" funding should meet criteria established by the Board and support tasks or strategies of Board and Center.
- Reservations. If you have a particular project that attracts interest do you turn it down?
- No. Need only require the source of support for the project to be public disclosed.
- No. in general but may be necessary.
- No, No reason to restrict that.

- Not sure on this. Maybe okay but with appropriate safeguards.
- Depends on project by project.
- No. This is not necessary; as long as the project fits the mission and guidelines of the Center.
- No. If the government is providing funding (as I suggest) I would think it would be appropriate for them to request that the Center focus attention on addressing specific issues that might be relevant to their actions (similar to an IOM report). If only unrestricted monies are permitted, the influence will be via appointments to a board which might not be free of influence either.

**Question 10. In accepting funding that is unrestricted, it is further being suggested that funding does not guarantee nor should it be allowed to give or guarantee the funding entity a ‘seat at the table’. Do you agree?**

Findings and observations:

All 100% of the respondents answered “yes” to this question which clearly suggests that merely because an entity provides funding it does not entitle them or their organization to a ‘seat at the table’. Decisions on who is involved in the discussions of the various substantive issues should lie with the Center itself and if it does its job effectively it will decide who needs to be around the table for any one discussion.

Respondent comments:

- Yes. A seat at an annual review of progress yes, but not otherwise.
- Yes. All interested parties should in effect think of themselves as having a seat at the table – neutrality and fairness must be the hallmark; like the Jim Lehr news hours. Merely funding should not guarantee that seat.
- Yes. “Seat” should be based on jointly developed criteria of Board and founding members.
- Yes. The Bylaws should establish where the participants will come from, not the funding.

- Yes. Funding should not automatically guarantee a seat at the table.
- Yes. Full disclosure of all sources is critical.

**Question 11. Summarizing, given that it is being suggested that all funding entities would be held to the same general requirements and that all funding would be unrestricted, do you agree that funding could be accepted from the following? Please check those you believe could be considered funding sources if the restrictions and parameters are effectively implemented.**

**Foundations** \_\_\_\_\_

**Nongovernmental organizations (such as ACS, ALA)**

**Corporate interests** \_\_\_\_\_

-cigarette companies \_\_\_\_\_

- smokeless companies \_\_\_\_\_

- pharmaceutical companies \_\_\_\_\_

- biotech companies \_\_\_\_\_

**Grower cooperative** \_\_\_\_\_

**Universities** \_\_\_\_\_

**Governmental (Such as CDC, NIH, FDA, USDA, WHO etc.)** \_\_\_\_\_

Findings and observations:

I was surprised that a majority of respondents indicated that funding could be accepted from the entire list. It seems that as some people worked through the survey and understood the functions, duties, and firewalls of the Center and its critical efforts to remain independent and neutral they may have concluded differently in the end. That said there were a number of people (20% or so) who indicated that all but the tobacco companies would be acceptable to them. One or two felt that no corporate money should be accepted. Another one of two favored funding coming only from foundations, universities or governmental sources.

**“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 establishing a process 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.

## **Conclusions**

The overriding conclusion is that there is a need for an independent 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. Dialogue works 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 indicated 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.



## **IV Miscellaneous statements and quotes in support of dialogue and new thinking**

What is being proposed in the establishment of an independent Center/ Forum as a means of convening people with differing views to discuss and debate issues in a safe environment is not something that is so new or so unique as to be discriminately ignored. In fact there is clearly a trend for this type of endeavor to help us through the many complex issues and challenges we are now facing as a society and as a nation. What follows are a few (of what are many) quotes that support what is being proposed as being worthy of serious consideration.

- ***Some men see things as they are and ask “Why?” I dream of things that never were and ask, “Why not?”.***

Robert F. Kennedy

- ***The monopoly on good ideas does not belong to a single party. If it is a good idea, we will consider it.***

President-elect Barak Obama, **Washington Post**, January 6, 2009

- ***..... the Commission, a collection of tobacco growers, representatives of public health organizations and economic experts, found much common ground in the seemingly incompatible goals of assisting tobacco farmers and safeguarding public health. The starting point goes back 15 years when tobacco growers and public health leaders first gathered in the mid-1980's for face-to-face discussions about the plight of tobacco farmers and their communities and the need to protect public health. With this report those years of effort have come to fruition.***

Presidential tobacco commission report, Tobacco at a Crossroad, May 2001, Executive summery p.4

- ***The success of the meeting was largely due to the willingness of the parties to put aside official titles and deal with each other as individuals. I was personally***

***moved by the genuineness of the spirit of cooperation. Our experience at Calloway Gardens will be an experience long remembered by all of us.***

Former President Jimmy Carter in a letter (September 20, 1985) to participants of a meeting (retreat) of public health advocates, growers, and selected others at Calloway Gardens, sponsored by the Carter Center.

- ***It is never easy for warriors to transfer themselves into peacemakers, to shirk from the comfort of combating a securely demonized enemy to the moral ambiguity involved in acknowledging an enemy as simultaneously a bargaining partner...But the accumulating pressures on the industry in 1997 –especially from its own investors-created an opportunity different in kind and dimension from anything that had come before. Yet ...many others were (not) capable of stepping back and asking themselves whether a time had indeed come to suspend the fighting – not end it forever- and negotiate.***

Michael Pertchuk, Smoke in Their Eyes: Lessons Movement Leadership from the Tobacco Wars, page 256.

- ***I hold that a little rebellion now and then is a good thing and as necessary in the political world as storms in the physical.***

Thomas Jefferson, in a letter to James Madison, January 30, 1787

- ***Clearly, our tobacco companies, together with the rest of the industry, played a major role in the development of the level of anger that is now directed against them-not just by many in the public health community but many in the general public as well. Put simply, ours was a culture of arrogance, bred insularity and enabled by spectacular business success. There was a bunker mentality, an “us-against-them” attitude, a belief that any one who disagreed with us was an enemy out to destroy us.***

Steven C. Parrish, (formerly a senior executive at Altria Corporation)  
“Bridging the Divide: A Shared Interest in a Coherent National Tobacco Policy”, Yale Journal of Health Policy, Law and Ethics.

- ***The remarkable dialogue that has taken place over the last several months has opened up new opportunities for partnership and for meaningful change that will benefit both sides. We in public health will have the grower’s support and assistance in reducing youth tobacco addiction, and farmers and their communities will have new options and opportunities for the future... Now the***

***growers, in dialogue with public health advocates have come to accept the role of FDA with respect to agricultural production.***

Press Statement of Bill Novelli, former President, Campaign for Tobacco Free Kids, concerning the release of the Core Principles Statement Between the Public Health Community and the Tobacco Producers Community, March 1998

- ***Today is truly a historic day for the tobacco farmer, the tobacco farmer community and the public health community. Two entities that have long viewed each other as adversaries have come together after many months of civil dialogue with a plan to enhance the public health of this nation and at the same time develop a plan to take the tobacco farmer and the tobacco farm communities into the 21<sup>st</sup> century and to sustain a healthy economy. Direct, face-to-face discussion invariably results in new more accurate understandings.***

Statement of JT Davis, Concerned Friends for Tobacco, concerning the issuance of the Core Principles Statement Between the Public Health Community and the Tobacco Producers Community, March 1998

- ***Two roads diverged in a wood, and I – I took the one less traveled. And that has made all the difference***

Robert Frost

- ***Even from a foe a man may wisdom learn.***

Aristophanes, The Birds

- ***If I always do what I have always done, I'll always get what I already got.***

Anonymous

- ***Love your enemies for they tell you your faults.***

Benjamin Franklin, Poor Richard

- ***If you meet a sectary, or hostile partisan, never recognize the dividing lines but meet on what common ground remains, -- if only that the sun shines, and the rain rains for both, the area will widen very fast, and ere you know it the boundary mountains, on which the eye has fastened, have melted into air.***

Ralph Waldo Emerson