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 re4duction 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.*
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> ("The Less Harmful Cigarette: A Controversial Issue. A Tribute to Ernst L. Wynder", D Hoffman, I Hoffman, K El-Bayoumy, Chemical Research in Toxicology (published by the American Chemical Society), Volume 14, Number 7, July 2001, page 784.

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

A 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 TSNAs in tobacco, including NNK are byproducts of the curing process involved with turning tobacco leaves into products like cigarettes, chew and snuff. He also acknowledged that there are many other toxins found in cigarettes that are not found in noncombustible smokeless products. But he argues that even the low TSNA products still contain nitrosamines. The questions that need to be asked are: what is the threshold at which one could conclude that TNSA levels do not present a health risk and, if there is a risk, how does that risk compare to other smokeless products, cigarettes and NRT products?

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 TSNAs. The emergence of these new products with relatively low levels of carcinogenic TSNAs 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 TSNAs. 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 consis tent within the framework of EU law.*
*b) It would create public health benefits through smok ing cessation and smoking substitution.*
*c) Its gives smokers an extra strategy for controlling their risks and eliminating ETS risk, and thereby re spects their consumer and human rights.*
*d) It would apply toxicity controls to the currently unreg ulated chewing products such as gutka and paan avail able 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 competi tion from tobacco products that do far less harm.*

*("European Union policy on smokeless tobacco- a statement in favour of evidenced-based regulation for public health," C Bates, K Fagerstromn, M Jarvis, M Kuntz, A McNeil, L Ramstrom, February 2003*

## 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-terms 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:
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> "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)

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> 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 sus pected 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 | Limit | Content 2006 | Component | Limit | Content 2006 |
|---|---|---|---|---|---|
| Nitrite (mg/kg) | 3.5 | 1.0 (<0.5 - 1.7) | Cadmium (mg/kg) | 0.5 | 0.2 (0.1 - 0.3) |
| TSNA (mg/kg) | 5 | 0.8 (0.5 - 1.1) | Lead (mg/kg) | 1.0 | 0.1 (0.03 - 0.3) |
| NDMA (µg/kg) | 5 | 0.5 (<0.5 - 0.7) | Arsenic (mg/kg) | 0.25 | 0.06 (<0.03 - 0.13) |
| BaP (µg/kg) | 10 | 0.6 (<0.5 - 1.1) | Nickel (mg/kg) | 2.25 | 0.6 (0.2 - 0.9) |
| Pesticides | According to the Swedish Matchpesti-cide policy | | Chromium (mg/kg) | 1.5 | 0.4 (0.07 - 0.7) |

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 **Gothia**Tek 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 **Gothia**Tek 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 **Gothia**Tek standards shall be selected so that the limits for undesired components in each specific product are satisfied. Leaf tobacco for Swedish snus by **Gothia**Tek must not contain gene modified tobacco.
- All additives in Swedish Snus by **Gothia**Tek 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 **Gothia**Tek shall be approved for food packaging.

### Processkrav

- Swedish Snus by **Gothia**Tek shall be heat treated, in a way which effective to kill the natural microbal 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 **Gothia**Tek 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. Cleanness 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 **Gothia**Tek.

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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 tunneled-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:*
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> - *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.*
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> *(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.)

| TOBACCO AND NICOTINE RISK | |
|---|---|
| **Type of Product** | **Risk** |
| Combustible (cigarettes, cigars, pipe, little cigars) | HIGH |
| Noncombustible (smokefree tobacco and nicotine products used for recreational use) | MODERATE/LOW |
| Nicotine products used for cessation/ therapeutic use | LOW/VERY LOW |

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.*

(Consumer Health Information for Better Nutrition Initiative, Task Force, Final Report, US Food and Drug Administration, July 10, 2003, pages 4-5.)

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?

(*Consumer Health Information for Better Nutrition Initiative, Task Force Final Report*, July 10, 2003, pages 8-9)

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 products such as nicotine 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 FDA's 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 under stand the population impact of tobacco products and PREPs, including attitude, beliefs, product charac teristics, product distribution and usage patterns, market messages such as harm reduction claims and ad vertising, 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 back lash 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 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 risk significantly. So they are willing to give up a little bit of satisfaction in exchange for a great reduction in risk.*
>
> (The Conference on Tobacco Dependence: Innovative Regulatory Approaches to Reduce Disease and Death, Food Drug and Law Journal, Volume 52 Supplement(1998), page 129)

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.