

SMOKELESS TOBACCO IN THE CONTEXT OF TOBACCO HARM REDUCTION

U.S. Smokeless Tobacco Company
Presentation to
LSRO Reduced Risk Review Project
Core Committee Meeting
July 14, 2005

Introduction

- Presentation responds to LSRO request for input regarding:
 - “current approaches for evaluating potential reduced-risk tobacco products”
 - possible “gateway effects” from smokeless tobacco use to cigarette smoking
- Matters are addressed in more detail in USSTC’s July 1, 2005 written submission to LSRO

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- Starting point for LSRO Reduced Risk Review Project
 - IOM Report (2001)
- Since IOM Report, much has been published about smokeless tobacco as a potential reduced-risk tobacco product
- Literature suggests additional research and testing regarding smokeless tobacco is not necessary

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- The reason: there is substantial support in the published literature that smokeless tobacco is a reduced-risk tobacco product
 - Taken as a whole, literature reflects general acceptance that smokeless tobacco use involves significantly less risk than cigarette smoking
 - Indeed, several groups of researchers have concluded some smokeless tobacco products involve at least 90% less risk than cigarette smoking

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- Issue of smokeless tobacco as a reduced-risk tobacco product has evolved
 - From whether smokeless tobacco involves significantly less risk than cigarette smoking
 - To whether cigarette smokers, who do not quit and do not use medicinal nicotine products, should be encouraged to switch completely to smokeless tobacco

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- Points of view
 - Those who believe a significant public health benefit should be achieved if cigarette smokers are encouraged to switch completely to smokeless tobacco
 - Those who believe that the evidence is insufficient

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- Analyses supporting a significant public health benefit
 - Rodu (1995)
 - 400,000 lives would be saved each year in the U.S. if all cigarette smokers used smokeless tobacco instead

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- Analyses supporting a significant public health benefit
 - Ault (2004)
 - If the smokeless tobacco usage rate in the U.S. could be brought up to that of Sweden, approximately 9.4 million cigarette smokers would begin using smokeless tobacco, and approximately 2.16 million "life years" and \$3 billion in potential health care costs would be saved per year

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- Proponents report on the Swedish Experience as follows:
 - Swedish males have the highest rate of smokeless tobacco use and the lowest rate of cigarette smoking of any Western country
 - Daily use of smokeless tobacco by Swedish males now exceeds that of cigarettes

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- Proponents report on the Swedish Experience as follows:
- 2003 European Policy Statement
"An important explanation for the low rates of tobacco related mortality in Sweden is the contribution made by the high use of smokeless tobacco."

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- The other point of view
 - One concern is the "gateway" hypothesis
 - Smokeless tobacco may cause some people to take up cigarette smoking when they would not otherwise have done so

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- The other point of view
 - Issues for discussion:
 - The hypothesis of a causal "gateway" in areas other than smokeless tobacco
 - The "gateway" hypothesis - smokeless tobacco

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- "Gateway" causality hypothesis in general
 - Multi-disciplinary group of scientists and researchers convened a conference in 1998 to examine the validity of the "gateway" hypothesis as it relates to substance use
 - The results were published in a 2002 book edited by Dr. Kandel, Professor of Public Health and Psychiatry at Columbia University
 - Kandel et al. concluded that "[t]he research reported in this volume and that reviewed in the various chapters provide no support for the proposition about causality."

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- "Gateway" hypothesis - smokeless tobacco
 - Researchers have reported that there is no consistent pattern or sequence of use of tobacco products among adolescents or adults.

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- "Gateway" hypothesis - smokeless tobacco
 - As an example, the 1994 Surgeon General Report stated that:
 - "Of those male seniors who had tried both [smokeless tobacco and cigarettes], 37 percent had tried cigarettes before smokeless tobacco, 24 percent had tried smokeless tobacco before cigarettes and 40 percent had first tried both at about the same time."

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- "Gateway" hypothesis - smokeless tobacco
 - Another example, Haddock et al. (2001), in reviewing the literature noted:
 - "Unfortunately, the evidence is mixed for SLT [smokeless tobacco] preceding smoking in polyusers."

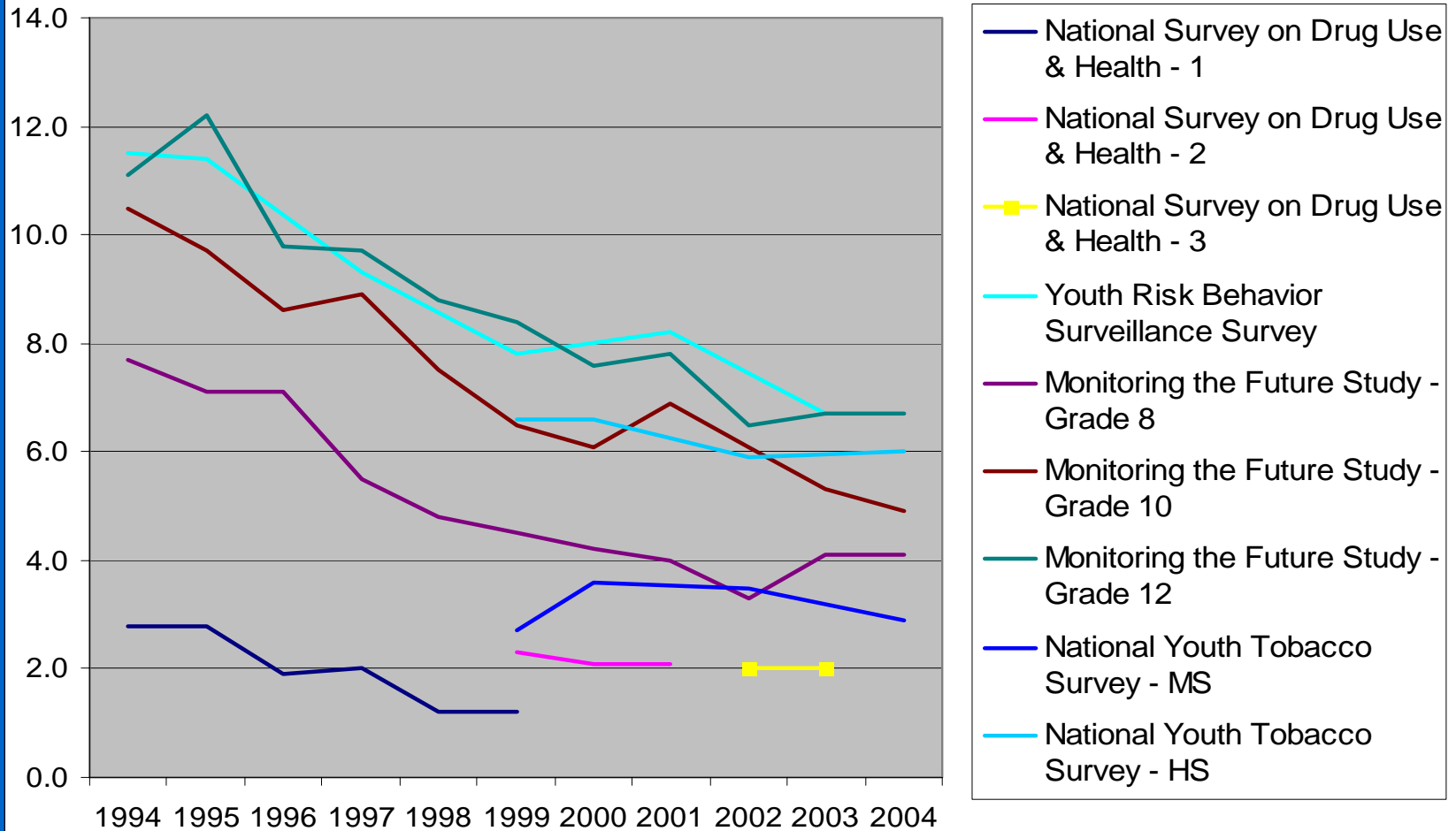
Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- "Gateway" hypothesis - smokeless tobacco
 - Two U.S. studies most frequently cited in support of the hypothesis
 - USSTC's written submission addresses methodological limitations
 - Haddock et al. (2001) (inconsistent definitions)
 - Tomar (2002) (adequacy of database)

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- "Gateway" hypothesis - smokeless tobacco
 - Other analyses relating to "gateway" theory
 - For example, the 2003 European Policy Statement
 - "The data from Sweden suggest that the gateway is more likely to be an 'exit' from smoking rather than an 'entrance'. . . . In total therefore, the Swedish data suggest that uptake of snus use prevents rather than promotes smoking and therefore contributes a net public health benefit."

Past 30-day youth usage of smokeless tobacco among males and females according to various national studies.

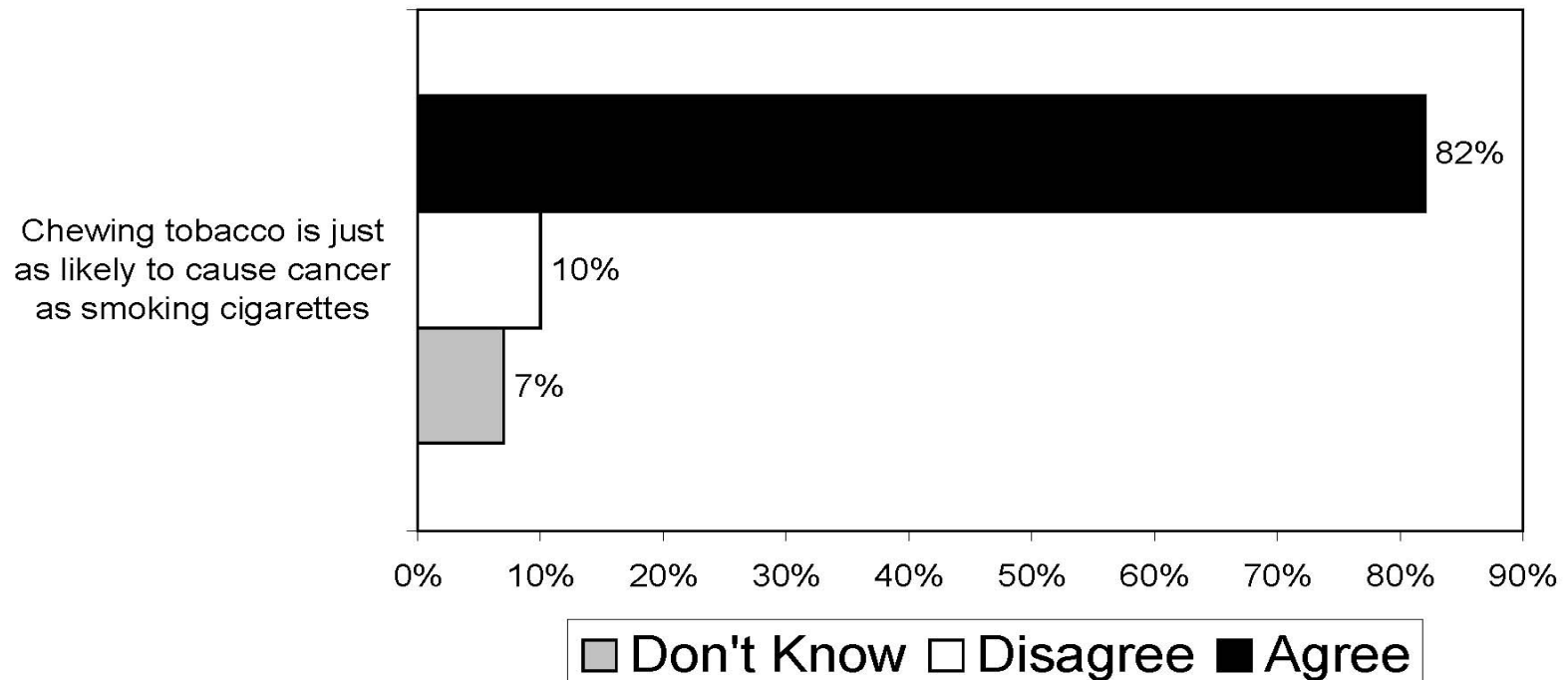


Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- Mitigation of population effects
 - Recent surveys indicate that the majority of adult cigarette smokers are misinformed about comparative risk
 - Cummings of New York's Roswell Park Cancer Institute has presented data indicating that 82% of smokers believe that chewing tobacco is just as likely to cause cancer as smoking cigarettes

Cummings Survey Data

Smokers believe chewing tobacco is as dangerous as cigarettes



Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- Mitigation of population effects
 - There is opinion in the scientific community that providing comparative risk information on tobacco products to adult cigarette smokers could mitigate some potential negative population effects
 - There is significant support for providing adult cigarette smokers with truthful and nonmisleading information regarding tobacco options that are available to reduce the potential risks to their health

Smokeless Tobacco as a "Potential Reduced-Risk Tobacco Product"

- Mitigation of population effects
 - For example, Cummings (2002) stated:
 - "Ironically, many smokers do not perceive much difference in health risk between smokeless tobacco products, nicotine medications and cigarettes. . . . **Until smokers are given enough information to allow them to choose products because of lower health risks, then the status quo will remain.** Capitalism, and not governmental regulation, has the greatest potential to alter the world-wide epidemic of tobacco-related disease."

Conclusions

- The scientific literature regarding smokeless tobacco as a “potential reduced-risk tobacco product:”
 - Reflects a general acceptance that smokeless tobacco use involves significantly less risk than cigarette smoking
 - Reflects support for the proposition that cigarette smokers, who do not quit and do not use medicinal nicotine products, should be encouraged to switch completely to smokeless tobacco

Conclusions (continued)

- Reflects support for rejecting the causal gateway hypothesis
- Reflects support for the proposition that smokeless tobacco is not a gateway to cigarette smoking
- Reflects support for communicating to consumers comparative risk information about tobacco products