

REDUCED RISK REVIEW

Background

- >440,000 people die each year in the US as a result of cigarette smoking
- Adult smokers lose an average of 13-15 years of life
- Almost one out of every four adults is a smoker

Background

- The tobacco industry is developing reduced-exposure products that are, in some cases, making reduced-exposure claims and qualified reduced-risk claims

“SCIENTIFIC STUDIES SHOW THAT, COMPARED TO OTHER CIGARETTES, BRAND X:

- **May present less risk of cancer, chronic bronchitis, and possibly emphysema;**
- **Reduces secondhand smoke by 80%; and**
- **Leaves no lingering odor in hair or clothes”**

—package insert

Overview of Project

LSRO will:

- Critically evaluate the science base necessary to assess potential reduced-risk tobacco products
- Identify research initiatives to address critical gaps in the science base
- Develop a framework for product assessment, if feasible

Core Committee

- Identify the necessary elements of an evaluative process

Departure Point

- This project will build on the findings and recommendations of the 2001 Institute of Medicine (IOM) study, *Clearing the Smoke (CTS)*

Modified Risk Assessment Process

- **Hazard Identification (HI):** Does a substance cause disease? / **Is there an indication that risk may be reduced?**
- **Dose-Response Assessment (DRA):** How much of the substance is needed to cause the disease? / **How much of a reduction in exposure is necessary to reduce risk?**

Modified Risk Assessment Process

- **Exposure Assessment (EA):** What dose(s) of the substance are people exposed to?/ **Are individual exposures reduced? Is the incidence of tobacco use within a population likely to be increased?**

Modified Risk Assessment Process

- **Risk Characterization (RC):** What is the estimated incidence of disease?/ **Is the evidence sufficient to conclude that a meaningful reduction in individual risk is likely to occur? What evidence is available to identify the potential for adverse population effects? If marketed as a reduced-risk product, how should the population be monitored?**

PROJECT ORGANIZATION

- Four Expert Committees
 - Core Committee
 - State-of-the-Science Review Committees
 - Hazard Identification/Dose Response Assessment (HIDRA)
 - Individual Exposure Assessment (IEA)
 - Population Exposure/Behavior Assessment (PEBA)

State-of-the-Science Review Committees (SSRCs)

- Critically assess the state of the science
- Identify critical gaps/uncertainties
- Identify appropriate research initiatives

IEA

- What methods are available to estimate/measure exposure to toxic substances in smoke/smokeless tobacco?
- How can studies of individual exposure account for inter- and intra-individual variability?

IEA

- Given methods currently available, what is the Committee's recommendation for the assessment of reduced exposure to toxic substances in smoke for potential reduced risk tobacco products?
- What are the critical uncertainties?
- What research is necessary to address these uncertainties?