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 role of science and technology
- The role of competition and incentives
- The role of tobacco agriculture
- The role of the consumer
- Summary and Conclusion

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).*
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> *(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.