Risk Continuum or Risk Cliff: Appropriate Evidence for Appropriate Claims

Bruce D. Clark PhD
Vice President Regulatory & Scientific Affairs
Philip Morris International
Science shows that nicotine is not the primary cause of smoking-related diseases. It has been acknowledged since the 1970’s that the delivery mechanism is the issue.

“People smoke for nicotine but they die from the tar.”

Prof. Michael Russell


Providing smokers with alternative products that do not combust tobacco is the key to harm reduction.
Scientific Evidence Must Support Decision Making

• “…direct and implied claims of reduced risk only if FDA confirms that scientific evidence supports the claim and that marketing the product will promote public health.”

Mitch Zeller
US Senate Health, Education, Labor and Pensions Committee
May 2014

• No ‘category’ approval
• Product specific decisions based on scientific evidence

• Don’t go beyond the science, but do to keep pace with the science that is available
Evidence for Continuum or Cliff

Philip Morris International’s Assessment Approach

- Aerosol Chemistry
- Non-Clinical Studies
- Clinical Studies
- Population Impact Assessment
- Post-Market Surveillance

**INDIVIDUAL RISK:**
- Does the product reduce a smoker’s risk of harm?
- Does evidence show similarity to cessation, the ‘gold standard’ for risk reduction?

**POTENTIAL TO BENEFIT PUBLIC HEALTH:**
- Do smokers switch fully or predominantly to the product?
- Do non-smokers take up the product in large numbers?
- What is the overall impact on public health?

Note: Reduced-Risk Products ("RRPs") is the term Philip Morris International uses to refer to products that have the potential to reduce individual risk and population harm in comparison to smoking combustible cigarettes.
Comparative Reductions in biomarkers of exposure compared to smoking abstinence

Reductions in levels of Biomarker of Exposure (BoE) one week after switching from Combustible Cigarettes (CC) to e-cigarettes (EC) or IQOS.

Goniewicz et al. Exposure to Nicotine and Selected Toxicants in Cigarette Smokers Who Switched to Electronic Cigarettes: A Longitudinal Within-Subjects Observational Study. Nicotine & Tobacco Research, 2016, 1-8

PMI Research & Development. Study ZRHR-REXC-03-EU Clinical Study Report, 2015
The Case for Transformation

“Philip Morris International (PMI) joined the UN Global Compact (UNGC) in 2015. By doing so we committed ourselves to making the UNGC Principles part of the strategy, culture and day-to-day operations of our company.”

“We recognize that combustible cigarettes are a dangerous product…”

“Technological innovation is transforming our industry…”

“Our ambition is to lead a full-scale effort to ensure that non-combustible products ultimately replace cigarettes to the benefit of adult smokers, society, our company and our shareholders.”
Encouraging Adult Smokers to Switch

High quality products that enable smokers to switch

Excellent science

Regulatory framework

Motivation to Switch