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 along side rigorously applied tobacco control policies.*

*Adding harm reduction to tobacco control,*
*Editorial, The Lancet,*
*(Vol. 1370, 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 relatives 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 TSNAs 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 to bacco-derived nicotine. They are being sold primarily as al ternatives to cigarettes (which are highly toxic in compari son). 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 sig nificantly reduce the levels of TSNAs, 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, Ettan, 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: www.cancercontrol.cancer.gov/tcrb/stfact_sheet_combined10-23-02.pdf

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 nitrosomines 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.