MODIFIED RISK TOBACCO PRODUCT MARKETING DECISIONS

Presented by
David Ashley, Ph.D.
Rear Admiral (retired), US Public Health Service
Director, Office of Science, CTP, FDA

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• Statutory Framework for Modified Risk Tobacco Products (MRTP)

• How was this framework applied to the Swedish Match MRTPA

• MRTPA Decisions
STATUTORY FRAMEWORK FOR MODIFIED RISK TOBACCO PRODUCTS
Tobacco products sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products

- Label, labeling or advertising represents that:
  - The product is less harmful or presents a lower risk of tobacco-related disease
  - The product or its smoke contains a reduced level of, presents a reduced exposure to, or does not contain/is free of a substance
The FD&C Act requires FDA to determine if a proposed MRTP, as it is actually used by consumers, will

(1) significantly reduce harm and the risk of tobacco-related disease to individuals and

(2) benefit the health of the population as a whole
The FD&C Act allows FDA to issue an order if:

- appropriate to promote the public health;
- the label, labeling, and advertising is limited to a claim that
  - the product does not contain or is free of a substance or
  - contains a reduced level or presents a reduced exposure
- scientific evidence is not available without conducting long-term epidemiological studies; and
- scientific evidence that is available demonstrates that a reduction in morbidity or mortality is reasonably likely.
The evaluation of whether the applicant has adequately demonstrated comes down to four questions:

1. Is there adequate scientific substantiation of the proposed modified risk information?
2. Will the MRTP significantly reduce the harm and risk of tobacco-related disease to individual tobacco users?
3. How do consumer’s perception, understanding, and comprehension of the modified risk information impact potential benefits and harms?
4. What are the potential benefits and harms to the health of the population as a whole?
• MRTP process is product-specific.
• Evaluations are in the context of a specific product and specific modified risk claim
• Form and wording of the claim have a critical impact on the final decision.
• Is not intended by the statute to make decisions on a class of products.
HOW WAS THIS FRAMEWORK APPLIED TO THE SWEDISH MATCH MRTPA?
The SMNA MRTPAs contained information addressing each of the areas identified by FDA including evidence from various types of scientific studies:

- Product analyses (chemistry, engineering, microbiology)
- Toxicological assessments
- Pharmacokinetic studies
- Clinical trials (for impact on cessation)
- Epidemiological studies (health and behavior)
- Consumer perception and comprehension studies
- Statistical modeling
- Plans for postmarket surveillance and studies
Like products and users in Norway and Sweden:

- Conform to the same standards
- Pose the same level of exposures of harmful constituents to users
- Users of these products will experience the same health outcomes

Have relatively low levels of harmful constituents, particularly TSNAs

In Sweden, smoking rates among men and rates of tobacco-related disease and death are lower

Lower smoking rates are due to a “grassroots” movement among Swedes
SMNA requested in their MRTP Application for warnings to be removed, revised and maintained.

**Warnings to be removed:**
- WARNING: This product can cause gum disease and tooth loss
- WARNING: This product can cause mouth cancer

**Revision to the warning:**
- WARNING: This product is a not a safe alternative to cigarettes
- WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes

**Maintain the required warning:**
- WARNING: Smokeless tobacco is addictive
• Omission of this warning indicates that the eight General Snus products cannot cause gum disease or tooth loss.

• Use of these products increases the risks of certain outcomes classified as gum disease or tooth loss, or precursors to gum disease and tooth loss.

• In conclusion, the eight products can cause gum disease and tooth loss.

• The evidence does not substantiate the proposed implied modified risk claim.
FDA FINDING ON MOUTH CANCER

- Omission of this warning indicates that the eight General Snus products cannot cause mouth cancer.
- Lack of a consistent association may be due to the lack of precision in the estimates of risk, the variability in the definition of oral cancer, and other study limitations.
  - Some studies have found no association
  - The most recently published study observed a large and statistically significant association.
- Products contain known carcinogens and no biologically plausible rationale for why these products do not pose an increased risk of oral cancer.
- Available scientific evidence supports the statement that smokeless tobacco products in general and these products in particular can cause mouth cancer.
- The evidence does not adequately substantiate the proposed implied modified risk claim.
• The eight General Snus products can expose users to levels of constituents at levels lower than smoking.
• Evidence supports that exclusive use of the eight General Snus products as compared to smoking cigarettes may significantly reduce harm and the risk of certain tobacco-related disease to individual tobacco users.
• The evidence partially substantiates the proposed implied modified risk claim.
FDA concluded that SMNA did not demonstrate that removing the gum disease and tooth loss warning from the products will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole.

This request was denied.
FDA concluded that there was not sufficient evidence in regards to removing the mouth cancer and revising the “not a safe alternative” warning.

However, the applications could be amended in several ways

- changing the proposed claims
- supplementing the evidence, and
- conducting new studies

which could provide sufficient evidence to support issuance of modified risk orders relating to mouth cancer and health risks compared to cigarettes for these tobacco products.
While the FDA isn’t authorizing these specific products as MRTPs at this time, the lessons learned through these first applications provide key insights for a potential path forward through an amended application and for others considering submitting an applications.

The FDA is committed to permitting MRTP claims for any company which submits adequate data demonstrating that certain tobacco products should be marketed with direct or indirect claims about reduced harm or risk.