TOBACCO AND TOBACCO PRODUCTS
AT A CROSSROADS IN THE 21ST CENTURY

» Reducing the Harm From Tobacco and Tobacco Products
» Can Tobacco and Tobacco Product Modification Play a Role?
» Seeking Civil Solutions in an Uncivil Environment

SCOTT D. BALLIN, JD
Tobacco and Health Policy Consultant
6220 30th Street NW | Washington DC 20015
T: 202 686-8898 E: ScDBa@aol.com

AUGUST 2006 | www.tobaccoatacrossroads.com

ABOUT THE AUTHOR

Scott D. Ballin has spent more than 25 years involved in issues related to tobacco and public health. He has worked on a spectrum of tobacco issues ranging from labeling reforms on cigarettes and smokeless tobacco products, FDA regulation of tobacco, excise tax increases, enactment of clean indoor air laws, and tobacco agricultural reforms.

For more than 10 years he served as the American Heart Association's Vice President and Legislative Counsel, as a Steering Committee Member and two- time Chairman of the Coalition on Smoking Or Health (ACS, AHA, ALA) which was the first truly active national coalition in the tobacco control movement. He has provided advise and consulting to the American Lung Association, the Campaign for Tobacco Free Kids, and Star Scientific, Inc. Most recently he has and continues to serve on the Steering Committee of the Alliance for Health Economic and Agriculture Development, an informal organization formed to bring parties together to work for the enactment of recommendations contained in the Presidential Commission report, Tobacco at a Crossroad. He remains a strong advocate for bringing parties together in neutral forums in order to discuss controversial issues, to remove barriers, to foster constructive dialogue, to look for new opportunities, and to find areas of common ground.

He is a graduate of the Georgetown University School of Foreign Service, and a graduate of the George Mason School of Law in Arlington, VA.

ABOUT THE PAPER

Although this paper contains many excerpts from numerous published scientific papers, the paper is not intended to be a scientific paper. It is intended to raise awareness, educate and stimulate discussion about a spectrum of issues that need to be considered if there is to any real effort to move tobacco harm reduction forward in a meaningful way. The readership audience is intended to include a very broad spectrum of interests including but not limited to public health advocates, scientists, industry, tobacco producers, consumers, human rights experts, economists, biotech companies, agronomists, policy makers, media and the general public. It is hoped that the paper will encourage new thinking and new leadership from the myriad of interested parties. The views expressed in this paper represent the views of the author and the author only. No organization or individual has dictated any expectations for or from this paper nor has any funding been provided for the writing of this paper. The author has no intention of restricting access or use of the paper and would welcome any and all interested organizations and other entities participation in producing and distributing copies. The author does reserve the right to seek publication of any and all parts of this paper, including an executive summary or the authoring of any other papers, articles or books related to the contents of this paper.

DEDICATION

This Paper is Dedicated to My Friends and Colleagues

The Honorable Michael Synar (D-OK)
John Slade, MD

ACKNOWLEDGMENTS

I wish to also acknowledge the many people, but particularly eight individuals both inside and outside the tobacco arena who encouraged the writing of this paper and who provided valuable insights and comments from many different perspectives.

Table of Contents

EXECUTIVE REVIEW AND SUMMARY

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

What is Tobacco Harm Reduction ?

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

What is Tobacco and What Makes it Harmful?

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

Issues, Players, Challenges and Opportunities

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

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

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

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

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

Transparency, Accountability, Unintended Consequences

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

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

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

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

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

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

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

The Relative Risk Reduction Continuum

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

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

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

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

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

FOREWORD

Some men see things as they are and ask 'Why?'.

I dream things that never were and ask, 'Why not?'.

–Robert F. Kennedy

The purpose of this paper is to suggest some ways to better stimulate and foster honest and open discussion about the role that harm reduction strategies might play in reducing the disease caused by the use of tobacco. I use the word 'might' because I believe that there are a number of things that must be considered and implemented if such policies are to be successful. However, I am also convinced and also caution that there may be equally important health consequences for failing to move forward in the development of such products. This paper attempts to identify and 'connect the dots' of the spectrum of issues that must be discussed and considered.

I have spent more than a quarter century working on tobacco policy issues. In the early 1980's a small group of people (and organizations) dared to step out and publicly challenge the tobacco industry and to expose them for what is now commonly accepted as decades of deceptions, cover ups, and irresponsible corporate behavior. It may seem odd to think in today's terms that many of the voluntary organizations were extremely fearful of saying anything about the industry out of fear of facing lawsuits. The efforts in those early years were the seeds of what resulted in the growth of a significant tobacco control movement not only at the federal level, but at the state, local and international level as well. These efforts continue to this day. While many of the issues remain the same, much has also changed as well and will continue to change. Change brings both new challenges and new opportunities and reminds us that without compromising our goals and objectives we need to consider new ways and opportunities to reduce the disease and death associated with tobacco use. Reducing disease and death from tobacco use was the underlying objective as to why we took on the industry and why the need for oversight of the industry became and remains so critical. But today's changing environment necessitates engagement and a realignment of strategies that is not easily accepted – by industry, the public health community, growers, leaf dealers, retailers and consumers of tobacco.

For many years the tobacco 'industry' was viewed as a monolithic economic giant. They spoke with one voice, they strategized together and they remained firm in their denial that their products caused significant harm. Their approach to dealing with the scientific and medical evidence about smoking was to conduct their own research in order to deny harm, while simultaneously developing low-tar and low nicotine products that consumers were made to believe were safer. Corporate accountability and transparency weren't a part of their vocabulary.

When talking about tobacco today, it is necessary to consider a spectrum of interests and issues that can influence (positively and negatively) what policy decisions are made. It is not just the public health community versus Big Tobacco anymore (and in some respects, never was). Today, decisions made about tobacco are impacted by and have far reaching effects on many constituencies and involve issues and questions that go to the heart of ethics, competition, free speech, science and technology, corporate and individual responsibilities, economics and political philosophies. Yet, we seem preoccupied with perpetuating the past instead of talking about and addressing issues of the future. Only by being willing to at least engage in a discussion to address the future can we ever hope to truly confront the industry in order to help reach our goal of reducing disease and death through the modification of tobacco and tobacco products. We must seek to expand the options available to us rather than limiting them.

The concept of harm reduction is not something that applies only to tobacco. We live in a society that is fraught with risks – in the foods and drugs (legal and illegal) we consume; in the consumption and abuse of alcohol; in the cars and manner in which we and others drive; in sexual activities including HIV and unwanted pregnancies, and in the water we drink and in the air we breathe. We can, I believe, learn from others outside of the tobacco industry and the tobacco control movement who can help us better define the parameters and methods for establishing effective and workable harm reduction efforts.

In the broader sense, tobacco harm reduction entails multiple strategies including tax increases, educational campaigns, cessation, point of purchase and age restrictions, and the elimi-

nation of environmental tobacco smoke in the workplace and in public places. No one approach is a 'silver bullet'. But harm reduction must also involve the science-based modification of products and the effective and responsible transmission of truthful information about the risks and relative risks of those products. And, it also entails and requires business entities to act more responsibly, and to be more accountable and transparent in conducting their business activities.

As we move towards what will and must inevitably be the oversight and regulation of tobacco products, something that will ironically serve the interests of public health, industry, growers and consumers, we must at the same time establish ways of engaging in legitimate debates and discussions that will not only shape policy outcomes but also the eventual regulations themselves. Today's sound bites and rhetoric must be replaced with searching for workable and effective solutions. – no matter how contentious or uncomfortable that might be. Merely saying 'nothing should be done until we get FDA' or attempting to preserve the 'status quo' as some of the tobacco manufacturers have sought to do, is and can no longer be an acceptable strategy. We should be employing well established techniques for engaging in dialogue and resolving conflict.

The late Dr. John Slade, to whom this paper is dedicated, observed in an unpublished assessment of the environment in May of 2001 that:

> ***Events are overtaking the orderly discussion of harm reduction for tobacco in the form of a range of novel product 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.***

More than four years after those words were written we have progressed very little. Part of the purpose and justification of this paper is to try and initiate an orderly process and discussion of harm reduction for tobacco – one that removes the tunneled vision approach that has plagued progress.

Not too long ago, I was struck by the closing paragraph in the foreword of G. Alan Marlatt's book entitled Harm Reduction: Pragmatic Strategies For Managing High Risk Behaviors. The foreword written by David B. Abrahms, PhD, and David C. Lewis both of Brown University concludes:

> *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 polarization 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 the shades of gray that reflect the reality of how to approach individual, collective and policy recommendations for the 21st century and beyond?*

As I look out over the tobacco landscape, I am struck by the challenges and opportunities that we face and which exist in changing this nation's tobacco policies. Not only do the special interests in the tobacco arena rely on oversimplifications and polarization as part of their efforts but our elected officials suffer from the same syndrome. The challenge we face in our efforts to move the ball forward is consideration of **how** we establish a process by which we can avoid the 'oversimplification and polarization' and find answers that will reduce disease and death caused by the use of tobacco. Greater transparency, and engagement of the players in a neutral environment will go a long way towards breaking what has been years of efforts in consciously or unconsciously preserving the 'status quo'.

Dr. Kenneth Warner, of the University of Michigan and a longtime player in the tobacco control movement may have encapsulated the situation best with respect to harm reduction products when he said in the New York Times Sunday Magazine (June 12, 2005):

> *On the one hand the optimists says, 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'.*

His assessment paints a picture of 'polarization'. I believe that somewhere, somehow there is a way through this 'complicated thing' that has to date either been ignored or which we are unwilling to acknowledge. Instead of saying 'let's do nothing until…' , we should be asking the more important question of 'how' we do it, given the realities of the times. How do we establish a civil and safe dialogue in an uncivil environment?

What road is taken depends on the willingness of the various stakeholders to embrace meaningful change, thereby finally surmounting the historic barriers to progress. For decades, tobacco and those who manufacture tobacco products – indeed everyone associated with tobacco – have suffered vilification. Given the serious risks of using tobacco and the industry's stubborn denial that its products were seriously harmful, such vilification has been both predictable and warranted. But vilification by itself merely prolongs conflict and does little to resolve serious outstanding issues. Similarly, some of the major tobacco companies seem intent on adhering to their past ways while others are willing to change or engage in serious discussions about change. We now confront a unique opportunity to move beyond all that and onto a potentially productive path leading to a more "good faith" dialogue. For many growers, public health advocates, scientists, manufacturers, and consumers, the opportunity for meaningful change is at hand and must be seized – but it must be seized carefully.

My views and the views conveyed in this paper are the result of years of involvement and contact with a broad spectrum of interests and people in and outside tobacco who have broadened my knowledge base, challenged me to think, to explore for new opportunities and to find creative (sometimes controversial) ways of removing barriers that impede progress in achieving public health goals. I don't have any answers. Answers will depend on the actions of people and I learned long ago that in the tobacco arena, people can often be their own worst enemies in failing to remove their blinders and see the realities (good, bad or indifferent) of a situation. I do however, have some ideas and suggestions, and I am not averse to stirring the pot up a little, especially when I see opportunities that should be discussed and seized because they could make a difference.

In some ways I see myself as a 'messenger' bringing some new facts, ideas and perspectives on how we might stimulate and produce a more open and transparent discussion about the future of tobacco. If there are those who wish to 'shoot the messenger' in order to preserve their own self-serving interests, they may do so. But my hope is that there will be those who will step forward and say "yes" we need to discuss these issues and we need to do it in an open, transparent and civil way.

The tobacco environment is in dire need of some new and visionary leadership, leadership that is not afraid of considering new ideas and ways of accomplishing the goals of reducing the disease and deaths caused by the use of tobacco.

In the end we can be accountable only to ourselves and to our abilities to focus on what we set as our real goals and objectives. **Are we in fact, 'secure and mature enough to allow for shades of grey' in our efforts to achieve our goals?**

WHAT IS HARM REDUCTION ?

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

–anonymous

The fault, dear Brutus, is not in our stars, but in ourselves, that we are underlings.

–William Shakespeare, Julius Caesar, Act I, Scene ii

Before considering issues of harm reduction as they relate to the topic of tobacco product modification, it might be useful to first get a clearer perspective on what harm reduction is and is not. While it is impossible to define all aspects of harm reduction, G. Alan Marlett in his text, Harm Reduction: Pragmatic Strategies for Managing High-Risk Behaviors observes that "Advocates of harm reduction see it as a grassroots movement that has emerged as a middle path between the polarized opposites of the moral and medical models – a path that promises to provide humane and practical help for drug users, their families and our communities. Critics of harm reduction reject it as being overly permissive in its rejection of strict "zero-tolerance" policies and its promotion of alternatives to abstinence."

I see it as a realistic and rational approach for dealing with complex challenges in a complex and changing environment- one that provides complimentary strategies designed to reduce disease and death caused by tobacco use.

David Abrahms and David Lewis in the foreword to Marlett's book, observed:

> *The breaking down of old rules and the formation of new movements is always filled with strong emotion, deep fear, and great hope. Policies and other cultural "rules" designed to balance community and individual needs generally exist in tension between extremes. Education can become brainwashing, police protection can become oppressive and public leadership can become monomania. Similarly, harm reduction can be oversimplified and then demonized as an extremist movement. Alternatively it can be viewed as a new overarching conceptual blueprint for integrating the best of medicine, public health, and prevention policy. Harm reduction can address the emergent needs of societies in a rapidly changing 21st century.*

A set of principles on harm reduction were presented at the First Conference on Harm Reduction held in Oakland., California in 1996 and are enlightening and instructive in thinking about tobacco.

> *Harm reduction is a set of practical strategies with the goal of meeting drug users "where they are at" to help them reduce any harms associated with their drug use. Because harm reduction demands that interventions and policies designed to serve drug users reflect specific individual and community needs, there is no universal definition or formula for implementing harm reduction. However, the Harm Reduction Conference considers the following principles central to harm reduction practice. Harm reduction:*

- *Accepts, for better and for worse, that licit and illicit drug use is part of our world and chooses to work to minmize its harmful effects rather than simply ignore or condemn them.*
- *Ensures that drug users and those with a history of drug use routinely have a real voice in the creation of programs and policies designed to serve them, and both affirms and seeks to strengthen the capacity of people who use drugs to reduce various harms associated with their drug use.*
- *Understands drug use as a complex, multi-faceted phenomenon that encompasses a continuum of behaviors from severe abuse to total abstinence, and acknowledges that some ways of using drugs are clearly safer than others.*
- *Establishes quality of individual and community life and well-being --- not necessarily cessation of all drug use – as the criteria for successful interventions and policies.*

- *Calls for the non-judgmental, non-coercive provision of services and resources to people who use drugs and the communities in which they live in order to assist them in reducing attendant harms.*

- *Recognizes that the realities of poverty, class, racism, social isolation, past trauma, sex based discrimination and other social inequalities affect both people's vulnerability to and capacity for effectively dealing with drug-related harms.*

- *Does not attempt to minimize or ignore the many real and tragic harms and dangers associated with licit and illicit drug use.*

(see Harm Reduction Coalition website at www.hamreduction.org)

Marlett's own summation of principles and strategies (see pages 49-58) related to harm reduction are also constructive:

1. *Harm reduction is a public health alternative to the moral/criminal and disease models of drug use and addiction.*
2. *Harm reduction recognizes abstinence as an ideal outcome but accepts alternatives that reduce harm.*
3. *Harm reduction has emerged as a 'bottom-up' approach based on addict advocacy, rather than a 'top-down' policy promoted by drug policy makers.*
4. *Harm reduction promotes low-threshold access to services as an alternative to traditional high-threshold approaches.*
5. *Harm reduction is based on the tenets of compassionate pragmatism versus moralistic idealism.*

The International Harm Reduction Association has noted that:

Harm Reduction should be understood to encompass alcohol, tobacco, prescribed and illicit drugs and other volatile substances. The term should be understood to refer to the reduction of harm to individual drug users, their families and their community. Attempts to reduce factors conducive to drug use should also be considered as harm reduction measures in a broad sense.

Some regard harm reduction and abstinence as mutually exclusive options. However, the promotion of abstinence should more realistically be regarded as a special subset of harm reduction. Abstinence has the attraction of generally being the most complete form of harm reduction…. But abstinence has a decided disadvantage in that it is usually the least feasible option to achieve and sustain. As relapse is a very common phenomenon in all forms of drug taking and is often accompanied by increased risk of adverse outcomes, the pursuit of abstinence can also have serious unintended negative consequences.

(See International Harm Reduction Association website at www.ihra.net)

The Institute of Medicine report, **Clearing the Smoke**, defined a tobacco harm reduction as follows:

A product is harm-reducing if it lowers total tobacco –related mortality and morbidity even though use of the product may involve continued exposure to tobacco-related toxicants. (page2)

As we noted in the foreword to this paper, harm reduction in the broadest sense of the word involves and entails multiple strategies and efforts- including increases on taxes, eliminating smoking in public and work places, enforcing sales to minors laws, restricting marketing and promotion, and cessation - all of which must be aggressively pursued, but none of which provides the 'silver bullet'. For purposes of this paper, harm reduction focuses primarily on tobacco and tobacco product modification and the use of novel tobacco or tobacco-like products as part of those broader strategies to reduce the incidence of disease and death caused by tobacco use. Harm reduction gives users more options to consider as they decide what products they wish to use to address their personal health needs and objectives.

Taken together the above principles should serve to enlighten and guide us in discussing harm reduction in a more civil manner than is currently being done. They will provide a clearer context in which to better understand the views and beliefs of those who may agree or disagree over the roles that harm reduction strategies can play in reducing disease and death caused by tobacco use.

WHAT IS TOBACCO AND WHAT MAKES TOBACCO HARMFUL?

A custom loathsome to the eye, hateful to the nose, harmful to the brain, dangerous to the lung, and in the black, stinking fume thereof nearest resembling the horrible Stygian smoke of the pit that is bottomless.

–King James VI

There is nothing quite like tobacco: it's the passion of decent folk, and whoever lives without tobacco doesn't deserve to live.

–Moliere

- Tobacco use is a serious public health problem
- Tobacco is big business
- We are doing far too little to understand 'tobacco' and what to do about it
- A market place filled with disinformation
- Summary and Conclusion

Tobacco is as defined by the American Heritage Dictionary (4th Addition 2000):

1. Any of the various plants of the genus Nicotiana, especially N.tobacum., native to tropical America and widely cultivated for their leaves, which are used primarily for smoking. 2. The leaves of these plants, dried and processed chiefly for use in cigarettes, cigars, or snuff or for smoking in pipes.

Tobacco Use is a Serious Public Health Problem

In the US, the use of tobacco is accountable for more than 400,000 premature deaths, and costs the nation well over $ 100 billion dollars in medical care costs and lost productivity. The majority of these deaths and disabilities are caused predominantly by cigarette smoking. Tobacco remains the nation's single most preventable cause of death. Tobacco use is associated with a number of different types of cancers, with cardiovascular disease and stroke, with chronic obstructive lung disease and emphysema, with premature births and a host of other health problems. Millions of people are dependent on and addicted to tobacco.

A recent report issued at the World Conference on Tobacco and Health in July 2006, noted:

Tobacco, the only consumer product proven to kill more than half of its regular users, is responsible for about 5 million deaths worldwide every year...today the burden is roughly evenly divided between industrialized and developing nations. However if current trends continue though 2005, tobacco will kill 10 million people worldwide each and every year and 7 million of these deaths will be in the developing world, in nations least prepared to deal with the financial. Social, and political consequences of this global public health tragedy.

If we fail to act to prevent this tragedy, the consequences will most certainly be dire. Tobacco will eventually kill about 650 million smokers alive today, about 10% of current total world population.

In the last century alone, tobacco killed 100 million smokers. If left unchecked, tobacco will kill more than 1 billion people in this century.

This extraordinary suffering and death is not inevitable, however. Without intervention, the tobacco pandemic will be the worst case of avoidable loss of life in recorded history. Yet, with comprehensive, concerted action, we can eliminate the global scourge of tobacco and save hundreds of millions of lives in the next few decades.

(A Message from John Seffrin PhD, CEO, American Cancer Society, Foreword to The Tobacco Atlas, Second Edition, July 2006, J. Mackay. M. Erikson, O.Shafey www.cancer.org/international)

The shocking statistics should be of concern not just to the medical and public health community, but to consumers, producers, manufacturers, policy makers and the public alike. Without dispensing with current policies and strategies that work , we need to consider new strategies that can meet the needs of the over one billion smokers worldwide.

Tobacco is Big Business

The production, manufacturing, and marketing of tobacco and tobacco products remains a multibillion dollar industry with tobacco being produced in over 100 countries and sold and manufactured in almost every nation (conservative estimates put the tobacco economy at close to $ 400 billion dollars a year). Tens of thousands of people are dependent on the production, processing, manufacture, sale, distribution and marketing of tobacco and tobacco products.

As the Tobacco Atlas further notes:

Globally, tobacco production has almost doubled since the 1960's, totaling nearly 6.5 million metric tons in 2004. In developing countries, increasing demand and favorable policies have resulted in a threefold increase in production, while production has declined by more than 50% in developed countries. If this trend continues as projected in 2010, more than 85 percent of the worlds tobacco will be grown in developing countries.

Tobacco agriculture causes widespread environmental and public health problems. Pesticide and fertilizer runoff from fields and massive deforestation associated with tobacco curing damage the environment. Workers suffer pesticide poisoning, green Tobacco sickness (an occupational hazard unique to tobacco), and lung damage from exposure to tobacco and field dust.

Although tobacco farming is very profitable for multinational corporations, many small farmers are caught in a debt trap perpetuated by the tobacco companies. (p.48)

Every year, more than 5 trillion cigarettes are manufactured worldwide. China is bay far the largest cigarette manufacturer followed by the USA.

The economic value of tobacco products amounts to hundreds of billions of dollars per year. Very little goes to farmers for growing tobacco leaf. More is spent on paper, filters, and packaging than on tobacco. In the USA, the manufacturing sectors share of the tobacco dollar has almost tripled since 1970.

The tobacco industry has taken advantage of countries with inexpensive labour and a more friendly business environment to open new factories in Eastern Europe for example. Technological advances both in farming and manufacturing are reducing the demand for manpower, this has a far greater impact on jobs than tobacco control efforts.

Aside from using less tobacco per cigarette, the composition of the cigarette is also changing. Manufacturers are increasingly using low-quality reconstituted tobacco because adding chemical additives is easier and making cigarettes from previously discarded parts, leaf stems and tobacco dust increases profit margins. (P. 50)

The different types of tobacco grown in the US and the world are almost as diverse as are the products that are on the market. Tobacco is grown, harvested, processed, cured, manufactured and used in many different ways. Yet, there is no uniform system either in the US or elsewhere that tracks tobacco production or tests the tobacco for quality and safety assurance. Nor are there uniform and sufficient standardized testing methods for tobacco products or the necessary regulatory structures in place to effectively oversee their manufacture and marketing, although it is hopeful that there will be significant changes as the Framework Convention for Tobacco Control continues to be implemented by the ratifying countries, now well over 100.

We are doing far too little to really understand the effects on tobacco use and what to do about it as an agricultural commodity and as a manufactured product

A recent paper published in the journal **Nicotine and Tobacco Research** concluded that:

With the growing introduction of PREPs, it is imperative that research and action be undertaken now to ensure that the public will be protected and to avoid a potential public health disaster. But more important, to have a significant impact on public health, all tobacco products should be regulated and undergo comprehensive evaluation. (Nicotine and Tobacco Research, Volume 7, Number 6, December 2005, " Methods to assess potential reduced risk products", page 841).

This also raises important questions about the use of techno-

logical advances in the production of tobacco such as technologies to significantly reduce the levels of tobacco smoke toxicity or the cancer causing agents polycyclic aromatic hydrocarbons (PAHs), tobacco specific nitrosmaines (TSNA's), as well as monitoring the use of pesticides and other chemicals applied to the tobacco both in the US and overseas. It also raises questions about the use of additives and flavorings in tobacco as well as other chemicals that may further increase the risks associated with tobacco use. And it also raises questions about the use of genetically modified tobacco which has the potential for removing toxins, reducing the use of pesticides, etc. but at the same time might present certain added risks. While all tobacco has inherent risks, it is the form of tobacco, what is done to the tobacco and how it is used that can determine a wide spectrum of the level of risk.

While the tobacco companies are in some ways incredibly sophisticated in their efforts to manufacture, and market their products, tobacco as a whole remains in the 'dark ages'.

The tobacco industry is in some ways where the food and pharmaceutical industries were in the early 1900's when there were no regulations and oversight of those industries and which were made up of manufacturers and salesmen often selling dangerous foods and 'snake oil' medicines. Science and technology, coupled with regulation (creation of what would become the FDA) were seen as a way to, on the one hand, protect the public while, at the same time encourage and allow for innovation, science and commerce. Today we find the tobacco industry existing and surviving under what can only described as a 19th century system, the result being that what we don't know about tobacco and tobacco products can and does hurt us. I have often said in my presentations and several white papers that we need to bring tobacco into the 21st century. I highly recommend that those in industry, the public health community, the scientific community, the agriculture community, policy makers and the media consider reading Philip Hilts' book on the history of the FDA, Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation, Alfred A. Knopf Publishing, New York, 2003. Some of the parallels are striking.

For decades many in the public health community have taken the approach that the use of all tobacco and all forms of tobacco are equally harmful. This approach is comparable to saying that all automobiles in the market place are equally dangerous (or safe), or that all drugs products in the market place carry equal risks and are equally effective. This however, is not the case. One reason for making such broad statements is that we may not know where the lines are drawn between products because there are no obligations for the industry to provide the information that is so urgently needed. Another part of the underlying reason for taking that approach may be to counterbalance the tobacco industry's historical efforts to deny consumers truthful information while aggressively and irresponsibly marketing their products in a nonexistent regulatory structure with no standards. For years the industry denied that their products caused harm and were addictive even while their own scientists were confirming such dangers – one of the major reasons why the federal government and others have sued the tobacco industry.

There needs to be a broader and more extensive educational effort to break down barriers and misperceptions about what tobacco is and what it is not, and to deal with the facts. There needs to be greater transparency among stakeholders, as well as participation and involvement of experts outside the tobacco environment (which has become potentially too confined and restricted). Broadening the discussions will not only force positive commercial changes in the tobacco industry itself but more importantly benefit public health goals.

We are finally beginning to see some public understanding and recognition that not all tobacco products are equally harmful. As noted in a Special Communication in Tobacco Control :

> *The epidemiology tells us that tobacco products delivering nicotine vary considerably in harmfulness. Within each category there is a (sometimes wide) variation of dose and manner of use, but the extreme ends of the spectrum differ in harmfulness by orders of magnitude. (Towards a comprehensive long term nicotine policy,* **Tobacco Control** *2005;14:161-165.)*

An article in **The New Zealand Medical Journal** offered some interesting observations and challenges everyone to think 'outside the box' about what we are trying to do and how we might get there.

The authors wrote:

> *Inhaling tobacco smoke is a remarkable and exquisitely refined mechanism, for delivering nicotine to the central nervous system. Remarkable for its acute safety*

and chronic catastrophe, and unique because it is tobacco not nicotine that causes the damage. Failure to make this crucial distinction is a tragedy.

Perversely the very success of tobacco control has left remaining smokers and most of the world's developing countries in the unfettered embrace of a demonized tobacco industry. The outrage from public health at the tobacco industry's intransigence and tactics has clouded the entirely separate issue of tobacco and nicotine, rendering the idea of developing recreational or long term replacement nicotine a heresy.

*(***The New Zealand Medical Journal***, "Time for major roadworks on the tobacco road?, Vol.117 No 1190)*

When it comes to implementing policy reforms and changes amongst the various stakeholders, little to no substantive engagement or discussions have taken place about what tobacco is, the reasons why it is harmful, what can and should be done about it, and how to better communicate accurate information to the public. While many studies have dealt with what causes tobacco related disease, much of it goes unrecognized by the health advocates except as ammunition for the perpetuating of an ongoing war with the tobacco industry. On the industry's side, there has been little to no flow of information and transparency in the industry research endeavors and marketing strategies. Their approach has been and for the most part remains to deny, suppress, and mislead the public. While the 'war' must continue on numerous levels the time has also come to begin to look seriously at other issues related to scientific research, tobacco's production, manufacturing and marketing.

Today there is a great deal of legitimate scientific research being conducted on tobacco that may hold promises for not only reducing risks associated with the use of tobacco products but also developing new products (pharmaceuticals, industrial enzymes) that may one day save lives. Transgenic tobacco (GMO tobacco) has been described by some as the 'white rat' of the plant world. Unless one wants to take a prohibitionist view (and there are clearly those who do) on tobacco, it is far more appropriate to talk about what it is about tobacco that causes harm and what can be done about it other than to make broad over-reaching statements that all tobacco is equally harmful. Such 'oversimplification', while useful as a public relations tool, now may in fact be a disservice to the public health goals of reducing disease and death caused by tobacco use- especially in an environment where products will continue to be modified and changed.

Mark Parascandola, an epidemiologist with the Tobacco Control Research Branch of the National Cancer Institute has noted that:

Despite the overwhelming amount of scientific knowledge available today about the harmful effect of tobacco products on human health, the need to expand scientific research efforts to understand specific characteristics of tobacco products and their effects is more urgent than ever.

(Science, Industry, and Tobacco Harm Reduction: A Case Study of Tobacco Industry Scientists' Involvement in the National Cancer Institute's Smoking and Health Program, 1964-1980, ***Public Health Reports****, May/June 2005, Vol. 20, p.338)*

In a recognized need and effort to better understand the differing risks associated with the use of tobacco, the World Health Organization (WHO) observed:

There is no single product testing model that is perfectly adaptable to tobacco product testing, although experience in testing foods and drugs of tobacco product emissions have provided the basis for the observations and protocols … For example, foods are generally labeled on the basis of ingredient content, while drugs are labeled on the basis of either content or estimated systemic delivery. In the case of non-combusted tobacco products, content provides an important starting point, but consideration must also be given to the components emitted from the product under the conditions in which it is actually used . In the case of combusted tobacco products the complexity of assessment is escalated dramatically because the hundreds of constituents in the unburned product can result in more than 4,000 products in the emitted smoke, and many of these newly created products are among the most deadly emissions. The generation of these products involves a complex chemical process that is influenced by factors ranging from the products ingredients and design to the way in which the product is physically smoked. Finally, the products themselves are rapidly

evolving, as indicated above, and this rapid change means that a testing protocol that is well suited to one product may be inadequate for a modified or novel product.

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

The health consequences of using tobacco (or breathing in cigarette smoke) thus depends on a spectrum of interrelated conditions which include:

- Whether the tobacco is combusted or noncombusted
- The type of tobacco (including whether the tobacco is reconstituted)
- The manner in which the tobacco is grown, harvested, cured and processed
- What pesticides (and combination of other chemicals) may have been used on the tobacco
- What additives and chemicals are used in the tobacco product (including quantities, how such additives may interact with one another in a raw or burned state)
- The manner in which the tobacco product is manufactured
- The frequency and manner of use
- Family history and pre-existing conditions

While all of the above items play some role in the risks and relative risks of using tobacco, currently, one of the most significant and visible of the above variables is whether the product is combusted or non-combusted. When tobacco is combusted, it produces 4,000 chemical constituents-many of which have been identified as carcinogenic. Others, such as gases like carbon monoxide, are associated with cardiovascular disease and stroke. It may well be that science coupled with fair and effective oversight will soon allow for a far better understanding of the risks and relative risks for combustible products as well as noncombustible products.

A market place filled with disinformation

The tobacco industry, and in particular the larger companies who have controlled the market place, have been guilty of failing to disclose critical information about the tobacco used in the products they manufacture and market. They have denied that their products caused harm, or were addictive, all the while developing marketing strategies designed to give consumers the false belief that there were 'safer' cigarettes. They pointed to so-called scientific studies designed to undercut the findings and conclusions of the Surgeon General and scientists in the public health community. The have spent billions of dollars over the years on marketing campaigns that provided little to no verifiable health information or health benefit to the consumer. They have done this in spite of 'arguing' that they are trying to serve their customers interests in providing products and information that the tobacco consumer wants.

In recent years, many health advocates have taken on similar tactics, advocating that the withholding of truthful and accurate information from the public and users of tobacco, or the exaggeration of information, is 'for their own good'. These positions are in many ways inconsistent with long held positions which have demanded full disclosure from the tobacco industry, as well as full disclosure in the labeling and marketing of tobacco products.

Today we are confronted with a market place in which a consumer has little to no substantive information about the tobacco and the tobacco product upon which to truly understand the dangers, risks and relative risks associated with various products. Verifiable substantive information about products is what is going to be required in an environment where we will see an increasing number of harm reduction products entering the market place. Currently, there is no level playing field. Warnings are outdated. Useful, truthful information about the products and the relative risks of products is suppressed or withheld, or distorted. We don't know where the tobacco comes from, what's been done to it or what if any tests may or may not have been done. We are in some ways, truly in a 19th Century 'snake oil' environment.

In both the case of the tobacco industry and to some extent the public health community, science has often been manipulated, and misused to achieve self-serving goals. While the public health goals obviously represent the higher good, two wrongs don't make a right. Taking the position that providing selective, exaggerated, or even false information can be justified sets a dangerous precedent and gives science a black eye. In the end, such an approach may dampen the respect and reliance that the public has come to expect from the well established public health organizations, government officials, and the scientific community. Yet,

as long as the industry continues to shirk its responsibility, and as long as we do not have a regulatory agency (or other avenues) that can ensure that the information flow is truthful, it may be that for the public health community, the ' end will continue to justify the means'.

The results of the disinformation campaigns conducted by a spectrum of interests have had effects on the public and the consumer of tobacco products. Below are just a few of the many examples where the withholding of information or the misuse of information can and has had negative public health impacts. It seems almost inconceivable to me that after more than 25 Surgeon General's Reports we would find ourselves in such a state.

- Several studies over the last several years have clearly demonstrated that so-called lower yield (low tar and nicotine cigarettes) are not safer than other cigarettes on the market and that the industry has deliberately with held information about their use and dangers. See for example , an editorial in the **Journal of the National Cancer Institute** (Vol. 92, No2, January 19, 2000), It's time for a Change: Cigarette Smokers Deserve Meaningful Information About their Cigarettes.

- A number of studies and surveys have shown that there is a misperception in the public that it is the nicotine in the tobacco product that is the agent that causes disease and in particular cancer.
- Many cigarettes are marketed as being an American blend, or 'made in America' when in fact a large proportion of the tobacco may come from overseas markets. One large US tobacco company that produces only US cigarettes has been suspected of using a very low proportion of US tobacco in its so-called American cigarettes. In addition, it has been suggested that many tobacco companies including some of the largest ones are using 'reconstituted' tobacco which is often called 'trash tobacco' because it consists of 'leftover tobacco' often gathered up from the manufacturing floor, which is then reconstituted for use in cigarettes.

- And finally, a recently published article found that while "A much greater proportion of smokers (82%) were aware of SLT products than were aware of modified cigarettes and cigarette-like products… only 10% of smokers believed that SLT is less harmful than smoking ordinary cigarettes. Here, smokers are misinformed in the opposite direction. Epidemiological data suggest that SLT products sold in the United States are significantly less dangerous than cigarettes". (O'Connor, Hyland, Giovino, Fong, Cummings, Smoker Awareness of and Beliefs About Supposedly Less-Harmful Tobacco Products, **American Journal of Preventive Medicine**,2005,29(2) page 89).

In the first case (low yield cigarettes) it has been the industry that has perpetuated the myth about the relative safety of these products--withholding valuable information from the public about these products and their risks and relative risks. In the second case (nicotine) it has been the public health community and governmental agencies that have unwittingly allowed the public to be convinced that 'nicotine' causes cancer and other serious health problems. In the third case the tobacco industry has attempted to misuse information about the tobacco used in US cigarettes in an attempt to suggest to smokers that the product has superior qualities including safety. And in the fourth case it has been governmental agencies and public health entities, and the interests of the pharmaceutical industry that have helped perpetuate the position that noncombustible tobacco is as dangerous as combustible cigarettes.

A 2002 Commentary appearing in the medical journal **Addiction**, noted:

> *Ironically, many smokers do not perceive much difference in health risk between smokeless tobacco products, nicotine medications and cigarettes. Yet if all nicotine products were put on a risk continuum the actual difference between smokeless and nicotine medications would be seen as fairly minor compared to the difference in disease risk between smoked and smokeless products. Until smokers are given enough information to allow them to choose products because of lower risks, then the status quo will remain.*
>
> *(Can Capitalism Advance the Goals of Tobacco Control?, Society for the Study of Addiction to Alcohol and Other Drugs, Addiction, 97.957-982, 2002)*

Summary and Conclusion

The need to separate out science and fact from public relations efforts, political influence peddling, and marketing strategies is imperative. The manner in which tobacco and tobacco products are produced, processed, distributed, manufactured, labeled and marketed needs to be brought into the 21st Century. Our current system is so fraught with problems and so antiquated that I found myself comparing the current state of affairs with how we dealt with drugs and foods in the early part of the 20th century. Tobacco and the tobacco industry has a lot of catching up to do.

In today's environment science should be used to shape and drive policy decisions–– not the other way around. Unfortunately, science has often become manipulated for self-serving objectives. But the science and the complexity of the issues surrounding tobacco are what tells us that we do need an agency like the FDA to play the role that has been so critical in both the food and pharmaceutical industries. Understanding what tobacco is, the different levels of risk associated with different types and use of tobacco, how it causes harm, and how it can even be used for beneficial outcomes (such as producing new pharmaceuticals, industrial enzymes, etc.) must be given a high priority, by the industry, public health organizations, scientists, growers, government and consumers. We need to get beyond the rhetoric and state of 'war' mentality and start seeking solutions to what is a major public health problem not only in the US but globally as well.

We have an obligation to ensure that the public and consumers of tobacco have all the facts. Our current understanding of 'tobacco' is comparable to a person being asked to assemble a puzzle blindfolded. The pieces are there but we are blind when it comes to assembling the larger picture and final product. In order to effectively deal with harm reduction, we must be willing and able to remove the blindfold.

THE TOBACCO SILO MENTALITY
WE SEE ONLY WHAT WE WANT TO SEE

Issues, Players,Challenges and Opportunities

Opportunity knocks, but doesn't always answer its name.

–Mason Cooley

Knowledge is what we get when an observer, preferably a scientifically trained observer, provides us with a copy of reality that we can all recognize.

–Christopher Lasch

The majority of people, organizations, businesses, and scientists I have talked with or who have made public comments and/or issued position statements about harm reduction seem, **in principle**, to support it as a **potential** strategy for reducing disease and death caused by tobacco use. This would obviously seem to make sense. The problem that seems to occur is **how** to move past these general statements and find a process by which harm reduction strategies can actually be implemented and applied on an ongoing and sustained basis. There is also serious and continuing reluctance from some public health advocates who, while sympathetic to harm reduction, strongly believe that the industry can't be trusted, and there are those on the manufacturing side who are fearful of upsetting the 'status quo' because it may impact their bottom line profits and potentially subject themselves to litigation. How do we sort through legitimate concerns and seek to take opportunities and remove barriers with those concerns that are 'tactics' designed to prevent or stall progress? How do we engage in discussions without compromising our goals and objectives, in a way that will allow participants to safely deal with the complex issues surrounding harm reduction? How can we better utilize and employ useful conflict resolution principles that will allow us to put the past behind us and focus on finding common ground? I remain cautiously optimistic that we can find a way.

In a survey of public health advocates, tobacco industry representatives, tobacco scientists et. al EG Martin, KE Warner and PM Lantz for example, found that:

> *Professionals with THR (tobacco harm reduction) expertise and interest. including tobacco control leaders, independent scientists, and tobacco and pharmaceutical industry scientists concur that that harm reduction is theoretically possible, that characteristics of desirable THR products can be identified, that governmental regulation is essential and that THR is a pressing issue. These experts exhibit much disagreement on specifics however, such as the nature of needed regulation or the potential contribution of specific product types to reducing harm. Continued dialogue and debate will be vital as we enter a new and uncertain era of products purporting to reduce tobacco produced harm.*
>
> *Martin, EG, Warner KE, Lantz PM, Tobacco Harm Reduction: What do the experts think?, Tobacco Control, 2004;13; page 128.*

This was also the conclusion expressed in the Institute of Medicine report, Clearing the Smoke, which stated:

> *The committee believes that harm reduction is a feasible and justifiable public health policy – but only if implemented carefully….."*
>
> *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction, Institute of Medicine, January 2001,p.7.*

US Tobacco growers have also weighed in support of the need to move towards the development of products that can potentially lower risks which includes looking at new methods of production for tobacco. (see Tobacco at a Crossroads, May 2001)

The success or failure of a workable, effective harm reduction effort will in large part depend upon what the tobacco industry does and does not do, and how the public health community, scientific researchers, tobacco producers, consumers and others pro-act and react. Will the industry,

or a large enough segment of them, fight to keep business as usual and preserve the status quo or will enough of them decide (for competitive purposes, litigation, ethics or other reasons) that the time has come to alter their ways? And what about those who grow, process and market leaf tobacco? Can they in a 'post buyout' environment change their methods of production, incorporating more science and technologies to produce tobacco that is truly lower in risk?

In an environment that is very different than the 1960's,70's, 80's and 90's, how do we even define the tobacco industry? Are we referring to the companies that for decades were a monopoly (now more commonly referred to as Big Tobacco), or are we including newer companies whose intentions are extremely diverse? Are growers really a part of the industry? And does the 'industry' include biotech companies and others businesses that may want a piece of the business? Resolving many of the challenges and opportunities related to successful implementation of 'harm reduction' strategies and policies undoubtedly will at one point or another involve interaction among the following players:

- Public health advocates
- Tobacco manufacturers
- Scientists researchers, toxicologists, and other academics
- Tobacco producers
- Harm Reduction Experts
- Users of tobacco
- Marketing experts
- Agronomists
- Biotech companies
- Pharmaceutical companies
- Retailers and wholesalers
- Leaf Dealers
- Regulatory and Legal Experts (GMP's. advertising, labeling etc)
- Policy makers

The Role of Science and Technology

Most would agree that 'science' is one of the most important determinants in what we do and do not do with respect to dealing with tobacco and, in particular, efforts related to harm reduction. Science is always evolving. Science should shape policy decisions. However, science has been and is often misused and abused to push policy decisions that support special interests goals and objectives. Policy goals are often established and science is then used to support the goal. For harm reduction to be given any real chance of success the misuse of science must end.

Eight years ago, Doctors Slade and Henningfield noted that:

> *…… tobacco companies have traditionally rejected otherwise broadly accepted, conventional and scientifically established perspectives about addiction, the harm that tobacco products cause and the harm that tobacco smoke causes nonsmokers.*
>
> *In the absence of a shared understanding about these fundamental matters, discussions with industry representatives are much more difficult than should be necessary, wasting time and resources.*
>
> **Food and Drug Law Journal Supplement** *Vol. 53, Tobacco Product Regulation:Context and Issues, 1998 John Slade, Jack Henningfield. page 62.*

But upon closer analysis, the tobacco industry's past use and abuse of science goes even deeper and further and also compels us to assess and consider how science is being used (misused) to further public policy goals and objectives by a spectrum of stakeholders.

As is well known, the tobacco manufacturers used the so-called "lack of conclusive science and medical evidence" to fight against efforts to either warn consumers about the dangers of tobacco or have their products appropriately regulated.

A recent book by Chris Mooney (The Republican War on Science, Basic Books, 2005) paints a distressing picture about how science continues to be used to achieve political goals and objectives. While the book focuses primarily on republican efforts to use science for their political objectives, the New York Times reviewer of the book notes that Mooney acknowledges that such

> *'science abuse is not an exclusively right wing sin. Mooney condemns Greenpeace for exaggerating the risk of genetically modified Frankenfoods',*

animal rights groups for dismissing the medical benefits of research on animals and John Kerry for overstating the potential of stem cells during his presidential run."

The book also contains a section on tobacco which the NY Times reviewer called the 'most original section of the book' and which credits "Big Tobacco" with inventing and refining this 'Orwellian tactic' of using science to promote policy decisions. As many tobacco control advocates know well, the industry tactics were designed to sow seeds of doubt about science which was, as Brown and Williamson noted in a 1969 internal memorandum, "the best means of competing with the 'body of fact' that exists in the mind of the general public".

The larger and more important question that must be considered and evaluated is whether all or part of the 'industry' is really changing, willing to change, or can change. Can they demonstrate through their actions a willingness to accept certain fundamentals and facts that makes 'discussions' now possible? There is no question that times have changed, but have they changed enough? The industry has and will continue to control much of the science. While most of the companies (both large and small) remain in denial there are a growing number of companies willing to conduct business differently (or at least say they are). Can these companies be catalysts for forcing changes in the industry and developing new standards for the entire industry?

While the industry has been reprehensible in its misuse of science, I have concerns that some tobacco control advocates are also using and distorting science in advocating their own goals and objectives, some of which may be driven by other corporate interests outside the tobacco industry. I am concerned when I see and read more and more scientific statements that focus on policy changes rather than on science and which often draw conclusions that are undefined or unsubstantiated and use such words as 'may' , 'could' , 'might' in order to make the science fit into a preconceived policy decision.

All that being said, I concur with Warner et al that the time may be ripe for a more extensive engagement and discussion of scientific and other issues related to the development and marketing of lower risk products. We cannot continue to operate and address issues related to science in what is a public relations 'war of words' that leads to no real end point.

But engagement and discussion must be a two way street especially when it comes to scientific research. There have been a sufficient number of statements made by health organizations, researchers, scientists and industry (cited throughout this paper) to indicate to me that engagement for many is not only possible, but more importantly may be necessary.

Currently, there is an absence of public health people including most importantly the scientific community at any and all of the tobacco industry scientific meetings where the public health community has many opportunities to listen, learn, criticize and challenge the industry. I have 'asked' a number of people why they don't attend such meetings if only to gather intelligence about what the industry is up to. I most always have gotten the answer, "I probably should, but I don't want to be seen as being with the enemy'. Similarly, there is an absence of industry people, particularly the scientists, at the tobacco control conferences or scientific meetings where the tobacco industry, tobacco growers and others could listen learn and challenge the public health community. It doesn't mean that people need to be given 'carte blanche' to attend a meeting. It does mean that there should be opportunities for controlled and meaningful engagement, or as one of my public health colleagues said, 'it is a good opportunity to smoke them out'. Several meetings have been held that have brought the parties together in a limited fashion (Risk Reduction meeting in Crystal City, VA, efforts of Greg Connolly, MD, in Massachusetts etc.) but much more must be done.

The Society for Research on Nicotine and Tobacco (SRNT)'s annual meeting is another place where there might be some interesting scientific panel discussions involving tobacco industry scientists. Again it would be an opportunity to debate and discuss scientific issues in a controlled setting.

Dr. John Slade, (to whom this paper is dedicated) convinced me that it would be well worth my attending some of the tobacco science meetings and in particular the Tobacco Science Research Conference that is held annually and which brings in scientists from all over the world to talk about their work. While the majority of those presenting appear to be industry funded scientists, they are not exclusively industry funded and it would be a mistake to reject the science merely because it is part of an industry sponsored meeting. The 2005 conference for example dealt with the, "The Tobacco Industry – Changes and Opportunities." The 2004 conference focused on biotechnology develop-

ments in the tobacco industry, the year before on harm reduction. The first one I attended in Montreal focused extensively on the potential of the use of GMO (genetically modified) tobacco.

The Life Sciences Research Organization has also been looking into the issues of risk reduction for tobacco. Although receiving a large grant from Altria, LSRO contends that their efforts are totally independent and free of any and all interference from Altria. Initially the grant seemed to focus solely on cigarettes but appropriately has been expanded to look at other issues including smokeless tobacco, and even other nicotine delivery sources. At one meeting that I attended to observe, there were no other public health advocates in attendance. Why? Would not this be a good opportunity to enter into a challenging discussion? Would this not be a good opportunity to observe first hand the legitimacy or illegitimacy of such meetings and discussions? Is this not where we must end up in an environment where reduced risk tobacco products are being developed and eventually marketed?

As many are aware, Philip Morris has publicly announced that it plans to build a $300 million research facility in Richmond Virginia to do, among other things, scientific research on the development of lower risk tobacco products. In an interview that was conducted by the late Peter Jennings, Jennings and Altria's Steven Parrish had an interesting conversation that went like this:

> *Jennings: Steve Parrish. He was a senior executive for Philip Morris in the 1990's. Now he works for the parent company, Altria. In those days I don't think I'd even been allowed in the building*
>
> *Parrish: I'm sure you wouldn't have been. Any member of the news media would have been barred from our building. I'm sure that's true.*
>
> *Jennings: Today for the first time, Mr. Parrish reveals what it was like inside an industry under siege.*

Along those lines it would behoove PM to invite public health scientists and researchers, (including governmental officials from NIH, CDC, the USDA and FTC) tobacco growers, policy makers and others to hear first hand what PM's goals are for this research facility and to talk candidly and openly about the directions that PM may or may not be taking. If PM refuses to provide transparency, it would behoove public health advocates and scientists to proactively ask PM to provide more information about what this research facility plans to be doing in the future, how PM plans to peer review the research and how they would plan to make it available to the public (scientific journals, conferences etc). This process should be initiated with other companies and entities in the tobacco business as well.

As many know, the FDA in 1999 charged the Institute of Medicine with the task of looking at the issue of harm reduction, to address four major questions and "to formulate scientific methods and standards by which potential reduced exposure products could be addressed." These four questions were:

1. *Does use of the product decrease exposure to harmful substances in tobacco?*
2. *Is this decreased exposure associated with decreased harm to health?*
3. *Are there surrogate indicators of this effect on health that could be measured in a time frame sufficient for product evaluation?*
4. *What are the public health implications of tobacco harm reduction products?*

The IOM report **Clearing the Smoke** published in 2002, made some important recommendations that need to be considered, discussed and debated as we move forward in dealing with harm reduction issues with or without FDA oversight.

> *The committee believes that harm reduction is a feasible and justifiable public health policy – but only if it is implemented carefully to achieve the following objectives:*
>
> 1. *Manufacturers have the necessary incentive to develop and market products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco-related disease;*
> 2. *Consumers are fully and accurately informed of all the known, likely and potential consequences of using these products;*
> 3. *Promotion, advertising, and labeling of these products are firmly regulated to prevent false or misleading claims, explicit or implicit;*

4. *Health and behavioral effects of using PREPs 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*
5. *Harm reduction is implemented as a component of a comprehensive national tobacco control program that emphasizes abstinence-oriented prevention and treatment.*

In the December 2005 edition of **Nicotine and Tobacco Research** a scientific paper entitled "Methods to assess potential reduced exposure products," in following up on the IOM report, provided what the authors referred to as a 'blue print' for determining the relative health risk of potential reduced risk exposure products'. The authors described a 'three step model' of evaluating reduced risk products that includes both premarket evaluation as well as postmarketing evaluation.

When talking about science, tobacco, and harm reduction we must also include the pharmaceutical industry in these discussions. The pharmaceutical industry has and will continue to play a significant role in the tobacco arena. The same types of concerns that have been raised about the tobacco industry and science are also being raised by many about the influence of the pharmaceutical industry and science. Recently a prestigious panel of medical experts, concerned about the pervasive influence of drug industry money called for the adoption of far-reaching conflict of interest policies. As Jordon Cohen, president of the Association of Medical Colleges noted:

> *"We've become overly dependent on these kinds of blandishments to support our core activities, and that is jeopardizing public trust and scientific integrity"*
>
> *(See Washington Post, Wednesday, January 25,2006,* **Distance Sought Between Doctors and Drug Industry,** *Ceci Connolly)*

For more on this subject see the chapter on Transparency, Accountability and Unintended Consequences

Is scientific research by governmental agencies on individual products the only solution ?

Some public health advocates feel that it is the federal government not the tobacco industry that should be conducting the scientific research on tobacco and tobacco products. But given the serious and considerable budget constraints within the federal government, is this even a feasible longer term strategy? Given that the tobacco industry itself is conducting extensive research that should be made available, is this strategy feasible? Personally, I think we need both.

On May 5, 2004, the National Institutes of Health (NIH) issued a federal register notice seeking applications to 'stimulate multidisciplinary research on potential reduced-exposure tobacco products, both smoked and smokeless, through the interplay of basic, biological, and behavioral research and surveillance and epidemiology". The announcement noted that the key research question to be considered is "Do potential reduced-exposure tobacco products provide a truly, less harmful alternative to conventional tobacco products, both on the individual and population level?"

Funded by NCI and NIDA important and significant work is being conducted by a number of academic institutions such as the University of Minnesota Transdisciplinary Tobacco Use Research Center (UMN TTURC). UNMN TURC is one of a number of institutions that is working to scientifically evaluate the level of toxicity of PREPs. Others include, Yale, University of Wisconsin, Brown University, the University of Pennsylvania/Georgetown University, University of California at Irvine, and the University of Southern California.

The difficulty in answering such a question is that it assumes a static unchanging environment. Given the rapid potential for technological changes, the development of more products and changes in public attitudes and perceptions, the research on specific products while very useful, may be outdated in a matter of only a few years. The IOM seemed to recognize this in its report when it noted:

> *The committee does not evaluate specific PREPS in this report, since the currently available tobacco-related PREPs in particular are most likely prototypes of limited lifespan. Under present regulatory conditions, tobacco related PREPs can be changed with little assessment and without disclosure of their contents. (***Clearing the Smoke***, page 5)*

In my research I found that a growing number of people seem to feel that it is the tobacco industry that must also be paying a large portion of the bill and/or conducting the scientific research that will continue to need to be done. But the challenge is how and under what conditions. We find a divide among many of the players that needs to be addressed and needs to be addressed quickly.

The American Legacy Foundation's Cheryl Healton has suggested that the Foundation expand its role in research ' by filling a special niche; funding academic studies of 'potential reduced-exposure products, or PREPS'. According to the American Legacy Foundation, "This research has to be funded by the tobacco industry- through a completely hands-off mechanism where they do not control the process at all – or through the federal government. What would bring the tobacco industry to the table to put some money into this is that they want to have some mechanism for making determinations about their claims. On the other side, the attorneys general want some mechanism of enforcement'. ("As Legacy seeks new money, critics fear symbiosis with Big Tobacco", The Cancer Letter …. Pages 3-4)

In the same article, John Hughes a professor of psychiatry at the University of Vermont argued that the tobacco companies, not the taxpayer, should pay for the testing of PREPS. "I had a grant from NCI to test these products that make claims, why should the taxpayer pay to assess that, which is what's happening now?"

An article from **Science (January 2005)**, entitled Is Tobacco Research Turning Over a New Leaf?, provided a number of interesting points of views and observations:

……."It's not a simplistic issue," says Ken Warner, a public health expert at the University of Michigan, and President of the Society for Research on Nicotine and Tobacco. He conceded that the tobacco industry was guilty of misconduct in the past but worries about restricting research "How do you avoid infringing on academic freedom, and what sort of slippery slope do you create by denying grants on moral ground? ," he asks. "There is a real need for reduced-harm research. The question is given their history, do we let the tobacco companies fund it?"

……..Anti-smoking activists tried to stop tobacco's research juggernaut more than a decade ago – and won some battles. But industry funding is flourishing, igniting debate on campuses over whether universities should ban tobacco money and whether grant organizations should deny funding to individuals or schools that take this money…

……..(Jed) Rose co-inventor of the nicotine patch, argues that vilifying the industry won't help the millions of smokers who are trying to quit. "The real enemy is the death and disease smokers suffer," he says. If we can use tobacco money to help people lead healthier lives, why shouldn't we?"

……..Others think academic researchers should just say no to tobacco money. Simon Chapman, editor of the journal Tobacco Control and a professor of public health at the University of Sydney in Australia, says that despite their new efforts to support harm reduction studies, the tobacco companies have little interest in public health. "They fund this research to buy respectability and ward off litigation" , he says. Some worry that reduced-harm products are just a ploy to keep smokers addicted.

……."I (Stephen Rennard of the University of Nebraska Medical Center who receives tobacco money) approach this from a public health perspective. People are going to continue to smoke and we need to make them as safe as we can. The tobacco industry needs university research to develop a safer product. In the end I realized that this research should be funded by tobacco companies. NIH resources should not be used to improve cigarettes. It would be like the government subsidizing the development of a better laundry detergent".

*……..Nor does the American Legacy Foundation have any qualms about denying grants to institutions that take tobacco money. "We don't see this as an academic freedom issue," says Ellen Vargyas, the foundation's general counsel. "The tobacco industry has a bad history, and this is our way of encouraging institutions not to take their money". **

* But the question must be considered and asked as to whether ALF (already receiving tobacco industry money through the MSA) will take tobacco industry money to help fund its newly established Tobacco Research Center ?

In a recent editorial in Tobacco Control, T. Eissenberg summed up much of what I feel must inevitably occur this way:

Industry support for product evaluation is a dilemma for those of us who have worked to develop the methods to evaluate PREP effects. On the one side, we learned from previous experience that PREP marketing without evaluation profits the industry and kills smokers. With this history in mind, many public health advocates now call for objective PREP evaluation. On the other side, tobacco industry funding or work completed by non-industry scientists is, at best a controversial topic. Researchers who accept tobacco industry dollars risk losing access to other funding sources, cannot publish that work in some journals, and may find their objectivity and integrity questioned. All of these outcomes are at least a partial result of the tobacco industry's documented history of scientific misconduct. Thus evaluation of specific PREPS, rightly funded by the tobacco industry and likely to provide significant health benefit may be suppressed because few independent researchers will perform the work.

Rigorous and objective industry funded PREP evaluation is a complex issue that will require innovation and flexibility. At the least, work must be completed in an atmosphere of openness and transparency, with financial arrangement and scientific methods accessible to all. Evaluation studies must be designed, conducted and reported without industry oversight, and researchers must retain ownership of their data. Data safety monitoring boards may be used to ensure that results are reported accurately and that conclusions can be supported by the data. Eventually, government may play a key role my mandating specific evaluations, managing a competitive process for awarding industry funded contracts, using industry funds to support expert review of premarketing testing procedures and results, limiting marketing based on evaluation, and requiring detailed post-marketing surveillance……

The time for industry sponsored evaluation of the exposure reduction associated with specific PREPs has arrived, even while these and other PREP evaluation methods are being refined and improved……

Failure to act in this manner will, at best, leave evaluation in the hands of an industry with a poor track record for objectivity. At worst, failure to act will doom us to repeat the very history that we remember too well; a history where uninformed consumers and many public health advocates embraced untested products that enriched the tobacco industry but did not reduce smokers' exposure to lethal smoke toxicants.

(T. Eissenberg, The time for tobacco industry sponsored PREP evaluation has arrived, Editorial, **Tobacco Control***, 2006;15:1-2)*

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

It is essential that adequate funding is secured in order to establish and maintain laboratories that conduct the independent and credible research and testing for tobacco product regulation. There is little question that simply establishing the capacity for developing performance standards and objective tests could cost a few million US dollars each, in addition to the several million US dollars that would be required to cover start-up costs. But this cost represents an insignificant fraction of the value of the global tobacco market, which is estimated to be in the region US $ 300-400 billion. However in absolute terms the cost of developing laboratory capacity and operations represents a significant financial commitment which is not likely to be readily undertaken by individual nations. It may therefore become essential that tobacco companies be required to finance laboratory capacity and testing.

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

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

Comment: The debate over the issue of tobacco money being used to fund research will likely continue. There may be no one solution to the problem. I believe, however, that there may be ways of better monitoring and controlling the manner and parameters under which such funds are provided and how the results of any studies that are funded are published. It is also possible to identify significant and important areas of research that should be given high priority by both the public and private sector. I am also convinced that we need to find a way to carefully integrate and more importantly evaluate the science that is being conducted by several entities including the tobacco industry and others in the public and private sectors.

The need for uniform testing methods for tobacco and tobacco products

There can be no doubt that there is a growing unanimity about the need for revisions that are currently used in the testing of tobacco products. It has long been argued and advocated that

> *"A fundamental perquisite for rational tobacco product regulation is the ability to predict relative doses of specific materials to which consumers will be exposed if they use particular tobacco products. This ability to predict is dependent on the existence of reliable tests methods for estimating what people ingest. The most widely used test however, is misleading and cigarette manufacturers have sought to maintain the status quo despite knowing the tests shortcomings for decades. In fact they have turned the test to their commercial advantage in the form of light and low tar cigarettes to the detriments of public health."(FN: Tobacco Product Regulation: Context and Issues,* **Food and Drug Law Supplement**, *Vol 53 1998, p.48)*

As the World Health Organization (WHO) has more recently noted:

> *"the current methods for product testing adopted by the International Organization for Standardization (ISO) and the United States Federal Trade Commission (FTC) are inadequate since they fail to provide the appropriate scientific basis for tobacco product regulation"*

In April of 2005, working off previous recommendations from a number of other bodies, the WHO's Tobacco Laboratory Network (TobLabNet) held its first meeting designed to look at the needs and to see provide some recommendations for the establishment and implementation of a national and regional network designed to develop capacity for tobacco testing and research. Included among its list of future activities were:

- *Develop a compendium of expanded testing methods for tobacco product contents and emissions.*
- *Develop additional methods and create a validation programme for testing methods for tobacco products and tobacco smoke other than tar, nicotine, and carbon monoxide(TNCO).*
- *Develop and validate testing methods for tobacco products other than cigarettes.*
- *Participate in international standardization activities.*
- *Define periodic meetings for scientific research, exchange of information and identify research priorities/agendas.*
- *Exchange information with policy makers and regulators.*

In the paper published in **Nicotine and Tobacco Research** already noted above, the authors concluded:

> *The recommendations made by the panel of experts for this paper as well as the World Health Organization recommendations emphasize the importance of an infrastructure that allows for an integrated, comprehensive and systematic evaluation of tobacco products, both conventional and PREPs. This system would include a product registry, which would have necessary information on all nicotine-delivery products on the market. Optimal coordination of data collection and analysis will be facilitated by the creation and long-term support of a transdisciplinary research network that would include experts from both the public and private sectors. A comprehensive premarket evaluation program will likely require multiple testing sites, with each site using a valid, reliable, and uniform or coordinated set of measures (with additional measures as needed or desired).*
>
> *(Hatsukami, Giovino, Eisenberg,Clark, Lareence, Leischow, Methods to assess potential reduced risk products.* **Nicotine and Tobacco Research**, *Volume 7, Number 6 (December 2005, page 841).*

It will be imperative that both current and future tobacco products not only be tested for various harmful constituents

but that consistent testing methods be employed. Testing may vary depending on the type of product and how it is used. Noncombustible tobacco products may (as suggested by WHO) employ modified food- oriented type standards where combustible products might better be assessed using pharmaceutical type standards.

Comment: Here again, if we are to effectively develop new and standardized methods for testing of tobacco and tobacco products, there will need to be participation by a wide spectrum of players that will need to sit down and discuss how to proceed. Testing should be done by both industry and independent agencies that should serve to validate the results. While I am not suggesting that things can be transformed overnight, I am advocating that real and meaningful harm reduction can only be done if the current environment is significantly altered and there greater cooperation.

The Role of Competition and Industry Incentives

The role of competition

The public health community often forgets the significant role that competition (particularly in a regulated environment) can have on changing the behaviors of tobacco manufacturers as well as the products they manufacture. It can also stimulate the need for enhanced research and the development of new technologies in order to produce a better 'science based mouse trap'. And it can drive players out of the market place who produce inferior products or who wish to cut corners at the expense of their consumers and the public health. The current environment in which we have an oliogopolistic market structure (favoring cigarette manufacturers), coupled with the lack of incentives and the availability of alternative products, serve as significant barriers to public health goals and objectives. Instead of criticizing and attacking innovators and preventing the development of new products it might be a far better strategy to support, encourage and even reward innovation so long as such efforts are fully transparent and operate under a set of verifiable standards. We in public health also assume that all tobacco companies (large and small) operate uniformly. They do not. Many companies, whose goals are to make quick profits regardless of the consequences will fight change; they will fight transparency and oversight, and they will fight and oppose the development of science- based lower risk products.

Competition and regulation often go hand in hand in that regulation often provides a level playing field and set of rules under which the 'competitors' must operate. For example, I cannot imagine an environment under which the food industry, or the pharmaceutical industry would want to have a completely 'laissez faire' market place. If an FDA - styled regulatory agency did not exist, these industries would seek to create one in order to establish a fair and level playing field, provide greater stability and predictability in the market place and a way to ensure consumer acceptability of their products. And so it should be the case for tobacco.

An interesting thought- provoking commentary appearing in the medical journal **Addiction** by Dr. Michael Cummings (and noted earlier in this paper) suggested that:

> *The real question for public health agencies interested in tobacco control is not whether public-private partnerships work but how to make such partnerships strong enough so that they can compete for market share with cigarette manufacturers.*
>
> *While Anderson (referencing the author of an article appearing in the journal* **Addiction***) was right when he advanced the concept of public-private partnerships to reduce tobacco dependence, his example of a partnership between public health agencies and the pharmaceutical industry is probably too narrow to make much of a dent in the emerging global epidemic of smoking related diseases. Public health advocates should consider expanding their partnership to include manufacturers of smokeless products and perhaps even companies that are willing to replace their conventional toxic cigarettes with lower-risk alternatives.*
>
> *Until smokers are given enough information to allow them to choose products because of lower health risks, then the status quo will remain. Capitalism not government regulation, has the greatest potential to alter the world-wide epidemic of tobacco related disease. It is up to the public health community to harness the powers of capitalism to speed the development of less dangerous alternatives to cigarettes.*

While I believe the commentary offers some important thought provoking ideas, I think that competition should also

be looked at as including biotech companies, entrepreneurs, growers and others who have the potential of driving and influencing changes in the industry. I also believe that competition must also involve governmental regulation and oversight so that the playing field is level and that all competitors play by a set of rules and standards.

The Role of 'Incentives'

One of the critical elements in motivating change and promoting competition in the industry will be to provide the manufacturers, producers and others with the necessary "incentives" to move them forward. The need for incentives has been talked about and suggested by many. The Institute of Medicine, in its extensive review of issues related to harm reduction products (PREPS) included as one of its principle recommendations:

> *Manufacturers should have the necessary incentives to develop and market products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco related disease.*
>
> *(Clearing the Smoke, Principal Recommendation #2, Institute of Medicine, page 7)*

The Presidential Commission Report, Tobacco at a Crossroad that was issued in May of 2001 noted that:

> *Independent science based decisions by FDA designed to protect public health by taking all reasonable steps to reduce the harm of tobacco products now being sold and promote the introduction of less harmful products will create fair standards and will provide predictability to farmers and to the industry (emphasis added)*
>
> (Tobacco at a Crossroad, *A Call for Action, Final Report of the President's Commission on Improving Economic Opportunity in Communities Dependent on Tobacco Production While Protecting Public Health. May 14, 2001, pages 42-43)*

Other statements have been made by the public health community including the Campaign for Tobacco Free Kids and its partners that noted that legislation (giving FDA authority over tobacco products) should:

> *" ..... encourage the development of products that reduce consumer health risks or serve as less harmful alternatives ..."*
>
> *Excerpts from Critical Elements of Any Legislation to Grant FDA Authority to regulate tobacco Products, the Campaign for tobacco Free Kids, The American Cancer Society, American Heart Association, American Lung Association, 4/9/02.*

In spite of these statements there has been little to no substantive discussions or policy recommendations about **what** incentives should be, **who** should be entitled to such incentives, and **how** they should be managed.

Potential incentives should not only be given to the more traditional manufacturers of tobacco but more importantly to producers of tobacco, new technology oriented tobacco companies, and biotech companies.

What are incentives?

The question is what kind of incentive or combination of incentives should be provided to the industry in order to stimulate effective change? And what if any conditions should be considered in giving those incentives?

Incentives could include such things as:

- Increased tax advantages for investing in independently funded scientific research on what makes tobacco and tobacco products harmful.
- Increased tax advantages that move science from the bench to practical applications in the development of new technologies (including in agricultural production) and new products.
- Application of a 'user fee' on tobacco products on a graduated scale that is determined by "risk" and which would entice companies (tobacco, biotech, growers, pharmaceutical companies etc) to devote greater resources to the development of lower risk products. Such user fees can be used to not only ensure proper and effective oversight of the industry but also as a 'fund' for assisting in further scientific research both within and

outside the tobacco industry.

- Setting variable and flexible marketing standards that are determined by the risk and relative risk of the product.

- Providing governmental assistance to conduct research on tobacco and tobacco products designed to reduce risks.

Conditions might include:

- Acceptance of the need for government oversight (i.e. FDA) governing the manufacture sale, distribution, labeling and marketing of tobacco and tobacco products.

- Agreement that the company's highest toxic products will be removed from the market place over a defined period as lower risk consumer- acceptable tobacco products enter the market place.

- Agreement that the industry will follow the principles and protocols of scientific research that are used by others in the scientific community including peer review, transparency, and the publication of studies etc.

- Agreement that there will be cooperation between government, industry and other interested parties in the surveillance of the tobacco industry in how it develops and markets its products.

The Role of Tobacco Agriculture

Often missing in the discussions about the feasibility of lowering risks associated with tobacco use is the entire tobacco production sector. In fact there have been virtually no articles written emanating from the public health community or the scientific community about what can and should be looked at in the production (growing, curing, and processing) of tobacco.

As the late Peter Jennings, standing in a farm field, noted in the opening of one of his *Specials* on obesity and issues related to food and nutrition (2005), "It all starts here". And so it is with tobacco.

What goes into a tobacco product first appears in the form of a seed, then a plant--a plant that goes through a series of stages before it is incorporated into the final product. What happens to that plant (or what doesn't happen) when, where and how it is grown, cured, processed can effect the toxicity and addictiveness of the tobacco in many ways. As technology changes the ability to change the tobacco in multiple ways will also increase.

Research on tobacco seed and plants is now being conducted at a number of university and private based research institutions but little of that information seems to be reaching those who are interested in harm reduction.

It was noted early in this paper that not all tobacco and tobacco products are the same and each carries not only relative levels of risk but in some cases can be used for the development of new products such as pharmaceutical products and industrial enzymes. Investing in research of plant based technologies and science could have a positive effect on not only the development non-traditional products but also on the ability to remove or reduce risks in more conventional products. It is interesting to point out that even tobacco products that are the same 'brand' have been tested and shown to have very diverse composition, including differing levels of toxins such as TSNA's, most likely due to the different leaf used in the blend.

It has been almost ten (10) years since the issuance of a report entitled **Prospects for Plant-Based Biotechnology Products –Capitalizing on the Southern Advantage** noted:

> *The existing tobacco industry possesses extensive knowledge and developed practices in agronomy, total plant processing, and production and distribution systems. Coupled with this is a world class network of state research universities and allied research centers. Additionally, the US Department of Agriculture (USDA) has until recently been a strong patron of plant research both basic and applied, directed at the commodity.*
>
> *Within the context described above, a weakness of the existing R&D and business infrastructure has been it's primary focus on traditional applications of tobacco. In addition, USDA research sponsorship is rapidly declining at the very time that a targeted effort could establish the nature of chemical products that can be derived from tobacco, optimize their production, and better understand the underlying mechanisms for increasing the future range of products through bioengineering.*

Another difficulty in using cutting edge research and biotechnology to transform the industry is the partial disconnect between academic researchers and business. Many of the more exciting potential applications of tobacco-based bioengineering are in large, highly competitive industries such as food, personal care products and agrichemicals. All of these industries have heavy investments in existing products and processes, zealously guard their trade secrets and proprietary information, and are loath the speculate about their future technology needs. If the research capabilities of universities are to be fully utilized, new structures and processes for interacting with industry need to be devised.

The above findings seem as relevant today as they were in 1996 when that report was written.

Genetically Modified Tobacco

In 1999, the symposium topic at the 53rd Tobacco Science Research Conference was on Genetics and the Future of Tobacco. It was noted in one of the presentations that ,

- *Tobacco with enhanced quality traits has the potential to address issues held by the manufacturers and consumers of tobacco and may add value to the growers or seed producer in the form of premium pricing. Products with improved processing char acteristics, novel flavor(s), and modified product chemistry would fall within this category. Specific traits could include: higher yield of quality leaf per unit area of land; flavor metabolism; reduced accumulation of metals; reduced alkaloids, reduced tobacco specific nitrosamines; and enhanced processing properties (p.52-53).*

- *The use of transgeneic plants has resulted in major advancements in agricultural biotechnology. Tobacco being one of the first plants to be genetically engineered, has played a vital role in the development of this technology. Comparatively little use has been made of the wealth of information available on genetically modified tobacco or to make technological contribution to the quality of tobacco as a crop. This may be due in part to the various issues and concerns that have been raised regarding the use of genetically modified organisms. Issue regarding safety (from a toxicological and environmental point of view) are and will continue to be addressed by scientists, the population at large and regulators. Acceptance is likely to increase provided these safety issues are adequately addressed and as the consumer becomes more knowledgeable about this technology. (p. 54-55)*

- *The opportunities available through the use of biotechnology are enormous. The full potential of its application for the agricultural community has not yet been realized. The design and development of plants with almost any characteristics that can be described in biochemical and genetic terms are theoretically possible. Basic research and industrial application have merged to produce commercialized products. It may be time that the tobacco world seriously considers the advantages that could be realized with the use of this new and powerful technology (p.55)*

As the *Washington Post* reported last June (2005):

Since 1999, the US Department of Agriculture has received 15 permit applications from companies seeking to grow genetically modified tobacco to produce pharmaceuticals. Some companies have already conducted trials on anthrax vaccines and anti-cavity drugs grown in the plant.

"There is no doubt in my mind, absolutely no doubt in my mind, that in the not –too-distant future—certainly our lifetimes -- we will see biomedical compounds derived from tobacco plants," said Val Giddings, vice president of the DC based Biotechnology Industry Organization.

(Washington Post, "Turning Over a New Leaf", Sunday,July 17, 2005)

In a recent article in the **Tobacco Reporter** the significant commercial and consumer benefits to using GM tobacco was again pointed out:

The reason why there has been explosive growth of GM crops worldwide is simple; biotechnology solves complex problems efficiently. He (Joseph Pandolfino of XXII Century a plant based biotechnology company) says

the tobacco industry could significantly benefit from GM tobacco. "Utilizing biotechnology in commercial varieties could immediately benefit tobacco farmers and consumers. GM tobacco plants would be less susceptible to various tobacco plant diseases. Farmers would also enjoy increased crop yields and use less fertilizer and less energy when curing flue-cured tobacco – thus benefiting their pocketbooks and the environment. On the consumer side, GM tobacco could be engineered so that it contains less harmful compounds, including tobacco specific nitrosamines. GM tobacco would be beneficial for all tobacco stakeholders". He also points out that Philip Morris USA is funding a $ 17.6 million research project at North Carolina State University to map the tobacco genome. This five year project is scheduled to conclude in about a year. "In a few years, the function of most tobacco genes will be known. This research will provide extremely powerful tools to commercialize reduced-risk cigarettes. In my opinion it is only a matter of time before GM tobacco is totally accepted by consumers and the cigarette industry," Pandolfino predicts.

(A Different Approach – Biotech firm says increased nicotine levels could be the key to risk reduction, **Tobacco Reporter**, *May 2006.)*

Pesticide Use and Other Chemicals

Many health advocates, growers and even some manufacturers have raised concerns about the application of pesticides and other chemicals on the tobacco plant. While some controls existed over the application and use of pesticides on US grown tobacco, there are little controls over the use of pesticides on foreign tobacco --- tobacco which often finds its way into the US market place unchecked and unaccounted for.

A 2003 GAO (General Accounting Office) report requested by the ranking minority member of the House Committee on Government reform made the following observations and recommendations concerning pesticide use on tobacco products.

In the 1990s, domestic growers used 37 pesticides approved for use on tobacco by EPA. Most of these pesticides were also used on food crops. When used in ways that deviate from conditions set by EPA, many of these pesticides can cause moderate to severe respiratory and neurological damage – and may result in death. Moreover, animal studies suggest that some of these pesticides may cause birth defects or cancer.

While EPA regulates specific pesticides that may be used on tobacco and other crops and specifies how the pesticides may be used, it does not otherwise regulate residues of pesticides approved for use on tobacco. USDA, however, is required by the Diary and Tobacco Adjustment Act to test imported and domestic tobacco for residues of pesticide not approved by EPA. As a result, federal regulation of pesticide residues on tobacco is limited to selected pesticides that are not approved by EPA for such use in the United States. USDA tests most imported tobacco, as well as the portion of domestic tobacco the federal government acquires under the tobacco price support system, for residues of 20 pesticides not approved use on tobacco that federal officials believe are used in some other countries. Most of these pesticides, such as DDT, are highly toxic, persist in the environment, and accumulate in the bodies of humans and animals. By helping to ensure that other countries do not use pesticides that US tobacco growers are not allowed to use, the federal regulation of pesticide residue on tobacco addresses trade equity as well as health and environmental issues. USDA has not revaluated since 1989 the pesticides the department monitors in its tobacco pesticide testing program, although EPA has subsequently cancelled tobacco uses for at least 30 pesticides not currently monitored by USDA. Consequently, USDA's testing program excludes some highly toxic pesticides that may still be used in other countries. To better protect the public from residues not approved for use on tobacco, we are recommending that USDA periodically reevaluate the pesticides it includes in its testing program.

*(***PESTICIDES ON TOBACCO – Federal Activities to Assess Risks and Monitor Residues**, *GAO Report to Ranking Minority Member, Committee on Government Reform, GAO-03-485)*

In spite of the concerns and recommendations made by the General Accounting Office, the situation has become far worse. During the 108th Congress, Congress enacted legislation that repealed all of the testing requirements for foreign tobacco (as well as domestic) entering this country as part of

the tobacco buyout legislation. It has been suggested that the repeal of these important health and environmental provisions were the work of one major US tobacco company that in spite of selling so-called US cigarettes has and continues to use large amounts of foreign, unregulated, and untested tobacco in its products.

Removal of TSNA's in tobacco leaf

One area where there has been attention focused by the public health community, industry, and growers and governmental officials is in the area of the removal of tobacco specific nitrosamines (TSNA's) long considered one of the most significant cancer causing agents in tobacco and tobacco products. TSNA's have been identified again and again by scientists and researchers as one of the most significant cancer causing agents found in tobacco. For example, Henningfield and Slade wrote in 1998 that:

> *Internal confidential memorandum from industry knew and recognized the seriousness of TSNA's as carcinogens as far back as 1963. (See for example a Philip Morris internal confidential memorandum from P. Waltz to H Wakeman, September 25, 1963 in which it is stated that " As a whole one can say that the nitrosamines are very potent carncinogens, potent mutagens, that they have a very good dose-repsonse relationship, an astonishing relation between structure and organotropic action, that their effect on the chemical structure of the attacked organism is better known than for most other carcinogens…"*
>
> *(* **Food and Drug Law Journal**, *Supplement Vol. 53, Tobacco Product Regulation:Context and Issues, 1998, John Slade and Jack Henningfield)*

There have also some concerns raised by the public health community about tobacco agricultural production. The National Cancer Institute for example noted:

> *Changes in the agricultural curing and manufacturing processes of cigarettes have resulted in an increase over the last several decades in the amounts of tobacco specific nitrosamines on tobacco smoke. These changes are considered to have contributed to the increase in adenocarcinoma of the lung observed in the past several decades.*
>
> *Risks Associated with Smoking Cigarettes with Low Machine Measured Yields of Tar and Nicotine*, **Monograph 13**, *National Cancer Institute, October 2001.*
>
> *"The proprietary blending and processing of tobacco can have significant effect on levels of toxic chemicals in tobacco. In a recent study (32), researchers identified a wide range of TSNA levels in tobacco in cigarettes purchased in 14 countries surveyed. Ashley DL et al. Tobacco-specifci nitrosamines in tobacco from US brand and non-US brand ciagerttes.* **Nicotine and Tobacco Research**, *5:323-331*

In March of 2005, USSTC issued a press release indicating that " scientists at its GenApps Inc. laboratories' had 'succeeded in discovering a key tobacco gene encoding nicotine demethylase. The gene has been cloned, sequenced and its function characterized" According to Dr. Robert Lawreance, Jr. EVP at UST, "This important and fundamental discovery holds promise for commercial production of low-nitrosamine tobacco with significantly reduced NNN levels within the next decade". The press release further noted that 'GenApps scientists are preparing presentations and articles for peer-reviewed publications that will fully detail this discovery over the next several months'. (Press Release, March 28, 2005, U.S Smokeless Tobacco Company Researchers Discover Nicotine Demethylase Gene.)

It is now feasible to grow, produce, cure and process some forms of tobacco that have significantly lower levels of TSNA's measuring not just in part per million but in fact parts per billion. A number of scientists and researchers in the public health community have taken an interest in the development of products (particularly noncombustible products) that use these technologies to remove some of the most significant cancer causing agents in tobacco (not the only one however).

The direction was recognized and supported in the presidential tobacco report, **Tobacco at a Crossroad** which recommended the formation of a Tobacco Growers Advisory Board that would allow agricultural issues and concerns to be considered and aired with respect to any action that the FDA might take on regulating tobacco products (See page 45 of the commission report).

The tobacco cooperatives, the two primary cooperatives being the Flue Cured Tobacco Stabilization Cooperative Corporation and the Burley Tobacco Growers Cooperative Association

have traditionally been the grower's voice in overseeing issues related to the tobacco program (recently terminated by the US Congress). Today the Cooperatives are looking to the future and reevaluating their roles on behalf of the growers in the US. In my opinion, working with public health, industry, agronomists, biotech companies and others, they have an important and significant role to play in reshaping national tobacco policies in the coming years- policies, which could also have a significant impact on how tobacco is produced in the global arena as well.

Comment: Because agriculture and agricultural based technologies have an important role to play in harm reduction, it is critical that agronomists, agricultural researchers, tobacco growers other agricultural biotech based interests be brought into and play a part in moving towards the development of harm reduction products. To date, they have been ignored as the debate has tended to focus on manufactured products only.

The Role of the Consumer -Human and Individual Rights

In the tobacco wars of the last several decades, consumers and the rights of consumers have often been ignored and/or manipulated in order to achieve policy and other business related objectives.

In spite of the fact that the tobacco industry, the Surgeon General , public health organizations, and others have routinely stated that consumers have the right to have full and complete information about the products they use, quite the opposite has occurred. Suppression of information coupled with exaggerated 'selective statements' have become more routine. Clearly the need for truthful, accurate and non-misleading statements about reduced risk tobacco products will have to be discussed and given a high priority. The attempt to control information, exaggerate information and suppress information seems to have become a 'legitimate' tactic in the ongoing war between the tobacco industry and the public health community.

The public health community has rightly criticized the tobacco industry for using claims such as 'light' 'low', 'reduced' etc, to sell their products by lulling consumers into believing these products are safer. As we noted elsewhere, while making such 'claims' the tobacco industry has for decades suppressed information about their products and have failed to warn consumers about the hazards of these products. The health groups have in recent years fought off any efforts to disclose full information on the basis that consumers might not interpret it correctly and that there might be 'unintended consequences' even if the consumer is completely and truthfully informed. The debate between the relative risks of combustible tobacco products versus noncombustible tobacco products and consumers misperceptions about those relative risks is a good example.

Over the last several years there has been increased discussion about both individual and human rights in tobacco control as well as the right for consumers and the public to be entitled to full and complete information about the products they use. Professor Lynn Kozlowski and his colleagues have probably done more to bring this issue to the forefront, raising these issues both in published articles at tobacco control conferences as well as before the US Congress and the NIH.

The most recent set of discussion 'papers' appeared in a special edition of **Tobacco Control** entitled Individual and humans rights in tobacco control,: help or hindrance?, BJ Fox and JE Katz, Tobacco control 2005;14 . While these 'rights' issues are being discussed and debated within the tobacco control community it is equally important for other stakeholders and in particular the tobacco manufacturing sector to also pay close attention to the importance of the issue. The articles challenge us all to ask some tough questions about several fundamental principles that govern modern society and to ask the question as to how and whether they should apply to tobacco. Fox and Katz suggest that most agree that rights do play a role in the formation and implementation of tobacco control policy and advocacy. But they then go on to ask some additional probing questions such as:

- *If rights form the foundation upon which tobacco control advocacy can or should be based how explicit should the use of rights language be in our communication with various stakeholders?*

- *Alternatively, if rights do not form the foundation of our movement (tobacco control), what should? And what would it mean for the moral stature of the human or individual rights movement were it not at its foundation?*

They suggest that the various views of the authors fall into two camps, one that argues that understanding rights is

important in order to fundamentally shape (and possibly re-shape) the way the tobacco control movement operates, the second camp arguing that gaining a greater understanding of rights can strengthen tactics to reduce tobacco use and counter the influence of the tobacco industry even if doing so does not fundamentally change the tobacco control movement.

I am not so sure that these two camps are mutually exclusive in that both rely on rights as a fundamental strategy for effecting change… with changing (enhancing) the tobacco control movement to make it more credible, which in turn will strengthen its tactics and ability to counter the tobacco industry for failing to apply human rights principles in the sale of their products. I see the issue of "rights" as taking the high ground and using that high ground to move the tobacco control agenda forward and to demand and force changes in the industry itself. While much of the discussion on consumer and human rights is taking place in health related journals, the importance of this debate obviously has and should have significant effects on the tobacco industry. The tobacco industry has a similar choices to consider and to make –especially in light of their efforts to convince the public that they embrace CSR (Corporate Social Responsibility).

Kozlowski has noted that:

Some authorities believe that not informing, or even deceiving, some individuals is justified to protect the health of vulnerable groups, in particular nicotine addicts and youth. ……. This perspective represents a classic utilitariian of consequential ethical position, where the "ends justify "means'," when trying to achieve the greatest good for the greatest number of people.

We in contrast, are a kin of "rule utilitarian" and try to do the greatest good for the greatest number of people while also following certain rules – here, to be honest and nondeceptive. In practice it is usually very difficult to predict what will happen in the future and we think it is a kind of ethical safeguard to limit steps that will be taken to try to achieve the best for the most. In the case of smokeless tobacco for example, although we think the concerns about net public health harm are more hypothetical than likely, even if the net ill-effects were likely; we disagree that deception in health information is an acceptable strategy.

The question of emphasis of content in tobacco risk communication is important and deserves attention. An urgent need for improving the quality of health information on tobacco is demonstrated by the troubling finding that a high percentage of tobacco control experts and advocates report that they would rather see a smoker switch to lower tar cigarettes than smokeless tobacco (a recommendation inconsistent with a science base).

Saying tobacco 'isn't safe' isn't incorrect, but it isn't saying enough. Going beyond the no safe tobacco message to provide better information on the nature of risks from tobacco products and nicotine delivery systems is necessary to respect individual rights to health relevant information.

(LT Kozlowski and BQ Edwards, "Not safe" is not enough: smokers have a right to know more than there is no safe tobacco product, **Tobacco Control** *2005;14:ii15-16.)*

Concerns raised by such reports as the IOM's Clearing the Smoke about how PREPS can and should be introduced into the market "underscore the importance of consumers' perceptions in the overall evaluation of PREPS", and other tobacco products. "To date, however, there have been relatively few efforts to document consumer awareness, beliefs, and use of PREPS". (O'Connor, Hyland et al, Smoker Awareness of and Beliefs About Supposedly Less Harmful Tobacco Products, **Am. J. of Prev. Medcine**, 2005 ;29(2) page 85.)

The issue of industry withholding of information from the users of tobacco was addressed recently by S. Chapman and J. Liberman this way:

The tobacco industry's past and current practice in communicating with its customers about health risks can be characterized as doing as little as possible, as slowly as possible, in as low a key as possible.

There is much more the industry could do to inform smokers both via packs and through other means. Rather than wait out the 10 year cycles that have characterized three new generations of health warnings in Australia, the industry could voluntarily add new warnings to packs whenever scientific consensus was declared via major agency reports like those of IARC.

The manufacturer that buries its head in the sand is hardly less culpable than the manufacturer that deliberately withholds information – the law recognizes this through its notion of "willful blindness". The industry has a continuing responsibility to inform itself, and to act.

In conclusion, the rights of consumers to adequate information about the health consequences of tobacco products when used as intended should be regarded as inviolable principle within the tobacco control policy debate. …Regulation of tobacco and the tobacco industry should be informed by empirical evidence about what smokers actually know and understand and how they actually behave, rather than self-serving, mythological ideas of informed smokers who, knowing all the risk freely choose to smoke.

(Ensuring smokers are adequately informed: reflections on consumer rights, manufacturer responsibilities, and policy implications, **Tobacco Control**, *Vol 14 Supplement II (p.ii11-ii12)*

Comment: Consumers and users of tobacco, in spite of statements to the contrary, have played a very limited role in deciding public health related goals and objectives. In my view consumers and users of tobacco should have and play an active role in deciding how harm reduction should proceed. Their views on the types of products that will be entering the market place and the consumer acceptability of those products will be important factors to consider.

Summary and Conclusion

Most of the stakeholders tend to look at the issue of tobacco harm reduction from their own tunneled -vision perspective -- based upon what it does and does not mean to their agenda. What they fail to realize is that achieving their goals and objectives must take into consideration the views, goals and objectives of the other stakeholders who have their own views as to what harm reduction is and how it might be implemented. The purpose of this chapter has been to hopefully educate others about a number of issues that are intertwined and must be considered as part of achieving an effective harm reduction effort. Not all of a stakeholder's objectives can or will be achieved especially in the short term. We must recognize that much has changed over the last decade and we must be willing to take advantage of it in order to reduce disease and disability caused by the use of tobacco. Science and technology will play a major role not only in the manufacture of tobacco and tobacco based products but also in the agricultural production of tobacco. We must also recognize that users of tobacco both currently and in the future may have different public health related goals and we need to develop products that will meet those goals and objectives --- from the use of combustible tobacco products, to noncombustible products, to nicotine replacement therapies, to total tobacco and nicotine cessation. In a democratic society consumers and the public have a right to know about the products they choose to use or not use. We must also promote and stimulate competition among the players to develop truly science -based harm reduction products and give them incentives to produce such products.

Transparency, Accountability, Unintended Consequences

Sunlight is the best disinfectant

–US Supreme Court Justice Louis Brandeis

Integrity without knowledge is weak and useless, and knowledge without integrity is dangerous and dreadful

–Samuel Johnson

One of the most critical ingredients in any effort to develop a workable and effective process for the discussion of the various elements involving harm reduction is the assurance and commitment of all stakeholders and parties to the notion of real transparency. Several other sections of this paper will address how that 'real' transparency might be encouraged and take place. Here we deal primarily with some of the underlying issues, past histories and the behaviors of the stakeholders, and the legitimate and illegitimate use of the arguments of unintended consequences.

What has been occurring in the political environment, rocked by scandals, influence peddling, special interests and money, should stimulate and encourage us to step back and look at what kinds of similar problems and behaviors are occurring in the tobacco environment.

For the most part I have found that a large segment of the stakeholders and other various parties intentionally or unintentionally have not been transparent, open, or honest about their positions, their views and what drives them. They perpetuate a 'silo' way of thinking only looking at their own interests and failing to either understand, take into account, or even more importantly take advantage of the views and actions of others. They often use the argument of 'unintended consequences' as a tool to prevent dialogue, to avoid transparency, to promote self-serving goals, and to impede progress. I can only conclude that we have a great deal of work to do in this area if there is to be real long term sustained progress in efforts to reform the tobacco industry and to reduce mortality and morbidity from tobacco use. Transparency is in many respects the lynch pin to effective harm reduction strategies and meaningful tobacco product modification. With it we can move forward. Without it, we are doomed to continue along the road we have been on for more than three decades. I think it can be done, but behaviors of all the stakeholders must shift.

The Tobacco Manufacturers

More than half a century ago, in January of 1954, in a statement to the public, the tobacco industry embarked on what would be decades of deceit and deception. A Frank Statement to Cigarette Smokers published in major newspapers proclaimed:

> *We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business.*
>
> *We always have and always will cooperate closely with those whose task it is to safeguard the public health.*

A Tobacco Industry Research Committee was set up and the industry further assured the public that:

> *In charge of the research activities of the Committee will be a scientist of impeccable integrity and national repute. In addition there will be an Advisory Board of scientists disinterested in the cigarette industry. A group of distinguished men from medicine, science, and education will be invited to serve on this Board. These scientists will advise the Committee on its research activities.*

In 1964 with the release of the first Surgeon General's report and facing action by Congress, the industry went on the defensive again, arguing that there was no causal connection between cigarette smoking and disease when in fact we now know that their own scientific research had concluded as much. From 1964 and for the coming decades, the industry would concede to nothing, quick to develop legislative and

public relations strategies to ensure that no laws affecting the industry were enacted. As a former VP of the Tobacco Institute, Frederick R. Panzer was to later acknowledge in a 1972 confidential memo to TI president Horace Kornegay, the holding strategy was 'brilliantly conceived and executed" and involved:

- *"creating doubt about the health charge without actually denying it."*
- *"advocating the public's right to smoke without actually urging them to take up the practice."*
- *"encouraging objective scientific research as the only way to resolve the question of health hazard."*

What would also follow would be years of so-called 'voluntary approaches' to the ever-mounting public health crisis that in the end were never intended to accomplish much except to head off legislation within the Congress and to buy time, good will and to put a faux-face of corporate responsibility on the industry. What would follow would be the funding of 'front groups' that would give legitimacy to the industry's efforts without leaving 'fingerprints'. What would follow would be efforts to be seen as 'cooperating' with government and the public health community as was the case in the NCI's efforts to look at the development of a 'safer cigarette'.

Millions of pages of industry internal memoranda, faxes, and other enlightening and damning documents have become available to anyone who wishes to review them, giving us a window into the industry's operations and thinking about how it sought to protect its business interests at the expense of public health.

And let's not forget that image, worth a million words, of the CEOs of the tobacco companies standing before Congress under oath and one after the other, stating straight-faced that 'nicotine is not addictive.'

The deceptions were not just limited to the cigarette companies but also applied to the smokeless industry as well which developed similar tactics and strategies in order to head off meaningful and needed oversight and regulation of their products.

"The rest," as they say, "is history."

Had the tobacco manufacturers, individually or collectively accepted the conclusions of the Surgeon General 's report(s) and taken appropriate steps as they had promised in the 1950's, millions of premature deaths might have been avoided, and the industry would have avoided the continuous litigation that today still plagues them.

Steven Parrish, today a Senior VP with Altria all but acknowledged the industry's serious shortcomings when he put it this way:

Put simply, ours was a culture of arrogance, bred by insularity and enabled by spectacular business success. Our tobacco companies evolved an approach towards important societal issues such that, if a given position was legally defendable, it was good enough for us. There was a bunker mentality, an " us-against-them" attitude, a belief that anyone who disagrees with us was an enemy out to destroy us.

This approach manifested itself in many ways and over time, had a disastrous impact on our corporate reputation. Take for example, our public position on key smoking and health issues. We focused on what was not known rather than listening as part of a meaningful dialogue. We argued over definitions rather than advancing solutions.

It seems clear in retrospect, that had out companies simply deferred to the Surgeon General's famous conclusion in 1964 that smoking causes lung cancer and not uttered a word of criticism against it, irrespective of the views of internal scientists much of the rhetoric and ill-will directed at us today would be without foundation. Perhaps even more strikingly, had they accepted the Surgeon General's revised definition of addiction in 1988 rather than argue about which definition had greater validity, that famous image of the seven CEOs raising their hands before a congressional committee would never have become ingrained in America's collective consciousness. The reservoir of public anger that has built up against us would have been deprived of one of its primary wellsprings, and there could have been a foundation for problem solving instead of continued conflict.

*(**Yale Journal of Health Policy, Law and Ethics**, "Bridging the Divide: A Shared Interest in a Coherent National Tobacco Policy," Winter 2002, Volume III, Issue I, page 111.)*

Today we have to ask, have parts of the industry really changed? Is there hard evidence of change? Do recent statements by Altria and BAT to subscribe to and adhere to corporate codes and guidelines of ethics and responsibility mean anything? Does Philip Morris' support for FDA reflect significant change warranting consideration? Or are these efforts just another sophisticated public relations ploy similar to tactics of the past? For the moment, it may be a little of both.

Can the tobacco industry be socially and corporately responsible and accountable?

Over the last several years the tobacco industry, at long last, has had to acknowledge and accept what was known and accepted for decades about the serious hazards of cigarette smoking. Now they are faced with new challenges in a world where they admit their products are hazardous.

There has been a great deal of focus on Corporate Social Responsibility (CSR) over the last several years. CSR means different things to different people. While CSR probably has roots dating back into the 19th century, its current focus seems to be on the notion that 'corporations should be required to return more to society, because of their impact on society was driven by pressures from civil rights, peace, and environmental movements, of the last half century.' (N Hirschhorn, Corporate Social Responsibility and the Tobacco Industry: Hope or Hype? **Tobacco Control**, 2004;13:447-453.)

In recent years the major companies have stepped up their appearances at CSR conferences and meetings –– talking about their new found corporate and social responsibility which has brought a clamor of noise and concern from some of the public health community and others interested in corporate ethics and accountability. The question that has to be asked, is this the same old wolf in sheep's clothing? Is there anything really different?

Australian tobacco control expert Simon Chapman has described the industry focus on the issues of social and corporate responsibility as follows:

Faced with the Niagara (release of damaging internal documents) of embarrassing revelations, including thousands from its highest officials, the international industry changed strategy. It embarked on the world's most public rebirthing exercise, asking to henceforth be appreciated as an ethical industry devoted to providing tobacco products to sentient adults, all supposedly fully informed of the risks they took.

There is wholesale cynicism and disgust in health and medical circles about this exercise. Critics point out that contrary to the most elementary procedures for wrongdoers seeking public contrition, the industry has made no public apology about its years of misleading conduct to accompany its volte face. Doubtless mindful of the legal ramifications of doing so, it has made no admissions that it lied to smokers in the past, and that for decades engaged in a globally orchestrated campaign to falsely reassure smokers.

Given an industry that intends to remain in the cigarette business for the foreseeable future, what are tobacco control advocates to do? They must maintain the pressure for bans on public smoking, higher taxes, counter-marketing, effective regulation, improved methods of cessation, and ratification of the FCTC. Also essential is to caution the public against uncritical acceptance of the tobacco industry's mantle of 'social responsibility.'

*(S Chapman **Tobacco Control**: Advocacy in Action: Extreme Corporate Makeover Interruptus: Denormalising Tobacco Industry Corporate Schmoozing, 2004;13:445-452)*

Mitch Zeller, a former an associate commissioner with the FDA and a consultant to pharmaceutical interests expressed concerns that the tobacco companies (PM) are using the issue of harm reduction as part of an effort to build corporate credibility. As the NY Sunday Times Magazine noted:

To Mitch Zeller, there is more than mere economics at work: Philip Morris's reduced-risk project fits into the company's broader campaign of corporate and social responsibility (the hundreds of millions of dollars spent on youth smoking-prevention efforts, for instance) and its cultural philanthropy. And of course it also enables the company to show judges and juries that it is taking steps

in the direction of harm reduction. "All of these programs are part of a much larger strategic effort by Philip Morris to change public perception," he says. "One of the goals here is to demonstrate to their target audience that they are a changed company, and they have achieved, -- 'social alignment' and 'corporate normalcy.' Already public opinion surveys have shown that the company has significantly improved upon its abysmal public image of the late 1990's. PREPs, Zeller says, might help even more. They present an enormous opportunity for the rehabilitation of a consumer product. And the rehabilitation of a corporate reputation that seemed beneath contempt as recently as just a few years ago.

(**New York Sunday Times Magazine,** *"A new cigarette filter may make smoking a lot less harmful. But is that a good thing? Incendiary Device," Jon Gertner, June 12, 2005, page 51.)*

As noted elsewhere in this paper (and worth repeating) the tobacco industry has been a dismal failure in its attempts to provide full and complete disclosure about its products to the very people who use their products. Even if there is value to establishing and enforcing new codes of corporate responsibility and accountability I firmly believe they should not be a substitute to the broader efforts related to tobacco control and they must be measured through action and transparency not merely words and rhetoric. They cannot and should not be used as public relations tools to give legitimacy to the industry without clear and demonstrable results.

That said, it is also useful to sometimes step back from our myopic approach to tobacco and take a fresh look at an issue to put it into perspective. A recent commentary by Mallen Baker entitled, *Can companies that make products that kill be socially responsible?*, provides some interesting perspectives on the issue. He first points out that "killing people is wrong. That is one of the earliest principles established by any civilized society. So how can a company be considered socially responsible if its products – used as instructed – result in loss of human life?" Part of the reason says Baker is a change in the definition of what corporate responsibility is. He says that the changes are obviously creating 'a certain degree of disquiet.' "The campaigners have dismissed any claims to responsibility on the part of such companies (including but not limited to tobacco) drawing attention to the worst impacts of the use of their products. Likewise some on the CSR movement have felt uncomfortable about their newly discovered allies, and would really wish they would go away and play their role of corporate villain with a little more conviction." Baker points out that while it is understandable to 'damn the tobacco companies', there can be some unintended consequences. He then asks a very important question. Can an industry such as the tobacco industry ever be legitimate, noting:

This is not a question that any individual company acting on its own can answer – it is the gift of a broader society to establish that something is legitimate or not. If people of the world believe that, for instance tobacco is a product that simply should not be allowed, governments can act to simply ban it. There is no doubt that if tobacco had been discovered for the first time today, it would never be allowed to go on sale if its full health consequences were revealed.

For the time being and for many reasons governments have not taken the steps to ban the product or the use of tobacco but rather to regulate it and control its use. Few public health authorities have called for a ban on tobacco. Baker then goes on:

That being the case, we then have an option on how that informed choice is met. We can have unscrupulous companies, very happy to sell as much as possible with little care to the consequences. Many would agree that such a description certainly fits some of the tobacco companies historically.

Alternatively we could see a different type of company. One that seriously invests in research to develop reduced harm products. One that manages its environmental impact carefully, and treats the people in the supply chain with respect. One that supports its own people, and which aims to improve society through a process of "giving something back".

That would surely be the definition of a socially responsible tobacco company. You might still not think that any existing company actually meets this definition. But a number of those companies are now stating that these are all things that they address or aim to address. If we agree that it is important how these companies operate, we should welcome the aim and then judge them by their actions.

The alternative is that we say that we don't care whether these companies ignore the harm caused by their product, despoil the environment and treat their suppliers and staff badly - because we think they are far beyond the pale.

(Can companies that make products that kill be socially responsible?, Mallen Baker, **Business Respect** *e-newsletter, September 2005)*

I believe that tobacco companies and those associated with tobacco companies should be corporately responsible and accountable to society. It troubles me however, that what they (BAT and PM) are doing smacks of some of the same approaches that have been used in the past--attempting to sell their legitimacy through backdoor routes by appearing in conferences and other public forums. As with much in the tobacco arena, success or failure of reforming corporations and holding them accountable will depend on what is done and what actions are taken. But we shouldn't just be concerned about the PMs and BATs of the world. In the long term we should be seeking to push for accountability standards that should be applied to the industry as a whole. Just as we need oversight of the industry under an agency like the FDA, we also need meaningful corporate accountability standards that all of the industry should operate under. Baker's points are therefore worth considering. While it is right to focus on the major, most economically powerful companies and the ones that have track records of dismal failures, it would be a mistake not to look down the road to see what might happen in an environment in which PM and BAT were no longer the dominant players. Does what they have said about corporate and social responsibility, independent of their actions, also send a potentially valuable message to the hundreds of other companies that are part of the global 'mix' of companies in or related to the tobacco business?

This raises other interesting questions and scenarios. There are a few other companies associated with the tobacco business who have begun to set or call for a different set of operating and manufacturing standards. Should such entities be routinely chastised because they are the 'low hanging fruit' or do they play an important role in helping to force change in the entire tobacco industry? Do we turn our backs on forcing accountability and change on the industry or do we push for establishing workable and measurable standards of accountability and responsibility for the entire industry? If we are in fact to have greater transparency on the sharing of data and scientific research, we will need to have complimentary standards in place that deal with the broader issues of corporate responsibility. Corporate social responsibility is in some ways similar to the issues and goals related to 'competition.' If some companies can actually demonstrate through their actions new ways of conducting their business, such actions could force changes on the broader industry.

Star Scientific for example, an upstart company that developed curing methods and standards for significantly reducing TSNA (and to whom I provided some advise to several years ago) issued a Board approved policy statement in 2002 that included the following:

Star Scientific accepts and supports effective measures at the national, state, and local levels to ensure that tobacco products are not distributed, sold or marketed to children and adolescents.

Star Scientific acknowledges that the use of tobacco products generally pose health hazards and that no known tobacco product or process, even the process that Star has developed, while virtually eliminating nitrosamines, eliminates all health hazards associated with the smoking of tobacco.

Star Scientific supports having the Food and Drug Administration (FDA) as the lead agency charged with overseeing the implementation of fair and meaningful regulations over the manufacture, sale distribution, labeling and marketing of all tobacco–containing products.

Star Scientific supports increased biomedical and allied research by the private sector as well as such federal agencies as the FDA, NIH, CDC, and USDA that will continue to identify and understand the complexities of what causes disease associated with tobacco use and work to find ways of reducing/or eliminating these causes, and setting standards and "bench marks" for the development of reduced risk and less hazardous tobacco products.

Star Scientific believes that adults who chose to smoke and or make an adult choice regarding the use of any tobacco products should be fully and completely informed about the dangers of the tobacco products they choose to use, including specific information regarding

ingredients and constituents of tobacco and tobacco smoke and the levels of such toxic constituent elements in tobacco and tobacco smoke. This should include any scientifically established information that indicates that a product may or will reduce certain exposure to major toxic elements associated with tobacco use.

Star Scientific believes that the time has come for health groups, researchers, scientists, policy makers, senior government officials, tobacco farmers, and responsible tobacco companies to sit down and talk about the future of tobacco and the tobacco industry, including an articulation of reasonable parameters under which new products that will reduce exposure to certain toxic constituents in tobacco and tobacco smoke can be developed, evaluated and marketed.

To my knowledge, Star is the only company (PM to a limited extent) that has through an *official* Board action laid out its views on a spectrum of issues that if accepted by the entire industry could have a significant impact on reshaping the tobacco environment – giving public health the primacy that it deserves and needs. It would seem that all tobacco companies, all grower organizations, all biotech companies and others who directly or indirectly are involved in the production or manufacture of products containing tobacco and tobacco products should enact similar *board-approved* statements that will commit them towards effecting meaningful and positive change.

The Public Health Community

It has become increasingly clear in the last several years that the rapidly changing tobacco environment is also forcing the public health community to deal with issues that can no longer be seen as black or white but which have multiple shades of gray. In my more than thirty years of committed involvement, I cannot recall an environment in which there has been more divisiveness and in some cases internal hostility and personal attacks than have been seen over the last five years.

While the public health community wants to convince the outside world that there is agreement on issues the reality is that the 'agreement' is in many areas only skin deep. Personalities, egos, turf protection, competition for funding, and other factors are all taking an unfortunate toll.

Several highly respected tobacco control advocates and scientists have made some recent off-the-record comments that are indicative that true open dialogue and transparency are often discouraged, and even suppressed and for which there are often retributions.

One commented, "if you dare express a different opinion, you are considered unethical."

Another pointed out that the community has taken on a "you're either with us or against us" philosophy.

And a third has suggested that "we in the public health community have taken on and use the very tactics that we accuse the industry of using."

As a community, the public health community can and must do better in its efforts to accept and respect the views of others, to involve broader and more extensive disciplines and to step outside of its own tunnel-vision approach to the world. Ideas and views should be encouraged, not suppressed. One thing is for sure, there are no silver bullets and no easy solutions.

It may be useful for the entire public health community to also lay its cards on the table as to who is who and who receives funding from whom. Those who carry the water for the pharmaceutical industry or who receive funding from them should be willing to make those relationships more publicly known, especially when they serve in positions or present views that are listened to by others. The community should be willing to take a collective stand against those who attempt to suppress discussion or who resort to maligning individuals for self-serving purposes.

I also struggle with the notion that while some condemn taking any and all money from tobacco interests, some are able to justify the use of tobacco dollars because of the conditions and manner in which it has been obtained and secured. There seems to be a tendency on the part of some to 'draw a line of convenience' when it comes to justifying the use of the money for their goals and objectives. The formation of the American Legacy Foundation and the grants it has provided to many tobacco control advocates and scientists for some very significant and valuable work is a good example. No matter how one wants to frame it, no matter what 'fire walls' there are, the money still comes from the industry and there are

conditions under which that money can be used and will continue to be made available.

I would also hope that for clarity, transparency and for the sake of discussion and debate that those, whose goals it is to 'drive the industry into the sea and out of existence,' would say so publicly. It would make their involvement in many tobacco control issues (including FDA oversight) unnecessary and moot.

The notion that "we don't talk to the tobacco industry" is in fact a myth and has been for some time. There is in fact much more engagement (mostly on a one to one basis) than people are willing to accept or acknowledge. Much of it is at the national level but there many examples at the state and local level as well. The time may be ripe for 'sunlight to shine' on these efforts and to acknowledge that carefully managed 'engagement' between parties is both necessary and inevitable.

The Pharmaceutical Industry

While the tobacco industry (and related industries) obviously is and remains the primary focus in the discussion in the development of harm reduction products, the pharmaceutical industry must be considered in the scheme of discussions relating to the development and marketing of harm reduction products. They are an increasingly influential corporate power in the tobacco control arena and are a corporate competitor to the tobacco companies. This has not just occurred overnight but has been steadily increasing for the last ten years.

The principles of 'transparency' should extend to the pharmaceutical industry just as rigorously as they are applied to the tobacco companies. But they are not. Like any corporate interest, whether in the automobile industry, the oil industry, or the food industry, the name of the game is the maximization of corporate profits and working for the interests of the shareholders. The pharmaceutical industry, like any other corporate entity, competes amongst itself as well as other entities and uses a variety of means to position themselves to maximize sales, visibility and credibility for their products. The pharmaceutical industry is deep into the development of cessation products, both in terms of drugs as well as devices. I don't see this trend changing.

Should the standards of transparency that we demand be applied the tobacco industry also be applied in a similar fashion to the pharmaceutical industry? Does pharmaceutical money going to the tobacco control community, NGO's and researchers have the same effects in shaping outcomes that people fear about tobacco money. Many believe they do.

As we did in the previous section it is sometimes good to step back and look at the picture from a distance.

According to the Center for Public Integrity the pharmaceutical industry," has spent more than $800 million in federal lobbying and campaign donations at the federal and state levels in the past seven years. No other industry has spent more money to sway public policy in that period." (Drug Lobby Second to None – How the pharmaceutical industry gets its way in Washington, Special Report, [**Center for Public Integrity**] website, www.publicintegrity.org) The strategies and tactics employed by the industry bear a striking resemblance to the very tactics that have been used by the tobacco industry.

In addition to its heavy influence on policy makers in the Congress, another of the strategies that the pharmaceutical industry regularly employs is its effort to partner with the public health community often in the form of significant financial contributions to fund programs. This obviously extends beyond tobacco related efforts. The funding often goes to the same NGOs who are heavily invested in tobacco control. In an article entitled "Surrogates for their Agenda: How the drug industry uses non-profits to push its interests" the Center for Public Integrity notes :

> *Many of the pharmaceutical industry's biggest names are no strangers to the world of corporate philanthropy. They shower millions on public advocacy non-profit organizations with a variety of missions. Some groups tout the support of pharmaceutical firms. But because these non-profit organizations are under no legal obligation to reveal their donors, they provide the drug industry with another avenue through which it can surreptitiously spread its message. And while some groups that the industry funds are independent many are little more than echo chambers, designed to support positions favorable to the pharmaceutical industry that pays their bills.*

The Center for Science in the Public Interest's Special Project Integrity in Science has noted:

There is strong evidence that researchers' financial ties to chemical, pharmaceutical or tobacco manufacturers directly influence their published positions in supporting the benefit or downplaying the harm of the manufacturer's product. (See www.cspinet.org)

In the tobacco environment it is not a misstatement to say that the pharmaceutical industry has spent tens of millions of dollars in its partnerships and relations with the public health community, scientists, consulting firms and public relations firms in its efforts to position themselves to tap into the cessation and risk reduction product markets. The pharmaceutical industry and its consultants can be found at every major tobacco control conference, not only making significant financial contributions but also working the crowds, helping in setting up workshops and providing conference paraphernalia emblazed with their logos. They can be found underwriting programs at the national, state and local level. Industry consultants and personnel routinely meet, strategize, and network with the public health community. While there is no question that much of what is being accomplished is meritorious, other issues and questions need to be asked and answered. Their products carry endorsements of well-recognized NGOs who receive significant financial support from their pharmaceutical partners. Tobacco control has become increasingly dependent on their 'good will.'

While "no strings attached money" from the tobacco industry is rejected and criticized as tainted by most, very few concerns seem to be publicly raised when it comes to pharmaceutical money. From the standpoint of 'corporate influence', aside from the fact that the products that the pharmaceutical industry produces are obviously very different than those of the tobacco industry, I am not sure there is much of a difference. Are we again, allowing a 'line of convenience' to be drawn?

This might be changing in some sectors. In 2003 the Society for Research on Nicotine and Tobacco (SRNT) debated and discussed the issue of pharmaceutical influences on both the organization and individual research. SRNT President Harry Lando (2002-2003) noted in his outgoing remarks:

Questions were raised concerning appropriate topics and tone for listserv postings and a number of heated exchanges occurred. There was discussion of appropriate sources of funding both individuals and the society and consideration of types of current funding and past financial support that should preclude eligibility for elected office. There were concerns raised that SRNT was too closely aligned with the pharmaceutical industry.

The issue(s) caused such a stir that SRNT developed a policy statement entitled "Declaration of Interest" noting that:

The science of nicotine and tobacco research, as does all science, needs to be beyond reproach. The presence of undeclared sources of support and financial interests has the possibility of undermining the credibility of published work regardless of whether the financial factors emminate from tobacco or non-tobacco industries. The issue of credibility is especially salient in the charged political environment in which this work is published.

Is the decision by some in tobacco control to aggressively push tobacco cessation (rather than nicotine cessation) partially influenced by the relationships and funds of the pharmaceutical industry? Is the backlash and split within the health community over the notion of harm reduction influenced in some way by the involvement of the pharmaceutical industry? **Real** transparency may provide some answers.

Just how much money is spent each year by the pharmaceutical industry to influence policy decisions and cultivate relations with the public health community and research institutions is unknown. It is obviously extensive. I will leave that investigation to be conducted by someone like the Center for Public Integrity. This paper is not intended to be an investigation into those issues but rather intended to point out a significant and important area where transparency is needed, and where it seems that a 'double standard' exists and has the potential to get worse.

Policy Makers

As I put the outline of this paper together, I did not initially include policy makers or governmental agencies in this section. But as I was writing it, it became very evident that it would be a serious omission not to consider a brief section on how our Congress, the Executive branch, and many of the independent agencies have become increasingly less and less transparent and more and more influenced by money, politics and special interests.

The recent Washington scandals involving the influences of money and corruption are really not isolated incidents but are indicative of a deeper set of concerns going to the very heart of our democratic processes and way of life. Effective democracy in fact depends on transparency and ethics and the critical need for ideas to be heard.

I would not be saying anything new or novel by suggesting that the tobacco industry (as well as the pharmaceutical industry) has a long history of influence peddling in the US Congress and in the Executive branch. The influence of Phillip Morris (Altria), RJR (Reynolds American) Lorillard, UST and several others is well known. The amount of cash that has been given to politicians is well documented and continues to this day. What is distressing is that even as there has been a growing consensus among many of the players that the time is ripe for action on tobacco policy, a few companies and special interests have the power to continue to block efforts for change.

Over the last several Congresses, in spite of the fact that there were efforts to pass FDA/tobacco legislation, no substantive hearings were heard on this issue or other important issues related to tobacco. A hearing on the tobacco buyout was clearly one of 'political expediency' forced to take place but with a predetermined outcome. What could have been a hearing to help reshape tobacco agriculture production in this country and address legitimate public health concerns was conducted in an effort to 'demonstrate' that there was no consensus when in fact there was significant consensus on the issues. Two hearings scheduled on the same day on issues related to harm reduction and tobacco product modification seemed to be more about a committee jurisdiction 'spat' than efforts to develop policy recommendations.

It would seem to me that if Congress were concerned about preventing the premature deaths of over 400,000 Americans; if Congress were concerned about reducing the billions of dollars that are spent each year on health care costs and lost productivity; if Congress were concerned about smuggling and illegal trafficking; and if Congress provided leadership in bringing parties together to craft effective and necessary legislation, it would have held hearings on the issues and moved forward with a truly workable and effective plan. But it has not. Committee Chairmen, particularly in the House, seem to be reigned in when an issue doesn't meet the views of members in the leadership. Outcomes are often predetermined with little to no input from those impacted or affected. In the 107th Congress, one company, through its monetary contributions, influence peddling, and political maneuvering basically derailed efforts that dozens of organizations in the public health community, in the grower community and even some big players in industry had supported and had worked on for years. These lobbying efforts extended to the White House as well with the result that the White House refused to take any leadership role on the issue. Democracy and transparency were sacrificed for politics, money and greed.

Earlier, we noted the influence that powerful political interests can have in distorting and manipulating science for self-serving goals. It concerns me that the very regulatory agencies that are expected to ensure effective protection of the public's health often find their hands tied, their budgets slashed, and their voices silenced in effort to promote the goals and interests of a few.

In the decades that I have worked on the tobacco issue, the times have been few and far between when an agency like the FDA, FTC, USTR, EPA have been able to do their work on tobacco issues. They have had to fight special interests, influence peddling, and politics every step of the way.

If Congress is serious about cleaning house and reforming itself and finding workable and meaningful solutions, it must take steps to hold a series of hearings to assess what changes are needed to reform this nation's tobacco policies. It needs to be willing to listen to *legitimate* views and recommendations and move forward. Staged hearings or refusals to hold hearings, and behind the scenes decision making must be ended and democratic systems restored to the Committee system and to our representative government.

Restoring the public trust and transparency in our democratic institutions is urgently needed.

Unintended Consequences

Before making any major decision, whether in business or in policy reforms, it is often essential to do a thorough evaluation of the pros and cons of a decision to determine possible consequences for the action. This process is obviously not a 'perfect science' because the environment can change which in turn can alter the consequences and outcomes. If a

decision is made to move forward, it then becomes important to determine how best to monitor the outcomes, to minimize the unintended consequences of the action and to consider possible safeguards and alternatives. Not only does one have to consider the consequences for taking an action, but also the consequences for not taking action, something that is often conveniently ignored.

It seems therefore, that the raising and use of 'unintended consequences' has become a routine way for people, organizations, corporations, movements and policymakers to justify action on how not to move forward, for stymieing discussions and preventing any possible resolution on a subject. Today it seems that the use of 'unintended consequences' often has self-serving motivations and goals. This continued trend is troubling in that it prevents transparency and reinforces the 'status quo.'

I have chosen to include this subject because I think that all the stakeholders and parties need to take into consideration the potential important uses of assessing unintended consequences versus its equally potential important abuses.

It brings us back to one of the themes in this paper and that is to stop talking about 'why we can't and shouldn't do something' and start talking about how we do it.

In the end we have to find a way to sort through what are legitimate issues and what are not. It can't be done in a poisoned, adversarial environment where parties refuse to engage in any meaningful discussion.

While many of the arguments of 'unintended consequences' concerning harm reduction seem to be emanating from public health advocates these days the tobacco industry has actually been the master and teacher in the use (and abuse) of such tactics.

A few examples are worth noting:

- When the smoking ban aboard commercial aircraft was being considered, the industry concocted unintended consequences arguments that there would be more smoking in the lavatories increasing the risks of fires, that fights would break out on planes as people were deprived of their needed pleasure to smoke. As the industry has done routinely, they hired 'experts' to make their case.

- When FDA oversight of tobacco was being advocated, the industry used the arguments of unintended consequences to accuse advocates of instigating a 'back door' ban on tobacco – trampling on the rights and freedoms of Americans. They also told tobacco growers that if FDA got jurisdiction, FDA agents would seize their farms and equipment and shut them down. (Side note: The growers eventually became accepting of the FDA jurisdiction over manufactured tobacco products, primarily through a process of dialogue and engagement.)

- When the issue of smoking in restaurants and public places was being discussed, the industry and its allies said that the unintended consequences of such actions would be significant reductions in businesses, cause customers to become irate and again the deprive them of their individual rights.

- When tobacco control advocates proposed restricting advertising and marketing practices that were misleading and deceptive, the industry was quick to conduct campaigns to argue that this would be an infringement on First Amendment rights and a slippery slope to depriving other businesses and Americans of their rights to free speech.

In all of the examples (and there are many, many more) facts were replaced with fiction, rhetoric and hyperbole. Because of the tobacco industry antics and efforts, any meaningful and legitimate discussions and clarification of the issues became impossible.

I have noted elsewhere in this paper that we as a society are confronted with many risks and need to make choices about how we deal with those risks. While 'purist approaches' to the ills confronting society are often meritorious to many, they are often unrealistic at the same time and even threatening to many others in a democratic society.

There are many in tobacco control who, using arguments of unintended consequences are also saying that the only true solution to tobacco's harm is "abstinence only."

We have witnessed a flurry of 'unintended consequences' arguments to make the case that 'nothing' should be done except to continue a 'war,' arguments that include:

- Fears that the mistakes of the low tar and low nicotine fiasco will be repeated – so we need to keep lower risk products off the market.

- Fears that the tobacco industry will continue to use seductive advertising and marketing tactics to encourage children and adolescents to take up the tobacco habit.

- Fears that the development, availability and marketing of reduced risk products will serve as a gateway to the use of higher toxic cigarettes, and prevent those who might otherwise quit from quitting.

- Fears that any positive action, change or position on the part of anyone associated with the industry will be seen as having been designed to establish 'legitimacy' for tobacco.

- Fears that incremental change (even if successful) will take the focus away from the need for comprehensive reforms and further legitimize the industry.

In many ways these are the same kinds of arguments that could be used in a variety of other areas that we confront in our daily lives. With the obesity epidemic quickly approaching the morbidity and mortality rates of tobacco, do we now say that foods should not be labeled for cholesterol, fat, and sodium because of the unintended consequences of people eating more of those foods and exercising less? Does developing safer cars mean that people will drive more recklessly and not use their seat beats possibly increasing the number of deaths and injuries in the total population? Does sexual education and the advocating of the use of condoms, birth control and other measures encourage adolescents to engage in more sexual activity and should therefore be prohibited?

Although I find merit and a critical need to ask important questions about the prospects of 'unintended consequences', I remain concerned when I see such arguments now being routinely raised to promote self-serving agendas and to prevent any real discussion of the issues from taking place. Again, I suggest that we focus on how to move forward taking into consideration legitimate unintended consequences rather than using such arguments as a justification for no action and no real discussion.

Summary and Conclusion

In the last section of this paper I will suggest some ways to deal with the issues of corporate funding and corporate accountability both in terms of harm reduction efforts as well as other broader issues related to tobacco. The issue is not whether I like the tobacco industry or not or whether I like the pharmaceutical industry. The issue is what are the standards of transparency, accountability and integrity which are expected from all of the stakeholders and players? Are there rules and standards? Should there be rules, standards and guidelines? Who should help define those rules, standards and guidelines? What allows one entity to take tobacco money (under certain restrictions) and disperse to others in the field who under other circumstances would chastise and criticize others for taking such money? What allows those who vehemently oppose the taking of corporate money from the tobacco industry to readily take money from the pharmaceutical industry? What is the responsibility of the public health community to encourage and foster discussion and dialogue even if it does not meet their self –serving interests? How do outside influences and money impact on the decision making within the public health community? These are all questions that must be confronted as we deal with the future of harm reduction.

The Relative Risk Reduction Continuum

It's the smoke stupid!

–anonymous

- A Changing Environment
- Combustible Versus Noncombustible Products
- Regulation Should be Commensurate with Risk
- Surveillance of Products is Critical
- Scientific and legal standards for allowing or disallowing claims and the disclosure of information
- Summary and Conclusion

We began this paper noting that not all tobacco and tobacco products carry 'equal harm' and that as technologies and science continue to develop there will be an ever-increasing number of tobacco products and tobacco like products appearing on the market (as well as nicotine containing products and other types of cessation products). We also noted that while we will need to continue to keep an active and careful watch on the tobacco industry to ensure that past abuses do not reoccur and to demand greater transparency of all stakeholders, we must also begin to look at how we can effectively modify tobacco products to reduce health risks associated with their use and to assess these products in terms of the level of relative risk.

Tobacco product modification, however, cannot be done in a vacuum and it must be considered in light of other important factors addressed in this paper, such as, public health, the need for governmental oversight, greater transparency of all stakeholders, technological advances, consumer and individual rights, agricultural production, economics and competition, etc.

We must also have a better system for assessing product risks. Many consumer products in our society carry risks—some more than others. And in various categories there are products that have differing relative risks. All automobiles require safety standards to minimize risks and yet we know that driving an automobile not only presents risks to ourselves but to others around us as well. And not all automobiles–in spite of mandated safety standards–carry the same risks. Some provide greater risk protection than others.

We know that unsafe sex not only increases the potential for HIV infection and other sexually transmitted disease but also unwanted pregnancies as well, both having significant ramifications on not only the individuals involved but on society as a whole. The foods we eat and the pharmaceuticals we use all have relative risks associated with their use and how much they are used. One only has to see the types of pharmaceutical advertising on television these days to realize that products that are promoted as 'life saving' also often carry significant risks, sometimes life threatening risks, associated with them. 100% safe, while commendable is not something that is feasible in a free society. Agencies like the FDA, the EPA, the CPSC, USDA, establish standards and requirements for the risks and relative risks of the products under their regulatory authorities, ensuring that there is a level playing field.

And so the case should also be for tobacco and tobacco products. Unless we ban tobacco there are certain tradeoffs that have to be considered in our efforts to reduce risks from the use of tobacco.

There are significant health risk differences between a combustible and noncombustible tobacco product. And there are relative risks for various products in each of these respective categories. Even with respect to products designed for cessation (whether tobacco or nicotine) there is a tremendous spectrum of products appearing on the market each having their own risks and benefits profile.

As a longer term goal, I believe that we need to try and move away from focusing on and attempting to classify a tobacco product as a PREP and begin to talk in terms of the risks and relative risks of products on the market and to label them based upon clearly established sound scientific standards and principles.

The concept of risks and relative risks allows one to compare products not only between categories (cigarettes, versus, smokeless, versus, pharmaceuticals) but also to compare the risks of products within categories. Consumers of tobacco need to be given a better picture as to what products are available and which products present what levels of comparative risks.

What might be considered a PREP today may not be a PREP in five years and in fact may even become one of the

relatively higher risk products on the market. There may be tobacco-based products, particularly in the noncombustible area whose risk may be commensurate with some of the pharmaceutical products on the market today. Swedish snus and the tobacco 'lozenge', as some like to call it, may be such products already on the market. And there may be cessation products (both tobacco and nicotine) that are yet to be developed and brought to the market that will be more effective than the cessation products currently on the market today. The nicotine vaccine is a good example. Assessing the risk and determining the extent of how the product should be labeled etc, cannot be left in the hands of the tobacco industry although it will be critical that they actively and openly participate in the process.

The prospects for an expanding 'continuum' of products starting with those having higher risk and moving down the continuum to total elimination of both tobacco and nicotine will, as pointed out elsewhere in this paper, require a governmental agency with the scientific, medical, and enforcement authorities necessary to ensure that the regulatory playing field is level and that consumers have full, complete and accurate information about the risks and relative risks of products-choosing products that are best suited to their personal preferences and health goals. But that will require Congressional action and the prospects for quick enactment of legislation is not good at this time. I have been working on the need for FDA oversight of tobacco products for over 15 years and I sometimes feel like I am 'waiting for Godot'. However, I still believe that governmental oversight of tobacco, is both necessary and inevitable. But we need to move forward even as we push for a more level and playing field.

A changing environment

We have noted two critical elements that will be necessary to sort through the complex scientific and marketing questions that will arise as new products enter current market place. We will need:

- Transparency and ongoing engagement of various stakeholders and experts to address a spectrum of inter-related issues, challenges and opportunities.

- A regulatory agency that can establish a meaningful and workable process and standards that establish a set of 'rules of the road' and which can provide validation by which any new products or claims will be made.

There are an increasing number of technologies that have either been developed or are soon to be introduced. These include new filter technologies, curing methods for tobacco leaf, the removal of pesticides and the elimination of chemicals that might cause harm. They also include the use of genetically modified tobacco, which according to many researchers holds great and significant potential for changing both the tobacco used in a tobacco product as well as the product itself. Such technologies may be a gateway to reducing toxicity, improving leaf qualities, reducing the use of pesticides and other potentially harmful components. Such technologies also hold promise for the development of pharmaceutical products and industrial enzymes of potentially great value to society.

We need to get beyond the rhetoric and the posturing that has so dominated tobacco control. Those who think that perpetuating current strategies of attacking the industry are the **only** way to affect change should consider that Wall Street analysts are today saying that given recent decisions in some of the tobacco litigation the industry is in a stronger position than it has been in since 1994. As David Adelman of Morgan Stanley noted in December 2005:

> *On the back of the Miles/Price decision, it is increasingly clear that the US Tobacco industry is in its strongest overall legal position since the 1994 emergence of the state health care cost recovery claims. Dynamics include: an increasingly conservative US Supreme Court; State Farm's limitations on punitive damages; the enactment of the Class Action Fairness Act; the increased prevalence of state appeal bond caps, the Illinois Supreme Courts extremely favorable ruling in Miles/Price; the Eight Circuit's unanimous favorable ruling in the Watson Lights class action, the US Supreme Court's denial of Certioari regarding the availability of disgorgement under Civil RICO; the Second Circuit's rejection of class certification in Simon II, a smoking and health class action claim of interest to the Florida Supreme Court (e.g., Engle; the industry low public profile; the absence of the emergence of any new large –scale legal risk; the filing of a few new claims; the continuation of defense verdicts in the few claims that survive trial; the passage of time, which because of the 1969 warning label preemption makes claims incrementally more difficult –over time—for plaintiffs.*

(Email assessment from David Adelman, Morgan Stanley – Tobacco: January US Tobacco Litigation Timeline, December 29, 2005

This may not only embolden the larger companies (particularly those opposed to regulation and transparency) but give smaller companies a green light to push the envelope in marketing cigarettes and other tobacco products free from any kind of controls, responsibility or accountability.

As has noted by N Gray, J Henningfield, N Benowitz et al in a recent edition of **Tobacco Control**,

The epidemiology tells us that tobacco products delivering nicotine vary considerably in harmfulness. Within each product category there is a (sometimes wide) variation of dose and manner of use, but the extreme ends of the spectrum differ in harmfulness by orders of magnitude.

("Towards a Comprehensive long term nicotine policy," N Gray, J E Henningfield, N L Benowitz, G N Connolly, C Dresler, K Fagersrom, M J Jarvis, ***Tobacco Control****/ 2005;14:161-165)*

O'Connor, Hyland, Giovino et al, have noted :

Future research should focus on methods of communicating relative risk information to smokers, so that smokers are not misled by comparative claims for either modified cigarettes or cigarette-like products or SLT products.

There is little doubt that the tobacco industry, especially the cigarette industry, will continue to develop and market supposedly less-harmful products with claims –explicit or implied – that such products will reduce the health risks of smoking. In an environment in which tobacco products – and the advertising and marketing that accompany them – are only loosely regulated or unregulated, these claims will continue to lull smokers into a false sense of security concerning health risks. The findings presented in this paper clearly demonstrate that smokers are confused about relative safety claims of reduced exposure tobacco products. More smokers believe that so-called reduced exposure cigarette products were safer than standard cigarettes than believed SLT was safer, even when awareness of products was controlled for. These data suggest that smokers are confused and mislead by cigarette marketing , even when such marketing does not include overt health messages. Companies looking to market reduced-exposure tobacco products should be required to demonstrate convincingly that smokers will not be confused or mislead by marketing claims.

(American Journal of Preventive Medicine, " Smoker Awareness of and Beliefs About Supposedly Less-Harmful Tobacco Products", Am.J.Med. 2005,29(2), page 89.)

For several years I have believed that there would be a *convergence of interests* between the tobacco industry and the pharmaceutical industry. I believe that such convergence is already taking place. I believe that some of the larger tobacco companies will devote more and more resources to the development of products using both pharmaceutical and food type technologies and science. One only has to realize that some of the largest of the tobacco manufacturers are in the food business and also have pharmaceutical interests to understand that they not only have the resources, but also the scientific capabilities to change their products. I cannot predict, however, the pace at which this will occur, but I believe that the market place of tobacco and nicotine products will be a dramatically different one ten years from now. In 2005, Altria/ Philip Morris, announced that:

We have chosen an adjacency growth strategy, looking at potential moves into complimentary tobacco and tobacco related products or processes that would allow PM to use its existing core infrastructure elements (Emphasis added)

(Statement made at the Prudential Back to School Consumer Conference, 2005)

In April and May of 2006, both Philip Morris and Reynolds American announced that they were moving into the noncombustible smokeless tobacco market with Reynolds purchasing the second largest smokeless tobacco manufacturer, Conwood. With these actions the two largest cigarette manufacturers virtually erased a line over night that had clearly divided cigarette manufacturers from the smokeless industry for decades.

Other signs and indicators that the industry is undergoing and will continue undergo change include the fact that:

- Vector Tobacco has used genetically modified tobacco in its Quest products.
- Reynolds acquired a pharmaceutical company some years back (Targacet).
- Star Scientific has developed a curing process for significantly reducing the TSNA's in tobacco leaf.
- Filligent, a biotech company out of Hong Kong has developed new filter technologies that are considered to be significantly different than anything currently on the market.
- There is research being conducted on the use of genetically modified tobacco for a spectrum of purposes.

And one has to ask, will pharmaceutical companies and other biotech companies one day develop tobacco-based products (particularly noncombustible products to start with) using food and pharmaceutical technologies that would be marketed and sold, not through their pharmaceutical divisions, but through their consumer product divisions?

The point of all this is that nothing would or will surprise me as to how the environment and the market place will continue to change over the next 5-10 years.

Combustible Tobacco Products Versus Non-Combustible Tobacco Products

We have noted in several places in this paper that there are wide differences between the relative risks of tobacco which is burned and tobacco which is used in a noncombusted form. A great deal of discussion and dialogue between the risks and relative risks of combustible and noncombustible tobacco products has taken place as well on whether noncombustible tobacco products in particular have a role to play in harm reduction strategies. If in fact they are lower in risk, the next question is what should harm reduction strategies using noncombustible tobacco products entail and how should they be implemented. How as noted above 'do we develop methods of communicating relative risk information to smokers so that smokers are not misled by comparative claims?'

Combustible Tobacco Products

Cigarette smoking remains this nation's leading preventable cause of death and disease – accounting for over 400,000 premature deaths each year.

When a cigarette burns, there are over 4,000 chemical constituents produced in the smoke that are inhaled into the lungs. As many as 60 such constituents are known carcinogens and many others (such as carbon monoxide) contribute significantly to other diseases such as cardiovascular disease, stroke and other pulmonary diseases.

In addition to the tobacco (for which there are different types and which contain varying degrees of toxins,) there are pesticides and chemicals used in both the tobacco leaf as well as the manufactured product. Little is known about the effects of such chemicals and pesticides when burned, either alone or in combination with other ingredients and pesticides.

Hundreds of additives and flavorings are used in the manufacture of cigarettes. According to the Department of Health and Human Services (HHS) while many of these additives and flavoring may be viewed as GRAS (generally recognized as safe) when used in their raw (non-combusted) state, such additives and flavorings may in fact pose additional toxic harms when burned.

Because of the complexity of a burning tobacco product coupled with a mix of chemicals, additives and ingredients that are burned, it will be a challenge to begin to logically, rationally and responsibly sort through not only the products that are currently on the market but also those that will be appearing on the market in the coming months and years.

There are, however, technologies (filters, curing methods, reduction of additives and the potential use of genetically modified tobacco) that are being employed that are demonstrating that it is possible to remove some but not all of the toxins contained in cigarette smoke. But does the reduction or elimination of one ore more toxins in a cigarette justify the allowance of any type of health claim (direct or implied)? At the moment, probably not.

A number of products which have already appeared on the market include:

- Elclipse -- a cigarette like tobacco product that heats rather than burns.
- Advance –- a cigarette that uses low TSNA tobacco and uses what is called the 'trionic filter'
- Accord
- Omni
- Quest
- Fact
- EHCCS –- This is an electronically heated cigarette system developed by Philip Morris USA

A company called XXII Century Tobacco, Inc. has indicated that it plans to develop and potentially bring to market tobacco products that are infused with higher levels of nicotine, thereby giving the smoker a 'satisfactory' dose of nicotine sooner thereby (theoretically) cutting down on the inhalations of toxins.

But as Ken Warner cautions as we look at the combustible market place in particular,

> *.....cigarette smoke contains thousands of chemicals with possibly hundreds of them hazardous to health. No one knows which chemicals, or which combinations, pose the greatest danger. Further, the novel products achieve their exposure through a variety of techniques that may themselves pose risks, possibly new risks to the health of the consumer. For example, one reduced brand of cigarette uses palladium to achieve its objective. Is inhaling combusted palladium dangerous? No one knows.*

If toxicity information and other information about ingredients, flavors, etc is to be made available in factual terms (not as direct health claim) what other information should be required to provide the necessary information to ensure that consumers fully understand the risks and relative risks for the product.

Many health groups have advocated that 'if the technologies exist then toxins should be removed'. As noted in the report Hope or Hazard? , "Although the extent of reduction in exposure to tobacco toxins may not necessarily lead to a proportional reduction in disease, if the technological capacity currently exists, all marketed tobacco products should meet performance standards that would reduce or eliminate toxins in tobacco products. Such an effort toward maximum risk reduction has not been pursued heretofore with respect to toxin exposure from cigarettes" (Hope Or Hazard? ,What research tell us about potentially reduced-exposure tobacco products, Transdisciplinary Tobacco Use Research Center, April 2005, p.8)

In addition, how does one provide incentives to the tobacco industry to remove such toxins? How do you encourage and acknowledge those companies willing and able to remove the toxins, as opposed to those manufacturers who will not use the technologies? How do you keep companies from using the tactics employed in the marketing of low tar and low nicotine cigarettes, that may ' potentially produce public health harm if these claims increase smoking initiation, maintenance, or relapse'? For me the answers lie in a variety of short term and long term efforts that must be undertaken and which will be dealt with in more detail later in this paper.

Noncombustible Tobacco Products

While still complex, the scientific issues surrounding noncombustible tobacco are far less complicated than when assessing combustible tobacco products. Because these products are not burned the number of hazardous constituents and toxins are significantly reduced.

It is a misstatement to suggest that smokeless tobacco products are as harmful as cigarettes as has often been the case. It is also a misstatement to suggest that all products within the smokeless tobacco category carry the same level of risk. The public health community has had to confront and begin to deal with the scientific realities that there are significant differences between products that are burned and those that are not. The idea that noncombustible tobacco products are not lower in risk neither stands up to common sense nor science. But does that mean such products are safe? No. While many have suggested that claims that smokeless tobacco are as hazardous as cigarettes are for the public good and 'well intentioned' to counter the industry's efforts to mislead the public, such tactics are contrary to the precept of 'truthful' disclosure. When the Surgeon General of the United States, no matter how well intentioned, goes before Congress and makes statements that are not an accurate reflection of science, it damages the credibility and role of the government as well as the public health community.

In reviewing the literature on smokeless tobacco, there seems to be a long overdue acknowledgment (and in many of cases an acceptance) of the fact that noncombustible forms of tobacco are significantly lower in risk than combustible products and that some forms of smokeless tobacco lower in risk than others.

As Hoffman, Hoffman and El-Bayoumy noted in a paper in 2001,

> *TSNA's are the major carcinogens in chewing tobacco and snuff and are associated with cancer in the oral cavity of snuff dippers.*
>
> *On the basis of our current knowledge, a drastic reduction of TSNA levels in chewing tobacco and snuff is expected to lower the risk for oral cancer; in fact such low levels of TSNA's may be below the threshold level for the induction of tumors in snuff dippers. However it will be of importance to investigate the possible endogenous formation of the carcinogenic TSNA in consumers of the snuff brands that contain only traces of TSNA.*
>
> *("The Less Harmful Cigarette: A Controversial Issue. A Tribute to Ernst L. Wynder," D Hoffman, I Hoffman, K El-Baypumy,* **Chemical Research in Toxicology** *(published by the American Chemical Society), Volume 14, Number 7, July 2001, page 784.*

Ken Warner who has been in the forefront in the discussion of harm reduction noted in a paper published on the subject of noncombustible smokeless products that:

> *Driving interest in low-nitrosamine smokeless products are two basic facts. First they are clearly dramatically less hazardous to health than cigarette smoking. Second, to many observers, the first of their bread, snus, a product used by 30% of Swedish males, serves as the worlds only major natural experiment in tobacco harm reduction. Thanks primarily to substantial tax-driven price differentials (ie cigarettes are heavily taxed; snus is not) snus has come to dominate smoking in male tobacco use in Sweden. As a consequence, Sweden has the lowest rate of male smoking in Europe, and the lowest rate of male lung cancer.*

An expert panel, asked to provide their opinions on the mortality risks associated with the use of low nitrosamine smokeless tobacco concluded:

> *On the narrow question of the relative risk of LN-SLT products, these results clearly indicate that experts perceive these products to be far less dangerous than conventional cigarettes. Based on the available published scientific literature as of 2003, there seems to be consensus that LN-SLT products pose a substantially lower risk to users than do conventional cigarettes. This finding raises ethical questions concerning whether it is inappropriate or misleading for government officials or public health experts to characterize smokeless tobacco products as comparatively dangerous with cigarette smoking.*
>
> *In comparison with smoking, experts perceive at least a 90% reduction in the relative risk of LN-SLT. The risks of using LN-SLT products therefore should not be portrayed as comparable with those smoking cigarettes as has been the practice of some government and public health authorities in the past. Importantly, the overall public health impact of LN-SLT will reflect use patterns, its marketing, and governmental regulation of tobacco products.*

Note: While reaching what is a strong consensus on the relative risk of LN-SLT with cigarettes, the study also found:

> *The results from this study should not be interpreted to mean that there is a consensus that smokeless products are an acceptable harm reduction alternative to conventional cigarettes. In addition to toxicity, an evaluation of the harm reduction potential of LN-SLT should consider who uses the product and how much they use it. Attention should be given as to whether it substitutes for smoking, is used in conjunction with or as a gateway to smoking, or substitutes for complete nonuse of tobacco products*

The panel additionally cautioned that :

> *The results from this study also should not be interpreted to mean that all smokeless tobacco products are less hazardous or less risky by the same margin than conventional cigarettes because our panel members only considered a handful of unique LN-SLT products.*

D Levy,E Mumford, KM Cummings, E Gilpin, G Giovino, A Hyland, D Sweanor, K Warner, The Realtive Risks of a Low-Nitrosamine Smokeless Tobacco Product Compared with Smoking Cigarettes: Estimates of a Panel of Experts, **Cancer Epidemiology ,Biomarkers & Prevention**, *December 2004.*

A position statement entitled **European Union Policy on Smokeless Tobacco – a statement in favour of evidence-based regulation for public health**, concluded that:

We support the replacement of the ban on oral tobacco with an approach that regulates the toxicity of all smokeless (and smoking) products. Our approach has the following advantages:

a) *It would create a legally defensible, fair and rational policy – in which public health is given primacy consistent within the framework of EU law.*
b) *It would create public health benefits through smoking cessation and smoking substitution.*
c) *It gives smokers an extra strategy for controlling their risks and eliminating ETS risk, and thereby respects their consumer and human rights.*
d) *It would apply toxicity controls to the currently unregulated chewing products such as gutka and paan available in the EU and currently unregulated.*
e) *It would have benefits beyond Europe if a good regulatory model is developed for controlling toxicity of smokeless tobacco – for example, establishing regulatory norms in the WHO Framework Convention on Tobacco Control*
f) *It opens the dominant cigarette makers to competition from tobacco products do far less harm.*

(European Union policy on smokeless tobacco – a statement in favour of evidence-based regulation for public health, C Bates,, K Fagerstrom M Jarvis, M Kuntz, A McNeil, L Ramstrom, February 2203, p. 10)

While it seems that there is now a consensus on the significant comparative risks between combustible and non-combustible products (especially those having very low levels of TSNAs), there are a number of issues (see above) that are being raised by some concerning whether noncombustible products can play a role in harm reduction efforts in the United States. See for example " The United States Isn't Sweden – Why UST's Efforts to Make Comparative claims is Wrong and Threatens Public Health", May 2003.

In that fact sheet, the CFTK argues that:

UST should not be allowed to make comparative claims about its products in the absence of an appropriate regulatory scheme that can provide review and approval of the claim. The government not the manufacturer, should decide what claims are appropriate and how and under what circumstances they can be made. Effective tobacco product regulation by the US Food and Drug Administration must include the ability to set product performance standards for toxins and carcinogens in smokeless tobacco products and must regulate the ability and circumstances under which a health claim can be made in association with a specific product.

The above statement raises the additional important question, challenge, and opportunity of being able to also determine differing levels of risk between the spectrum of noncombustible products on the market. There are many different products currently on the market and there will undoubtedly be more. Even products that are currently used in other countries (Gutkha, Zarda, Tombak etc.) may find their way into the American market place as more and more diverse populations become a part of American society. An interesting study from the UK looked at various forms of smokeless tobacco, including products from India, Sweden, Asia and the US, some of which are used in the UK and others which are currently prohibited. The study found wide differences of various toxins in the products concluding that:

Toxin standards should be set for all the smokeless tobacco products available on the UK market, with a reasonable timescale for compliance. The toxin standards set by parts of the industry – for example, the Gothiatek Standard used by Swedish Match – could be used as a starting point, but it should be possible over a short time frame to reduce key toxins and carcinogens to the lowest levels which are technically feasible which in most cases would be non-detectable levels.

(A McNeil, R Bedi, S Islam, MN Alkhatib, R West, "Levels of toxins in oral tobacco in the UK, **Tobacco Control** *2006;15:64-67, page 65)*

In the US, we continue to have a more divisive debate and discussion over smokeless tobacco with some still making the argument that smokeless tobacco is not a 'safe' alternative to smoking even though there is agreement that these products are significantly lower in risk than cigarette smoking. As was reported in the press:

Dr Stephen Hecht and colleagues from the University of Minnesota Cancer Center in Minneapolis compared the levels of cancer-causing nitrosamines in popular smokeless tobacco products and medicinal nicotine products such as the nicotine patch, nicotine gum, and nicotine lozenges. The results' clearly show that the levels of cancer causing nitrosamines are far higher in smokeless tobacco products that they are in medicinal nicotine products" Hecht said during a press briefing.

Nitrosamine levels were highest in oral snuff tobacco products made in the US, followed by Swedish 'snus(another type of smokeless tobacco) where as the 'lowest levels were found in hard snuff lozenges. The snuff lozenges actually did "quite well in our study" - it does appear to have lower levels of carcinogenic nitrosamines" than most of the other smokeless tobacco products, Hecht said.

Yet, while recognizing that there some products that 'did quite' well, Hecht goes on to conclude that "smokeless products are dangerous".

These findings were recently elaborated on in an April 2006 article in the journal Nicotine and Tobacco Research which looked at the range of tobacco specific nitrosamines (TSNA's) in new tobacco products. The study noted:

A number of new brands (alternative smokeless tobacco products) are being test marketed in the United States. These products are targeted to smokers and smokeless tobacco users who wish to reduce or quit tobacco use or who want to use 'safer 'products. Manufacturers' claims include statements of reduced toxin content and implied reduced risk, but it may take years before the real health effects of these new tobacco products are known. TSNA's are among the most important carcinogens in tobacco, and it is imperative that objective data on levels of these compounds be available.

The lowest TSNA levels in the tobacco-containing products we analyzed were found in the compressed tobacco lozenges Ariva and Stonewall. Levels of strongly carcinogenic NNN and NNK were only 56-99/ng/g with most of the TSNA content comprised of NAT, which is apparently noncarcinogenic. These products use Star Scientific specially cured tobacco known to be low in TSNA's. The emergence of these new products with relatively low levels of carcinogenic TSNA's is an encouraging sign.

The Swedish snus General, which is manufactured using the GothiaTek process and quality standard designed to minimize nitrosamine contamination, contained relatively low levels of TSNA's, compared with conventional smokeless tobacco products. The variation in TSNA content observed in General in 2002 and 2003 is consistent with a study done by the Swedish National Food Aministration that demonstrated a noticiable decrease in TSNA content in moist snuff on the Swedish market. However, TSNA levels in Exalt, which is supposedly produced by the same technology, were comparable with those in the same conventional commercial brands of smokeless tobacco such as Copenhagen and Kodiak, which have had relatively high amounts of these compounds for many years. (Hecht & Hoffman, 1988; Hoffman et al. 1995; Radu et al 2004). Lower levels were found in Revel;howver, these levels were still considerably higher than nitrosamine levels in other products such as food and beer.

(I Stepanov,J Jenson, D Hatsukami, S Hecht (2006). "Tobacco-specific nitrosamines in new tobacco products", **Nicotine and Tobacco Research**, *Vol.8,No 2)*

All of the above points out the urgent need for us to devise a way in which we can have transparent discussions and consider options that can or should be taken. If as both the UK studies and the US studies indicate – that it is possible to reduce the TSNA levels to virtually non-detectable levels (as well as other possible toxins), and if there is a consensus on the fact that L-TSNA smokeless tobacco products are clearly and substantially lower in risk than cigarettes, shouldn't we be talking about how to implement standards and technologies within the smokeless category to achieve that goal?

As we have indicated throughout this paper, the question in my mind is not so much if but rather how and under what

conditions and parameters we can move forward in testing products and determining how any claims or statements can be made. The last section of this paper will outline what I believe may be a process for discussing and dealing with some of those outstanding issues and questions now, even as we work towards governmental oversight by an agency like the FDA. Several of these issues and questions might include:

- How such products can and should be labeled and marketed, including how and under what circumstances comparative claims should be allowed?
- What kind of regulatory system needs to be in place to ensure a level playing field (and what can be done in the interim without FDA oversight).
- How can current scientific studies be assessed and 'ranked' to guide efforts and activities?
- At what levels do TSNA's in smokeless tobacco constitute a health threat?
- Can a system similar to the Swedish 'Gothiatek' system be devised to establish quality standards for ingredients, TSNs and other toxins?
- What is the role of competition and what 'incentives' can be provided to force changes on the industry?
- What kind of monitoring and surveillance systems should be developed and implemented?

In assessing the risks and relative of cigarettes, and smokeless tobacco, what should those risks be compared with?

Consumers of tobacco and nicotine products should be able to make an across-the-board assessment of the risks and relative risks of products that are available to them. As we noted at the beginning of this paper, harm reduction entails trying to meet users 'where they are'. There are no silver bullets and what might work for one person in reducing their risks or quitting might not work for another person. In order for consumers to fully and completely understand the spectrum of products available to them we need to bring some order to the existing chaos that currently exists in the market place. This will be even more critical as more and more products and players enter into the stream of commerce.

I have been somewhat baffled as to why a few in the public health community have taken the position that smokeless tobacco products should only be compared with the risks associated with medicinal nicotine and cessation products, rather than looking across at a spectrum of products including cigarettes. Is this because many find it difficult to bring themselves to make scientific and medical distinctions that might require them to acknowledge that there are differing degrees of risks between tobacco products?

I would argue that it is equally important for users and consumers of tobacco to understand the spectrum and relative risks of different types of tobacco products as it is for them to understand the risks and relative risks of using different forms on tobacco and using different nicotine replacement therapies. Such factual, fair and balanced information will need to come from and/or be verified by government in the form of improved labeling and disclosure and regulatory oversight of the industry; from educational initiatives by the public health sector, and even from industry itself.

Thus a goal should be for users of tobacco products (and NRT) to be able to understand and compare:

Between Categories

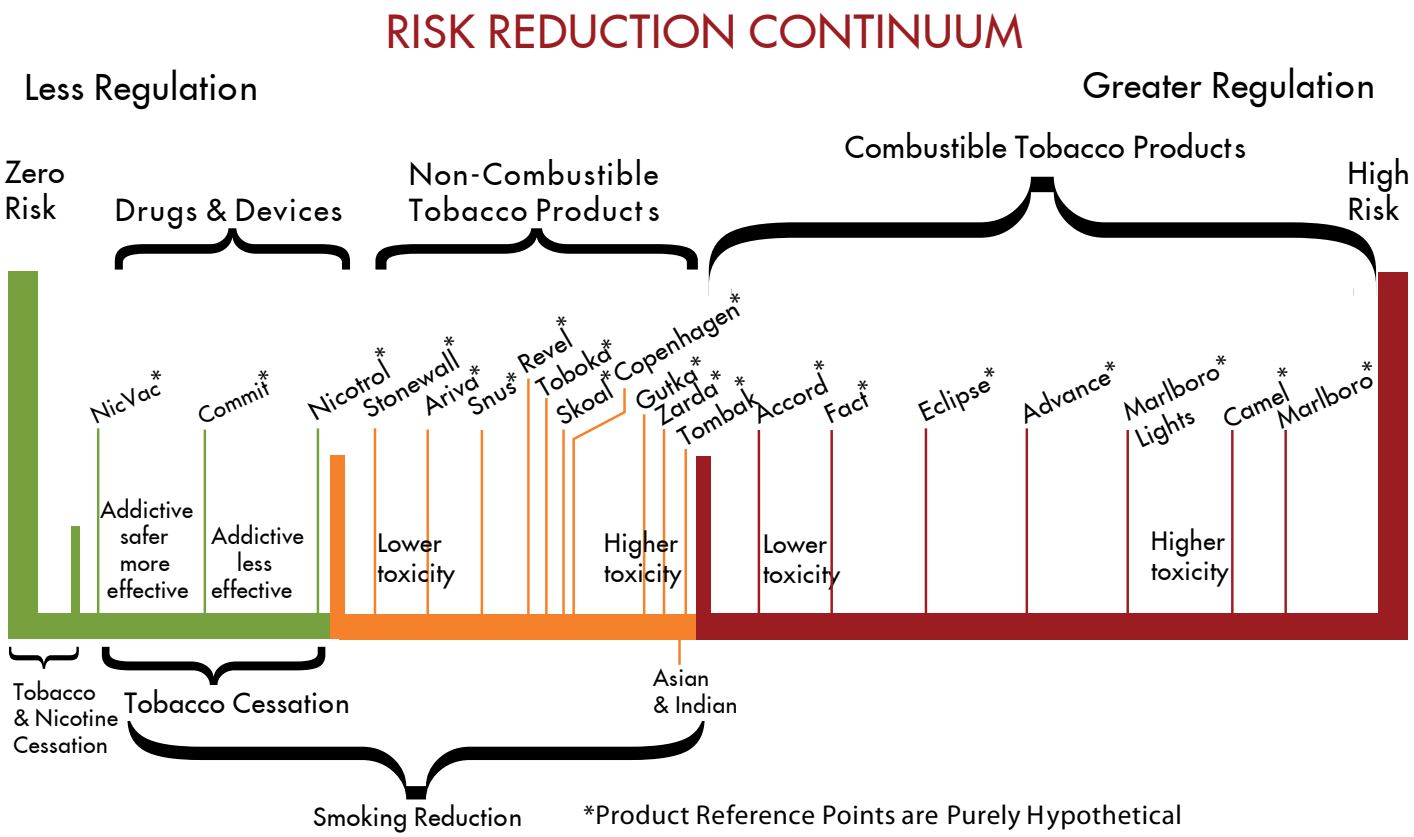
- Cigarettes with smokeless and NRT products
- Smokeless with cigarettes and NRT Products
- NRT products with smokeless and cigarettes

Within Categories

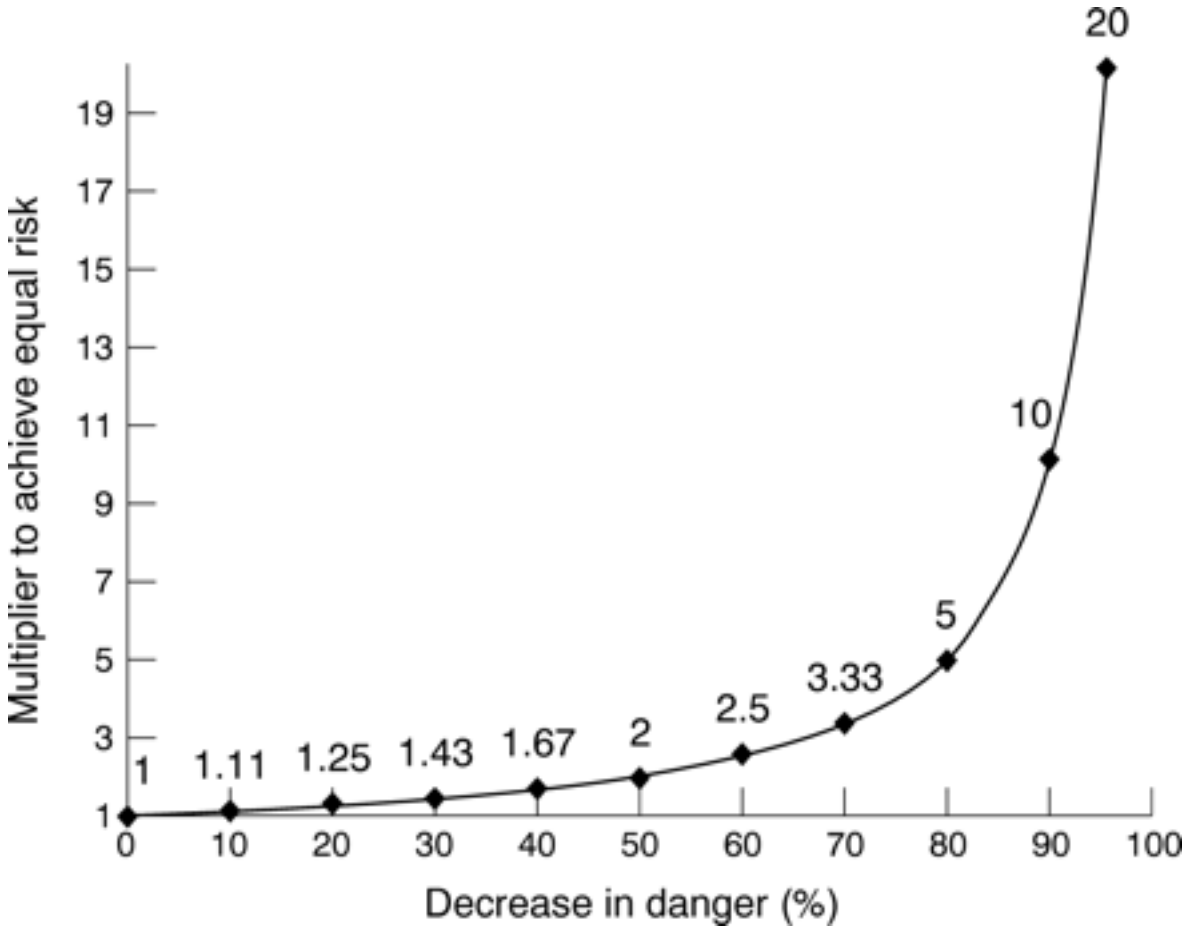
- Cigarettes with cigarettes
- Smokeless with smokeless
- NRT with NRT

The Comparative Risk Reduction Continuum Chart

The following chart is a hypothetical representation of the relative risks that are presented by spectrum of products–from those that are highly toxic and in the form of combusted tobacco to those that are at the other end of the spectrum, where risks are very small or even negligible. In each case, the regulation of the product should be based on risk. The higher the risk the more the more regulation (labeling, warnings, marketing restrictions, taxation etc.) The lower the risk the less regulation. I believe that if we begin to develop better and more consistent methods for testing tobacco products (and NRT), we can in fact plot where we would expect products to fall on the continuum.



POPULATION RISK V. INDIVIDUAL RISK
RISK/USE EQUILIBRIUM



Kozlowski LT, et al. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. *Tobacco Control* 2001; 10: 201-203

The Risk Reduction Equilibrium

In addition to getting a better idea of the risks and relative risks of various products, it is also useful to use the Risk Reduction Equilibrium", that was devised by Professor Lynn T. Kozlowski but also employed and referenced by others (Gionno, Warner, Cummings, Sweanor)

The risk/use equilibrium allows for the evaluation of possible problems (and benefits) caused by increased use of a less dangerous product-an equilibrium achieved by increasing use as risk decreases.

Both the Relative Risk Assessment Continuum and the Risk Reduction Equilibrium analysis could be further refined and allow for a more organized evaluation of products in the future. Such refinement would help in labeling and marketing efforts as well as surveillance, two critical components of an effective harm reduction effort. How we might proceed will be addressed in the last sections of this paper.

Regulation of Products on the Continuum Should be Commensurate with Risk

As we suggested on the Risk Reduction Continuum Chart, the degree of regulation of a product should be commensurate with level of harm caused by the product. This includes the labeling and marketing allowances for each product category and for each product within that category. A highly toxic combustible product for example should carry the most stringent warnings, labeling and marketing restrictions, while a noncombustible tobacco product would have less stringent labeling and marketing restrictions and requirements. Pharmaceutical would have even less restrictions. Products in each of these two (three) categories could be further differentiated based upon the level of scientific evidence available on each product. Such might be the case for making distinctions between smokeless tobacco products that have varying (and meaningful differences) levels of tobacco specific nitrosamines. Such might be the case for combustible products that have demonstrated (through agreed upon testing methods) that certain significant toxins have either been reduced or eliminated. This type of product differentiation based on the level of risk is not unique to tobacco but is applied to other products such as pharmaceuticals, and foods. The FDA already has extensive experience with labeling and disease claims. The FTC has extensive experience with unfair and deceptive marketing practices, the CDC with surveillance issues as well as a state of the art laboratory testing facility. There is also a great deal of experience and models on labeling and marketing (including assurances of operating within the parameters of the First Amendment) that can be drawn on.

The IOM Report contains a set of regulatory principles that should be used for mapping out potential short term and long term goals and objectives, including such things as disclosure of product ingredients; assessing yields and testing of various toxicants; pre-marketing approval of products making health claims; criteria and methods for the labeling and marketing of products; conducting post-marketing surveillance; and establishing performance standards. (For a complete listing of the regulatory principles and a more thorough discussion, see IOM report, Clearing the Smoke, pages 206-229)

Surveillance of Products is Critical

There is little disagreement that if we go down the harm reduction path we will need to be able to monitor use of such products both within the broad categories under which they are marketed and as individual products. This will require a cooperative effort of the government, the public health community, industry, retailers and wholesalers, and consumers.

The IOM report **Clearing the Smoke** (page 180) noted that:

> *The goal of surveillance systems in epidemiology and public health is to provide timely information from populations on the occurrence of disease and conditions of interest, the presence of risk factors for those conditions, and the impact of disease control programs.*
>
> *The Centers for Disease Control and Prevention (CDC) offers the following definition of surveillance (Thacker and Berkelman, 1988):*
>
> > *Public health surveillance is the ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link in the surveillance chain is the application of these data to prevention and control. A surveillance system includes a capacity for data collection, analysis, and dissemination linked to public health programs.*

It is unfortunate, however, that when it comes to tobacco, effective and comprehensive surveillance systems have not been instituted. The IOM report goes on:

> *One important issue is who would conduct surveillance on conventional tobacco products and PREPs. The types of data recommended above (see report pages 183-195) would almost preclude all surveillance being*

conducted by one organization or agency. It is likely that the elements of surveillance will come from many sources, and a coordinated effort will be needed to plan, assimilate, and interpret information for reasons of efficiency and standardization. As noted elsewhere, it will be important to include all conventional tobacco products, since they become one critical reference for health outcome studies, and to monitor changes in these products themselves. A part of the surveillance system would be to validate manufacturer claims of product distribution, content and biological and clinical effects.

The report concludes with the following recommendations (page 197):

1. *There is an urgent need for a national and comprehensive surveillance system that collects information on a broad range of elements necessary to understand the population impact of tobacco products and PREPs, including attitude, beliefs, product characteristics, product distribution and usage patterns, markets messages such as harm reduction claims and advertising, the incidence of initiation and quitting and non-tobacco risk factors for tobacco related conditions. There should be surveillance of major smoking-related diseases as well as construction of aggregate population health measures of the net impact of conventional products and PREPs.*
2. *The surveillance system should consist of mandatory, industry-furnished data on tobacco product constituents, additives, and population distribution and sales.*
3. *Resources should be made available for a program of epidemiological studies that specifically address the health outcomes of PREPs and conventional tobacco products, built on a robust surveillance system and using available basic and clinical scientific findings.*

Scientific Standards for Allowing or Disallowing Claims and the Disclosure of Information

The scientific methods by which the risks of the spectrum of products are assessed that will allow or disallow claims and other information will be critical. There must be agreed upon standards. This is particularly important if we are to avoid the problems of the low tar and low nicotine fiascos of the recent past. Currently there are no uniform specific standards or rules for tobacco relating to misleading and deceptive claims and marketing (and other information) which is broadly governed under the authorities of the Federal Trade Commission. The FTC reviews claims and labeling for misleading and deceptive statements on a case by case basis, falling far short of what will be needed in an ever- more complex and expanding market place. The development of scientific standards will be critical if we are going to establish a process and a yardstick by which all products on the market can be measured both for validation of the product itself and any claims that may be made.

I believe that given the Supreme Courts decision preventing FDA from regulating tobacco products and putting the burden back in the hands of Congress, there will be efforts by many in the industry to push the envelope in making claims. The provisions of the MSA can continue to be used to prevent false and misleading claims but this is not a system that in my view will serve the long term interests of the parties if harm reduction is going to continue to move forward.

In addition, the First amendment cases on commercial speech have increasingly given commercial speech greater protection. Several cases concerning the allowance or disallowance of health claims on foods are very instructive as to how the courts might deal with tobacco and how health claims and other information is made available to the public. We need to consider the case law and to develop labeling and marketing systems that will meet First amendment requirements.

Summary and Conclusion

Not all tobacco products carry the same level of risks. Whether in combustible or noncombustible form, the level of risk associated with a particular tobacco product can vary substantially. Combustible forms of tobacco carry the highest level of risks because of the number of harmful constituents produced in the smoke. Noncombustible forms of tobacco, because they are not burned generally carry a significantly lower level of risk. And within each of these two categories there can also be very different degrees of risk associated with the product. Each product, in effect, carries its own 'risk profile'. The challenge to the scientific community, the public health community, the tobacco industry, biotech companies, growers, government and others is to work towards the development of

standards and testing methods by which tobacco products can be evaluated so that we can understand the risks and relative risks of such products not only between categories but within those as categories as well. Models and regulatory standards that the FDA uses for both food and pharmaceutical products (prescription and OTC) could be very useful in developing a similar a system for tobacco products.

The manner in which products are labeled and marketed would therefore be commensurate with the risks they pose-based on their 'risk profile'. The higher toxic products would have greater labeling and marketing requirements and restrictions, while those products deemed to be lower in risk would have fewer and different requirements. All products, including NRT products can, with the use of agreed upon testing and evaluation methods be placed on the 'relative risk continuum,' allowing consumers and the public to better understand the products that are in the market place and the level of risk they produce. Competition would be stimulated under this system rewarding companies who are true innovators and pushing those who wish to circumvent science and health out of the market place.

This process of being able to evaluate products based on relative risks will be critical if we are going to be able to meet the individual 'health needs' of users of both tobacco products as well as NRT.

Why Oversight of Tobacco and Tobacco Products is Both Necessary and Inevitable

We must recognize the roles business managers are required to play and simply set in counterposition a group with a fundamentally different role. Against businesses, whose first job is profit, we must set groups whose first job is safety. It is after all, common sense.

Philip Hilts, "Protecting America's Health – The FDA, Business, and One Hundred Years of Regulation"

- Voluntary programs do not work
- What FDA oversight should entail
- Why other agencies are not qualified to take the lead in product regulation
- Need for coordination with other federal agencies
- USDA's regulatory role in overseeing tobacco production
- The need for effective oversight is not just a US concern but a global one as well
- Summary and Conclusion

As tobacco companies line up to develop and market 'reduced risk' products, many in the public health community worry that we are headed down the same road that resulted in the development and marketing of low tar and low nicotine cigarettes: a market place filled with chaos and deceptions. As the IOM report, **Clearing the Smoke** noted, the reality is that the development and availability of these products in the market place is upon us now. How harm reduction products are dealt with in the future cannot be looked at in isolation, but must be considered as part of the broader regulatory framework for tobacco products and in the context of the spectrum of tobacco products on the market. The market and the products available to the public will continue to change as the industry is faced with having to comply with responsible regulatory standards coupled with competition to develop and market products that are *truly* lower in risk.

The question we are facing is how do we sort out what might be legitimate science based products and claims versus illegitimate products that, like their low yield cigarette predecessors, are fraught with Madison Avenue marketing gimmicks designed to sell products with little real concern about public health. In addition to transparency and corporate accountability, we will need to have effective but fair oversight and regulation of tobacco products by an agency like the Food and Drug Administration.

Any discussion, dialogue, or engagement with the industry should be based on a clear acceptance by tobacco manufacturers that oversight of the industry and its products is not only the right thing to do for public health but the right thing to do with respect to the manufacturing and marketing of an inherently dangerous consumer product. In fact the IOM concluded:

> *Regulation of all tobacco products, including conventional ones as recommended in IOM, 1994, as well as all other PREPs is a necessary precondition for assuring a scientific basis for judging the effects of using PREPs and for assuring that the health of the public is protected. Regulation is needed to assure that adequate research (on everything from smoke chemistry and toxicology to long term epidemiology) is conducted to ensure that the public has current, reliable information as to the risks and benefits of PREPs. Careful regulation of claims is needed to reduce misperception and misuse of the products. If a PREP is marketed with a claim that it reduces (or could reduce) the risk of a specific disease(s) compared to the risk of the product for which it substitutes, regulation is needed to assure that the claim is supported by scientifically sound evidence and that pertinent epidemiological data are collected to verify that claim.*
>
> *(IOM,* **Clearing the Smoke***, Conclusion # 5, page 6. See also, the IOM's suggested 11 regulatroy principles for regulating PREPs, page 1o—11)*

In spite of 'reservations' made by some, it is also clear from statements suggested in the IOM report as well as some in the public health and scientific community that engagement with the industry and other stakeholders will be required and is inevitable.

The question, therefore, is not whether such engagement will take place, but rather when and how. As we noted in an earlier chapter, it is not just public health organizations and the tobacco manufacturers who will be involved in the discussion, but tobacco producers, scientists, researchers, biotech companies, agronomists, pharmaceutical companies, marketing experts, and consumers. We need the involvement of key experts to help shape policies and craft legislation that will serve the public interest both in the short and long-term.

The effort to secure FDA oversight of the tobacco industry and its products has been and remains a hard fought battle. The first Surgeon General's report was released in 1964, at a time not unlike today where the prospects for the development of lower risk cigarettes was on the 'horizon'. In the late 1980's, several petitions to the FDA (coupled with the introduction of legislation) renewed efforts to have it regulate tobacco either as drugs and devices under the agency's existing jurisdiction, or to establish a separate chapter under the Food Drug and Cosmetic Act (legislation). In 1996, the FDA issued proposed regulations and a massive and extensive record as to why it was regulating tobacco products under its existing drug and device authorities. These efforts brought a swift and massive counter attack from the tobacco industry which at the time was unified in its opposition. The battle was taken all the way to the Supreme Court, where in a 4-3 ruling, the court found that the agency did not have jurisdiction over tobacco products. This threw the issue back to the US Congress for further consideration., where it has since remained. Several efforts within Congress have come close to giving the agency jurisdiction but, for a variety of reasons the Congress has failed to act. As noted below, the players in the debate, their views and their support have changed the environment significantly to the extent, that many now believe that some form of oversight over the tobacco industry and its products is not only possible but inevitable.

An investment prospectus prepared by JP Morgan in 2005 on the development of reduced risk-products noted:

> *"One of the main obstacles facing PREP cigarettes is the industry's inability to clearly and credibly communicate reduced risk attributes to smokers".*

The prospectus further noted that:

> *We see two major benefits of FDA regulation for the industry:*
>
> - *Reduced forward looking litigation risk, as FDA regulation of product content, marketing and distribution makes it more difficult for plaintiff – lawyers to attack the industry in the court room, and*
>
> - *Opportunity to successfully market PREPS cigarettes as the FDA determines which products are reduced risk and authorizes health claims.*

The issue of FDA oversight over tobacco products will need to be discussed and dealt with even as we await action from the Congress, which may take several years. Even if Congress were to enact legislation in the near future, the promulgation of regulations would be several years in the making and, given past history, challenged at ever step by some manufacturers.

The positions of the spectrum of stakeholders have been articulated in a number of places, including testimony before Congress, websites, public statements to the press, etc. Some have specifically refered to the need for the FDA to have authority including public health organizations, growers, some in industry, and consumers. A set of core principles issued by growers and health groups in 1998 and the presidential commission report, **Tobacco at a Crossroad** (May 2001) included recommendations for the regulation of tobacco by the FDA. More than one hundred grower organizations, health groups and others signed on to the recommendations contained in those documents. Philip Morris (Altria) has been most public with its endorsement of the FDA approach to oversight of the tobacco industry although other companies such as Star Scientific endorsed FDA as far back as 2000.

Philip Morris' website notes:

> *PM USA strongly supports the passage of this legislation (DeWine/ Kennedy) and remains committed in our support for comprehensive, meaningful, and effective FDA regulation of tobacco products. We believe FDA regulation would play a significant role in reducing the harm caused by tobacco. This is a goal that we share with the public health community and society and believe is good for our company, our employees and the industry as a whole.*

For more information on the position and views of PM

USA on FDA, see http://www.philipmorrisusa.com.

.

Two of the larger smokeless tobacco companies (UST and Swedish Match) have indicated a willingness to accept FDA under certain conditions. The UST 2005 annual report released in March 2006, for example, included the following statement:

> *Proposals for comprehensive regulation of tobacco products* will continue to be considered. To date, the Company has opposed such proposals because they fail to completely recognize the distinct differences between smokeless tobacco and cigarettes. However, the company would consider supporting such regulation if the proposed regulatory scheme included the following components:*
>
> 1. *a meaningful regulatory process whereby the agency could certify, based upon submissions by a manufacturer, that the use of smokeless tobacco involves significantly less adverse health effects than cigarette smoking.*
> 2. *a meaningful regulatory process whereby the agency could approve, based upon the submission of a manufacturer, comparative risk communications to current adult users of tobacco products (e.g. cigarette smokers who do not quit and do not use medicinal nicotine products should switch completely to smokeless products; and*
> 3. *a meaningful regulatory process whereby the severity of any provisions regarding regulation of ingredients, constituents, advertising, promotion and availability could be reduced for products that were classified on a continuum as involving less risk (e.g. less restrictive regulations for products classified as significantly reduced risk, such as smokeless tobacco.*
>
> **including FDA*

Others remain opposed (including Reynolds American, and Lorillard) to regulation, preferring to preserve the status quo and using many of the same arguments used by the industry for years. We can also expect some of the smaller companies who are in it for quick profits to also work against FDA regulation of tobacco products.

The mainstream public health groups have long supported FDA regulation of tobacco products going as far back as the late 1980's, many of the them endorsed the DeWine/ Kennedy legislation in the 108th Congress. Some in the public health community remain opposed to 'FDA' because they say that the bills or approaches in Congress don't go far enough. Others remain opposed to FDA, arguing that the states should be fighting the battles with the industry. Given this current state of affairs, I am prompted to ask the fundamental question: Is preserving the status quo because of our failures to move perfect legislation forward a viable alternative when that means control by the tobacco industry? Common sense and history should tell us it is not. We have not employed an all or nothing approach to other tobacco control strategies, including excise taxes, clean indoor air legislation, or marketing and advertising restrictions and we should not do it here.

If we compare where we were on the issue for the need to have the industry regulated 5-10 years ago, we can only conclude that there has been a major shift in support of that goal by a widening spectrum of interests. While motivations may differ, there is some common ground that needs to be explored. The common ground has not only come from the more mainstream public health organizations, but from companies, growers, and consumers as well, who see that their interests may be best served in the long term by accepting such oversight and working within a system and process rather than against it.

Voluntary Programs Do Not Work

The lack of meaningful and enforceable standards and rules has led and will continue to lead to abuses from the industry. Even if some companies change their ways, there will always a few (or more) bad apples who will want to make quick profits at the expense of public health by doing things that could be ethically and corporately irresponsible. Such unchecked activities are a green light for other companies who might otherwise be willing to accept and play by a set of rules to continue their own abuses in order to protect market share. What is needed is a set of rules that prevents abuses, encourages science -based innovation, and makes reduction of disease and death from tobacco something that the industry fully accepts as a goal.

In years past, whenever there were discussions about the prospects of regulating the tobacco industry and its products, the tobacco industry would always initiate voluntary programs

which, for the most part, were merely words soon forgotten once the prospect for congressional action was beaten back.

We are beyond voluntary programs; interim efforts must be with the full understanding and acceptance that governmental oversight of tobacco and tobacco products is both necessary and inevitable. Not only do voluntary approaches not serve public health interests but they also destabilize the tobacco production and manufacturing sector.

What Should FDA Oversight Entail?

Separate Chapter:

Legislative proposals in Congress over the last several years have shifted from regulating tobacco products under 'drug and device' provisions of the FD&C Act to establishing a separate chapter specifically designed to deal with the regulation of tobacco and tobacco like products. Public health organizations, growers, and some in industry have all agreed that tobacco should be regulated under such a scheme. In spite of this agreement and consensus, there are some companies who continue to deliberately cause confusion by suggesting that regulating tobacco under FDA will ultimately result in all tobacco being regulated as drugs and banned. I am unaware of any of the major stakeholders who supports FDA oversight advocating such a position.

Key elements of FDA oversight:

The key elements of what areas FDA should have over tobacco products have been well spelled out. Some of those elements include giving FDA the authority:

- To restrict the sale, distribution, marketing, and promotion of tobacco products to children and adolescents
- To require warnings labels and other information on all tobacco products, in tobacco advertisements, or other means that allows adult users of tobacco products to fully understand the risks and relative risks of the products they are using
- To restrict and prohibit advertising and marketing that is misleading and deceptive (consistent with the First Amendment). This includes advertising targeted at children and adolescents as well as advertising and marketing that makes unsubstantiated false and misleading health claims (e.g. low tar and low nicotine).
- To require that all tobacco products (generically and individually) disclose toxins, ingredients, additives, country of origin and other information to which adult users of tobacco are entitled
- To establish Good Manufacturing Practices (GMP's) for the industry

The FDA should also:

- Encourage the development of technologies and tobacco based products that have a reasonable expectation of reducing risks associated with tobacco use
- Work with other federal agencies CDC, NIH, USDA, EPA, FTC, DHHS, ATF etc) in establishing a cohesive and workable national tobacco program
- Work with entities in the private sector including scientists, researchers, public health authorities, industry, growers, and others

In his book, Protecting America's Health- The FDA, Business and One Hundred Years of Regulation, Phil Hilts, who has followed and written about the tobacco issue extensively, made the following observation:

> *We must recognize the roles of business managers are required to play, and simply set in counter-position to them a group with a fundamentally different role. Against businesses, whose first job is profit, we must set groups who first job is safety. It is, after all, common sense. Warren Kiefer, a public relations executive for Pfizer International, several decades ago spoke before Congress and then wrote, in a letter to the Saturday Review, "It was my experience in the drug industry that most executives were honest most of the time. But they were businessmen, who in the old American tradition, placed company interest first. Public interest was the FDA's lookout", he said. "It is the regulatory officials who are responsible to the people"*

In contrast to the FDA's poor resources but dedication and openness, American corporations overall have failed to evolve much as organizations. They have remained rigid hierarchies, with little input from the public or stakeholders when key decisions are made. Some management experts have begun to press for more open corporations, ones that include members of the board some workers, or members of the communities where the companies reside, or suppliers. Essentially, though, the logic of "profit alone" that dominated the companies in the nineteenth century dominates them today. This is one reason the FDA's job is difficult and necessary.(p 342)

Why Other Agencies Are Not Qualified to Take the Lead in Tobacco Product Regulation

For many years there have been arguments made (mostly by the tobacco industry and its allies) that regulation and oversight of tobacco products might be better dealt with by the Federal Trade Commission or the Centers for Disease Control and Prevention. While each of those agencies has a role to play in the tobacco arena, neither is suited to regulate the complexities of the tobacco product. FTC authorities should, as they do in the area of pharmaceutical products, compliment the FDA's primary authority, letting the FDA, as a science-based agency, set the primary directions of oversight and regulation as a public health matter. The CDC should, as it does in many other areas (obesity, nutrition, physical activity, etc.), continue to focus on tobacco control education, prevention, and surveillance. Suggesting that CDC regulate tobacco products would be similar to suggesting that CDC assume regulatory responsibility over the pharmaceutical, food, device, and dietary supplement industries. Some argue that, given FDA's current challenges and limited resources in other areas adding tobacco to its responsibilities will further erode the agency's ability to do its job. While there is some truth to such a suggestion, we cannot and should not forget that we are dealing with products that cause the deaths of over 400,000 Americans each year. We cannot forget that tobacco use accounts for annual medical and lost productivity expenditures totaling billions of dollars each year. Nor can we forget that the FDA is the most logical place to put tobacco given tobacco's complexities and public health ramifications. Creating a Center on Tobacco within the FDA, funded and staffed separately can and should be done. This would neither detract the agency from its other responsibilities nor siphon away funding from its other important regulatory responsibilities. From all perspectives, the FDA is the best suited and most logical place for tobacco products to be placed.

Need for Coordination with Other Federal Agencies

Missing in the discussion of FDA oversight is the need for greater coordination and interface between the FDA and other agencies. This is particularly important in dealing with issues related to harm reduction and the development of reduced risk products.

I have been and remain a big advocate for establishing a comprehensive and cohesive national tobacco policy for this nation. There is a tendency on the part of some to look at FDA as the savior, as the only agency that has the capability for dealing with tobacco and which should have the authority to deal with the health ramifications of tobacco. In fact, while FDA is central to overseeing the industry and its products, other governmental agencies will also need to be involved. Agencies that need to be involved might include USDA, EPA, NIH, NIDA, CDC, FTC, ATF and even DHS.

Of particular importance to harm reduction is the role that the USDA must play.

USDA's role in Harm Reduction Efforts

FDA's working with the USDA will be particularly important for harm reduction efforts. As the JP Morgan prospectus noted:

There are two main ways in which cigarette manufacturers can produce a safer cigarette:

- *The tobacco leaf or ingredients can be altered*
- *Cigarette construction can be modified*

In a special program on obesity in America, the late Peter Jennings began by standing in a field of agricultural

crops saying "It all starts here". And so it is with tobacco. It would be naïve to think that somehow the production, curing, and processing of tobacco has nothing to do with issues related to harm reduction. The fact is that technologies and changing methods of production will have an increasingly more important role to play in harm reduction.

In the 108th Congress, as part of the tobacco buyout deal and at the behest of political interests and the special interest of one major tobacco company in particular, the Congress terminated the 1938 tobacco program. In effect, this dismantled programs that not only protected growers but also benefited public health. Instead of visionary thinking about tobacco and dealing with it effectively, Congress chose to in effect move the issue backwards. Once again, the fox has been left guarding the chicken coop. The interests of some in the tobacco industry have won out over public health and growers.

In order to effectively implement harm reduction efforts through product development and modification, changes must be made and important provisions and authorities restored to USDA that will not only help farmers but protect public health. These should include:

- Monitoring, tracking and testing tobacco that is produced in the US and overseas.
- Developing and implementing production standards that ensure the quality, health, and safety of the tobacco leaf.
- Providing incentives to tobacco producers, biotech companies, agronomists, and manufacturers to invest in and develop new forms of leaf that are scientifically tested and evaluated to reduce harm associated with tobacco.
- Identifying research priorities that have a reasonable expectation of lowering risks associated with tobacco use (at the production level).

Regulatory oversight and the development of regulation will not occur overnight

It would be foolish to believe that even if FDA legislation and complimentary USDA legislation were passed by Congress tomorrow, the issues surrounding the production, manufacture, sale, labeling, promotion, and marketing of tobacco products would change overnight. The development of rules and regulation might take several years at a minimum. This does not mean that, as we pursue FDA and USDA oversight, there aren't important steps to be taken that could not only speed up the process of change under the current environment, but also have a significant influence and impact on helping the FDA and USDA when such authorities are finally provided. Recommendations on how that process might be accomplished and implemented are dealt with in the last chapter, "Where do We Go From Here?".

The need for effective oversight of tobacco and tobacco products is not just a US concern - but a global one as well

The challenges we face in ensuring effective but workable oversight of the tobacco industry and its products in the US are the same ones that need to be addressed and confronted globally. The World Health Organization's (WHO) Framework Convention on Tobacco Control (articles 9,10,11) established the groundwork for the regulation of the contents, disclosures, packaging, labeling, and marketing of tobacco products. The WHO Study Group on Tobacco Product Regulation has laid out a series of recommendations including establishing some **Guiding Principles for the Development of Tobacco Product Research and Testing Capacity and Proposed Protocols for the Initiation of tobacco Product Testing**. This research and testing capacity will be essential for the effective oversight and regulation of existing and new tobacco and tobacco like products. More information can be accessed through the WHO FCTC website at www.WHO.org).

Summary and Conclusion

The development of harm reduction products cannot be done in a vacuum. There must be a level playing field and a set of rules and standards developed that will ensure that all tobacco and tobacco products are what they claim to be (both products currently on the market as well as new ones). We cannot and should not depend on tobacco industry voluntary efforts. With new products on the hori-

zon with significant technology changes and more to come, we must bring order to what is currently chaos. Without effective oversight by both the public and private sector, we are doomed to a repetition of the mistakes that have been made in the past. The Food and Drug Administration is clearly the best suited and most logical governmental agency for overseeing the tobacco industry and its manufactured products, although it is critical that the FDA also work closely with other governmental agencies such as the EPA, FTC, CDC, NIH, Homeland Security etc. Of particular importance in the ensuring proper and effective oversight of tobacco and tobacco products will be the critical role that the USDA must also play.

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

If you meet a sectary, or a 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

Introduction

If there is one conclusion to be drawn from my review, it is that we need a long term stabilized process that will allow stakeholders and other experts to engage in discussion and debate on the spectrum of issues surrounding tobacco and tobacco products. This is particularly true for harm reduction. This process should move forward even as we work to have an agency like the FDA oversee the tobacco industry and the products they produce. In fact, the establishment a private sector body charged with looking at a spectrum of issues related to tobacco and pharmaceuticals would assist not only the FDA, but the USDA, the EPA, the NIH, the FTC, the CDC and other governmental agencies as well. It could also assist other private sector organizations identify and focus their efforts. It could be the first permanent step towards "transparency" within and between the tobacco industry, the scientific community, and the public health community.

With or without FDA oversight, the introduction of a variety of new products, are and will continue to be forthcoming. For many reasons, many of which have been discussed throughout this paper, the tobacco industry is undergoing significant fundamental changes and realignment. What all those changes are, how rapidly they occur, and whether they can benefit public health remain to be determined. However, I believe that through more direct engagement in a neutral and safe haven it is possible to shape that change in a way that can positively impact on public health and avoid the missteps of the past.

One thing is clear, the tobacco industry's words and rhetoric of responsibility will not be enough. Much will depend on what the tobacco industry or individual companies decide to do or not do. The industry's past behaviors and actions have created an environment of deep distrust that has polarized parties and created behaviors that have not been conducive to finding meaningful solutions.

Words must be supported by actions, that demonstrate that the deceptions and irresponsible practices are truly things of the past. As the Campaign for Tobacco Free Kids noted in its testimony to a House subcommittee in June of 2003:

> *How can you have a meaningful discussion about the potential to use a cancer causing product to reduce the harm of smoking with an industry that won't acknowledge that its products cause harm and hasn't agreed to meaningful government regulation?*

While the tobacco industry must change, so must the rhetoric and posturing that has occurred from the public health community. Tobacco control advocates have matched the industry's rhetoric with tactics and words of their own. Statements such as "no FDA bill (legislation) is better than a bad FDA bill", while playing well with the press and their constituencies seems, after its initial use, done little to move the ball forward. In fact may be causing more public harm than good in that it preserves the 'status quo' in allowing the tobacco industry to dictate and dominate federal policy. In this instance, I would suggest that we start thinking that "a good bill is better than no bill at all". Having worked on the FDA/tobacco issue for close to fifteen years, I believe we would be farther down the road had we accepted a strong but not perfect bill. We would have had a base to work from to improve the legislation as data accumulated. Instead, we have nothing. I cannot think of any legislation in FDA's 100–year history that was perfect when enacted or that wasn't later modified because of the evolving science and development of new products. (see **Protecting America's Health –The FDA, Business and One Hundred Years of Regulation**, Philip J. Hilts, Alfred A. Knopf Press, 2003)

There have been efforts in the past to bring parties together on neutral ground and from my perspective, they have had a positive impact. In 1985, President Carter, through the then newly established Carter Center, attempted to bring public

health groups, growers, and industry together in what was the center's first domestic conflict resolution effort. In spite of the president's personal request, the tobacco manufacturers, save one representative from the smokeless industry, in a typical act of arrogance declined the invitation.

In the mid 1990's growers and health groups met through the auspices of the Southern Tobacco Communities Project, funded by the Robert Wood Johnson Foundation. Overtures to the manufacturers were again met with a refusal to participate. But the dialogue proved extremely useful and the willingness of cooperation continues to this day. What was done then could serve as a working example for engagement in today's environment.

Conditions and Parameters of Engagement

Those who are legitimately seeking solutions to reducing disease and death caused by tobacco and tobacco products should support short-term and long-term initiatives to engage in a productive dialogue. The question that remains is, given the hostility and polarization of the past, how can such a discussion or engagement be initiated and then managed and maintained? First, I would suggest that there are some key elements and conditions of participation that we must strive for:

- Neutral ground; An independent safe harbor outside of the politics of Washington DC.
- Being able to check organizational 'hats' at the door, and ensuring that the right individuals who have expertise are involved.
- *No media;* Agreement that discussions and engagement will not be used for public relations purposes.
- Agreement that rhetoric and hostility will be replaced with civil dialogue and that only 'real, substantive' issues will be discussed. Purpose should **not** be to 'negotiate' legislation but identify issues.
- Acceptance that the FDA (or an equally comparable regulatory agency) must have regulatory authority over the manufacture, sale, labeling, distribution and marketing of tobacco products.
- Acceptance that under a regulatory framework, tobacco manufacturers, growers, and other entities (biotech companies, pharmaceutical companies) should be 'encouraged' and given incentives to modify existing products and to develop new products and practices that have a reasonable expectation of reducing disease caused by the use of tobacco.
- Acceptance that there needs to honest and transparent discussion about science, technology, future needs and directions.
- Focus on finding common ground, identifying avenues for future actions including mutually agreed upon collaborations if possible.

Need for an Independent/Permanent Tobacco Policy Research Center

In 1996 I first suggested the idea that some sort of an independent center might be what we needed at the next stage of tobacco control, something that would serve the public health and scientific communities, provide a neutral forum for discussing the increasingly complex issues related to tobacco, and confront and challenge the tobacco industry. Except for some limited engagement between tobacco growers and public health organizations, and secret negotiations over legislation, there has been little to no substantive or structured engagement over the last five to ten years. We continue to struggle with **how** to move the ball forward in changing the manner in which tobacco products are manufactured, labeled, sold, distributed and marketed. As we noted earlier the current environment seems to be one of 'polarization' and a propensity to harp on the past rather than looking at the future. But there also seem to be an increasing number of people who believe that change is inevitable and must be seized. This proposal (the creation of a policy center) is, to use and paraphrase the words of some others in discussing the need for a nicotine policy, " a pragmatic attempt to look and plan into the future in a policy area where there is a significant vacuum. Nothing here is intended to side track efforts to reduce tobacco initiation or cessation. The question of whether nicotine addiction [tobacco] can be eradicated is highly speculative and lies into the future. However short term and medium term nicotine [tobacco] policy can be developed on the basis of what we know and can do now". (See Toward a comprehensive long term nicotine policy, **Tobacco Control** 2005:14:161-165)

Much anxiety (almost an obsession) persists with many in the public health community about the mistakes that were encountered in the late 1960's and early 70's when efforts were undertaken to explore the possibility of developing a safer or safe cigarette. In a article published in **Nicotine and Tobacco Research**, Mark Parascandola of the National Cancer Institute offered his views and recommendations to the research community:

- *First, a research agenda on tobacco products and harm-reduction claims should be broad and should include input from a variety of disciplines.*
- *Second, it is important to study user's behaviors and products on the market rather than generic products.*
- *Third, although tobacco company scientists may provide data to the research community about their products, they should not be in a position to influence a public health-oriented research agenda.*
- *Finally, research on tobacco harm reduction should not focus solely or primarily on modified cigarettes; the concept of tobacco harm reduction broadly defined has received qualified support among scientists but evidence is still lacking…that changes to cigarettes over time have had any measurable benefit to health.*

(Parascandola, M. **Lessons from the history of tobacco harm reduction: The National Cancer Institutes Smoking and Health Program and the "less hazardous cigasette,, nictotine and Tonbacco Research, Vol. 7, Number 2 (October 20005)p. 787.**

Doctor Parascandola's views reinforce my overall conclusions that while we must learn from the past, we shouldn't be talking about why we shouldn't do anything but rather *how we* can move forward. The reality is that we need to find a way to engage the industry in a fair and open manner under conditions that ensure protection and integrity of science and public health.

Essential Elements for a Tobacco Policy Research Center

What should the purpose and mission of the Tobacco Policy Research Center be?

The mission of the center should be to serve as an independent convener of parties with the objective of discussing a spectrum of issues related to the production, processing, manufacturing, sale, distribution, labeling, and marketing of tobacco and tobacco products. The Center could be a free-standing entity in the private sector or be associated with a university-based entity with conflict resolution capacity and capabilities.

How Should a Tobacco Policy Research Center Be Structured?

The center must be independent and have the highest standards of respect for science, fairness and integrity. It should provide and make high-quality, impartial, and relevant assessments on issues pertaining to all aspects of tobacco, including its production, manufacturing, sales, distribution, labeling and marketing.

The center cannot and should not be operated or influenced by any of the major stakeholders, such as the tobacco industry, public health advocacy groups, the pharmaceutical industry, or grower organizations. A number of organizations and models that exist are instructive, **but** each, in addition to the some positive attributes, has many negative attributes and shortcomings as well. Some of entities that I came across (and I am sure there are others) include:

- **The Health Effects Institute***: The HEI is an independent, nonprofit corporation chartered in 1980 to provide high-quality, impartial and relevant science on the health effects of air pollution. Supported jointly by the US Environmental Protection Agency and industry, HEI has funded over 170 studies and published over 10 research reports and several special reports producing important research findings on the health effects of a variety of pollutants, including carbon monoxide, methanol, and aldehydes etc. (form ore information on HEI go to www.healtheffects.org)*

- **The International Life Sciences Institute**: *Founded in 1978, the ILSI is a nonprofit foundation that seeks to improve the well being of the general public through the advancement of science. Its goal is to further the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment and the environment by brining together scientists from academia, government and industry.(www.ilsi.org)*

- **Transdisciplinary Tobacco Use Research Center (TTURC)**. *The TTURC "is funded through the NCI and NIDA. The overall goal of the TTURC is to stimulate integrated research across scientific disciplines such as the neurosciences, economics, epidemiology, genetics, behavioral sciences, pharmacology, and medicine to significantly advance our understanding of tobacco use, nicotine addiction and tobacco harm reduction" (www.tturc.umn.edu).*

- **Society for Research on Nicotine and Tobacco**. *The SNRT mission is to 'stimulate the generation of new knowledge concerning nicotine in all its manifestations- from molecular to societal. The Society has three main aims: 1. to sponsor scientific meetings and publications fostering the exchange of information on nicotine and tobacco. 2. To encourage scientific research on public health efforts for the prevention and treatment of tobacco use. 3. To provide a means by which legislative, governmental, regulatory and other public agencies can obtain expert advice and consultation on nicotine and tobacco. (for more information go to wwww.srnt.org)*

- **The Life Science Research Organization**. *According to the LSRO website, "When decision makers want unbiased answers based on scientific knowledge they turn to the LSRO, a non-profit organization located in Bethesda Maryland. For more than 40 years, LSRO has utilized the talents of many of America's best scientists to analyze fundamental issues that arise in biomedicine, healthcare, nutrition, food safety and the environment (www.lsro.org)*

- **Institute of Medicine.** *"The US turns to the Institute of Medicine (IOM) for science-based advice on matters of biomedical science, medicine and health. A nonprofit organization specifically created for this purpose, as well as an honorific membership organization, the IOM was chartered in 1970 as a component of the National Academy of Science. The institute provides a vital service by working outside the framework of government to ensure scientifically informed analysis and independent guidance. The IOM's mission is to serve as advisor to the nation to improve health. The Institute provides unbiased, evidence-based, and authoritative information and advice concerning health and science policy to policy-makers, professionals, leaders in every sector of society, and the public at large. (www.iom.edu)*

- **American Legacy Foundation.** *The American Legacy Foundation (ALF) is dedicated to building a world where young people reject tobacco and anyone can quit. The foundation is a 501(c)(3) organization that was established in March 1999 as a result of the Master Settlement Agreement (MSA) between a coalition of attorneys general in 46 states and five US territories and the tobacco industry and is funded primarily by payments designated by the settlement. The foundation develops programs that address the health effects of tobacco use through grants, technical training and assistance, youth activism, strategic partnerships, counter-marketing and grassroots marketing campaigns, public relations, research and community outreach to populations disproportionately affected by the toll of tobacco. (www.americanlegacy.org)*

NOTE: On March 15, 2006, ALF announced its intention to establish a tobacco research institute 'to advance science behind social marketing, smoking cessation, and tobacco control policy. Findings will be shared though scientific meetings, reports, various forums, all with the intent of advancing the knowledge base of tobacco use prevention and cessation and then translating the findings into public practice'.

- **Institute for Science and Health**. *The IFSH is 'a research organization without physical boundaries conducting independent third-party research in critical health related area. Accessing a virtually unlimited*

pool of researchers distributed around the globe, seeking the best and brightest in their respective fields. (for more information go to www.ifsh.org).

- **American Council on Science and Health**. *The ACSH is a consumer education consortium concerned with issues well related to food, nutrition, chemicals, pharmaceuticals, lifestyle the environment and health. ACSH was founded in 1978 by a group of scientists who had become concerned that many important public health policies related to health and the environment did not have a sound scientific basis. (for more information go to www.acsh.org)*

- **CORESTA** . *Coresta (Cooperation Center for Scientific Research Relative to Tobacco) is an association founded in 1956 "notably to respond and where practicable resolve non-competitive issues associated with tobacco production, product manufacture and use. Its Scientific Commission consists of four study groups: Agronomy, Phytopathology, Smoke Science, and Product Technology. The Coresta Board is composed of 14 elected member companies, including Philip Morris International, British American Tobacco, Japan Tobacco etc. (for more information go to www.coresta.org)*

Unlike some of the organizations noted above, the Center should not and **cannot** be a membership organization. Many organizations are set up to be independent but then indirectly or directly actively involve their membership, many of whom are corporate entities and who stand to benefit from the outcomes of the organization. The ILSI for example has a membership list of who's who in the corporate world including Kraft Foods, Monsanto, Glaxo Smith Kline, etc. Its board is made up of at least 50% of public sector members (primarily academia) with the remainder coming from its members. Some of the other organizations are comprised of individual members who often have financial ties to corporate entities.

Some organizations are constrained by their bylaws, mission statements or other terms and agreements.

The Center should **not** conduct research, undertake studies, hold meetings or conferences on behalf of 'clients' as in the case of the LSRO and several of the other organizations—even if such funding is considered to be 'hands off'. This has also been the case for the ISFH that held meetings on tobacco harm reduction in March of 2006, using funds (from what I can ascertain) from a tobacco company.

The process that was used by the Institute of Medicine (IOM) in putting together the publication, **Clearing the Smoke**, is one that could be replicated in some form on a more permanent basis in the formation of a permanent Tobacco Policy Research Center. The IOM was able to engage a broad spectrum of stakeholders in the process and publish a report that had the support and backing of many in the public health community, the scientific community as well as the tobacco industry. The IOM report also laid out an extensive menu of issues that needed to be considered and addressed in the area of harm reduction.

The Center could serve as the avenue through which to engage the industry in order to answer some of the questions that were laid out in the report, **Hope or Hazard**? , " What we should ask the tobacco industry about "reduced exposure" and "reduced risk" (page 11), as well as to focus attention on some areas identified in the "What is Needed Now" section of the same report (page 10) and which included:

- Methods and measures to test these (PREPs) products
- Better understanding of consumers' perception regarding PREPs
- Better Surveillance of these products (PREPS)
- Government Regulation of tobacco products and how they are marketed

(For a complete copy of the **Hope or Hazard?** Report, go to www.tturc.umn.edu)

I want to emphasize, that I am not suggesting that the above organizations and entities not carry forward with their work because I believe that what each may be doing, could be very useful to the Center in conducting its broader more *independent* work. Thus for example, the American Legacy Foundation's new tobacco research institute could be a tremendous asset in helping the Center move forward with its more extensive work. And I am sure there is knowledge to be gained from even industry based organizations such as Coresta. I am suggesting however, that for the *Center* to be effective it must be structured and operated very differently.

In addition to the institutions and organizations noted above, it might also be extremely useful to consider how some of the 'watch dog" organizations operate. This is important to ensure that transparency, ethical conduct and accountability are maintained. Although the primary role of the Center is not to be a 'watch dog' organization, if it is to do its job effectively, it will need to monitor the activities of all of the stakeholders, organizations and individuals it may wish to involve and to ensure that involvement is conducted with the highest of standards and integrity.

Some of the organizations worth taking a look at include:

- *The Center for Public Integrity: The CPI is a nonprofit organization that 'conducts investigative research and reporting on public policy issues in the US and around the world'." Through thorough, thoughtful, and objective analysis, the Center hopes to serve as an honest broker of information- and inspire a better in formed citizenry to demand a higher level of accountability from its government and elected leaders. The 'exponential increase in usage of the Center's reports by the media, academics, nongovernmental organizations and the public at large shows the growing impact of its mission (for more information go to www.publicintegrity.org).*

- *The Integrity in Science Project (CSPI): This project, a part of the Center for Science in the Public Interest, seeks among other things to "raise awareness about the role that corporate funding and other corporate interest play in scientific research, oversight, and publication; investigate and publicize conflicts of interest and other potentially destructive influence of industry-sponsored science; advocate for full disclo sure of funding by individuals governmental and non-governmental organizations that conduct, regulate, or provide oversight of scientific investigation or promote specific scientific findings; encourage policy makers at all levels of government to seek balance on expert advisory committees and to provide public, web-based access to conflict of interest information collected in the course of committee formulation (for more information go to www.cspiet.org/integrity)*

An Independent Board: – The Board of Directors should consist of highly respected individuals both inside and outside the tobacco environment. The Board members should not be 'representatives' of any of the stakeholders. Their charge is to ensure the highest level of independence, scientific integrity and fairness in overseeing the operations of the Center.

Authorities and Functions: The Center would be given broad authorities to:

- hold hearings, meetings and conferences
- set up discussion panels and debates
- issue reports, and recommendations,
- establish expert advisory committees,
- review scientific evidence,
- recommend scientific criteria,
- review and make recommendations for labeling, claims and marketing practices
- identify new areas of potential research,
- provide oversight over corporate accountability
- interface with academic institutions
- interface with governmental agencies
- provide a forum for conflict resolution and negotiation
- hire and retain highly qualified staff and consultants

.

Sepctrum of organizations and experts that would be solicited to participate in the Center's Activities

- Tobacco manufacturers,
- Public Health Organizations
- Scientists and researchers
- Pharmaceutical companies
- Tobacco Producers (growers)
- Agronomists
- Corporate accountability experts
- Biotech companies
- Governmental agencies
- Experts on labeling and marketing issues
- Behavioral scientists
- Economists
- Governmental agencies
- Consumers (users) of tobacco products
- Conflict Resolution experts
- Policy makers

What are some of the Issues that a Tobacco Policy Research Center should address?

The number of issues that the Center will need to address is extensive. Here are several that come to mind:

- Monitor, collect, and evaluate scientific studies.*
- Identify and evaluate current and future scientific issues and needs.
- Compile and document a listing of all tobacco products on the market both in the US as well as abroad.
- Assist in the development and make recommendations for establishing standardized testing methods, bench marks etc. for all tobacco products (Current testing methods such as the ISO and FTC methods are outdated).**
- Discuss how best to implement better surveillance systems (including pre-marketing and post-marketing surveillance)that involve the tobacco industry, the public health community, government agencies, and consumers etc.
- Evaluate and make recommendations on labeling and marketing issues.
- Identify and make recommendations concerning GMP's (Good manufacturing Practices) for the tobacco industry
- Involve consumers and users of tobacco in discussions about their perceptions of labeling, claims, marketing , products etc. including issues related to 'consumer acceptability'.
- Review advertising and marketing of all tobacco products to determine if such advertising and marketing is misleading and deceptive.
- Identify incentives for tobacco manufacturers, tobacco producers, biotech companies, pharmaceutical companies etc. designed to develop and manufacture lower risk products.
- Monitor and make recommendations for ensuring accountability and transparency from all of the stakeholders and in particular the tobacco industry.
- Convene focus groups to evaluate public and consumer perceptions about a spectrum of issues including specific products etc.
- Recommend mechanisms by which tobacco, pharmaceutical, and other corporate research funding could be provided to universities and other entities –– in order to ensure protection from undue corporate influences.
- Consider how, in a 'post buyout' environment tobacco production might be best structured to deal with harm reduction issues and changing technologies.
- Design and make recommendation for establishing a more effective tracking, monitoring and testing system for tobacco leaf both within the US as well as globally.

* The FDA has used 'evidenced –based ranking systems for scientific data. These ranking systems have also been used by such organizations as the Institute for Clinical Systems Improvement (ICSI) and adapted by the American Diabetes Association as well as others. An FDA Task Force Report on Consumer Health Information for Better Nutrition Initiative recommended that a ranking system should consist of a six-part procedure that includes: 1. Define the substance/disease relationship. 2. Collect and submit all relevant studies. 3. Classify and therefore rate each study as to type of study. 4. Rate each study for quality. 5. Rate the strength of the total body of evidence 6. Report the rank. The development of an evidence based ranking system should involve independent scientists and other experts.

** A number of 'questions' concerning 'reduced risk' products that should asked of the tobacco industry were presented in "Hope or Hazard?" These questions could be considered as part of a menu of issues that need to be considered both in the short term and long term.(p.11) The Center could develop and recommend a process by which these questions could be addressed.

How should the Center be funded?

As we noted in previous section on transparency, corporate funding of academic researchers and institutions has become a hot subject of discussion as it relates to conflict of interest issues -- not only when it comes to the area of tobacco but in terms of general industry involvement, including the pharmaceutical industry. Science has in some cases been distorted or misused to achieve results. In addition to corporate money targeted for research by various academic institutions, nonprofits are relying more and more on corporate

funding. Many believe that such funding does have impacts on decision- making and positions. How the Center is funded is therefore of the utmost importance.

In funding the Center, funding should be open to all entities and subject to full disclosure. There should not be and cannot be a 'quid pro quo'. It essential then that the Center:

- remains independent and objective
- that it is not membership based,
- that it serves as a neutral and independent organization and forum to convene stakeholders, independent experts etc.,
- that it has the ability to address a spectrum of issues on a continuing and flexible basis,
- that it can make recommendations and provide advice to policy makers, health professionals, regulators, industry, producers, etc.

Potential Contributor/ Funders could include:

- Foundations
- Non-Governmental Organizations(NGO's)
- Corporations (including tobacco, pharmaceutical, biotech , and agribusiness interests)
- Individuals
- Government

Summary and Conclusion

If we are serious about moving forward in developing strategies towards "reducing risk from disease and death" caused by tobacco and tobacco products it will be essential that a spectrum of interests be involved in an ongoing honest, open and transparent dialogue. We need to focus on the question: If tobacco and tobacco products are to remain legal, what are both the short term and long goals and objectives that we need to start talking about? No one entity, whether it's the public health community , scientists, industry, or growers, can go it alone. Each currently has constraints---- even those with the best of intentions. Each has a role to play. There therefore needs to be a well- funded, independent organization that will bring the various interests together in a 'safe haven'--- an organization that has both expertise and flexibility to deal with complex issues.

The proposed Center's primary focus would on bringing parties together to discuss issues related to tobacco and tobacco product modification designed to reduce the incidence of disease and death caused by tobacco use. The Center would fill a void that must be filled and which no existing organization has the ability to fill. It would not be an organization designed to represent anyone's special interest, nor is the intent of such a Center to detract from the necessary tobacco control efforts that are currently employed. Such a Center would also have the capacity to deal with issues and topics as they arise, so that open and transparent discussion of issues can take place on an ongoing basis.