



**GTNF 2016**

*Global Tobacco & Nicotine Forum*

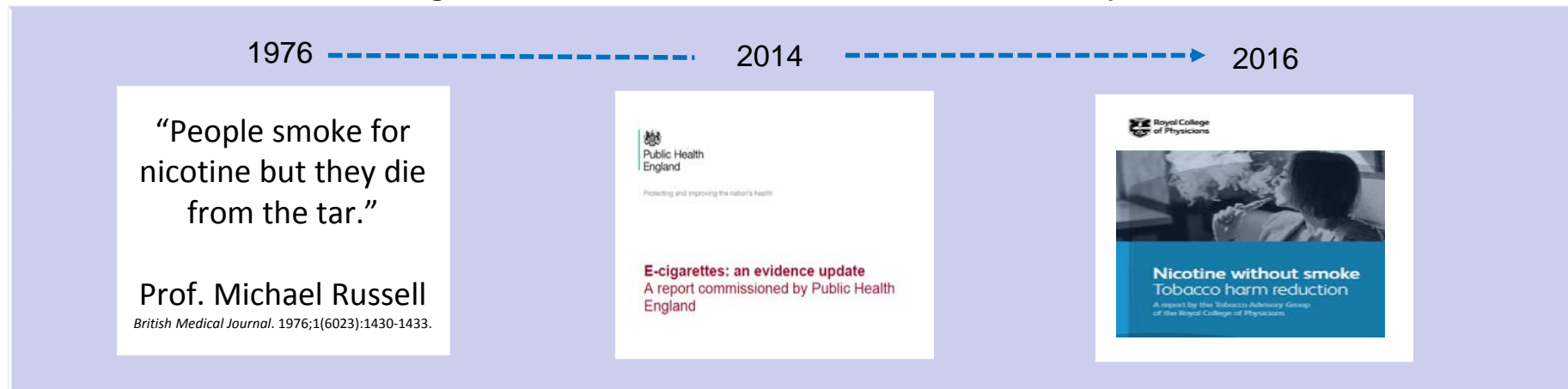
Dynamic dialogue, expanding perspectives.

**Risk Continuum or Risk Cliff:**  
Appropriate Evidence for Appropriate Claims

**Bruce D. Clark PhD**  
Vice President Regulatory & Scientific Affairs  
Philip Morris International

## What is the Key to Harm Reduction?

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



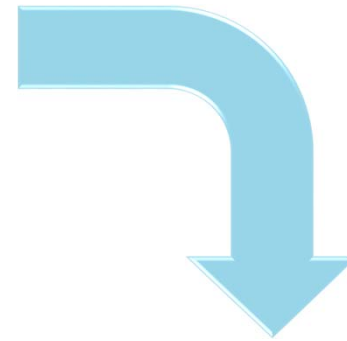
Providing smokers with  
alternative products that do not combust tobacco  
is the key to harm  
reduction

## *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

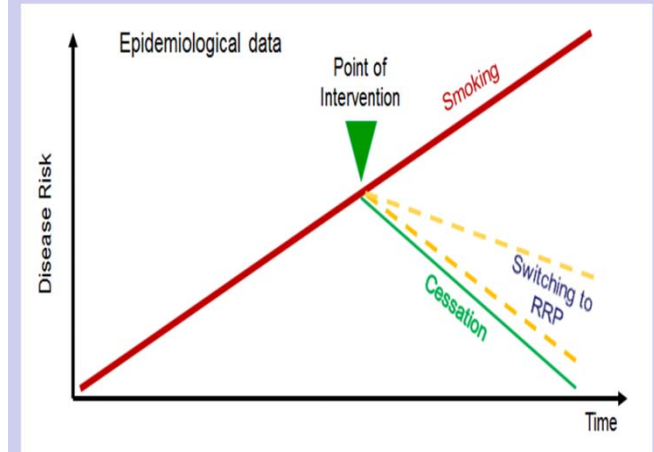
Post-Market Surveillance

#### INDIVIDUAL RISK:

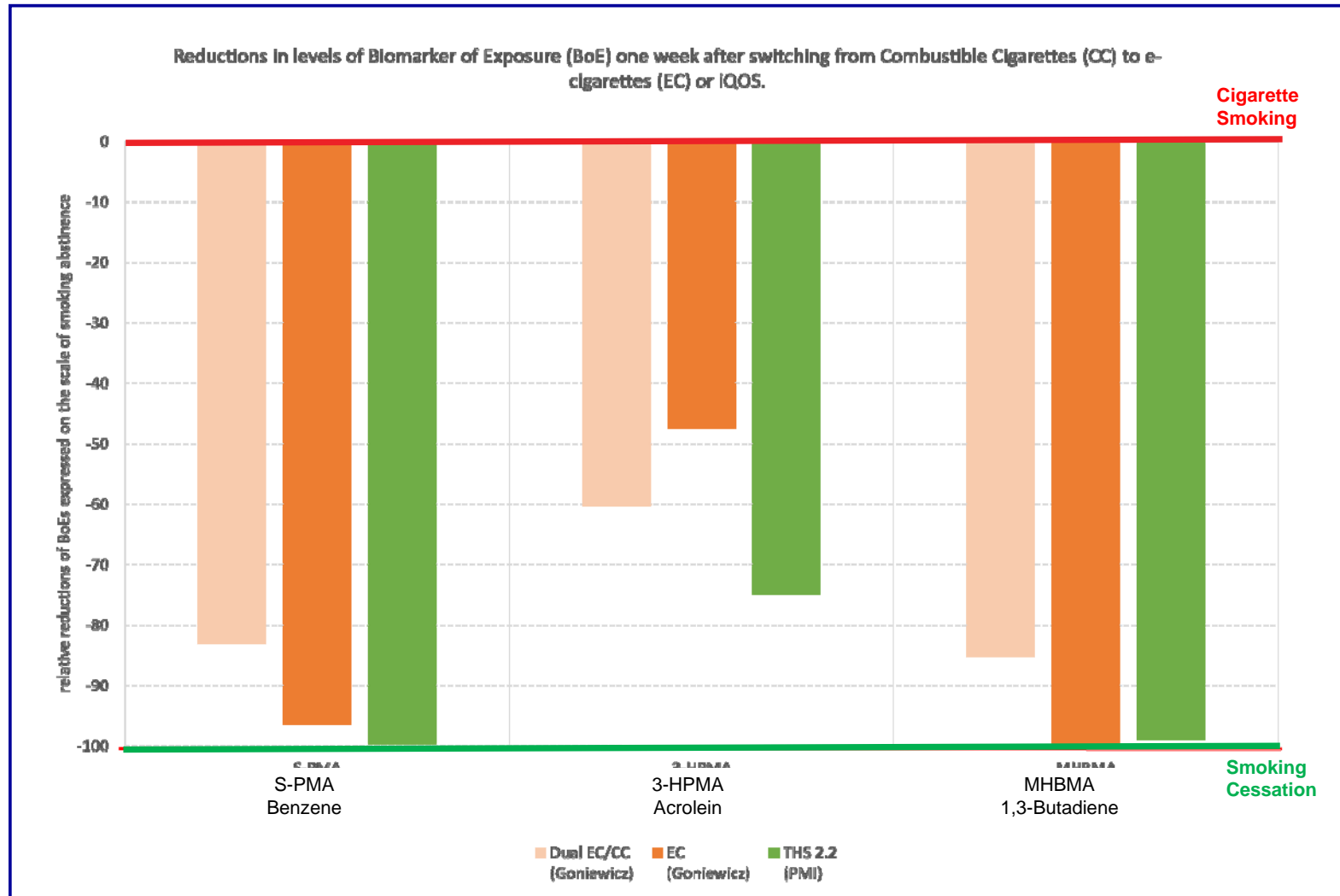
- Does the product reduce a smoker's risk of harm?
- Does evidence show similarity to cessation, the 'gold standard' for risk reduction?

#### 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?




# Comparative Reductions in biomarkers of exposure compared to smoking abstinence



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

United Nations Global Compact  
Communication on Progress 2015



**HUMAN RIGHTS & LABOR RIGHTS**  
**ENVIRONMENT**  
**ANTI-CORRUPTION**



“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.”



ANDRE CALANTZOPoulos  
CHIEF EXECUTIVE OFFICER  
PHILIP MORRIS INTERNATIONAL

## *Encouraging Adult Smokers to Switch*



High quality products that  
enable smokers to switch

Excellent science

Regulatory framework



Motivation to Switch



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