

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 be 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 an 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 cigarette," nicotine and Tobacco Research, Vol. 7, Number 2 (October 2005)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 bringing together scientists from academia, government and industry. (www.ilsa.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 www.smt.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 through 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 informed 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 disclosure 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

Spectrum 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, benchmarks 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 be 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 is 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 be 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.