“SMOKEFREE” TOBACCO AND NICOTINE PRODUCTS REDUCING THE RISKS OF TOBACCO RELATED DISEASE

A CONSTRUCTIVE AND PRACTICAL “ROAD MAP” TOWARDS A CIVIL DIALOGUE TO INFLUENCE PUBLIC AND PRIVATE SECTOR POLICY DECISIONS

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Harm reduction is a fundamental component of many aspects of medicine and, indeed, everyday life, yet for some reason effective harm reduction principles have not been applied to tobacco smoking. This report makes the case for radical reform of the way that nicotine products are regulated and used in society. The ideas we present are controversial, and challenge many current and entrenched views in medicine and public health. They also have the potential to save millions of lives. They deserve serious consideration.

**Harm reduction in nicotine addiction, Helping people who can’t quit,**
A report by the Tobacco Advisory Group of the Royal College of Physicians, October 2007

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

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

This paper is dedicated to the memory and work of Judy Wilkenfeld

ACKNOWLEDGMENTS

The writing of this paper is made possible through funding from the Virginia Tobacco Indemnification and Community Revitalization Commission, Richmond, Virginia.

Thanks to the six people who reviewed this paper and provided constructive ideas and suggestions.

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For more than 10 years he served as the American Heart Association’s Vice President and Legislative Counsel, as a Steering Committee Member and two-time Chairman of the Coalition on Smoking OR Health (AHA, ACS, ALA) which was the first truly active national coalition in the tobacco control movement. He has provided advice and consulting services to the American Lung Association, the Campaign for Tobacco-Free Kids, and Star Scientific, Inc. Most recently he has served and continues to serve on the Steering Committee of the Alliance for Health Economic and Agriculture Development (AHEAD), an informal organization formed to bring parties together to work for the enactment of recommendations contained in the Presidential Commission report, Tobacco at a Crossroad. He remains a strong advocate for bringing parties and experts together in neutral forums in order to discuss controversial issues, to remove barriers, to foster constructive dialogue, to look for new opportunities, and to find areas of common ground. In August 2007 he authored an extensive white paper on tobacco harm reduction issues, entitled Tobacco and Tobacco Products at a Crossroads in the 21st Century (www.tobaccoatacrossroads.com ).

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Tobacco use, and in particular the use of combustible cigarettes, continues to cause over 400,000 premature deaths in the United States each year. Globally that figure jumps to 5 million deaths annually. We are indeed in the middle of an epidemic that requires not only expanding on what already works in tobacco control but which also requires consideration of new ideas and approaches (See IOM (Institute of Medicine) 2007. *Ending the tobacco problem: A blueprint for the nation*. Washington, DC: The National Academies Press.). Greater attention needs to be given to how we can reduce the harms caused by the current products on the market and to encourage the development of noncombustible *tobacco and nicotine products* that can be used as consumer acceptable science-based alternatives to the use of highly toxic cigarettes. This paper refers to these noncombustible forms of tobacco and nicotine as “smokefree” products – products which “are tobacco based or nicotine based and which are used or taken in a noncombustible form for recreational or therapeutic uses”. We can no longer rely on the simplistic view that all tobacco products are equally harmful. There are significant differences in the risks and relative risks between many tobacco and nicotine products. Even the term smokeless tobacco has outlived its usefulness as a term for describing the many very diverse noncombustible tobacco-based products currently on the market or in the process of development.

There is an urgent need for transparent, in-depth discussion about how we can restructure the way in which we define and look at these products; how we can and should regulate them; and how we make available a wider range of products that are significantly lower in risk than the toxic cigarette. What many fail to realize is that it is not so much the ‘tobacco’ that is the major purveyor of harm but rather how the tobacco is produced, cured, processed, treated, manufactured and used (i.e. combusted or non combusted). A significant number of the smokeless products (both traditional and novel) currently on the market are as much as 90% plus lower in risk than cigarettes (some are considered potentially even lower in risk). Nicotine replacement therapies (from which the nicotine is derived from tobacco) are even lower in risk—so low as to be, according to many researchers, of only a slight risk. Some of the products, such as the nicotine replacement therapies that are the lowest in risk, are the most heavily regulated while the traditional and novel smokeless products are only moderately regulated. The highly toxic cigarette falls way short of how it should be regulated when compared to both smoke-free tobacco and nicotine products. The number and types of products that are on or expected to be on the market are diverse and there is a need to move towards a more coherent, rationale and more flexible tobacco and nicotine policy that will deal with a dynamically changing environment.

The purpose of this paper is to lay out a process by which we can not only discuss issues in a neutral, independent environment but that will allow for the development and suggestions of policy recommendations for both the public and private sectors. Failure to move forward with these important discussions is a disservice to the public health and to the millions of users of deadly cigarettes worldwide. A recent landmark report from the Royal College of Physicians put it this way:

*Harm reduction is a fundamental component of many aspects of medicine and, indeed, everyday life, yet for some reason effective harm reduction principles have not been applied to tobacco smoking. This report makes the case for radical reform of the way that nicotine products are regulated and used in society. The ideas we present are controversial, and challenge many current and entrenched views in medicine and public health. They also have the potential to save millions of lives. They deserve serious consideration.*

**Issues needing to be addressed**

Although many issues have been identified as important for the consideration in the discussion and implementation of harm reduction strategies there has been very little in the way of substantive and organized discussion on issues or the steps that need to be pursued towards implementation. A number of topics that come to mind when considering how best to consider the future role of smokefree products as part of harm reduction strategies include:
Science and Technology

What is the state of the science with respect to the risks and relative risks of the ‘category’ (smokefree tobacco and nicotine products) when compared with combustible cigarettes? What is the state of the science with respect to the risks and relative risk of the various products within the smokefree category? What kind of short term and long term research priorities should be set? How can cutting edge technologies be applied to the development of new products as well as reduce the risks of products currently on the market? Who should be doing the research and who should be funding it? How can the science and research be made more readily available?

Labeling

How should the spectrum of smokefree products be labeled so that consumers understand the risks and relative risks between not only categories of products (i.e. combustible versus smokefree) but also between specific products within the category? How can other models that are used in the food, pharmaceutical and dietary supplement industries be used in helping design labeling schemes that ensure that consumers are not misled about the risks and relative risks of products? Who (in addition to a governmental regulatory authority) should be involved in developing effective models and recommendations for how smokefree products should be labeled?

Standard Setting for Both Agriculture Production and Manufacturing

What kind of benchmarks and standards should be set for how tobacco is produced, cured, processed and marketed? What kind of benchmarks and standards should be set for how smokefree tobacco and nicotine products are manufactured? Who should be involved in discussions about how the standards in these areas might best be developed and implemented? What are the best governmental agencies suited to oversee and set regulations for the development of such standards?

Marketing and Promotion

What are the marketing and promotional restrictions (and allowances) that should be imposed on smokefree tobacco and nicotine products, especially when compared to the marketing and promotion restrictions that should be applied to cigarettes? What kinds of marketing and promotional allowances should be made for smokefree products that are considered the ‘lowest’ in risk? What is the experience for other products, such as in the food, pharmaceutical and dietary supplement industries?

Surveillance

How do we set up an effective and workable surveillance system that allows for the monitoring of how smokefree products (as well as all tobacco and nicotine products) are being marketed and used by consumers? Who should be involved in discussing how best to set up such a system and what governmental agencies would need to be involved?

Incentives

What kind of incentives can be provided to producers and manufacturers (broadly speaking) of both tobacco leaf and other tobacco and nicotine products that will encourage producers and manufacturers to move towards the development of the lower risk tobacco and smokefree tobacco and nicotine products?

Consumer Acceptability

How do we move towards encouraging (and allowing) the development of science-based smokefree products that will be consumer acceptable? Should there be standards and/or allowances for the use of flavorings for products that are low in risk (smokefree tobacco and nicotine products) as compared with products that are significantly higher in risk (i.e. cigarettes)?

The need for an integrated regulatory framework

There is now almost universal acceptance that the tobacco industry needs to be brought under a regulatory scheme such as that of the Food and Drug Administration. The question that needs to be considered is: What should that authority entail and what other agencies should be involved in other aspects of overseeing and regulating tobacco production and manufacturing? This paper suggests that all tobacco and nicotine products should be brought under the same regulatory umbrella (i.e.
establishment of a new Center for Tobacco and Nicotine at the Food and Drug Administration.) and that various categories (combustible, noncombustible, NRT) and the products within those categories be regulated based upon the risks and relative risks of those products. In addition to the FDA it is important that the USDA be actively involved in overseeing the production side. This includes monitoring where tobacco is grown, how it is produced and cured, as well as tested for quality, health and safety specifications. Other agencies that will need to be involved include the Centers for Disease Control, the Federal Trade Commission, and the National Institutes of Health. Better and more effective measures for ensuring greater coordination within the government should be complemented with better and more effective measures for actively working within the private sector.

The need for a process for openly discussing issues

There has been a tendency to over-rely on the legislative route (i.e. enactment of FDA legislation) as the primary mechanism by and through which we can effectively change the behaviors of the tobacco industry and the products they produce. There is no question that legislation to oversee the tobacco industry (through an agency like the Food and Drug Administration) is critical and long overdue. But it is equally important that there be ‘engagement’ and discussion of issues that can shape, guide and influence policy-related decisions both in the public and private sectors. While there have been limited efforts at engagement in the tobacco arena, where it has been used it has paid dividends and resulted not only in a better understanding of the complex issues and differing opinions involved but also in finding common ground that serves as a basis for substantive change. The experience and process that was used that brought the public health community and the tobacco producing communities together through the Southern Tobacco Communities Project is a case in point. The type of dialogue I am referring to is not one that is focused on “negotiations” but rather that of a facilitator-based dialogue of experts and interests that focuses on issues rather than on crafting a piece of legislation.

A proposed Road Map for dealing with ‘smokefree’ tobacco and nicotine products

We have a unique opportunity to make a paradigm shift in how we deal with the growing diversification of tobacco and nicotine products in the market place, a shift that, as noted above, could save millions of lives. The question is no longer whether we need to be pursuing new avenues but rather how we move forward. Building on the past experiences where dialogue and discussion has occurred and been productive, this paper recommends the establishment of a Center for the Evaluation of Smokefree Tobacco and Nicotine Products. This Center would be independent and would focus on the discussion of substantive issues pertaining to how tobacco and smokefree tobacco and nicotine products should be produced, cured, processed, tested, distributed, labeled, and marketed. The Center would not be a place for ‘negotiations’, although its efforts would significantly influence negotiations in other venues. The Center would have the ability to hold conferences, meetings and round table discussions using independent facilitators and experts—thereby bringing the dialogue and debate to a civilized level free from rhetoric and personal and institutional bias. Using other models and experiences both within and outside the tobacco control movement, funding would be accepted from any legitimate entity. However, any contributions from any entity would be made with no strings attached and based upon a very detailed and rigid set of criteria. Funding contributions would not entitle any contributor to a seat at the table or give such contributor any role in determining or setting the Center’s agenda.
FOREWORD

“Opportunity knocks, but doesn’t always answer to its name.”

–Mason Cooley

Many people both inside and out of the public health community have often suggested that we need to develop a more rational and coherent tobacco and nicotine policy – one that will serve public health interests for the next decade and beyond. Yet in spite of these calls, we continue to rely on traditional models of tobacco control, which have their roots in the 1980s and 90s, even though a great deal has changed during the last ten years. We also cling to the idea that all tobacco is equally harmful and that anyone associated with tobacco is part of an “evil empire.” Then, anyone who takes issue with these views is quickly marginalized under a mantra of “you’re either with us against us.” But this is changing, as more and more people take the time to “educate” themselves about a wide variety of issues related to tobacco and nicotine.

This paper is a follow-up to a white paper I wrote in August 2006, entitled Tobacco and Tobacco Products at a Crossroads in the 21st Century. The paper focused on a series of issues pertaining to tobacco harm reduction (www.tobaccoatacrocks-roads.com). The focus of this paper is on what I will refer to as “smokefree” tobacco and nicotine products – those that are not combusted and which are, may, or may not be an important component of a harm reduction strategy to significantly lessen or even one day eliminate the use of combustible products such as cigarettes. This paper does not recommend any substitutes for the continued need for other effective tobacco control efforts (many of which have been outlined in a recent Institute of Medicine report released in June 2007). However, with a general consensus that noncombustible tobacco products are significantly lower in risk than combustible products and that nicotine replacement therapies (containing nicotine derived from tobacco) are even lower in risk, it seems both logical and necessary to begin a process by which we can have an open and more thorough discussion about the future of how these products can and should be produced, processed, manufactured, tested, labeled, distributed and marketed. Such a process of discussion must involve a range of interests that are committed to the notion that tobacco and tobacco product modification (whether tobacco- or nicotine-based) can play a role in reducing the incidence of disease and death. Merely relying on or hoping that a regulatory body like the FDA can do the job without the help or involvement of the private sector is neither prudent nor wise, even though such a third-party entity is essential in establishing the rules and regulations that will govern the tobacco and nicotine industries. Nor is it prudent or wise to maintain the “status quo” approach, which calls for waging an all-out war with the enemy to the exclusion of other strategic avenues. Understandably, but also unfortunately, tobacco control has not been generally effective at practicing or employing diplomacy either internally or externally. This must change. In addition, measurable, demonstrable and transparent change is going to have to come from other stakeholders and interests, including tobacco producers, tobacco manufacturers, pharmaceutical companies, biotech companies, among others.

As an additional caveat, please note that this paper is not intended to be a scientific study or a heavily annotated document. Much of the research that supports this paper can be found in the longer, aforementioned white paper. This paper is intentionally more compositional and essay-like in structure, designed to clearly communicate a proposed Road Map for change that encourages transparency and civil discourse on issues that can help shape policy changes, foster new relationships and expedite efforts to reduce the devastating toll caused by the use of cigarettes and other high-risk tobacco products.

To colleagues in the tobacco control, public health and scientific communities, I encourage you to step back and think about how serious discussions of harm reduction can occur and the role that product differentiation and product modification can play as a component of broader tobacco control efforts. To the producers of tobacco, I encourage you to begin to lay out a detailed strategy that will move your business towards a more standardized system for the production and testing of leaf that meets specific health and safety requirements. To tobacco manufacturers (new and old) and the pharmaceutical and biotech industries, I urge you to develop science-based, lower-risk products and commit to labeling and responsibly marketing your products based on the risks and relative risks of those products and as part of a regulatory scheme under the FDA.
INTRODUCTION

Two roads diverged in a wood, and I—
I took the one less traveled by,
And that has made all the difference
—Robert Frost

In August 2006, I produced a white paper entitled, Tobacco and Tobacco Products at a Crossroads in the 21st Century (see www.tobaccoatacrossroads.com ). The paper primarily focused on the “essential elements” that needed to be considered as part of the discussion and debate on tobacco harm reduction. It included consideration of such topics as:

- What is tobacco and what makes it harmful?
- What are some of the Issues, Players, Challenges, and Opportunities?
- Issues related to Transparency, Accountability and Unintended Consequences
- The Relative Risk Reduction Continuum
- Why Government oversight is essential and inevitable

and

- Where do we go from here?: A Process for Future Engagement

For both those familiar and unfamiliar with the issues of tobacco harm reduction (as well as the broader topic of harm reduction), I would encourage you to take some time to review that white paper, as much of what will be proposed in this paper is built upon its elements and recommendations.

In addition there are two other valuable resources for understanding harm reduction issues. One is the “Top 50 Harm Reduction Papers” that can be accessed at www.ihra.net. The other is the landmark report of the Royal College of Physicians released in early October 2007, entitled, Harm reduction in nicotine addiction – Helping People who can’t quit. It can be accessed at http://www.rclondon.ac.uk/pubs/contents/e226ee0c-cccf-4db4-861046371dfb.pdf.

The purpose of this white paper is to focus more specifically on the elements addressed in the August paper from the standpoint of what I wish to collectively refer to as “smoke-free” products, which includes tobacco-based products as well as nicotine-containing products from which the nicotine has been derived from the tobacco. This paper is designed to provide a suggested Road Map – and more importantly a process – for dealing with a variety of issues in both the short and long term in an open, civil, transparent and productive way. This noncombustible “smokefree” category is where there may be some significant opportunities for developing an appropriate and effective model that could serve the interests of public health, producers, tobacco manufacturers, pharmaceutical and biotech interests, as well as meeting consumer needs and expectations.

With the reintroduction of legislation (S. 625, H.R. 1108) in the 110th Congress that would give the Food and Drug Administration (FDA) authority to oversee the manufacture, sale, distribution, labeling and marketing of tobacco products, many in the public health community have come to view this legislation as the avenue to at long last force change on the tobacco industry. Having been actively involved with this legislation for the last 15 years, I for one have been and continue to be a strong advocate for giving the FDA such authority. An independent, third-party governmental entity is essential to ensure that the rules and regulations of how these products are manufactured sold and marketed are fair and consistent and carry the force of law. We need a level playing field by which all products are regulated based on their risks, relative risks and intended use. We also require a system by which we can ensure that children and adolescents do not use or have access to tobacco or nicotine products.

The current legislation, pending in Congress as this paper is being written, has many of the essential and critical elements needed. But the legislation has not been seriously reviewed or considered in light of a rapidly changing tobacco (and nicotine) environment – one in which there are many new opportunities that can be taken to assist in achieving a goal of reducing disease and death caused by the use of tobacco products, particularly in highly-toxic combustible products (i.e., cigarettes). In fact, the legislation remains virtually identical to legislation introduced in two previous Congresses and in some ways remains very much like the McCain legislation of almost ten years ago. The failure to hold open and comprehensive hearings on the legislation represents a serious failing on the part of Congress. I will address some of these opportunities,
issues, and concerns, particularly as they relate to noncom-
bustible smokefree products further into this paper. I will also
present ideas, such as incentives, for what Congress should
be considering as it crafts legislation that will need to serve
both short- and long-term goals.

It is important to stress, however, that what is being sug-
gested in this paper is not primarily a legislative solution, but
rather a way to engage parties in a constructive dialogue that
will allow for creative solutions both in the public and private
sectors. Constructive legislation (partially through constructive
dialogue) may follow; but having worked in the public policy
arena on the FDA tobacco front for 15 years, I still am amazed
with the lack of engagement and civil discourse on and off
Capitol Hill. Yet, where there has been engagement (mostly
outside of the Washington Beltway) and a willingness to be
transparent and to talk, there have been positive outcomes.
These beneficial results are evidenced by cooperation between
the public health community and tobacco producers, and, to a
more limited extent, with some manufacturers.

The decades of entrenchment by various stakeholders must
come to an end if we are to break away from a war of words
and look for effective solutions. There are clearly those in the
various camps whose solitary goal is the preservation of the
status quo. Many will choose to remain on that path. But many
others believe that there are other paths that must be pursued
simultaneously.

The discussion of smokeless tobacco has polarized the
tobacco control community to the point where science and
civility have been replaced with the innuendo of “unintended
consequences” and often dogmatic rhetoric. Sound bites, not
science or rationale thinking, are preventing us from having
important discussions about whether, or most importantly
how, we can move forward to resolve and deal with legitimate
issues and concerns. The issue is further complicated by the
roles of the pharmaceutical industry, new technology-based
companies, and even changes by some tobacco manufacturers
themselves.

In re-reading one of the primary resource materials that I have
relied on for a number years, I was struck by how civil discus-
sion and dialogue can take place, even when you have some
of your worst adversaries present. I think it is important to take
a moment to consider just how far afield we have gone due
to our inability to move beyond the notion that the only thing
we are doing is fighting a “war” with Big Tobacco. We need
to separate this out from discussions about science, product
regulation and product development.

In the late 1990s the Georgetown University Center for Drug
Development Science and the Food Drug and Law Institute
sponsored a conference on Tobacco Dependence: Innovative
Regulatory Approaches to Reduce Death and Disease (Food
Drug and Law Journal, Volume 543 Supplement (1998)). We
are fortunate that the discussions that took place as part of
that conference were transcribed and published, because they
reflect the type of dialogue and discussion that needs to take
place regardless of the views and organizations represented.
Present at the conference were well known tobacco control
experts and scientists, former FDA officials, pharmaceuti-
cal representatives and even tobacco industry scientists and
representatives. Some of the individuals are still a part of
these discussions today; some probably need to be brought
back into the fold. Unfortunately for all concerned, however,
there is an unfilled void left by the passing of Dr. John Slade,
who more than anyone else brought civility and integrity to the
discussions and who had a clear vision of what needed to be
accomplished.

A few excerpts from the Georgetown proceedings are worth
taking a fresh look at because, not only are we today dealing
with many of the very same complex issues that were raised
in 1998, but we are also provided with an example of a far bet-
ter and civil approach as to how to discuss those issues:

Ken Warner: I have to say I think these are three of the
very best conference papers that I have ever read. I was
deeply impressed with all three of them. They’re com-
prehensive. They are very analytical, very thoughtful and
certainly very provocative in many instances. I don’t agree
with everything I read. I hope and expect that nobody in
here agrees with everything they read, probably including
the authors who wrote it. But they just laid it out beauti-
fully for us, and I think that the discussion this morning
showed us what an incredibly complicated issue we are
dealing with. (p. 129)
Dietrich Hoffman: We have good background knowledge to develop standards for toxin levels in tobacco smoke and I think we should start doing that. The tobacco industry has better knowledge than we do in academia. For example, a number of years ago there was much aversion against the use of the pesticides DDD and DDT. Today you will hardly find DDD and DDT or any organochlorine compounds in American cigarettes, and if you do find them, they stem from imported tobacco. There is a similar situation with snuff. Everybody agrees that the nicotine-derived nitrosamines are the major cancer-causing agents in snuff. The Swedes have managed to develop a method of snuff preparation that significantly lowers the levels of nitrosamine formulation derived from nicotine and nornicotine during curing. Here, nothing is done about product modification. This is a great disappointment. (p.123)

Curtis Wright: We will all be dead from old age before tobacco products cease to be a problem for this culture. No one has discussed the fact that you could try and regulate this product out of existence and you would fail. We have very strong laws against other controlled substances on the books and we enforce them vigorously, with harsh and punitive sentences, and we have failed to substantially reduce their availability. We have kept it under control but we have not eliminated the problem. In that context, failing to provide incentives for a less-toxic product doesn’t make much sense. (p.125)

Neal Benowitz: The challenges involving regulation highlight the importance of the issue and the resources needed by FDA to implement a regulation. Because of the issues of the pharmacology of nicotine, the addiction, and the safety issues, there are very few agencies or bodies that could intelligently regulate tobacco. It requires the sophisticated knowledge of drug action and its various manifestations, which FDA has, to do this properly. So I think there’s really not much choice, other than to have an agency like FDA, or something parallel to FDA do this. One thing that will be required, that’s much different, is the capacity to do a lot of research which cannot be done by NIH alone. It’s not something which the industry can be relied on to do properly. I think that if FDA gets involved in regulating tobacco there’s a need for enough resources to be able to evaluate the products, to evaluate their safety, and to really develop a very substantial research program. And I think that any legislation that occurs involving FDA must include adequate resources for doing all this because there’s no other body which can really do it. (p.121)

Dorothy Hatsukami: I think we need incentives for tobacco companies to make safer products. But we also need incentives for pharmaceutical companies to develop new indications for nicotine replacements or to come up with indications for different populations of tobacco users. We have to be expeditious in this. (p.125)

Jed Rose: I worry about moving too slowly. There would be some very big immediate advantages to having these other alternatives out there. For one thing, as new products with reduced toxicity (according to whatever surrogates seem reasonable) do reach the market, that would speed up the process by which existing products could be viewed as defective and incur additional liability. The longer it takes to get the safer products out there the longer we have to live with the current products. (p.122)

Carl Peck: I am of the persuasion that clever and visionary regulation can actually be a major incentive to the flow of useful products into the market that are safe and effective and benefit public health. There are actually numerous examples during the last couple of decades… What I heard this morning is the need for safer tobacco products, more and better medications to treat nicotine and tobacco abuse, and more research. And so I’d like
to stimulate discussion of how the government (through incentive programs, either money for research funneled in the right directions or regulation, perhaps through the Food and Drug Administration) might stimulate the kinds of medications to treat nicotine and tobacco abuse that we want or produce nicotine products that are safer and more fully disclosed and labeled. (p. 131)

**Ken Warner:** I think it was that our representative from RJ Reynolds who was reminding us of this at the end of the morning discussion. He's absolutely correct. We must have consumer-acceptable alternatives to existing cigarettes if we are going to continue this discussion at all. Consumer acceptability does not mean that we're talking about a product that is as satisfying as cigarettes. We are extraordinarily unlikely to ever come up with a product that is that successful at delivering nicotine and satisfying consumers, however you want to define satisfying. What it means is that we're going to come up with products that will be acceptable substitutes that people will find adequate when they balance the fact that they are reducing their risks significantly. So they are willing to give up a little bit of satisfaction in exchange for a great risk reduction. (p. 129)

**Jack Henningfield:** With respect to abuse liability of new products, it is worth noting that the actual use of nicotine medications in people who have never been nicotine-addicted is very low, but that is not just due to the products. It's also due to how they are packaged, marketed, labeled and so forth. (p. 132)

**David Burns:** The advantage that we have with FDA regulation currently (for pharmaceutical), if it is applied to these products, is that the approval can be removed. So if either the marketing practice or the formulation of the products turns out to not fulfill its promise, then it can be removed from the market. The critical piece I think, that several people pointed out, is that for incentives to work, they have to be very clear. I think we have been very unclear about the incentives, particularly as we get into this harm-reduction strategy. (p. 132)

**John Pinney:** I think rather than incentives, we need a reasonable regulatory framework. And it seems to me that I heard some ideas about what that might look like. And then we need to forge ahead with that because I think the product is going to be there, whether we like it or not. I think it's inevitable. I don't think Congress is going to block the appearance of these products. So faced with the inevitable, what do you do? Well, you adopt some reasonable standards. And you do the other thing that I keep hearing, and that is you put surveillance in place. (p. 136)

Dr. Slade closed the conference. Here are a few of his closing thoughts:

**John Slade:** This has been an extraordinary day. It has explored dimensions of this problem that I expected and dimensions that I hadn't expected, and it has put things in a framework that I found really helpful.... I very much appreciated the concept of "co-regulation." I think that's a useful framing of the kind of problem we have with the two divergent intellectual streams from tobacco companies and pharmaceutical companies. It keeps both of them in the same range of vision without requiring that they be in lock-step with each other, because I think lock-step is not going to come in the foreseeable future for all the reasons we know. The issues of incentives that were talked about and the interagency cooperation that we didn't get quite to speak about are other key themes. (p. 137)

With all of these thoughts noted, this paper will seek to present a process for rationally allowing ongoing discussions and engagement of important issues related to noncombustible smokefree products. Rather than dwelling on the same issues of "unintended consequences" and trying to justify why we should not move forward, this paper will take the position that we should be focusing more on the issues of what needs to be addressed and, most importantly, how we address and implement them.
Shifting the Paradigm

I find myself continuously asking the question: Are we at war with an industry for the sake of having a war, or are we looking for solutions designed to reduce the disease and death caused by the use of tobacco products that cause significant harm? Dogmatic, one-size-fits-all approaches for dealing with the dangers of tobacco and the tobacco environment can no longer be the only tactics that are used.

While we cannot afford to be complacent with the tobacco industry, we should also not be afraid to engage them and to challenge them for meaningful and transparent change. I do not think that Dr. John Slade was ever complacent with the tobacco industry as he pursued avenues of engagement and dialogue; nor were the many public health people who were a part of the Southern Tobacco Communities Project which brought growers and public health interests into a dialogue with each other. Today, even more than ever, there is a need for transparent and open dialogue. Issues are no longer black and white. For example, who and what is the “tobacco industry”? Does the tobacco industry consist of anyone and/or any entity that deals with or produces a product containing tobacco or a derivative of tobacco? In addition, who is the public health community? It seems to be a community that is more divided today than ever before.

Some of the signs of this shifting paradigm include:

- The need exists to redefine what we mean by “tobacco industry.” Increasingly, we use this term to talk about not just the tobacco industry but the pharmaceutical nicotine industry as well – thus, we are increasingly referring to the tobacco and nicotine issue. This “reshaping” has actually been going on for several years and can be expected to accelerate.

- Tobacco companies themselves are becoming more pharmaceutical- and food-like in their business practices (accepting greater regulatory controls), and the pharmaceutical companies are looking to market their NRT products more as consumer products than pharmaceutical products. There is a competitive convergence taking place, especially in the smokefree area. Tobacco companies are increasingly recruiting scientists, researchers and executives who have pharmaceutical and biotech backgrounds and who have never been associated with or a part of Big Tobacco’s past.

- There is recognition by many in the public health community and amongst policy makers that all tobacco products can no longer be considered equally harmful and that, in fact, there are significant differences between the relative risk of combustible products (such as cigarettes) and noncombustible products (such as smokeless tobacco products and nicotine replacement therapies).

- Health groups, scientists and researchers increasingly have differing views of approaches and tactics that should be applied to the tobacco problem and in particular to tobacco and nicotine product regulation.

- There is a greater recognition that the “players” can no longer be defined in simple black and white terms. This includes not just tobacco manufacturers but the public health community.

- The tobacco producing environment is changing for a variety of reasons and growers will have to consider changing production methods to meet the challenges and opportunities of the future, within both the U.S. and abroad.
Comments on the Recent IOM Report: “Ending the Tobacco Problem”

The most recent Institute of Medicine (IOM) report, *Ending the Tobacco Problem (June 2007)*, which will be used by many in tobacco control for many years, is a bold initiative to:

“…substantially reduce, if not eliminate, the use of this unusual damaging product without replicating the problems associated with the prohibition of alcohol in the 1920’s and with the contemporary prohibitions of illegal drugs (e.g., widespread noncompliance, violent black markets, corruption and high rates of arrest).” (Page 6-1, Changing the Regulatory Landscape).

It would, perhaps, be better to slightly rephrase its objective as:

*Substantially reducing if not eliminating the unusual damaging effects associated with the product and its use.*

We need to move away from drawing the unsubstantiated conclusion that all tobacco and all tobacco products are equally dangerous and damaging. Is it also the view of the IOM report that all nicotine replacement therapies also should be included as part of this *elimination*, because the addictive drug nicotine used in nicotine replacement therapies is derived from tobacco? It is what’s in the tobacco, and how it is used that represents the level of risk and damaging affects.

When it comes to discussing the issue of “harm reduction,” the IOM report seems to want to avoid discussion of the issue, and is seemingly “confused” about what harm reduction is. As I read the section on *Changing the Regulatory Environment*, I was struck by the fact that the report indicates that, “Although harm reduction might be a useful adjunct to comprehensive tobacco control strategy, it is not at the center of the committee’s charge, which is to propose a blueprint for reducing tobacco use in the United States” (p. 6-13). I take issue with that conclusion and would suggest that a significant portion of the chapter on changing the regulatory landscape is all about harm reduction. A few excerpts from the chapter will underscore my point.

In the third paragraph of the first page of Chapter 6 (page 1), the Report asks:

“Can anything be done to substantially curtail the availability of tobacco? Can anything be done to change the tobacco products to make them less hazardous? Is it possible to bring the industry’s incentives into closer alignment with the public health goals of tobacco control? No existing regulatory statute provides a model for tobacco products because there is no other lawful product for which the declared public goal is to suppress it altogether. A new legal regime, models and new policy paradigms are needed.” (Emphasis added.)

**Comment:** I would suggest that the IOM is correct in that we need new models, but not just with respect to regulatory statutes. We need them with respect to how we adapt to and take advantage of a changing environment that has as its foundation a “health” component and objective.

The report goes on to state (Chapter 6, page 9):

“The regulation of tobacco product characteristics can be seen as having two primary goals. One is to reduce the harm from the continued use of tobacco products. This might be achieved by reducing the toxic emissions from cigarettes or the toxic constituents of smokeless tobacco. Reducing toxic exposures would potentially lower the risk and severity of disease in people who continue to smoke. It is essential however, that the federal government assures that consumers are informed about what is and what is not known about the risks of using products that result in toxic exposures (reduced exposure products). Moreover regulators must take steps to reduce the likelihood that the availability of reduced-exposure products will increase initiation or reduce the number of users who quit. The danger that the marketing of reduced exposure products could lead to an increase in smoking prevalence by altering risk perceptions about smoking is one of the greatest challenges that FDA will need to address.” (Emphasis added.)
Comment: The issues raised in this paragraph are ones that reinforce why we need to expand the dialogue and not merely rely on governmental agencies to resolve the issues. Dealing with some of these problems will require the involvement of a wide range of interests and experts, because there may be solutions lying just below the surface in dealing with many of these issues. And there are other issues to consider, such as determining the unintended consequences of not finding ways to develop and responsibly market products that will assist users of highly toxic cigarettes into using cleaner nicotine delivery products.

The report continues (pages 6-9):

“The second goal of regulating tobacco product characteristics is to reduce consumption. The most promising way of reducing consumption through product regulation would be to make cigarettes less addictive, thereby making quitting easier and preventing initiating smokers from becoming addictive. Another promising strategy is the development of new medications for the treatment of nicotine addiction. To the extent that harm reduction policies are pursued, it would be desirable to bring modified tobacco products and medications for smoking cessation within a common regulatory framework.” (Emphasis added.)

Comment: This is clearly a “harm reduction” strategy. One has to ask, however, additional questions about this approach, just as one should question and consider other harm reduction strategies. First, we need to ask: consumption of what? IOM says cigarettes. But are they also talking about smokeless tobacco products? Are they or should they be talking about all products that are tobacco-based or derived from tobacco? If we wish to discuss tobacco, then we need to also be talking about NRT products from which the nicotine is derived from tobacco. If we are talking about reducing and eliminating the use of nicotine (Chapter 6, pages 9-10) how does such a strategy fit into the recommendations of the report that promote the use of medicinal nicotine products? Does not the use of medicinal nicotine perpetuate the addiction in conflict with the stated goals to reduce addiction through elimination of nicotine? In addition, one has to ask what the effects of such a strategy might be on the very issues raised in the beginning of the chapter related to black markets, crime, etc.

My point in raising these questions (and there are many others I have not yet mentioned) is that we do need some new thinking, players to discuss the issues, strategies, and directions that need to be taken. We do need new “policy paradigms,” and we need to establish better processes by which to proceed. This paper is about finding that process so that we can have a more engaging, enlightening and civil discussion about the potential role that smokefree products can play as part of a public health strategy.
CHAPTER 1

WHAT ARE “SMOKEFREE” PRODUCTS?

Greater availability of medicinal nicotine, and perhaps even low-toxicity of smokeless products, along with increasing restrictions on smoked tobacco, is likely to reduce tobacco-related mortality and morbidity. Given the known hazards of smoked tobacco, and the numbers of people who smoke, innovative thinking is needed. We support harm reduction alongside rigorously applied tobacco control policies.

Adding harm reduction to tobacco control, Editorial, The Lancet, (Vol. 370, October 6, 2007)

The market for both existing and new, novel “smokefree” products is expected to continue to expand – not only for traditional users of smokeless tobacco products but also for users of highly toxic cigarettes looking to find alternatives, including effective ways of quitting. These products may be tobacco-based or they may be products from which the nicotine is derived from tobacco. For many it may be difficult to accept or to even acknowledge that smokeless tobacco products (including the new technologically advanced products) have more in common with nicotine replacement therapies than they do with highly toxic cigarettes. It is important as we look to the future that we begin to make distinctions between the types of smokefree products on the market, as well as their intended purpose and use. It is no longer acceptable from a public health standpoint to group all tobacco products together; nor is it justified to consider all smokeless (smokefree) products as being equally harmful or intended for the same purpose. For example, if a smokeless tobacco product is used as an alternative to highly toxic cigarettes, it does not mean the product is or would be marketed as a “cessation” product, as we currently define such products (i.e., nicotine replacement therapies).

Down the road, we may wish to consider and discuss the type of criteria that should be used to evaluate these products and how the spectrum of “smokefree” products should be defined. There are more traditional smokeless products. There are smokeless tobacco products with significantly lower levels of toxins (e.g., TSNA’s) than other smokeless products – and which may be more consumer acceptable to current cigarette smokers. There are products that look like tobacco products but are actually tea-based, yet contain tobacco-derived nicotine. There are a number of NRT products in the form of patches, gums, inhalers and lozenges – some of which are more effective than others. And there are other nicotine products such as gels, sprays, inhalers and water, many of which we know very little about. Each one of these products is in need of a rational evaluation.

As Professor Lynn Kozlowski has stated in several of his papers and presentations, we may want to consider starting from the premise of “telling the truth” about what these products are and what their risks are. If we can develop a rational, scientific and transparent approach to discussing what these products are, what we should know about these products and how they might be part of a harm reduction strategy, we could develop labeling, marketing, information and educational initiatives based on the risks and relative risks of the products and their intended uses. Such discussions would be invaluable to an agency like the Food and Drug Administration in developing regulations.

For purposes of this paper, a smokefree product is defined as:

A product that is a tobacco-based or nicotine-based (from which the nicotine has been derived from tobacco) that is used or taken in a noncombustible form for recreational or therapeutic uses.

This paper divides the smokefree products into three basic categories, recognizing that these categories are themselves potentially overlapping.

Below are a number of the products that are traditional, new and novel.

1. Traditional Smokeless Tobacco Products: Often referred to as spit tobacco, chew or snuff, these products are traditionally made of dark fire tobacco from the Tennessee and Kentucky regions and include such products as:
USSTC:

- Skoal, Skoal Longcut, Skoal Bandits
- Red Seal
- Copenhagen, Copenhagen Long Cut, Copenhagen Black
- Husky
- Rooster
- Bruton

Conwood (Reynolds American):

- Moist: Kodiak, Grizzly, Cougar
- Plug: Taylors Pride, Canon Ball, Black Maria, etc.
- Snuff: Dental Mild, Honest Scotch, Peach Sweet Snuff, Tude rose Scotch Snuff, etc.
- Twist: Kentucky King, Cotton Ball, Cumberland, RT Junior, Moores Red Leaf, etc.

From what I have been able to determine, the majority of the tobacco used in these more traditional products is produced in the United States. Some manufacturers use only U.S. tobacco.

Note: There are also many other foreign manufactured smokeless tobacco products, such as Gutka, Tombak, and Zarda, which are known to have significantly higher levels of TSNA's and other toxins. These products may or may not one day see increased uses among specific ethnic populations in the U.S. and should be monitored and tracked for purposes of developing better information about where they fit in with respect to the smokefree products in the U.S and around the world.

2. Newer/Novel Smokefree Tobacco and Nicotine Products: Many of these products use either a tobacco base or are composed of substances infused with tobacco-derived nicotine. They are being sold primarily as alternatives to cigarettes (which are highly toxic in comparison). These products generally do not contain dark fired varieties but are made with flue-cured tobacco and burley tobacco. Included in these are products are a number of low TSNA tobacco products.

Tobacco Based:

- Ariva and Stonewall: According to Star Scientific, these products are made with all American flue cured tobacco. The tobacco is cured using a method designed to significantly reduce the levels of TSNA's, which are considered the most significant cancer causing agent in noncombustible tobacco products. Ariva is a product intended as an alternative for cigarette smokers; while Stonewall is positioned for the more traditional smokeless tobacco user. Flavorings used in these products are FDA/GRAS approved.

- Swedish Snus (Catch, Etan, General, Grovsnus, Kronan): According to Swedish Match, “Swedish Snus is a semi-moist, ground, oral tobacco product which is placed in the upper lip.” Swedish Snus is made from flue-cured tobacco, water salt and flour additives. It is pasteurized in a proprietary heat treatment process that satisfies Swedish (and other countries’) food requirements.

- Camel Snus: According to Reynolds American, the tobaccos used in this product are air-cured varieties from North and South America, Asia and Africa. Camel Snus is manufactured outside of the U.S. and imported. Camel Snus, like Swedish snus, is a pasteurized product that is formulated and intended to be spitless. According to Reynolds, all flavorings used are FEMA or FDA/GRAS approved for use in foods, and the product formation and production method are consistent with the GothiaTek standard used by Swedish Match.

- Taboka, Marlboro Snus: According to Philip Morris USA, “As part of our adjacency growth strategy, PM USA is test marketing a smoke-free and spit free tobacco pouch called Taboka...designed especially for adult smokers interested in smokeless tobacco alternatives to smoking” (June 2007). PM USA states that the product is made with flue-cured tobacco grown in the U.S. The Taboka product, however, seems to be short-lived as PM has now announced the development and test marketing of Marlboro Snus, using a well recognized cigarette brand name, similar to what Reynolds American has done with Camel.

- Revel: According to U.S. Smokeless Tobacco Co., Revel is a spitless tobacco product wrapped in a discreet white packet and developed for adults “looking for great tobacco satisfaction without lighting up”. The product is made with all U.S. tobacco and is flavored with FDA/GRAS flavors approved for use in foods.
- Nicofix: According to its manufacturer, NicoFix “is a substitute for smoking. It contains less than 1/10 the tobacco found in a cigarette and approximately 1 billion less carcinogenic chemicals found in cigarette smoke.” Instructions for use say “rub just one pump or two on the palms of your hand. The near clear gel will be absorbed in under a minute.”

- Firebreak: This product is a tobacco-based “smokefree” tobacco chewing gum made by Swedish Match (outside the U.S.). According to SM it is comprised of finely ground tobacco flour that is embedded in a chewing gum base.

- Blue Whale: According to Blue Whale, Blue Whale Smokeless is an alternative to more traditional smokeless tobacco products but with less tobacco and less nicotine. Blue Whale accomplishes this by “extracting just enough of all of the constituents, which includes nicotine and tobacco and mixes it with specially selected black tea leaves.” According to the company, the tobacco used in the product comes primarily from African sources. It is sold in a variety of flavors, which according to the company, are FDA/GRAS approved for use in foods.

- Zuka Black: According to press reports, Zuka Black is “a tobacco powder inhaled through the nose that gives the user a hit of nicotine. Zuka comes in a fag-packet-size box. Inside are a cotton handkerchief and a bullet-shaped dispenser, which can be loaded and sniffed from. It contains 60 hits of tobacco, the equivalent of 20 cigarettes.

For more information on the diverse range of smokeless tobacco products produced not only in the U.S. but globally as well see:

**Nicotine Based (derived from tobacco):** A few of the novel nicotine smokefree products include:

- Nicogel: This product is a tobacco based “gel” that supposedly allows the user to adsorb nicotine through the skin.

- Nicowafer

- Nicotine water (currently off the market)

I suspect that we will continue to see these types of non-tobacco-based nicotine products coming into the market both in the U.S. and globally. It is going to be important for nontraditional tobacco/nicotine companies to provide more information about their business goals and objectives, as well as scientific data and information about the products they are developing and marketing. They will also need to accept that their products will have to be reviewed and regulated.

3. **Nicotine Replacement Therapies (NRT):** These are products that contain nicotine derived from tobacco and used in products that have been reviewed by the Food and Drug Administration under the drug provisions of that Food Drug and Cosmetic Act. Many of these products come in a variety of flavors and are increasing being advertised and marketed more like consumer products rather than traditional pharmaceutical products.

- Commit
- Nicotine Gum (Nicorette)
- Nicotine Patch (Nicoderm CQ, Nicotrol, Habitrol)
- Nicotine Nasal Spray (Nicotrol NS)
- Nicotine Inhaler (Nicotrol Inhaler)
- Zyban
- Chantrix
- Perrigo (“store brand” fruit coated nicotine polacrilex gum)

4. **Other Smokeless Tobacco Products:** As noted above, there are other smokeless tobacco products that are produced overseas but may find their way on to the U.S. markets, targeting ethnic populations. Many of these products are extremely high in TSNAs and include such products as:

- Gutka
- Zarda
- Tombak
The Current and Long Term Markets for Smokefree Tobacco and Nicotine Products

For many years, the smokeless tobacco market has been distinct from the cigarette market, accounting for less than 5% of all tobacco products sold. For a variety of reasons, this market has the potential for significant changes. These reasons include:

- Enactment of clean indoor air laws across the U.S. (and globally)
- Scientific acknowledgement that smokeless tobacco products are significantly lower in risk than combustible tobacco products
- Changing technologies that will allow smokefree tobacco products to be made with significantly reduced levels of toxins, pesticides, etc. (see section on Smokefree Products); many of these technologies are and will occur at the plant level
- Increased research and development activities by a number of stakeholders, including cigarette companies (i.e., PM USA’s $350 million research facility that opened in August 2007)
- Several major cigarette companies (Altria/PM USA, Reynolds American) have recently entered into the smokeless tobacco category
- General acceptance that the cigarette market will be declining
- Greater competition among tobacco companies and pharmaceutical companies to develop products that can be used as science-based lower risk products (e.g., tobacco companies are hiring more researchers with pharmaceutical backgrounds)
- Future markets will not only include those using the traditional dark fired forms of smokeless tobacco but also those wanting lower TSNA products, as well as acceptable alternatives to combustible cigarettes; this latter category may be very large given the number of cigarette smokers in this country (and globally) who may be looking for alternative tobacco products as well as smoking cessation products
- Competition coupled with a variety of economic and legal “incentives” could also hasten the changes in the market place

- Several companies are producing nicotine-based products intended as alternatives to tobacco products; these products might be described as pseudo-tobacco products, as well as pseudo-pharmaceutical products.

A broad range of stakeholders indicate that they expect to see this market grow in the coming years. How fast and under what kinds of regulatory conditions remains to be determined. However, the final chapters of this paper will explore some of the avenues by which there might be opportunities for the public and scientific community, growers, manufacturers and consumers alike to influence and shape that future environment.

The Impact of Large Cigarette Manufacturers Entering the Smokeless/Smokefree Market

As the larger tobacco companies, including BAT, Philip Morris International and USA, and Reynolds American, enter the smokeless tobacco category, one must inquire about their motivations. We cannot forget that all of these companies have shareholders to whom they are obligated. I believe that all of these companies are pursuing parallel marketing efforts – designed to maintain their profits in the cigarette business while simultaneously looking at the prospects for significant declines in the cigarette market in the years ahead (this could be 5, 10 or 15 years down the road). PM has called these “adjacency strategies.” While it might be interesting to see one of these companies announce that they plan to be out of the cigarette business and plan to focus their attention on researching, developing, and eventually marketing significantly lower risk consumer-acceptable smokefree products, I am not sure that at the moment any of them see that as a short-term strategy or option. PM USA’s recent introduction of Marlboro Snus seems more of a “bet-hedging” strategy designed to make sure that if there are rapid changes in the market place that impact on the cigarette business, then a PM product will be there to fill the void and be competitive with companies like Reynolds, BAT, USST, and others. These companies are also becoming increasing aware that they must begin applying food and pharmaceutical models to their products to prepare for possible regulation by the FDA and to compete with the pharmaceutical companies and other smokefree tobacco manufacturers.
It is possible, however, that through regulation (legislation that
gives true incentives to the development and marketing of
science-based smokefree tobacco and nicotine products) and
competition, we might see changes beginning to take place
sooner rather than later. The current legislation in Congress
unfortunately seems to protect the cigarette market providing
no incentives for the development of the
smokefree marketplace.

The Role of the Pharmaceutical
Industry in the Smokefree
Marketplace

The Pharmaceutical industry has been involved in the
development, production and marketing of smokefree nicotine
products for many years, keeping close ties and working
with the public health community. They have, as we noted,
developed a range of nicotine-based products in the form of
patches, gums, lozenges, and nasal sprays. It has been clear
to me and several others that as with any corporation they
have sought to maintain and protect their competitive edge
and market share both among themselves and from potential
new competitive entrants. The pharmaceutical companies
have been major sponsors at tobacco control meetings,
have helped influence and shape the positions of the public
health community on tobacco harm reduction and have
made significant contributions to many non-governmental
organizations (NGOs). They have clearly seen that the
smokefree tobacco interests are indeed their competition and
that that competition will only increase as there is more and
more attention focused on significantly reducing the
use of cigarettes.

Types of Tobacco Used in
Smokefree Tobacco and Nicotine
Products

The primary “type” of tobacco used in traditional smokeless
tobacco is a dark fired tobacco grown primarily in Tennessee
and Kentucky. This tobacco is cured using fire that gives the
tobacco a certain taste but also increases the levels of tobacco
specific nitrosamines in the tobacco. While these products are
lower in risk than cigarettes and other combustible products, it
may be possible to develop and produce products that provide
the traditional taste and texture of these products while
significantly reducing some of the toxins (such as the TSNAs)
in the tobacco by using different types of tobacco and curing
methods. FDA approved flavorings (as they are done in foods)
could be used to maintain consumer acceptability.

In addition, new types of smokefree products are being
developed to appeal to current cigarette users who
undoubtedly have a very different taste preference than
the traditional smokeless user. These products are and will
undoubtedly continue to be made from a variety of other
tobaccos, including, flue-cured, burley tobacco and air-cured
varieties. My research indicated that most of the snus-type
products, as well as products like Ariva and Stonewall, are all
made with flue cured tobacco. But in some cases, the tobacco
used is not only U.S. tobacco but comes from a variety of
sources overseas. For example, Blue Whale products, which
contain derivatives of tobacco and are tea-based, currently use
tobacco produced in Africa.

I was unable to ascertain what types of tobacco are used for
the extraction of nicotine that is used in nicotine replacement
therapies. I did obtain several independent comments from
people who indicated that they believe much of the tobacco
used comes from India.

Unfortunately, unless we are able to legislatively require full
disclosure of what tobacco is used, where it comes from and
whether it is being tested, we will continue to be operating
in the dark. We cannot conduct effective oversight of the
smokefree marketplace unless and until we are able to obtain
the necessary data – which can only be obtained through
governmental oversight and/or with the cooperation and full
support from both tobacco and nicotine manufacturers.
Conclusion

While we know that smokefree tobacco and nicotine products are considerably lower in risk than combustible products, such as cigarettes, and that there is strong scientific and substantiated evidence about the very low relative risk of pharmaceutical nicotine products, we need to gather a great deal more information about the spectrum of smokefree tobacco and nicotine products. We need to begin discussions about how to define these products from the standpoint of whether their intended use is as an alternative tobacco product for tobacco users (cigarettes or traditional smokeless) or whether they are more therapeutic in nature and are used as tobacco (but not nicotine) cessation products. We also need to begin thinking about what kind of regulations and private sector initiatives related to the testing, labeling, marketing and educational initiatives will be needed to ensure that users of these products fully understand the risks, relative risks and intended uses of such products. All manufacturers of these products must be transparent and willing to engage in discussions about what their products are and their intended uses. Scientists and other experts need to be engaged, and we need to step back from advocacy and aggressive public relations campaigns that may not always be in the best interests of public health.
CHAPTER 2

WHY SMOKEFREE (NONCOMBUSTIBLE TOBACCO AND NICOTINE) PRODUCTS?

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

N. Gray, JE Henningfield, NL Benowitz, GN Connelly, C Dresler, K Fagersstrom, MJ Jarvis, P Boyle

Each year, more than 400,000 Americans die from cigarette smoking, making smoking the single most preventable cause of disease and death in the United States. On a global level, the devastating effects are even more frightening. The “Tobacco Atlas”, Second Edition, released in July 2006, noted:

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

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


Many believe that all tobacco carries equal risks, which is not a scientifically valid statement. Risk is dependent upon what is done with the tobacco – how it is grown, cured, processed, manufactured and used. There is great deal of discussion and debate (much of it public-relations oriented) about the risks and relative risks of combustible and noncombustible tobacco products and, in particular, the role that noncombustible tobacco products might play in harm reduction strategies. If in fact these products, which we are calling smokefree tobacco (and nicotine products), are significantly lower in risk, then the next question is what should harm reduction strategies using such products entail and more importantly how should they be implemented?

As noted in Chapter 1, I use the word “smokefree” tobacco and nicotine products because the marketplace that was once traditionally called smokeless tobacco (SLT) is changing and will continue to change. Traditionally, the cigarette market and the smokeless market were very distinct. But given the influx of clean indoor air laws, coupled with changing technologies the development of new products that appeal beyond the traditional smokeless tobacco user, the potential demand for smokefree products could see a surge in the coming years.

How those products are developed, what incentives are provided and what controls are to be placed on these products has yet to be determined and will depend a great deal on how we decide to approach the issue.

It is very unlikely, due to the complexity of the cigarette, that we will see any combustible products in the near future that are scientifically proven to be lower in risk than current products – although technologies do exist to move these products in the right direction. When a cigarette burns, there are more than 4,000 chemical constituents produced in the smoke that are inhaled into the lungs. As many as 60 such constituents are known carcinogens and many others (such as carbon monoxide) contribute significantly to other diseases, including cardiovascular disease, stroke and pulmonary diseases.

In addition to the tobacco (for which there are different types and which contain varying degrees of toxins), there are pesticides and chemicals used in both the tobacco leaf and in the manufactured product. Little is known about the effects of such chemicals and pesticides when they are burned, either alone or in conjunction with other ingredients.
Hundreds of additives and flavorings are used in the manufacture of cigarettes and other tobacco products. According to the Department of Health and Human Services (HHS), while many of these additives and flavorings may be viewed as “generally recognized as safe” when used in their raw (non-combusted) state, such additives and flavorings may pose additional toxic harms when burned.

The complexity of a burning tobacco product mixed with a number of burning chemicals, additives and ingredients represents a challenge to begin to logically, rationally and responsibly sort through the products that are currently on the market as well as those that will be appearing in the months and years ahead.

Long time tobacco control expert Ken Warner (as well as others) cautions about how we look at and deal with the combustible marketplace:

“…cigarette smoke contains thousands of chemicals with possibly hundreds of them hazardous to health. No one knows which chemicals, or which combinations, pose the greatest danger. Further the novel products achieve their exposure through a variety of techniques that may themselves pose risks, possibly new risks to the health of the consumer. For example, one reduced brand of cigarette uses palladium to achieve its objective. Is inhaling palladium dangerous? No one knows.” (New York Times Sunday Magazine, June 12, 2005)

A recent study by Dr. James F. Pankow of Oregon Health and Science University demonstrated that cigarettes that reduce some of the toxins in cigarette smoke do not offer lower predicted cancer risk. The study, which appeared in the journal Cancer, Epidemiology Biomarkers & Prevention (March 16, 2007), “found that the predicted risks of lung cancer from PREP [potential reduced exposure products] cigarettes is not meaningfully lower than for conventional cigarettes that most smokers puff on every day.” Pamela Clark, Ph.D., a senior researcher with Battelle Centers for Public Health Research and Evaluation noted that “simply lowering the levels of a few known harmful compounds from tobacco smoke may not significantly reduce the risks of smoking.” (See Statement from the Oregon Health and Science University website, Research Shows New Cigarettes Designs Don’t Offer Lower Predicted Cancer Risks, March 16, 2007)

While still complex, the scientific issues surrounding noncombustible smokefree tobacco products are far less complicated than when assessing combustible tobacco products. Because these products are not burned, the number of hazardous constituents and toxins are significantly reduced. It is a misstatement to suggest that smokeless tobacco products (even traditional products on the market today) are as harmful as cigarettes, as has often been suggested. It is also a misstatement to suggest that all products in the smokefree tobacco category (as well as nicotine products) carry the same level of risk. Willing or not, the public health community has had to confront and accept the scientific realities that there are significant differences between products that are burned and those that are not. The idea that noncombustible tobacco products are not lower in risk stands up to neither common sense nor scientific evaluation. But does that mean that such products are safe? No. While many have suggested that smokefree tobacco products are as hazardous as cigarettes, and may have good intentions to counter the tobacco industry’s efforts to mislead the public, such tactics are contrary to the precept of “truthful and full disclosure.” As Professor Jonathon Foulds has noted in an undated presentation:

Cigarettes (the most harmful nicotine products) have a near monopoly in most countries. If a non-combustion nicotine delivery product could be successfully compete with cigarettes and other smoked products for the nicotine maintenance market, this would likely produce a vast reduction in tobacco-caused death and illness.

Numerous smokeless tobacco products exist and these can vary by as much as 130-fold in their levels of harmful chemicals.

Swedish snus appears to be relatively low in content of virtually all toxic chemicals, but is capable of providing venous blood nicotine levels comparable to cigarette smoking (and higher than typical levels from NRT).

What is the rationale for banning such products in a marketplace dominated by a far more harmful addictive product (cigarettes) that is freely available (EU)?

What is the rationale for exaggerating the dangers of such a product relative to cigarettes (USA)?

There are only 3 logical options:
1. Allow/encourage high nicotine delivery NRT products to aggressively compete with cigarettes for the nicotine maintenance market.

2. Allow low nitrosamine smokeless tobacco products to do that job.

3. Do both 2 and 3 simultaneously.

I’d advocate for option 3, but if one can’t allow option 1 to occur, then option 2 is the next best harm reduction option.

(Foulds, Jonathon, Professor, UMDNH-School of Public Health, Director. Tobacco Dependence Programme, New Brunswick, NJ. Excerpts from a recent but undated presentation.)

Yet there are legitimate concerns about how smokefree tobacco products might be marketed and used. These concerns have been raised and echoed by many experts. Most recently, for example, a European Commission, Scientific Committee on Emerging and Newly Identified Health Risks, noted that there is a delicate balance between the benefits of promoting and the risks of using smokeless tobacco products (in this case Snus). The balance “will be highly dependent on the marketing of the product, the health messages delivered with it and the extent to which switching to STP as a harm reduction strategy is endorsed by health professionals and their organizations.” (Health Effects of Smokeless Tobacco Products-Preliminary Report, Scientific Committee on Emerging and Newly Identified Health Risks, European Commission, June 2007, p.108).

Some in the public health community fear that we could go down the same path that we went down in allowing low tar and nicotine products to be marketed and advertised with the idea that such products would encourage tobacco use rather than promote cessation.

While acknowledging that a professional panel of experts found that “there exists at least a 90% reduction in the relative risk of low nitrosamine smokeless tobacco use when compared to cigarette smoking and that the risks of using low nitrosamine smokeless tobacco should not be portrayed as comparable with those smoking cigarettes,” the Campaign for Tobacco Free Kids (CTFK) has raised several concerns:

The evidence that has been presented (by the expert panel) argues in favor of using smokeless tobacco as a harm reducing product relative to continued smoking, when contrasted with the evidence that smokeless tobacco in various forms poses significant health risks and is not safe nor is it safer than the use of clean, medicinal forms of nicotine, is a clear reason for the need for strong and effective regulation of all tobacco products, their marketing and associated health claims, including the ability to make evidence-based, comparative health claims among tobacco products. In the absence of such a regulatory framework, there is nothing to prevent marketing that encourages non-tobacco users from starting to do so, discourages smokers from quitting or encourages former smokers to return to tobacco use. In any of these cases, the use of smokeless tobacco would increase the risk of harm to both individuals and society as a whole. There is nothing to prevent a tobacco company from altering the content of the smokeless tobacco product in ways that make it more toxic. In the absence of regulation, there is no evidence that smokeless tobacco as sold and manufactured in the United States has reduced the harm of tobacco use to the population.

(Smokeless Tobacco in the United States – An Overview of the Health Risks and Industry Marketing Aimed at Children and the Compelling Need for Effective Regulation of All Tobacco Products by the FDA, Campaign for Tobacco Free Kids (www.tobaccofreekids.org), May 2006.)

One of the questions that the CTKF does not ask is what are the unintended consequences for both individuals and the population as a whole for NOT making these products available? Until these products are made available and are labeled and marketed with accurate information about their risks, the relative risks and intended use will never be known. Are not the same questions that are being asked about smokeless tobacco products also some of the same questions that need to be asked and answered about other nicotine products, including NRT? Some suggested ways of dealing with these and many other issues will be forthcoming in subsequent chapters of this paper.

With all due respect to many of the people I have worked with on FDA regulation over the years, regulation by itself, while critical, it is not the only avenue that needs to be pursued. There are many other ways to force or coax changes on the
industry (broadly speaking) that also promote the critical need for third-party oversight. The stalemate that has existed for what is now going on 20 years as we await FDA oversight has had significant, negative impacts on the public and, more importantly, on those who use tobacco products. A March 27, 2007 article in The Wall Street Journal noted:

To date smokers have had little guidance on how to give up cigarettes. But public health officials in growing numbers are suggesting that a pinch of smokeless tobacco between the lip and gum can provide a smoker with nicotine – the addictive agent in tobacco – while posing a substantially reduced health risk compared with smoking. And they say that if smokers are going to make the switch, they should use smokeless products that are low in nitrosamines – the carcinogens in smokeless tobacco. But users have no way of knowing which products are low in nitrosamines because that information isn’t included on the labels.

Scientific studies are distinguishing one product from another. A presentation last month at the annual scientific conference of the Society for Research on Nicotine and Tobacco corroborates other research showing that the level of carcinogens in smokeless tobacco varies widely from brand to brand.

The carcinogenic level of smokeless tobacco is drawing scientific attention in part because sales of this product are growing, unlike sales of cigarettes. A large reason is the debate over its use as a cigarette-cessation aid. Low nitrosamine smokeless tobacco poses 10% or less of the health risks of cigarettes according to various studies, including a 2004 National Cancer Institute-funded article.

Some health officials worry that promoting snuff as a cigarettes cessation aid would induce nonsmokers to take up smokeless tobacco, which can be as addictive as cigarettes. And smokeless tobacco isn’t without risks. Findings from a federally funded study of over 100,000 smokers, published last month (February 2007) in the journal, Tobacco Control, showed that smokers who switched to smokeless tobacco had an 8% higher mortality rate over 20 years than smokers who quit altogether.

The study didn’t compare switchers with people who kept smoking, but researchers say differences would be significant. “There’s no question that switching to spit tobacco and quitting tobacco altogether are both far less lethal than continuing to smoke,” says Michael Thun, vice president of epidemiology for the American Cancer Society and an author of the Tobacco Control article.*

(“If you want to quit smoking, consider chewing,” Kevin Helliker, The Wall Street Journal, March 27, 2007.) * Michael Thun in a letter to the editor (The Wall Street Journal, July 25) noted: “The Journal article used one comment in a long interview with me to imply in this article and one in March that switching to spit tobacco is a reasonable alternative to quitting tobacco use entirely. There is no sound evidence that switching to smokeless tobacco is as or more effective than the many proven methods for quitting, such as nicotine replacement, antidepressants, behavioral counseling and for many people cold turkey.

My only comment about the Journal article and Mr. Thun’s response is that it makes the point as to WHY we need dialogue on these important issues. While there may be no sound evidence that the use of smokeless products is a proven method for reducing cigarette smoking (primarily because they have not been marketed as such), there is equally no evidence that these products could not be effective. There seems to be agreement, even from those who are raising concerns, that these products are significantly lower in risk than cigarettes. Using a food analogy, should we have prevented the development of low-fat and low-cholesterol products because there was no sound evidence that switching had any public health benefit? While nicotine replacement therapies have some proven benefit and success, they are far from being the “silver bullet” to quitting smoking.
Misperceptions about the Risks and Relative Risks of Smokefree Tobacco and Nicotine Products

There have been several studies and surveys that indicate that the public does not understand the risks and relative risks of smokeless tobacco and nicotine products. Many believe that it is the nicotine that causes cancer. A 2002 commentary in the journal “Addiction” noted:

Ironically, many smokers do not perceive much difference in health risk between smokeless tobacco products, nicotine medications and cigarettes. Yet if all nicotine products were put on a riskcontinuum the actual difference between smokeless and nicotine medications would be seen fairly minor compared to the difference in disease risk between smoked and smokeless products. Until smokers are given enough information to allow then to choose products because of lower risks, then the status quo will remain.

(Can Capitalism Advance the Goals of Tobacco Control?, Society for the Study of Addiction to Alcohol and Other Drugs, Addiction, 97:957-983, 2002)

In a 2005 article in “The Journal American Journal of Preventive Medicine”, the authors noted:

A much great proportion of smokers (82%) were aware of SLT products than were aware of modified cigarettes and cigarette-like products… only 10% of smokers believe that SLT is less harmful than smoking ordinary cigarettes. Here, smokers are misinformed in the opposite direction. Epidemiological data suggest that SLT products sold in the US are significantly less harmful than cigarettes.

(O’Connor, Hyland, Giovino, Fong, Cummings, Smoker Awareness of and Benefits about Supposedly Less Harmful Tobacco Products, American Journal of Preventive Medicine, 2005, 29(2) page 89)

Professor and researcher LT Kozlowski and his colleague have noted:

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 they would rather see a smoker switch to lower tar cigarettes than smokeless (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 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.)

And in a more recently published study:

Students (college freshmen) were asked to compare the perceived harmfulness of 11 nicotine delivering products with that of a regular cigarette.....

A statistically significant association was found between nicotine product harm perception and sex, race, income citizenship, and smoking behavior. Regarding the three medicinal replacement therapies, 19.6% of respondents incorrectly perceived the nicotine patch to be as harmful as or more harmful than a regular cigarette; corresponding values were 24.1% for nicotine gum and 52.9 percent for nicotine inhaler. Respondents incorrectly perceived the following smoked products to be less harmful than cigarettes: ultra-light cigarettes (40.4%), waterpipe (37%), light cigarettes (35.2%, cigarillos (17.4 %) and cigars (16.9%). Regarding smokeless nicotine products, 89.3% of respondents incorrectly perceived dip and chew to be as harmful as or more harmful than regular cigarettes; corresponding values were 36.2% for nicotine lollipops and 35.2% for nicotine water. Our findings reveal misperceptions about nicotine product harmfulness and underscore the importance of developing a science base to inform policies and educate consumers about these products. (emphasis added).
While the current market of smokeless tobacco use is small (less than 5%), it has seen a growth pattern over the last several years that analysts expect will continue. For example, Citigroup’s Tobacco Weekly Trends report noted that the total U.S. snuff market grew (and is likely to maintain growth) at a rate of about 10% (Citigroup, Tobacco Weekly Trends, March 28, 2007, Bonnie Herzog and Jonathan Loveless).

In addition, the trend of banning smoking in all public places, workplaces, restaurants, hotels, etc., is growing rapidly and will continue. As of the end of March 2007, some 15 states had enacted laws banning smoking in the workplace for all workers including restaurant and bar workers (See Citicorp Tobacco Weekly Trends, March 28, 2007). Even tobacco states are seeing increasing support for the enactment of clean indoor air laws and regulations. This trend is expected to drive many smokers to using alternative products, including smokeless tobacco products and nicotine replacement therapies.

While the best thing to reduce disease and death from the use of cigarettes is to quit all tobacco (and nicotine) use completely, the number of people who are actually able to quit and stay off cigarettes continues to be rather low. And though many use different nicotine replacement therapies (patches gums, lozenges, inhalers, etc.), the success rate of quitting smoking still remains very low, estimated to be about 6%. There are, therefore, a large number of cigarette smokers who though wanting to quit (about 70% of cigarette smokers say they want to quit) have been unable to do so. Many in the public health sector believe that more needs to be done to help those smokers, including the development of consumer acceptable lower risk products. It is the what and how that presents interesting points for discussion and debate.

The Royal College of Physicians report on harm reduction echoes many of my views, noting for example:

The fundamental argument of this report is that this current situation is perverse, unjust, and acts against the rights and best interests of smokers and the public health. Harm reduction has the potential to play a major part in preventing death and disability in the millions of people who currently smoke and who, in the context of exposure to currently available drivers and supports to cessation, either cannot or will not otherwise quit smoking. These smokers have a right to be able to obtain and choose from a range of safer nicotine products, and they have a right to accurate and unbiased information to guide that choice (pages 223-224)

A Convergence Between The Tobacco and Pharmaceutical Industry

For a number of reasons, it is now very evident that the tobacco industry and the pharmaceutical industry’s interests are converging in a number of areas – one of which is the role that reduced-risk products will play in the marketplace and who will control the sale and marketing of those products. Both the dominant cigarette manufacturers have now entered the smokeless tobacco market with recognized brand names (Marlboro and Camel Snus). For a number of years, I have suggested that the pharmaceutical industry’s products would become more “consumer-like” and less “drug-like,” while the tobacco industry would begin moving towards developing newer lower-risk, science-based products brought about by intensified anti-tobacco campaigns, the development of new technologies, and the entry into the marketplace of new players willing to do things significantly different. This is also part of the reason why some tobacco companies have supported the need for an agency like the Food and Drug Administration to assume regulatory oversight of the industry. Tobacco companies are increasingly hiring researchers, scientists and executives who have backgrounds in the pharmaceutical industry and former staff from agencies like the FDA. Philip Morris’ commitment to build a $350 million research facility in Richmond, VA – opened in August 2007 – is further indication of where they (and their competitors in both the tobacco and pharmaceutical industry) will be heading in the coming months and years.

It would, therefore, be short-sighted to ignore these significant realignments and not to take advantage of them by calling on the industry (tobacco and pharmaceutical) to be transparent and open about what their directions are.
The Relative Risk Reduction Continuum

To visualize the range of products that are currently on the market, consider the following chart. This chart is a hypothetical representation of the relative risks that are presented by a variety of products—ranging from those that are highly toxic in the form of combustible tobacco to those for which risks are very small or negligible. In each case, the regulation of the product should be based on the risk and intended use. The higher the risk, the more the regulation (labeling, warnings, prohibitions of health claims, marketing restrictions, taxation, etc.); the lower the risk, the less regulation. I believe that if we begin to develop better and more consistent methods for testing tobacco and nicotine products, we can in fact plot where we would expect products to be on the continuum, and we can begin a process by which each product (or category of products) can be labeled according to those risks and relative risks.
Taking this one step further, we can also break down the risk and relative risk within a product category. In the case of the smokefree tobacco and nicotine products category, there are and will continue to be differences in the risks and relative risks, intended use and effectiveness of the products on the market. So that even if we have a 90% lower level of risk for all these products compared with cigarettes, we have an opportunity to develop and make available products that may be even lower in risk and that will be consumer-acceptable.

* This chart is hypothetical, designed to demonstrate the risks and relative risks of a spectrum of smokefree tobacco and nicotine products.
The Role of Nicotine

While nicotine is the component of a tobacco product (and most NRT products) that causes addiction, most experts agree that it is relatively benign with respect to disease risks. There are differences of opinion as to whether it is better to keep nicotine high in products (so as to reduce total intake of other toxic substances) and in particular in science-based, lower-risk products, or whether to reduce nicotine – to gradually help tobacco and nicotine users curtail their addiction. There actually may be useful public health reasons for doing both, given that the goal is first and foremost to reduce the levels of smoking and the harm caused the use of cigarettes. Many in the public health community and particularly those with ties to the pharmaceutical industry speak in terms of developing “cleaner” nicotine delivery systems that are free of many of the toxins found in tobacco but in particular in cigarettes.

Thus, employing a strategy of gradually reducing nicotine levels in cigarettes while increasing or providing sufficient nicotine doses in lower risk/cleaner smokefree tobacco and nicotine products may be a strategy worth discussing further.

Conclusion

So the question is that if there is agreement that smokefree tobacco and nicotine products are significantly lower in risk when compared to the dominant cigarette market, why is it that there remains significant push back from many parties about allowing these products to be manufactured, truthfully labeled and marketed in a way that will give consumers information that will allow them to make a truly informed choice? Why are NRT products not allowed to have more flexibility in the manner in which they are marketed when compared to cigarettes? Why are smokeless tobacco product manufacturers discouraged when they wish to provide truthful and science-based information about the relative risks of their products when compared to cigarettes? Are there ways of dealing with legitimate issues and concerns in a civil and transparent manner? We will explore these and other issues in the next sections of this paper. We will look for ways that stakeholders and other interested parties can engage in a discussion about how to move forward in both the public (through governmental intervention in regulating the tobacco and nicotine industries) and private sector, where many of the outstanding issues can be discussed and debated and which can influence important policy decisions.

Note: For conclusions and recommendations on smokeless tobacco and nicotine products contained in the Royal College of Physicians report, “Harm reduction in nicotine addiction; helping people who can’t quit,” See Appendix, item 1.
CHAPTER III

TOPICS FOR DISCUSSION:
SCIENCE AND TECHNOLOGY,
LABELING AND MARKETING,
PRODUCTION AND
MANUFACTURING
STANDARDS, CONSUMER
ACCEPTABILITY, SURVEILLANCE,
INCENTIVES

Science and Technology

Science will be one of the most important discussion topics in looking at how smokefree tobacco and nicotine products are manufactured, labeled and marketed – now and in the coming years.

In reviewing the current literature on smokeless tobacco, there now seems to be a growing acceptance that noncombustible forms of tobacco are significantly lower in risk than combustible tobacco products and that some forms of smokefree tobacco are potentially lower in risk than others. As Hoffman, Hoffman and El-Bayoumy noted in 2001:

"TSNAs are the major carcinogens in chewing tobacco and snuff and are associated with cancer in the oral cavity of snuff dippers. On the basis of our current knowledge, a drastic reduction of TSNA levels in chewing tobacco and snuff is expected to lower the risk of oral cancer; in fact such low levels of TSNA's may be below the threshold level for the induction of snuff dippers. However, it will be of importance to investigate the possible endogenous formation of the carcinogenic TSNA in consumers of the snuff brands that contain only traces of TSNA."


Ken Warner, Dean of the University of Michigan’s School of Public Health and someone who has been in the forefront in the discussions on the broader topic of harm reduction, noted in a paper published on the subject of smokefree tobacco products that:

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

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

In the narrow question of the relative risk of LN-SLT products, these results clearly indicate that experts perceive these products to be far less dangerous than conventional cigarettes. Based on the available published scientific literature as of 2003, there seems to be a consensus that LN-SLT products pose a substantially lower risk to users than do conventional cigarettes. This finding raises ethical questions concerning whether it is inappropriate or misleading for government officials or public health experts to characterize smokeless tobacco products as comparatively dangerous with cigarette smoking.

In comparison with smoking, experts perceive at least a 90% reduction in the relative risk of LN-SLT. The risks of using LN-SLT products therefore should not be portrayed as comparable with those smoking cigarettes as has been the practice of some governmental and public health authorities in the past. Importantly, the overall public health impact of LN-SLT will reflect use patterns, its marketing, and governmental regulation of tobacco products.

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

The panel additionally cautioned:

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


A recent study by Dr. Stephen Hecht and his colleagues published in the August 2007 issue of Cancer Epidemiology, Biomarkers and Prevention found that “users of smokeless tobacco are exposed to higher amounts of tobacco specific nitrosamines – molecules known to be carcinogenic – than smokers.” Hecht, while arguing that smokeless products are not safe and should not be used as alternatives to cigarettes, also acknowledges that the TSNA content comprising NATm is apparently noncarcinogenic. These products use Star Scientific’s specially cured tobacco, known to be low in TSNA. The emergence of these new products with relatively low levels of carcinogenic TSNA is an encouraging sign. (Tobacco specific nitrosamines in new tobacco products, I Stepanov, J Jenson, D Hatsukami, S Hecht, Nicotine and Tobacco Research, Volume 8, Number 2 [April 2006] p.311).

A study that Dr. Hecht co-authored in 2005, for example, noted that Star’s Ariva and Stonewall were the lowest of all the smokeless products tested. “Levels of strongly carcinogenic NNN and NNK were only 56-99ng/g, with most of the TSNA content comprising NATm, which is apparently noncarcinogenic. These products use Star Scientific’s specially cured tobacco, known to be low in TSNA. The emergence of these new products with relatively low levels of carcinogenic TSNA is an encouraging sign.” (Tobacco specific nitrosamines in new tobacco products, I Stepanov, J Jenson, D Hatsukami, S Hecht, Nicotine and Tobacco Research, Volume 8, Number 2 [April 2006] p.311).

The most recently published study (August 2007) only reinforces the critical need for various players to meet on neutral ground and to discuss these scientific issues. It raises the more important questions about the need for an industry-wide standard, potentially setting tolerance levels for such compounds as TSNA. But it also reinforces the need to find incentives for manufacturers that will encourage the reduction of certain toxins in their products and which have consumer acceptability. These products may one day be produced not only by the traditional smokeless companies (and now cigarette companies, such as PM and RJR), but by technology-based entrants and pharmaceutical companies.

I must confess a certain frustration with some of the articles I read that, while scientifically accurate, seem to be missing key opportunities in suggesting what needs to be done. There has been a tendency in some cases to make broad-sweeping policy conclusions when the focus of a study may be on a limited number of products. It would be comparable to testing only high-fat and high-cholesterol foods as part of a study and concluding that we should stop eating all foods that contain fat and cholesterol. Moreover, the articles usually conclude with cautionary policy recommendations that seem to be grounded in decades-old public relations rhetoric.

A position statement entitled the “European Union Policy on Smokeless Tobacco” – a statement in favor of evidenced-based regulation for public health – concluded that:
We support the replacement of the ban on oral tobacco with an approach that regulates the toxicity of all smokeless (and smoking) products. Our approach has the following advantages:

a) It would create a legally defensible, fair and rational policy—in which public health is given primacy consistent within the framework of EU law.

b) It would create public health benefits through smoking cessation and smoking substitution.

c) Its gives smokers an extra strategy for controlling their risks and eliminating ETS risk, and thereby respects their consumer and human rights.

d) It would apply toxicity controls to the currently unregulated chewing products such as gutka and paan available in the EU and currently unregulated.

e) It would have benefits beyond Europe and if a good regulatory model is developed for controlling toxicity of smokeless tobacco—for example, establishing regulatory norms in the WHO Framework Convention on Tobacco Control.

f) It opens the dominant cigarette makers to competition from tobacco products that do far less harm.


Technology Advances

Several developments in the science and technology area clearly indicate that it may be possible to develop products that are low in tobacco specific nitrosamines and other toxins and that might also meet the expectations of adult consumers (taste, form, etc.), who are interested in either changing their current use of smokeless products or who use highly toxic cigarettes and are looking for a significantly lower risk alternative. For example:

- Swedish Match has developed a low TSNA Snus product
- Star Scientific has developed two very low TSNA products (Ariva and Stonewall)
- UST has produced a lower TSNA product (Revel) and are bringing the TSNA levels in their other products down.
- RJR and Philip Morris have now crossed over into the smokeless arena, manufacturing their version of Camel and Marlboro Snus, which I assume have levels of TSNA’s comparable to Swedish Match.

There is also a significant amount of research being done on the genetics of tobacco, which is often called the “white rat” of the plant world because tobacco has certain traits that are superior to other plants, such as corn. This area has significant potential for not only developing products that are lower in risk (reducing TSNAs and other toxins; being able to control nicotine levels; significantly reducing the use of pesticides, etc.) but also for the development of pharmaceutical products and industrial enzymes. Few individuals in the public health community or policy arena seem even to be aware of this important potential area for change. This year’s 60th Tobacco Science Research Conference (September 2007) focused on biotechnology developments. Several fascinating presentations were made including one on the work being done at NC State on mapping the tobacco genome. As noted by one of the researchers who presented at the conference:

The stated goal of this project was to sequence and identify >90% of the open reading frames in the Nicotiana tobacum genome. The unstated goals are to leverage the vast database generated from this effort to understand the genome structure of Solanceous plant species, to understand plant pathogen interactions, to identify and manipulate important biosynthetic pathways related to harm reduction, and to generally improve tobacco as a crop and as a biological factory for value added traits. (Frontiers in Tobacco Biotechnology, Recent Advances in Tobacco Science, Symposia proceedings, September 23, page 6.)

Production and Manufacturing Standards

With or without enactment of legislation and the establishment of rules and regulations by an agency like the Food and Drug Administration (even with legislation, the development of regulations could take at least several years at a minimum), it is essential for growers, manufacturers, scientists, agronomists and others to begin a process by which clearly established and uniform production and manufacturing standards can be discussed and implemented. Only through the estab-
lishment of such standards and with the transparent cooperation of the industry (broadly speaking) will the public health community, consumers and governmental agencies be able to “verify” the quality and integrity of the tobacco leaf and the tobacco/nicotine products on the market. Such standards will enable a fair and consistent evaluation, allowing products to be labeled and marketed based on sound science and careful surveillance. They will also provide the ability to truly understand the risks and relative risks of products.

**Side Note:** Many believe that FDA has to come first before anything is done to begin a process of looking at steps that need to be taken to set industry-wide standards. Many see FDA as the only route to industry and product reform. I concur wholeheartedly that we need a third party “street cop,” but I disagree that we should be sitting around waiting for FDA and the implementation of regulations that could take years, as evidenced by the FDA’s slow pace in developing regulations for the dietary supplement industry (10-plus year effort). It would be irresponsible, however, not to begin engaging in a productive and transparent dialogue about these important issues now.

**Agricultural Production Standards**

Whether the product is tobacco-based or nicotine-based (but derived from tobacco), it will be important to know where the tobacco used in the product was produced; what kind of tobacco is being used; under what conditions it was grown; what chemicals and pesticides were used in its production and the potential health and safety impact of such chemical applications; how the leaf was cured, processed and stored; and what are and what should be acceptable levels of various elements in the tobacco, such as tobacco specific nitrosamines (which are considered to be the most significant contributor to cancers caused by the use of smokeless tobacco).

Currently, there are no uniform producer- or industry-wide standards or criteria. The tobacco used in both tobacco-based and nicotine-based products comes from a variety of sources in the U.S. and around the world and no governmental agency is tracking, monitoring or testing tobacco anywhere. When Congress provided the U.S. tobacco producers with a “buy-out” several years ago, they also dismantled other critical and important components of the tobacco program – essential elements that will need to be restored and expanded upon.

This remains, therefore, an area in need of discussion, with the goal of developing both short-term and long-term goals and objectives – both for the public and private sectors. This is an area where a range of interests will need to work cooperatively and in good faith, and where there may need to be some significant retraining of a new breed of tobacco producers to take advantage of new technology advances. They will also need to meet the challenges demanded by society to develop and produce truly science-based, lower-risk products. It is possible to reach a consensus on what the critical elements are for the establishment of effective but fair agricultural production practices used for smokefree tobacco and nicotine products. But we will never reach that goal by taking the position that agriculture has no bearing on the manufacturing and development of new products. Agricultural production has an important (and probably increasing) role to play.

**Manufacturing Standards**

Whether a product is tobacco-based or nicotine-based, all smokefree products should be required to meet basic manufacturing standards and criteria. Currently, while there are many new products that could play a role in reducing disease and death caused by highly combustible products, we know very little about how these products are made; what is in them; what their level of risk is; how they might be used by the public; and what are fair but appropriate benchmarks that could be applied industry wide. The pharmaceutical industry’s NRT products are much further along to adhering to standards. We need to move tobacco-based products (especially those that are lower in risk) in that direction, recognizing that this may be a multi-year endeavor as the industry is both forced and “incentivized” to change. We do not unfortunately have the same level of science for smokefree tobacco products that we currently have for smokefree nicotine replacement therapies; however, sufficient information exists to begin thinking about developing a short-term and long-term research (and surveillance) agenda that will enhance what we already know. That will move our knowledge base about all of these products further down the road in an effort to protect public health. We do know that when compared with highly toxic, combustible products, both smokefree tobacco products and smokefree NRT are significantly lower in risks. For the short
term, we will need to use what Slade and others have referred to as co-regulation – keeping these products under the same umbrella but recognizing that there are differences that will take additional time to change. One day, we would hope to see a more coherent tobacco and nicotine policy in place that regulates all of these products based on their risks and relative risks regardless of whether they are tobacco-based or nicotine-based.

Side Note: Many have talked about the need for co-regulation of tobacco and pharmaceutical nicotine. As Dr. John Slade remarked some 10 years ago:

“I very much appreciate the concept of co-regulation. I think that’s a useful framing of the kind of problem that we have with these two divergent intellectual streams from tobacco companies and from pharmaceutical companies. It keeps both of them in the same range of vision without requiring that they be in lock-step with each other because I think the lock-step is not going to come in the foreseeable future for all the reasons we know”.

I believe Dr. Slade would find today that we are in fact moving towards a convergence between the smokeless market and the NRT market recognizing that co-regulation still has its place under current circumstances but which will become increasingly blurred in the coming years.

In addition, we will need to develop and agree upon good manufacturing standards; agree upon the appropriate methods for testing toxins, pesticides and other components and elements in the final manufactured product; agree upon criteria for the use of additives, (including agreements on the use of flavorings that are deemed “safe” and that do not inadvertently increase risks); and agree on issues related to storage, shelf life, etc. that could impact the products’ health and safety profile.

There is a great deal of experience already available for consideration based on food and pharmaceutical models (especially OTC), and we could gain further insight by looking at the standards by which nicotine replacement therapies are manufactured. As we move forward in both the production and manufacturing standards-setting arenas, we need to involve experts from outside traditional tobacco control and manufacturing sectors to assist in the discussions and recommendations of what effective, appropriate and fair production and manufacturing standards might be for the range of smokefree tobacco and nicotine products (not only on the market today but for the coming months and years as well.)

The efforts of Swedish Match could serve as a starting point for broader discussions on what moving towards industry-wide standards might entail. They have been reasonably transparent about production and manufacturing specifications and requirements for their products (such as Swedish Snus). This example may shed light on what specifications and requirements should consist of and what kind of incentives might be useful and workable for both producers and manufacturers. SM has criteria for the selection of the raw leaf it buys and uses in its products. It also has a set of criteria called the GothiaTek Standard that it uses in testing all its products and uses GMP’s that may not yet be employed by others in the industry. Below are excerpts from SM’s website (www.gotiatek.com)

* * * * *

In order to ensure the specific quality requirements of Swedish snus we have developed a quality standard called GothiaTek.

GothiaTek is the result of decades of research and development work that has led to unique products, produced in an unique manufacturing process.

Our quality standard GothiaTek rests on three legs:

- Requirements on maximum permitted levels of suspected harmful elements that occur naturally in tobacco.
- Requirements on the manufacturing process and raw materials.
- Requirements on qualified product information to consumers.

The following pages will give you more details about Swedish Snus GothiaTek.
GothiaTek Standard

Product requirements

GothiaTek limits for undesired components

Basis for the standard is requirements on maximum allowable limits of certain undesired components in Swedish Snus. These components can be found in nature and therefore various plant species, e.g. tobacco. Some of these components have by scientists been pointed out as potential health risks if they occur in too high concentrations. The Gothiatek standard stipulates that the following limits must never be exceeded.

The concentrations of the undesired components are regularly analyzed in all products in quality control programs. The average content of each undesired component in snus, manufactured by Swedish Match in 2006, is presented in the table below. The confidence intervals of 95% are presented within the brackets.

In the table below, the limits and average contents are based on moist snus. Because of variations in water content between products a standardized water content of 50% has been used. In scientific papers, concentrations are often based on dry matter. Conversion is easily done by multiplying the limits in the table by two.

### Component limits and average contents 2006

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
<th>Content 2006</th>
<th>Component</th>
<th>Limit</th>
<th>Content 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrite (mg/kg)</td>
<td>3.5</td>
<td>1.0 (&lt;0.5 - 1.7)</td>
<td>Cadmium (mg/kg)</td>
<td>0.5</td>
<td>0.2 (0.1 - 0.3)</td>
</tr>
<tr>
<td>TSNA (mg/kg)</td>
<td>5</td>
<td>0.8 (0.5 - 1.1)</td>
<td>Lead (mg/kg)</td>
<td>1.0</td>
<td>0.1 (0.03 - 0.3)</td>
</tr>
<tr>
<td>NDMA (µg/kg)</td>
<td>5</td>
<td>0.5 (&lt;0.5 - 0.7)</td>
<td>Arsenic (mg/kg)</td>
<td>0.25</td>
<td>0.06 (&lt;0.03 - 0.13)</td>
</tr>
<tr>
<td>BaP (µg/kg)</td>
<td>10</td>
<td>0.6 (&lt;0.5 - 1.1)</td>
<td>Nickel (mg/kg)</td>
<td>2.25</td>
<td>0.6 (0.2 - 0.9)</td>
</tr>
<tr>
<td>Pesticides</td>
<td>According to the Swedish Matchpesticide policy</td>
<td></td>
<td>Chromium (mg/kg)</td>
<td>1.5</td>
<td>0.4 (0.07 - 0.7)</td>
</tr>
</tbody>
</table>

Legends:

- mg/kg = thousandth gram per kilogram product (based on Snus with 50% water content)
- µg/kg = millionth gram per kilogram product (based on Snus with 50% water content)

Declaration of contents

A declaration of contents in accordance with food labeling shall be publicly available for GothiaTek products. Substances that are used in the manufacturing of each product are listed in declining order of weight. Flavour additives shall be listed as group.

Declaration of certain components

The GothiaTek standard requires that concentrations of the following components in each specific product shall be publicly available:

- Water
- Nicotine
- Salt

The concentrations shall be based on the finished product.
Manufacturing Requirements

Raw Material Requirements

- Leaf tobacco for Svenskt Snus by the GothiaTek standards shall be selected so that the limits for undesired components in each specific product are satisfied. Leaf tobacco for Swedish snus by GothiaTek must not contain gene modified tobacco.
- All additives in Swedish Snus by GothiaTek shall be approved food additives, or approved tobacco additives, according to specific regulations in each country where the products are actively marketed.
- Material which is used in packaging of Swedish Snus by GothiaTek shall be approved for food packaging.

Processkrav

- Swedish Snus by GothiaTek shall be heat treated, in a way which effective to kill the natural microbial flora of the tobacco to specific residual bacteria limits ("snus pasteurization").
- The manufacturing process from the point of charge to discharge of the batch shall be performed in a closed system to prevent the product from being contaminated by external microflora or foreign objects.
- The tobacco shall be comminuted in a controlled process. The process must be able to identify and separate any foreign object.
- Finished Swedish Snus by GothiaTek shall directly after packaging be brought to cold storage (max. 8 degrees C).

Hygienkrav I tillverkningen

- All exposure of product to an open environment such as filling of product into consumer packages shall be performed in premises which satisfy the sanitation requirements for food manufacturing. These premises shall be controlled with establish procedures.
- Process equipment shall be cleaned and disinfected at least once every 24 hours during production days. Sanitation control shall be made in accordance with specified procedures.
- Control of water activity, bacteria content and shelf life stability shall be performed on finished products according to specified schedules and procedures.
- Purchased packaging material which will have contact with product shall be produced and shipped according to specifications so that contamination of the materials is prevented. Cleanliness and sanitation standard of this packaging material shall be controlled according to a specified schedule.
- Results for all controls must meet tolerance levels that are specified for Swedish Snus by GothiaTek.

In a very informal verbal survey I conducted with a number of people in the public health community, I found that the overwhelming majority had never heard of the Swedish Match Gothiatek Standard. Several who had heard of it could not provide any details about its implications. This suggests to me how insular, uninformed and tunnel-visioned we remain.

Star Scientific has also made an effort to be open to dialogue and discussion about the development of its curing technologies that have reduced the TSNAs in their noncombustible products. They have achieved levels even lower than those of Swedish Match. Yet with those products, few in the public health community have taken the time to really look at these products as alternatives to cigarettes in terms of relative risk, focusing instead on the public relations-oriented efforts – the “they’re marketing candy to kids” approach. When one considers that some of the pharmaceutical companies are also heavily promoting flavored nicotine lozenges, gums, etc. (mint, orange, fruit chill, etc.), one has to question why similar criticisms are not being leveled at the pharmaceutical industry.

Labeling and Marketing

One of the most routinely raised concerns about smokeless tobacco being used as part of a harm reduction strategy is the fear that the manufacturers of these products will label and market their products with health claims that may mislead consumers about the risks and relative risks of the products. Such claims, for example, might be based upon unproven evidence. These are legitimate concerns but they can be rectified with the proper regulatory structure. At the same time the smokeless manufacturers (and probably the pharmaceutical manufactures) take the view that many in the public health and scientific community are out to suppress
truthful information about their products. Again, this concern can be dealt with within the proper regulatory framework and based on the extensive experience that the FDA has in the regulation of other areas (foods, drugs, dietary supplements, etc.), as well as through private sector dialogue.

The balance between these competing interests is something that the Institute of Medicine (IOM) clearly recognized in its report “Clearing the Smoke.” It hopefully will instigate some new thinking about how we go about reaching a balance that will serve public health interests. While its discussion focuses on cigarettes, given the state of the science, the IOM comments may be far more pertinent to smokefree tobacco and nicotine products, especially when claims are comparative in nature (i.e., comparing smokefree products to combustible products). The report states:

The regulatory process should not discourage or impede scientifically grounded claims of reduced exposure, as long as steps are taken to ensure that consumers are not misled into believing (in the absence of sound evidence) that smoking (use of) the modified product is (or is likely to be) less hazardous than smoking (using) the conventional product. How the complex claims and caveats associated with PREPs can be best articulated in labeling is one of the major challenges facing the regulatory agency. On the one hand, the public health is not well served by the continued use of poorly defined terms such as “light,” “low tar,” or other phrases that imply a benefit when none has been proven to exist. On the other hand, neither is the public health served if smokers (users of tobacco) are discouraged by unduly cautionary language from using a new product (or alternative product) with the potential for real risk reduction. The problem of conveying balance in communicating health benefits and risks is not unique to tobacco related PREPs and the large body of experience in other areas of health and safety regulation may be applicable to these products as well. The agency will have to direct its attention to the language used as well as the labeling format. Some illustrations, based on existing formats follow:

- Current cigarette labeling contains warnings that smoking causes lung cancer, heart disease and emphysema and may cause birth defects. If warranted by scientific evidence, such warnings could be accompanied by a statement that the modified product might carry a reduced risk of one or more of these conditions.
- Current food labeling has on each package a table displaying a qualitative analysis of nutritional content. This approach could be applied to selected ingredients and constituents of tobacco products or tobacco smoke, such as known carcinogens and CO.
- Food labeling tables express nutritional content not only as grams per serving but also as a percentage of daily intake. One could envision tobacco product labeling with a similar table that shows exposure or yield ranges for particular toxicants or perhaps ranks the levels of exposure as high, average or low. These terms could be specifically defined and would perhaps be less misleading than such terms as “light.”
- One could also envision the use of words such as “high,” “average,” or “low” again carefully defined, in a “risk” column in such a table. Pictograms such as those that appear in poison control warnings, or icons might be used instead of words. It is essential that such labeling in the end be perceived as denoting degrees of risk, not as signifying or implying safety. The message that cessation is the only safe choice must not be obscured or lost.
- The agency should also consider requiring that labels for PREPs that make exposure reduction claims disclose that the reduction in exposure depends upon the user not compensating for the reduction by increasing use or by inhaling more deeply. Consideration should also be given to a disclosure that the health benefits have not been established in scientifically recognized tests or ongoing studies. Such a disclosure would guard against consumer confusion that risk reduction benefits have been proven. Furthermore such a disclosure would provide an incentive to manufacturers to do more research on the health effects of exposure reduction.

(Bold emphasis added; “Clearing the Smoke,” Institute of Medicine, pages 218-219.)
There is a tremendous amount of experience at the FDA with respect to labeling and claims in the food and drug areas. Former FDA experts in a number of areas should be consulted and become more involved in the discussions on what kinds of production, labeling and marketing standards would be most appropriate for smokefree products.

**PREPS, Health Claims and Relative Risk**

I have suggested in other writings that we might want to consider moving away from the use of the word PREP (potentially reduced exposure product) and start talking more in terms of risks, relative risks and intended use. A PREP today may not be a PREP in five years given the dynamically changing tobacco and nicotine environment. By labeling all products based on risks, relative risks and intended use, and avoiding allowing a product to be called a PREP we can develop a labeling and marketing scheme that will serve the interests of the consumer of these products. Such a scheme would give consumers information that will for the first time allow them to understand the risks and dangers associated with all the products.

I also would suggest that because of the uniqueness of tobacco and nicotine and the hazards associated with them that we also try to move away from talking about “health claims” and talk more about “health risks”. This approach (one that was also recognized by the IOM) would allow all products to be evaluated using the same scientific standards and will allow for both positive information and negative information to be provided to the consumer based upon the risk profile of the category and the particular product. For example, one way of differentiating between the various categories of products that FDA might come up with is the following type of labeling chart that would be required on all tobacco and nicotine products (or through websites, at points of purchase, etc.)

Given the current science and position of the public and scientific community, smokefree products would probably fall in the category of moderate-to-low risk. Additional warnings and information could be provided about dosage, quitting, etc.

Each tobacco/nicotine product could then be labeled and marketed based on the category they fall under and given a specific risk profile for the product itself.

This is particularly important in looking at how the FDA differentiates between various types of claims (health claims, structure function claims, etc.). For example, in the food area, an FDA Task Force on Consumer Health Information for Better Nutrition Initiative noted:

*Health messages on product labels that may influence consumer knowledge and hence dietary choices fall into three categories. Agency policies on all three may have important consequences for consumer behavior. First, “health claims” have a different definition and regulatory provisions compared to other types of claim statements on conventional foods and dietary supplements. Health claims are specifically about the relationship between a substance and a disease, and they are reviewed and authorized by the FDA. An example of a health claim related to the disease osteoporosis is: Calcium may reduce the risk of osteoporosis. Second “structure/function” claims are also allowed on foods, but make no reference to disease. Instead, they highlight how the food substance works within or otherwise supports the body. An example of a structure/function claim would be: Calcium helps build strong bones. These structure/function statements are not pre-reviewed by FDA but must be truthful and substantiated and not misleading. Though statutory standards for structure/function claims differ from health claims, they too affect consumer behavior and thus assuring their accuracy is another important element for effective regulation of product claims for consumers. Finally, truthful and non-misleading general “dietary guidance” statements can also be made on food labels without FDA review. These statements, unlike health claims which target a specific substance and a certain disease, focus instead on general dietary patterns and practices that promote health. An example would be the “5-a-Day” program from the National Cancer Institute which encourages consumption of fruits and vegetables for better health. Such general practices encourage better nutrition.*

<table>
<thead>
<tr>
<th>TOBACCO AND NICOTINE RISK</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Product</strong></td>
</tr>
<tr>
<td>Combustible (cigarettes,</td>
</tr>
<tr>
<td>cigars, pipe, little</td>
</tr>
<tr>
<td>cigars)</td>
</tr>
<tr>
<td>Noncombustible (smokefree</td>
</tr>
<tr>
<td>tobacco and nicotine</td>
</tr>
<tr>
<td>products used for</td>
</tr>
<tr>
<td>recreational use)</td>
</tr>
<tr>
<td>Nicotine products used</td>
</tr>
<tr>
<td>for cessation/therapeutic</td>
</tr>
<tr>
<td>use</td>
</tr>
</tbody>
</table>
This type of approach to the labeling and regulation of claims and to providing truthful, non-misleading information on foods could serve as a model for differentiating the types of risk claims and information that might be allowed on tobacco products and, in particular, on smokefree tobacco and nicotine products.

Again, I want to strongly reiterate that we not look at claims and statements from the standpoint of “health claims” (i.e., “This product is safe...”); rather, we should look at statements in terms of “risks and relative risk claims” and “intended use”. While many will find little difference in this, I believe it is important because we are dealing with products that are inherently harmful and/or addictive. We are thus trying to ensure that consumers understand not only the risks of using tobacco and nicotine products (i.e., “Never start, and if you use any of these products you should quit.”), but also the relative risk that different products present when compared to one another (i.e., “If you chose to use tobacco and nicotine products here’s what you should know.”).

Several advocates in the public health community worry that they and their colleagues might be viewed as “endorsing, promoting and encouraging the use of smokeless products.” I do not see that the regulatory-based requirements of providing truthful, accurate and non-misleading information to the public through labeling and marketing restrictions do. I believe that by making a clear statement that all tobacco and nicotine products carry certain risks, consumers should then be entitled to know the degree of risk of each product.

The aforementioned Task Force was charged with developing a framework to help consumers obtain accurate, up-to-date and science-based information about conventional food and dietary supplements. The charge included:

- Report on how the agency (FDA) can improve consumer understanding of the health consequences of their dietary choices and increase competition by product developers in support of healthier diets, including how the agency should apply the “weight of the evidence” standard established under the consumer health information initiative for qualified health claims in order to achieve these goals.
- Develop a framework for regulations that will give the principles the force and the effect of law.
- Identify procedures for implementing the initiative, as well as determining the organizational staffing needs necessary for timely review of health claim petitions.
- Develop a consumer studies research agenda designed to identify the most effective ways to best present scientifically based, truthful and non-misleading information to consumers and to identify the kinds of information known to be misleading to consumers.

It is interesting to note that the Task Force met eight times, and four of the meetings included participating stakeholders from the industry, health professionals community, the consumer community and the academic and research community. At those meetings the participants were asked their views on six general questions:

1. What body of scientific evidence do you think should be adequate for a qualified health claim?
2. What types of safety concerns should be factored into FDA decision making?
3. What specific claims do you think are currently ready for consideration under the new guidance?
4. On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?
5. What kinds of empirical data should FDA rely on to show that consumers are, are not, mislead by claims?
6. Should conventional foods and dietary supplements be treated the same or treated differently, and why?

I refer to the above because these are some of the types of issues and questions that the Center (being proposed in the last Chapter of this paper, as well as the FDA) needs to be considering. These types of questions could easily be adapted for consideration of tobacco and nicotine products and, in particular, the role that smokefree products might play in a public health initiative.
Using more of a food-type model, we might see the allowance for relative risk claims for smokefree products as:

1. For the broad category of risk differences between cigarettes and smokefree tobacco products:
   - No tobacco product is safe.
   - Cigarettes are the most dangerous and significant risk to health.
   - Scientific evidence supports the finding that smokefree tobacco and nicotine products are significantly lower in risk than cigarettes.
   - The safest way to reduce all risks from tobacco is to never start using tobacco or to quit. Pharmaceutical nicotine products such as patches, gums and lozenges may be a lower risk alternative for those wishing to quit all tobacco use.

2. From the standpoint of comparing a low-TSNA, smokefree tobacco product to both cigarettes and other smokefree tobacco and nicotine products:
   - All tobacco products have public health risks and are addictive.
   - Cigarettes are the most dangerous and significant risk to health.
   - Scientific evidence supports the finding that smokefree tobacco products made with very low tobacco specific nitrosamine tobacco (a cancer-causing agent in tobacco) are significantly lower in risk than cigarettes, and lower in risk than many other smokefree tobacco products.
   - The safest way to reduce all risks from tobacco is to never start using tobacco or to quit. Pharmaceutical nicotine products such as patches, gums and lozenges may be a lower risk alternative for those wishing to quit all tobacco use.

3. For a specific low nitrosamine product for which scientific substantiation has been provided:
   - All tobacco products have public health risks and are addictive.
   - However, this product contains significantly lower levels of toxins than compared to both cigarettes (highly toxic) and other smokefree tobacco products and significantly reduces the risk of cancer, and cardiovascular disease.*
   - The safest way to reduce all risks from tobacco is to never start using tobacco or to quit. Pharmaceutical nicotine products such as patches, gums and lozenges may be an even lower risk alternative for those wishing to quit all tobacco use.

* Note: Claims that specifically reference a disease should be assessed using higher standards of scientific evidence. As FDA does with food health claims, the allowance of the claim is based on the “publicly available scientific evidence (including evidence from well-designed studies conducted in a manner consistent with generally recognized scientific procedures and principles) that there is significant scientific agreement (SSA) among experts qualified by scientific training and experience to evaluate such claims that the claim is supported by such evidence. Under existing regulations, health claims are put in place through a petition process by which FDA reviews the science in support of and against the claim and determines whether to authorize the claim through notice-and-comment rulemaking.” Consumer Health Information for Better Nutrition Initiative, Final Report of the Task Force, U.S. Food and Drug Administration, July 10, 2003 (pp. 5-6).

4. Pharmaceutical nicotine smokefree products would be give greater leeway for making risk/health-based claims while still warning the public about the dangers of nicotine addiction. These products might have labeling along the following lines:
   - All tobacco and nicotine products carry public health risks and are addictive.
   - Cigarettes are the most significant and dangerous risk to health.
Many smokefree tobacco products while significantly lower in risk than cigarettes still carry risks.

Nicotine replacement therapies have lower risks and should be used as tobacco cessation efforts when a user of tobacco cannot quit.

Note: The above suggestions that might be considered for the labeling of smokefree products obviously do not preclude the need for the labeling and disclosure of other critical information, such as health warnings, disclosure of ingredients, flavorings, or other toxins, etc.

Marketing and Advertising

Also to be considered are issues related to how smokefree tobacco and nicotine products are marketed and promoted – issues that are routinely raised when considering whether these new lower-risk products will have benefits or unintended consequences.

Again, the FDA’s (and FTC’s) experiences in these areas should be tapped. Experts in marketing and advertising outside tobacco control and the tobacco and pharmaceutical industries should be utilized (This could include former experts from FDA, FTC, tobacco and pharmaceutical companies who understand the business and marketing end of the business and academics). What are the parameters and conditions under which these products can and could be marketed especially when compared with other highly toxic tobacco products on the market, such as cigarettes? Should there be differing marketing and advertising allowances for those products that are scientifically evaluated to be lowest is risk? What should those scientific standards be? These are issues that obviously cannot be answered in this paper but will need to be discussed and evaluated. Surveillance tools will be critical in assessing the impact of any marketing and advertising campaigns to determine how consumers view these products, as well as who is using them (see Surveillance below).

A Word about the First Amendment – Labeling and Marketing Restrictions

Much of the debate and discussion about the use of smokefree tobacco products entails issues related to how the products are and will be labeled, marketed and sold. These are issues routinely (and rightly) raised by the public health community. Often the first concern of the public health community is that we will risk going down the same road that we did when low-tar and low-nicotine cigarettes were developed and marketed. Those issues dealt with the public health community being “used” and seen as promoting and endorsing these products. Yet such concerns can be appropriately addressed, particularly if there is a third-party agency like the FDA in place and if there is a transparent and open discussion within the private sector. While some people are concerned about anything positive being said about any tobacco product, there is the flip side that would argue that the withholding of truthful and accurate information about products is equally misleading and deceptive and that such excessive restrictions could violate First Amendment commercial free speech protections. As discussions ensue on issues related to labeling, marketing and advertising, we need to be cognizant as to what is and is not feasible given the case law on the issue.

While some have advocated complete bans on all advertising and even restricting the dissemination of truthful, accurate and non-misleading information, I would suggest it is prudent to do some prospective thinking about these issues. Time and space does not permit going into too much depth about the regulation of commercial speech under the First Amendment, but it is useful to note some of the basic parameters under which such speech might be restricted and protected.

The four-pronged test that was laid out in the Central Hudson Gas case has provided the framework upon which decisions have been made about how commercial speech is protected under the First Amendment. First, it must be determined if the “the speech concerns lawful activity and is not misleading”, because a complete ban on commercial speech can only occur where the government is able to establish that the “the expression itself was flawed in some way either because it was deceptive or related to unlawful activity”. Second, if the speech is protected (not misleading or unlawful), then it must be determined whether “the asserted governmental interest
is substantial.” Third, if the government’s interest is substantial, the court must then determine “whether the regulation directly advances where government interest asserted.” Finally, and perhaps most critical in recent years, is “whether the regulation is not more extensive than necessary to serve that interest” and “whether the fit between the government’s ends and the means chosen to accomplish those ends is reasonable.” A series of decisions (Pearson I, Pearson II and Pearson III) involving FDAs attempt to restrict speech related to a health claim is worth considering as such cases may have some impact on what FDA can and cannot do in the smokefree tobacco and nicotine arena. One might argue that level of protections afforded smokefree tobacco and nicotine products could be substantially greater than more limited protections given to the more dangerous combustible products (cigarettes).

Surveillance

Surveillance provides the tools to be able to track and evaluate how consumers and the public perceive the risks and relative risks of smokefree products. Surveillance gives us the ability to track who is using these products, and how and why these products are being used. Are they cigarette smokers who want to give up smoking and are using these products as alternatives? Are they using these products (both tobacco and nicotine) in a regime of “dual use” – using smokefree tobacco and nicotine products when they cannot smoke, but still using cigarettes when they can?

Currently, the tobacco and nicotine surveillance system is severely lacking. If we do our homework up front in developing the best labeling and marketing schemes possible, then we will hopefully be able to validate the results of that work through an effective surveillance system. But we need to institute an effective surveillance system, and we must make surveillance a major priority. Again, the IOM report “Clearing the Smoke” lays out the issue and the focus of future discussions quite well:

One important issue is who would conduct surveillance on conventional tobacco products and PREPs. The types of data recommended above (see pages 183-185 of the report) would almost preclude all surveillance being conducted by any one agency. It is likely that the elements of surveillance will come from many sources, and a coordinated effort will be needed to plan, assimilate and interpret information for reasons of efficiency and standardization. As noted elsewhere, it will be important to include all conventional tobacco products, since they become one critical reference for health outcome studies, and to monitor changes in these products themselves. A part of the surveillance system would be to validate claims of product distribution, content and biological and clinical effects.

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

1. There is an urgent need for a national and comprehensive surveillance system that collects information on a broad range of elements necessary to understand the population impact of tobacco products and PREPs, including attitude, beliefs, product characteristics, product distribution and usage patterns, market messages such as harm reduction claims and advertising, the incidence of initiation and quitting and non-tobacco risk factors for tobacco related conditions. There should be surveillance of major smoking related diseases as well as construction of aggregate population health measures of the net impact of conventional products and PREPs.

2. The surveillance system should consist of mandatory, industry-furnished data on tobacco product constituents, additives and population distribution and sales.

3. Resources should be made available for a program of epidemiological studies that specifically address the health outcomes of PREPs and conventional tobacco products built on a robust surveillance system and using available basic and clinical scientific findings.

Agriculture

We have noted throughout this paper that what happens at the agricultural level impacts the final manufactured product. With the termination of the tobacco program there is no system by which we can track, monitor, and test tobacco whether here in the U.S. or abroad. If we are to be successful in making sure that the tobacco used in tobacco and nicotine smokefree products is what it claims to be, we will need to discuss what
authorities and mechanisms need to be restored to make accountability possible. We also need to discuss the role of the U.S. tobacco producer and what incentives and retraining will be necessary to produce the type of tobacco necessary for use in smokefree products; what kinds of new research needs to be undertaken and funded; how do producers interface more effectively with not only agencies like the USDA, but also with the FDA (assuming that agency gains regulatory authority over manufactured tobacco products); and what are the mechanisms by which tobacco producers are able to interface with the public health community, scientists, agronomists, industry and academic institutions?

Consumer Acceptability

Because of the recent efforts by RJR to market flavored cigarettes that would arguably have some appeal to children and adolescents, there has been a backlash against the idea of flavorings being used to make products more acceptable and palatable for consumers. This is an area of discussion where we need to consider sorting out what products should and should not either prohibit or discourage the use of such flavorings and which products should be allowed to use flavorings. Dr. Greg Connolly in his testimony to Congress in February (Senate HELP Committee) of this year suggested making Marlboro and other products taste like “lard.” Some have gone so far as to suggest that other bad tasting ingredients should be added to the products or that nothing should be allowed in a product that would make it taste better.

We might consider having different standards for different types of products. Products which have been deemed to have a “reasonable expectation” of reducing disease could be allowed to use FDA approved flavorings. Currently, although nicotine is an addictive drug, and the nicotine used in NRT products is derived from tobacco, these products are flavored to provide consumer acceptability and to satisfy taste preferences. Prohibiting the use of any flavors would make the product unacceptable to a consumer. These NRT products come in flavors such as orange, lime and fruit chill. Other noncombustible smokeless products also use flavors to provide consumer acceptability. These include peach, mint, apple and a host of other flavorings.

I believe that it would be useful to set flavoring allowances and standards based on the risks and relative risks of the product – which would not only provide incentives to industry (tobacco, pharmaceutical, biotech) to develop new science-based, lower-risk products, but would incentivize users of highly toxic combustible products to consider using more consumer acceptable alternatives, whether in the form of a low TSNA tobacco based product or an NRT.

Dr. Ken Warner probably laid it out best almost 10 years ago when he made the following statement during a discussion on the development of lower risk products:

*We must have consumer-acceptable alternatives to existing cigarettes if we’re going to continue this discussion at all. Consumer acceptability does not mean that we’re talking about a product that is as satisfying as cigarettes. We are extraordinarily unlikely to ever come up with a product that is as successful at delivering nicotine and satisfying consumers, however you want to define satisfying. What it means is that we’re going to come up with products that will be acceptable substitutes that people will find adequate when they balance the fact that they are reducing their risk significantly. So they are willing to give up a little bit of satisfaction in exchange for a great reduction in risk.*


We therefore cannot merely dismiss the issue of consumer acceptability as only a benefit to the cigarette manufacturer. We need to look at it from the broader more important perspective of what we are trying to do in moving users of tobacco and other nicotine products down the risk reduction continuum. Consumer acceptability discussions are not isolated or unique to tobacco, obviously, but cover all consumer products in the market place, including foods, drugs, automobiles, etc.
Incentives

Ten years ago, at the Georgetown Conference (that was referenced in Foreword of this paper), the issue of incentives for both tobacco and pharmaceutical companies to develop science–based, lower-risk products was raised and discussed.

The Institute of Medicine’s report “Clearing the Smoking” stated as one of its principal recommendations that:

Manufacturers should have the necessary incentives to develop and market products that reduce exposure to tobacco toxicants and that have a reasonable expectation of reducing the risk of tobacco related disease.

(“Clearing the Smoke,” Principal Recommendation # 2 Institute of Medicine, page 7)

The Presidential Tobacco Commission report issued in May 2001, and signed by major public health leaders and tobacco producers, called for:

Independent 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 Opportunities in Communities Dependent on Tobacco Production While Protecting Public Health, May 2001, pages 42-43)

The Campaign for Tobacco Free Kids (CTFK) and its partners noted that legislation (giving FDA authority over tobacco products) should:

“…encourage the development of products to reduce consumer health risks or serve as less harmful alternatives…”

(Excerpts from Critical Elements of Any Legislation to Grant FDA to Regulate Tobacco Products; the Campaign for Tobacco Free Kids, the American Cancer Society, the American Heart Association and the American Lung Association, 4/9/02.)

The current FDA tobacco legislation pending in Congress does little to provide incentives to the tobacco industry, the pharmaceutical industry, or even producers to develop science-based, lower-risk products – instead taking more draconian approaches to the regulation of such products (particularly tobacco-based) that raise the bar so high as to keep such products off the market as lower-risk alternatives to the highly toxic cigarette. If those advocating for FDA are serious about implementing the recommendations noted above, then they should actively support and work for the inclusion of language in legislation that will achieve those objectives.

Conclusion

There are many issues that must be addressed and discussed with respect to how smokefree tobacco and nicotine products should be produced, manufactured, distributed, sold, labeled and marketed – issues that will require involvement and participation from a range of interests. Yet there have been no substantive discussions that have taken place. There has only been an excessive preoccupation with the passage of FDA legislation without understanding how that legislation might be better crafted to meet a dynamically changing tobacco and nicotine environment. Instead of looking at the larger picture and considering creative new ideas and options, many in tobacco control have reverted to a “silo mentality” seeing only what they want to see and hearing only what they want to hear. The issues and processes set out in this chapter demand that if there are to be any real and substantive discussions on important issues (instead of rhetoric and public relations tactics), then it is time that we make a concerted effort to abandon those “silos” and find avenues by which we can engage (re-engage and expand engagement) in discussions in a transparent and neutral environment.
CHAPTER IV

THE NEED FOR AN INTEGRATED REGULATORY FRAMEWORK

The options for rationalizing nicotine regulation include making all nicotine product regulation the responsibility of an existing agency such as a food or drug regulation agency, or by coordination and rationalization of the activities of different agencies that regulate nicotine products. We conclude however, that meeting the challenges of implementing effective tobacco control and nicotine harm reduction policies both nationally and internationally, needs the creation of dedicated, autonomous, and fully resourced national (and where appropriate international) nicotine and tobacco regulatory authorities.


One of the challenges that must ultimately be resolved is a determination about what is the proper and most effective and workable regulatory framework that will ensure that tobacco leaf and tobacco products (and nicotine products) are adequately tested, labeled and marketed – and more importantly how do noncombustible products fit within that framework. We noted earlier that there seems to be a well accepted consensus that noncombustible products are significantly lower in risk than combusted cigarettes but there is a great struggle with respect to how to deal with this reality.

The agency most suited for such regulation on the manufactured side, is, as I argued in my longer white paper on harm reduction, the Food and Drug Administration (FDA). The agency most suited for dealing with the leaf side is the USDA. The number of public health organizations, manufacturers and growers who recognize the critical importance of these twin regulatory and intertwined functions has been steadily grow-
FDA, USDA – Coordinated Regulatory Authorities

1. FDA – Oversight of manufactured tobacco and nicotine products

There has been a “stand off” of sorts when it comes to deciding how and under what circumstances a noncombustible tobacco product should be labeled, marketed and sold. What can a manufacturer say about the risks and relative risks of the product? When does such information become a health claim? Should we be talking in terms of “relative risk claims” instead of health claims? What level of scientific evidence will be needed to evaluate the basis for accuracy and truthfulness of the claim? How do we determine if consumers are being misled by information or a claim? What kind of information should be provided to the consumer to allow decision making about the use of products to be a truly informed one? What are the First Amendment issues that need to be considered in restricting commercial speech? These are all questions that often get raised but have rarely to my knowledge ever seriously been discussed with respect tobacco.

I will not go into further detail about why the FDA is the appropriate agency for overseeing the regulation of tobacco. More details on that can be found in the paper “Tobacco and Tobacco Products at a Crossroads in the 21st Century”, Chapter VIII. This paper proposes that for the FDA to deal with an ever increasing number and variety of tobacco and nicotine products on the market, all tobacco and nicotine containing products should be brought under the same “regulatory umbrella” by establishing a Center at the FDA, entitled the “Center for Tobacco and Nicotine Products”. The legislative proposals reintroduced at the beginning of the 110th Congress have many gray areas that will treat some products as tobacco and others as drugs under what would be two very distinct categories. While that approach may have made some sense at one time, the rapidly changing tobacco and nicotine market suggests that we should be rethinking what the proper regulatory structure should be. Many public health experts have called for a more coherent and comprehensive tobacco and nicotine policy. (See for example, Toward a comprehensive long term nicotine policy, “Tobacco Control” 2005:14:161-165, N Gray, JE Hennigfield et al.; See also the discussions on pages 124-137 of the Special.


With all tobacco and nicotine products subject to a more cohesive integrated regulatory system, the FDA would be able to establish labeling and marketing restrictions and allowances based upon the risks and relatives risks of the products and their intended use. The model proposed below is based on the model used by the FDA for medical devices. As the Institute of Medicine noted in its report “Clearing the Smoke”:

The medical device provisions of the FDCA provide a model for this policy in that high risk products are subject to pre-market approval, while products of lesser risk are subject only to pre-market notification.

(Clearing the Smoke, Institute of Medicine, National Academy Press 2001 page 214)

Within this new “Center” at the FDA, it would make sense to establish three distinct but inter-related categories – one for combustible products, one for noncombustible products and one for cessation/therapeutic products.

To oversee and set regulatory requirements for each of these categories the FDA should establish a Tobacco and Nicotine Classification Panel (TNCP), composed of three sub-panels. The TNCP (and the three sub-panels) would be charged with overseeing a range of regulatory issues (manufacturing, sales, distribution, labeling, marketing, GMPs, performance standards, etc.) for all tobacco and nicotine products. The panel would be composed of “persons who are qualified by training and experience” to evaluate issues and to make recommendations for meaningful workable regulatory controls. Such persons might include experts in:

- Public Health
- Pharmacology
- Toxicology
- Addiction
- Biotechnology
- Advertising, marketing and promotion
- Production and agronomy
- Labeling
- Good manufacturing practices
The TNCP and the three sub-panels would be structured as follows:

Each of the three sub-panels would do the majority of work in looking at the science related to a particular category and the products in that category. Each panel would develop proposed labeling and marketing requirements and allowances for not only the category, but for individual products within each of those categories. The panels would have the authority to convene hearings and call witnesses to assist them in their duties. Classification panels would make recommendations to the larger panel, which would then, on behalf of or through the Commissioner (Secretary), publish proposed rules and issue final regulations governing the labeling and marketing of products. New products that do not meet “substantially equivalent” requirements would require pre-market review and approval. Any interested party would be allowed to petition the panel for reclassification of a product or even removal of a product not meeting regulatory specifications. In addition, each panel might also include non-voting members representing the interests of consumers, tobacco manufacturers, biotech, pharmaceuticals, producers, etc.

2. United States Department of Agriculture

In October 2004, as part of the tobacco buyout legislation (“Fair and Equitable Tobacco Reform Act of 2004”), Congress effectively repealed all aspects of the U.S. government’s involvement with tobacco production.

From the standpoint of ensuring the health, safety and quality of tobacco leaf produced in the U.S., but more importantly being imported into the U.S., this action represents a significant disservice to U.S. tobacco producers, the public health and responsible tobacco manufacturers.

As we move towards what will inevitably be oversight over the manufacture, sale, distribution, labeling and marketing of manufactured tobacco products by the FDA, it makes no sense to in effect deregulate the production system, leaving no accountability. FDA’s working with the USDA will be particularly important. As a JP Morgan prospectus noted last year, one of the ways that a lower-risk tobacco product can be produced is through the “alteration of the tobacco leaf and ingredients.”

In the 108th Congress, as part of the “buyout” deal and at the behest of special interests (in particular one of the major tobacco companies), Congress terminated the 1938 tobacco program. This in effect dismantled programs that not only protected and served the interests of U.S. growers but also benefited the public health. Instead of visionary thinking about tobacco and dealing with it effectively, Congress chose to move the issue backwards, once again leaving the fox to guard the hen house.

To effectively implement strategies for smokefree tobacco and nicotine products that encourage science-based modification of products, important authorities will need to be restored to the USDA that will not only help U.S. producers, but also protect public health. At a minimum, these should include:

- Monitoring, tracking and testing tobacco that is produced in the U.S. and overseas.
- Developing and implementing production standards that ensure the quality, health, safety and integrity of the tobacco leaf.
- Providing incentives to tobacco producers, tobacco manufacturers, biotech companies, agronomists, etc. to invest in and develop new technologies and new forms of leaf that are scientifically tested and evaluated to reduce harm associated with tobacco.
- Identifying research priorities that have a reasonable expectation of lowering risks associated with tobacco use. This is particularly important in the area of smoke free, noncombustible products.
Without the restoration and expansion of important functions, we will not be able to effectively track where the tobacco used in manufactured products comes from. We will not know the levels of toxins and pesticides in the leaf. We will not be able to ensure adequate quality controls over products which may claim to be lower in risk. The regulatory chain must include production, processing, manufacturing, sales, distribution, labeling and marketing of not just manufactured products but in the tobacco leaf itself.

As Congress considers the enactment of the FDA legislation it must also consider and implement parallel standards and requirements for tobacco leaf. It must give the U.S. tobacco farmer the tools and support they will need to produce the type of crop that public health and safety requirements will demand.

To that end, we should work toward the establishment of a system that would parallel that of the FDA, establishing a Center on tobacco at the USDA that would be charged with carrying out the objectives noted above. A Tobacco Production Advisory Committee or Panel could be established composed of experts in tobacco agricultural production, agronomy, toxicology, biotechnology, pharmacology, etc.

As with FDA, a small user fee could be assessed per pound of leaf to pay for a number of programs that would serve to benefit producers, manufacturers (broadly speaking) and the public health.

3. Other Agencies that Need to be Involved

In addition to the important dual, complementary functions that will need to be played by the Food and Drug Administration and the U.S. Department of Agriculture, there are other agencies that will have to be involved as part of a broader more comprehensive approach to ensuring proper oversight of tobacco and nicotine products. These include but are not limited to the Centers for Disease Control and Prevention, the Environmental Protection Agency, the Federal Trade Commission, the National Institutes of Health, the National Institute on Drug Abuse, the Bureau of Alcohol Tobacco and Firearms and even the Department of Homeland Security.

Conclusion

To effectively deal with the complex issues associated with the production, processing, manufacture, sale, distribution, labeling and marketing of tobacco and nicotine smokefree products (as well as all tobacco products), Congress must enact legislation that gives the FDA and the USDA the complementary authorities needed to effectively get the job done. At the FDA, such legislation must seek to bring tobacco and nicotine products under the same umbrella instead of treating them separately (as does the current legislation pending in Congress). FDA must also ensure that the manner in which this spectrum of products (from highly toxic cigarettes to significantly lower-risk tobacco and nicotine smokefree products) are regulated is based upon their risks and relative risks and that manufacturers of the lower-risk products are given 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.” Other agencies such as the CDC, FTC, EPA and NIH should also be integrated into the efforts of the FDA and USDA.

Note: For conclusions and recommendations suggesting restructuring and enhancing regulatory authorities over tobacco and nicotine products contained in the Royal College of Physicians Report, “Harm reduction in nicotine addiction; helping people who can’t quit,” See Appendix, Item 2.
CHAPTER V

THE NEED FOR A PROCESS FOR OPENLY DISCUSSING AND DEBATING ISSUES

“Diplomacy is the art of fishing tranquilly in troubled waters.”

– J. Christopher Herald, Bonaparte in Egypt, Ch.1, p.17)

“My personal experiences in tobacco control over the last 20 years have led me to the conclusion that without sacrificing one’s principles and objectives it is increasingly important to engage in substantive discussions with both friend and foe. Issues are neither black and white, nor are they static. Yet much of how the various stakeholders approach the tobacco issue are both antiquated and counterproductive for achieving the goal of reducing disease and death caused by tobacco use. Foes might actually turn out to be friends or at least collaborators. The inability of the various players to remove their blinders and to see opportunities is not dissimilar to criticisms about how we have managed the war in Iraq where dogmatic, entrenched thinking and an unwillingness to engage parties in finding solutions has created a polarization that increasingly hampers progress. Tobacco control at the national policymaking level is in need of an Iraq Study Group-like organization, one that focuses on problem solving. We need less of the attitude that “you’re either with us or against us.”

Why Over Reliance on the Legislative Process Falls Short

The American public has consistently given Congress and the Administration increasing low marks in their ability to get things done and to restore ethics and democratic principles to our governing bodies. The approval of Congress has consistently maintained ratings of less than 20%. When the Republicans retained control of Congress, Democrats were critical about how democratic processes were routinely circumvented, how legislation was brought to the floor having had no substantive hearings, and how non-germane amendments were slipped into legislation in the dead of night. Today, Republicans are accusing the Democrats of using similar practices. Although some in Congress keep promoting “change” and are having some success, I am not so sure that we can ever really reverse these patterns of behavior. I am convinced, however, that there are ways to better influence the decision-making process in such a way to bring ideas and solutions to Congress that have the chance of being seriously considered and enacted.

The issue of FDA regulation over tobacco products has been around for more than 20 years and yet, while progress has been made, the lack of understanding of the legislative proposals in Congress by many has created a polarization between parties unprecedented in past years. Part of the difficulties in getting this legislation enacted has been the process and the environment in which it has been considered. It has been pretty much an “inside the Beltway” effort with a few individuals and organizations dominating control over what is done. Accepting that the legislative process must be one of transparency, participatory government and compromise, we have fallen short.
During the entire two-year cycle of the 109th Congress and with the knowledge that the legislation “wasn’t perfect”, there were absolutely no discussions on how it might be improved or made fairer or more workable. No efforts were made to sit down and review the legislation. Prior to that, in the 108th Congress, there were no hearings on the legislation, nor any legislative markups.

It is now well accepted that the legislation was the product of negotiations between Philip Morris and the Campaign for Tobacco Free Kids. The legislation has remained pretty much in the same form as it was two Congresses ago, yet much has changed with respect to technologies, tobacco production issues, and the development of new lower-risk products that gained little consideration or attention at the introduction of the legislation or during the hearings or subsequent markup in the Senate.

The 110th Congress came in with great fanfare and great expectations about how that way of doing business was a “thing of the past” and that integrity and open government was going to be restored. But as with many issues this unfortunately has not been the case and once again special interests have been allowed to gain control and to influence outcomes at the expense of open government.

On several occasions (both in the 109th and 110th Congresses), the Alliance for Health Economic and Agriculture Development, in an effort to promote dialogue and transparency, suggested to Congress that they convene comprehensive hearings on tobacco with the purpose of hearing from all interested parties to establish national tobacco policy reforms. This included participation of the public health community, tobacco industry (broadly speaking), the pharmaceutical industry, producers, researchers, scientists, retailers, consumers and other experts. Holding hearings would have, not unlike the infamous hearings of the seven tobacco CEOs testifying before Congress, allowed for some tough questioning of the industry. It also would have provided an opportunity for smaller tobacco technology and biotech-oriented companies to express their views, as well as scientists and researchers doing important work on tobacco and nicotine to provide their views about the future.

I fully recognize that part of the problem is that the number of bills and activities in Congress has accelerated at light speed. Internet and email communications have increased the work load of members and staffers to the point where there is little time to deal with the complexities of issues – let alone provide time for creative thinking and consideration of new ideas. The need and ability to compete for public and media attention day-in and day-out puts demands on legislators and their staff unheard of just five-to-10 years ago. And the role of partisan politics seems to be constant with no break or let up. One only has to look at the day-to-day attention that is being given to the presidential race that began some two years before the election.

Even for those in the private sector there have only been a few who have taken (or who have had) the time to even read the legislation or to place the legislation in the context of what is occurring in the broader tobacco environment. Today’s rhetoric and strategies for enhancing FDA legislation are not so different than the same rhetoric and strategies used in the mid to late 1990s. For the most part organizations merely sign on as part of a coalition endorsing only the broad concepts of what is being proposed and taking no time to consider the details. Even staff in the various organizations who are taking a lead role seem unaware or unconcerned about the details. I have made it a point to not only read the legislation but to consider it in the context of how the stated goal of reducing disease and death caused by the use of tobacco products might be more effectively achieved. But I understand the limitations and challenges facing congressional staff and under these circumstances it is not surprising that consideration of the FDA legislation has taken more than 10 years.

Here are a few suggestions that Congress and those in the private should have considered to ensure greater transparency and to make a good bill better:

- On the date of introduction of S. 625 and HR 1108, the “parties” to the agreement should have openly and transparently acknowledged that the legislation was the result of an agreement between CTFK and PM.

- Rather than privately agreeing that the legislation could not be altered in any way, it would have been far more appropriate to indicate that while the parties to the agreement opposed changes, they recognized that the legislation should be carefully reviewed and that the views and legitimate concerns of parties affected by the legislation should be given the opportunity to be heard.
• The various Committees of jurisdiction in both the Senate and House should have committed to open and comprehensive hearings on the legislation. This includes the prestigious and powerful House Oversight and Government Reform Committee (The Chairman of that Committee and the Ranking Minority Member of that Committee are the primary sponsors of the House legislation). Rather than hearing only from those who endorsed the legislation, it is important to hear from researchers, scientists, growers, industry and consumers. Rubber stamping legislation is as much a disservice to public health as having the industry use its clout to kill it. Two wrongs do not make a right.

If, as the CTFK has stated (and to which I would probably concur), this is the most important health legislation that Congress can consider in the 110th Congress (statement released on the occasion of the Senate HELP Committee’s reporting of S. 625), then it only makes sense that a full and transparent consideration of the issues is given.

Why Dialogue and Engagement Outside of Congress Can and Will Help Shape Policy Decisions

There is no question that what happens to the tobacco issue in this country and globally will require meaningful, effective and workable policy changes. But there are far better and more effective, complementary ways of influencing policy decisions and outcomes that are made in an open, transparent and civil manner and to which time and focus can be dedicated (unlike the legislative process). The irony of what I am suggesting is that it has been the goal and battle cry of the 110th Congress to promote open dialogue transparency and cooperation for finding common ground. If Congress and the special interests working on the FDA/tobacco issue cannot bring themselves to achieving these goals then we need to find a way to help them do it “outside of the Beltway.”

The Southern Tobacco Communities Project

In the mid-1990s, a bold and creative idea surfaced. Through a grant from the Robert Wood Johnson Foundation a project called the Southern Tobacco Communities Project came into being. Started in Virginia, the project soon expanded to cover other tobacco producing states including Kentucky, North Carolina, South Carolina, Tennessee and Georgia. The stated purpose of project was:

1. Understanding and documenting how cultural, political and economic factors affect tobacco growing communities;
2. Identifying and evaluating new economic opportunities and strategies in tobacco communities;
3. Establishing relationships and seeking creative ideas and advocates for federal state, and local policy change;
4. Informing and enhancing the public debate on tobacco and economic issues.

As was noted by Dr. Frank Dukes, Director of the Institute for Environmental Negotiation, the above purposes were encapsulated publicly through invitations to participate by advocating four relational goals. These goals:

“...as articulated in the STCP promotional literature, declared that participants were working to create constructive relationships among tobacco producers, health advocates and others concerned with changes facing these families and communities, to enable them to:

1. Replace inflammatory rhetoric, stereotyping and automatic enmity in favor of civil problem solving dialogue;
2. Understand each others’ needs, values and concerns;
3. Identify areas of common ground and even interdependence, while acknowledging areas of difference; and,
4. Work together to create realistic, sensible and sustainable options for communities and families facing pressures associated with transition.”

For decades, the public health community had viewed the tobacco growers as an integrated part of the tobacco manufac-
The growing industry and considered them the enemy. The growers, heavily controlled and influenced by the tobacco manufacturers, were told that the public health community was intent on destroying their way of life. As an example, the industry, as part of its efforts to defeat FDA tobacco legislation, initiated a major public relations campaign in the tobacco producing states that used growers to send a strong message to Congress in opposition to FDA oversight. The campaign under the banner “Keep FDA Off The Farm” was bought and paid for by the manufactures who realized that grower views would resonate with policymakers on Capitol Hill. It was only through the face-to-face dialogue that growers would come to realize what the real intent of FDA oversight was and how they could actually benefit from it.

The dialogue that was conducted resulted in a greater understanding of the goals, objectives, opportunities and barriers that both the public health community and the tobacco producing communities faced.

Congress and the political environment surrounding tobacco had made it impossible for issues to be considered in an open manner. Polarization and the “us against them” attitude remained entrenched on Capitol Hill. Not unlike the debates and discussions surrounding FDA and the broader need for national tobacco policy reforms today. Congress at that time seemed to be at least two years behind where the dialogue and discussions had taken grower and health groups under the auspices of the STCP.

The diligent work of many who put their professional integrity and careers on the line and who checked their organizational and individual egos at the door made it possible for a historic set of Core Principles to be released at a press conference in 1998. Those principles included agreement that served the interests of both the public health community and the tobacco producing communities and would be endorsed by more than 150 organizations. They would serve as the basis for the establishment of the presidential tobacco commission in 1999 and with the issuance of a report in 2001. Time and space does not allow me to elaborate on the many meetings and discussions that took place as part of the STCP and which would lead to both the Core Principles Statement and the presidential commission report, and I suggest that for those of you who are interested in taking more time to recognize how significant this work was, consider reading, “From Enemies to Allies: The Unlikely Collaboration Between the Tobacco Farm and Public Health Communities”, E. Frank Dukes, Ph.D., Director, Institute for Environmental Negotiation, University of Virginia.

I will say that while we all started out with great formality and trepidation, what eventually occurred was a willingness on the part of all the participants to openly talk with each other not only through structured meetings but increasingly in one-on-one conversations as well. We learned that having a dialogue and discussion did not mean having to agree on everything or having to give away essential positions. The issue was not whether we agreed with everything each other said but whether there was sufficient trust to make these discussions productive, if not essential, to moving forward toward finding common ground and potential avenues for resolution where we all thought none existed.

We learned that discussion and dialogue can take place in a neutral forum, away from pressures of legislative negotiations that often fall victim to politics and time constraints. As one grower who had been a part of the process and who would also go on to serve on the presidential commission noted: “The best thing we could have done was to have these discussions outside of the beltway and away from Washington.”

The Core Principles Statement led to the establishment of a presidential tobacco commission charged with advising the president on “changes occurring in the tobacco farming economy and recommend such measures as may be necessary to improve economic opportunity and development in communities that are dependent on tobacco products while protecting consumers, particularly children, from hazards associated with tobacco” (Executive Order 13168). The commission report provided a blueprint for successfully achieving those goals.

Membership included both tobacco producers and public health representatives. The commission’s work included a deliberative open process with several hearings being held to gather information and views related to the commission’s presidential charge. As the commission noted:

We emphasize that the Commission, a collection of growers, representatives of public health organizations and economic development experts found much common ground in the seemingly incompatible goals of assisting tobacco farmers and safeguarding public health. The
starting point goes back more than 15 years when tobacco growers and public health leaders first gathered in the mid-1980s for face-to-face discussions about the plight of tobacco farmers and their communities and the need to protect public health.

(Tobacco at a Crossroad: A Call for Action, May 2001, page ES4)

It is somewhat of a disappointment that many of the recommendations of the commission (both in substance and philosophically) have been ignored and in many ways forgotten as the FDA issue on Capitol Hill became tunnel-vision and as behind the scenes discussions replaced transparent and open dialogue. The current legislation, rather than seeking to accomplish many of the agreed upon goals and intentions in the report, comes up short in many areas, including “promoting the introduction of less harmful products.”

Just as the opportunity and need to enter into dialogue between growers and public health organizations was able to move forward with positive and productive outcomes, so it now seems that there is an opportunity to enter into discussions about smokefree tobacco and nicotine products – a process that must take place and be independent of the politics of Washington. Just as there was great uneasiness on the part of many of the players when the dialogues and discussions started through the STCP, so too are there apprehensions about talking about smokefree tobacco and nicotine issues.

Yet I believe that there is clearly enough of a consensus to make such discussions and dialogue productive. Whether to engage the so-called “tobacco industry” is a particularly challenging issue, one that, as with so many issues in tobacco control, is unfortunately looked at in terms of black and white (good and evil). I would suggest that it is not so easy to define who the tobacco industry is. Is it what we in public health community came to call “Big Tobacco”? Or is it any business or individual who deals with tobacco and the tobacco business in any shape or form? Does it include the hundreds of small, very diverse companies scattered around the globe? Does it include the farmers, processors and leaf dealers? Does it include retailers and wholesalers of both tobacco leaf and manufactured products? Does it include biotech companies and other technology companies that are working on developing new, very different tobacco and nicotine-based products than what we see on the market today? Does it include those who are developing GMO tobacco for use in a variety of different products including pharmaceutical and industrial enzymes? In terms of what I see needing to happen in fostering dialogue in a neutral setting, it should include all of these.

We need to be asking ourselves broader questions about the who, what, when, why, how and where such dialogue might take place. These questions should not only pertain to the industry, but also to the broad range of interests and experts within the tobacco control community, the public health community and scientific community where there are very diverse views.

The situation in tobacco control is not so different than some of the challenging issues and questions that the U.S. faces on issues related to Iraq, global terrorism and the role of the U.S. as part of the international community. The current Administration not so long ago referred to Iran, North Korea and Iraq as the “Axis of Evil,” taking a hard line position that diplomacy could not play a role in dealing with them. Yet, today “diplomacy” is playing an increasingly important role as another tool for fostering change. Hard line positions need not be abandoned merely because other avenues are also being used.

In the final chapter, we will lay out a blueprint for changing the way we approach engagement in an area where there may be great potential for helping shape the dynamically and rapidly changing tobacco and nicotine environment.
Conclusion

In our efforts to find ways to regulate the tobacco industry and to force changes on them to modify their products, we have tended to over-rely on the legislative process as the only means for accomplishing those goals. Legislation, and in particular the enactment of fair but effective legislation that would give the FDA oversight authorities, is and will be essential. But because of our over-reliance on the legislative route as the only route, we have suffered from being able to have meaningful dialogue about what the goals of the legislation should be and the best means of accomplishing those goals. Experiences of engagement such as those that took place between tobacco producers and the public health community are indicative of what can be accomplished and how engagement can in fact assist Congress in making better policy decisions. There is an urgent need for engagement to discuss how smokefree tobacco and nicotine products can be used as part of overall strategies to reduce disease and death caused by the use of tobacco (and most importantly highly toxic cigarettes). We cannot expect that Congress will or has the time to consider the intricacies and complexities of these issues, and we cannot and should not rely on those doing advocacy work to take the time either. It is necessary to use our experience and the experience of others to develop mechanisms by which engagement can take place in a neutral and transparent fashion that will influence policymakers and hopefully change the behaviors of stakeholders in a way that will promote public health.
A ROADMAP FOR DIALOGUE AND DISCUSSION OF SMOKE-FREE TOBACCO AND NICOTINE ISSUES

“At first people refuse to believe that a strange new thing can be done, then they begin to hope it can be done, then they see it can be done—then it is done and all the world wonders why it was not done centuries ago”

— “A Secret Garden”, Frances Hodgson Burnett

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

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

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

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

Center for the Evaluation of Smokefree Tobacco and Nicotine Products

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

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

Among other things the Center would:

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

The Center should be composed of a Board of Directors which is recognized in various fields related to science and technology, public health, agriculture, harm reduction, business, conflict resolution, etc. No member of the Board should serve on the Board as a representative of any corporation, public health organization or entity that has a vested interest in the outcomes of the Center’s work. The Center will not be a membership organization but will remain independent and serve
to represent a process for debate and dialogue and making recommendations and providing guidance on issues concerning smokefree tobacco and nicotine products. In addition, the Center would seek to retain the necessary staff and funding to carry out its mandate.

### Funding

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

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

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

- First, funding should and could be accepted from any of the above entities (and others).
- Second, funding must be made as unrestricted contributions.
- Third, there must be no intention or effort on the part of the funder to try to influence the Center’s setting of its goals, objectives or priorities. Any funder who attempts to influence the Center in this area should have its funding returned immediately.
- Fourth, funding cannot be earmarked for a specific topic or project at the request of the funder. Those decisions must be made by the Center through its Board, Executive Director, Staff, and/or independent advisors.
- Fifth, funding cannot be used as a means to gain access to or as an entitlement for participation in the Center’s activities. Participation in roundtable discussions, meetings, etc. is a decision that must remain the prerogative of the Center.
- If possible, funding should go into an account or trust in which all funding is co-mingled and becomes an unrestricted account available to the Center to carry out its mandate.

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

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

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

> It is essential that adequate funding is secured in order to establish and maintain laboratories that conduct the independent and credible research and testing for tobacco product regulation. There is little question that simply
Other Activities and Avenues To Enhance Dialogue and Transparency on Important Tobacco Issues

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

I. “Smokefree” Tobacco and Nicotine Companies

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

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

• Second, commit to fair but effective oversight of tobacco agriculture production, including the monitoring, tracking and testing of all tobacco leaf in the U.S. and abroad. Accept that the leaf used in manufactured products (both tobacco and nicotine based products) would need to meet specific standards for quality, health and safety.
Third, commit to developing a mission statement with core goals and objectives that recognize the development and responsible marketing of smokefree products as key elements for reducing disease and death caused by tobacco (in particular cigarettes).

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

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

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

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

2. The Scientific, Public Health and Tobacco Control Communities

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

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

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

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

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

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

3. Tobacco Cooperatives

For many years, the tobacco cooperatives played the primary role of representing the interests of tobacco growers. Following the tobacco “buyout”, the tobacco cooperatives are in a process of reassessing the roles they will play in the post-buyout environment. This process, like much of the rest of the tobacco
environment, is one of constant change, uncertainties and opportunities. There are several things that the cooperatives might want to consider that will serve their interests in the domestic and global arenas:

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

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

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

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

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

4. The Role of Tobacco Commissions/Foundations etc.

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

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

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

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

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

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

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

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

**Next Steps**

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

1. Through the auspices of the Alliance on Health Economic and Agriculture Development (AHEAD), which grew out of the Southern Tobacco Communities Project, establish a working group of 6-10 individuals who:
   - Have demonstrated a sincere commitment towards the development of new strategies and policies related to the use of noncombustible tobacco and nicotine products for purposes of reducing risks associated with the use of
highly toxic combustible cigarettes.

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

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

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

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

1. The report of the Royal College of Physicians on harm reduction concluded that:

The epidemiology of tobacco use in Sweden suggests that if the public is offered substantially less harmful smokeless tobacco product along with access to accurate information on relative risks, a substantial proportion can switch to the less harmful product. (The risk profile of smokeless tobaccos, page 161)

The report then went on to make the following additional conclusions:

- Smokeless tobacco is not a single product but rather a summary term for a range of different tobacco products which deliver nicotine without combustion.

- Smokeless tobacco products differ substantially in their risk profile on approximate relation to the content of toxins in tobacco.

- In some parts of the world (particularly Asia) smokeless tobacco is commonly mixed with other products that are themselves harmful.

- On toxicological and epidemiological grounds, some of the Swedish smokeless products appear to be associated with the lowest potential to harm health.

- These Swedish smokeless products appear to increase the risk of pancreatic cancer and possibly cardiovascular disease, particularly myocardial infarction.

- Some smokeless tobacco also increase the risk of oral cancer, but if true of Swedish smokeless tobacco, the magnitude of this effect is small.

- All of the above hazards are of lower magnitude than those associated with cigarette smoking.

- Smokeless tobacco products have little or no effect on the risk of chronic obstructive pulmonary disease or lung cancer.

- Therefore in relation to cigarette smoking, the hazard profile of the lower risk smokeless products is very favorable.

- Smokeless tobacco use by pregnant woman is harmful to the unborn fetus, but the hazard of smokeless use relative to maternal smoking is not clearly established.

- In Sweden, the available low-harm smokeless products have been shown to be an acceptable substitute to many smokers, while ‘gateway’ progression from smokeless to smoking is relatively uncommon.

- Smokeless tobacco, there, has potential application as a lower hazard alternative to cigarette smoking.

- The applicability of smokeless tobacco as a substitute for cigarette smoking if made available to populations with no tradition of smokeless use is not known.

With respect to medicinal nicotine the Royal College of Physicians report concluded (page 126):

- Extensive experience with nicotine therapy in clinical trial and observational study settings demonstrates that medicinal nicotine is a very safe drug.

- Adverse effects are particularly local and specific to the mode of delivery used.

- NRT does not appear to provoke acute cardiovascular events, even in people with pre-existing cardiovascular disease.

- There is no direct evidence that NRT therapy is carcinogenic or influences the risk of other common smoking-related diseases in humans.

- Evidence on the safety of NRT during pregnancy is limited, but suggests that NRT does not increase the risk of major developmental anomalies or reduce birth weight. However, NRT may increase the risk of minor musculoskeletal anomalies. Further evidence on these effects is needed.
Evidence on the safety of long-term use of NRT is lacking but there are no grounds to suspect appreciable long-term adverse effects on health.

In any circumstance, the use of NRT is many orders of magnitude safer than smoking.

These findings both reflect and confirm why a new approach to dealing with these and other “smokefree” tobacco and nicotine products is urgently needed. There are significant opportunities from a public health standpoint, but where we go and how we get there must be done with greater dialogue and transparency involving a spectrum of interests and experts.

There clearly seems to be growing support for further discussions of the regulatory framework needed to ensure a more level playing field for tobacco and nicotine products (consistent with the recommendations of this paper). The Royal College of Physicians in their October report noted (pages 185-186):

- Nicotine product regulation has developed in a largely reactive and piecemeal fashion over the years.
- Smoked tobacco products remained free from regulation for many years, and are now subject to minimal controls on content, delivery and safety.
- Some smokeless products are regulated very strictly (that is, they are prohibited) whilst others are subject to even less regulation than cigarettes.
- Medicinal nicotine products are regulated very strictly, medicines.
- The lax regulation of most tobacco products affords considerable market freedom for tobacco companies to innovate and develop their products.
- The tight regulation of medicinal nicotine imposes very strict restrictions on new product development.
- Some newly launched tobacco products, including PREPS, seem to lie completely outside of the current regulation.