Smokeless Tobacco and Modified Risk

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Regulatory Oversight
Smokeless Tobacco and Modified Risk

RAIS agrees (1) smokeless tobacco presents substantially lower risks to health than cigarettes; and, (2) informing consumers on relative risks would have “net” population health benefit

- RAIS’s Citizen Petition (July 2011) requested rulemaking to modify “not a safe alternative” warning for all smokeless products
- 2nd Supplement to Citizen Petition (March 2013) summarized U.S. and Swedish studies on smokeless tobacco use behaviors, and presented modeling evidence of “net” population health benefit
Deficiencies in SMNA’s MRTPAs

Methodological flaws in “consumer understanding/perceptions” and “likelihoods of use” studies raise questions on whether Swedish Match met evidence threshold (per Draft Guidance)

- experimental design insufficient to examine impact of all proposed warning label changes
- critical questions flawed in terms of wording and/or response scale, and thus provide data that is not informative

In addition, flawed methodologies result in data that likely detract from evidence of “net” population health benefit
Modeling Population Health

RAIS fully supports use of statistical modeling to predict likely effects of use behavior changes on population health

- modeling more informative when based on empirical evidence (e.g., “likelihoods of use” projections), with hypothetical inputs used for sensitivity analyses

However, Swedish Match’s use of statistical modeling is lacking in at least two important areas

- fails to examine “net” population effect, with no modeling of primary drivers of population health (i.e., gateway and switching)
- includes unsupported/unrealistic use behaviors as inputs, which may lead to conclusion that requested change to warning label may not have “net” population health benefit
Concluding Remarks

To promote greater public understanding of the evidence-based risks associated with smokeless tobacco use, current warning label(s) should be revised for all smokeless tobacco products.

Flawed studies and analyses presented in Swedish Match’s MRTPA’s should not be used to support a conclusion that changes to the current warning label(s) would not benefit population health.
Questions?