

How the tobacco industry has used the harm reduction narrative to interrupt cessation opportunities

Vaughan Rees, PhD

Center for Global Tobacco Control



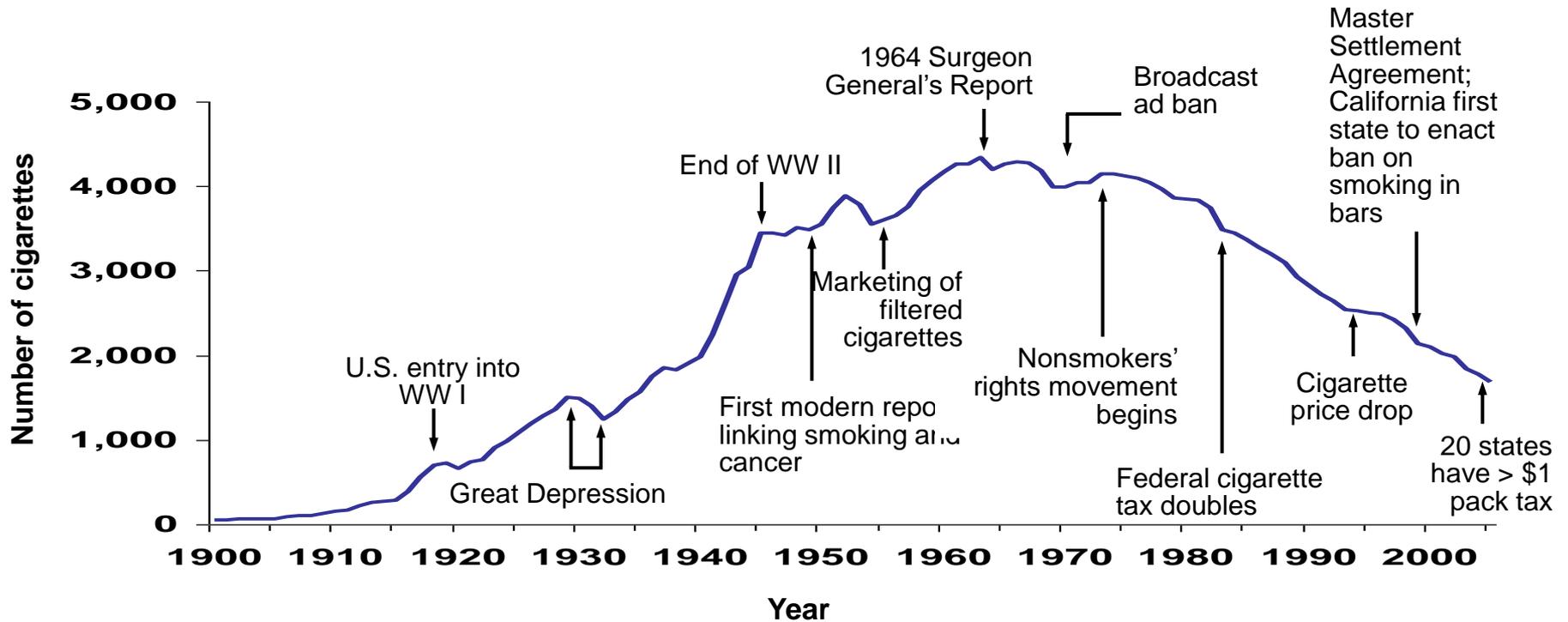
HARVARD
T.H. CHAN

SCHOOL OF PUBLIC HEALTH

Department of Social and
Behavioral Sciences

Trends in Adult Cigarette Consumption, USA: 1900–2010

Annual adult per-capita cigarette consumption and major smoking and health events



Centers for Disease Control and Prevention. (1999). *MMWR* 48:986–993.
Per-capita updates from U.S. Department of Agriculture, provided by the American Cancer Society.



World Health Organization recommended approaches for tobacco control

- **6 major strategies endorsed by World Health Organization:**
 - **M**onitor tobacco use and prevention policies
 - **P**rotect people from smoke
 - **O**ffer help to quit tobacco use
 - **W**arn about the danger of tobacco use
 - **E**nforce bans on promotion
 - **R**aise taxes on tobacco

WHO, 2009



Smoking Cessation Opportunities

Almost 70% of smokers say that they would like to quit (Babb et al, 2017)

By 2016, almost 60% of smokers who have ever smoked had quit

State-of-the-Art Cessation Resources

- A nationwide Tobacco Cessation Quitline
- Tailored, digital technologies to increase reach of evidence-based interventions
- Free/subsidized Nicotine Replacement Therapy (NRT)
- A multi-faceted, paid national media campaign
- Insurance coverage
- A new tobacco training infrastructure
- A new tobacco research infrastructure
- A Smokers' Health Fund to help people quit smoking

Yet the vast majority of smokers do not succeed in quitting



Beyond “Safe and Effective”: The urgent need for high-impact smoking cessation medications

Laura J. Rosen^{a,b,*}, Tal Galili^c, Jeffrey Kott^d, Vaughan Rees^b

^a Dept. of Health Promotion, School of Public Health, Sackler Faculty of Medicine, Tel Aviv University, Israel

^b Center for Global Tobacco Control, Department of Social and Behavioral Sciences, Harvard T. Chan School of Public Health, Boston, MA, USA

^c Department of Statistics and Operations Research, The Sackler Faculty of Exact Sciences, Tel Aviv University, Tel Aviv 69978, Ramat-Aviv, Israel

^d Stony Brook University Hospital, New York, USA

ARTICLE INFO

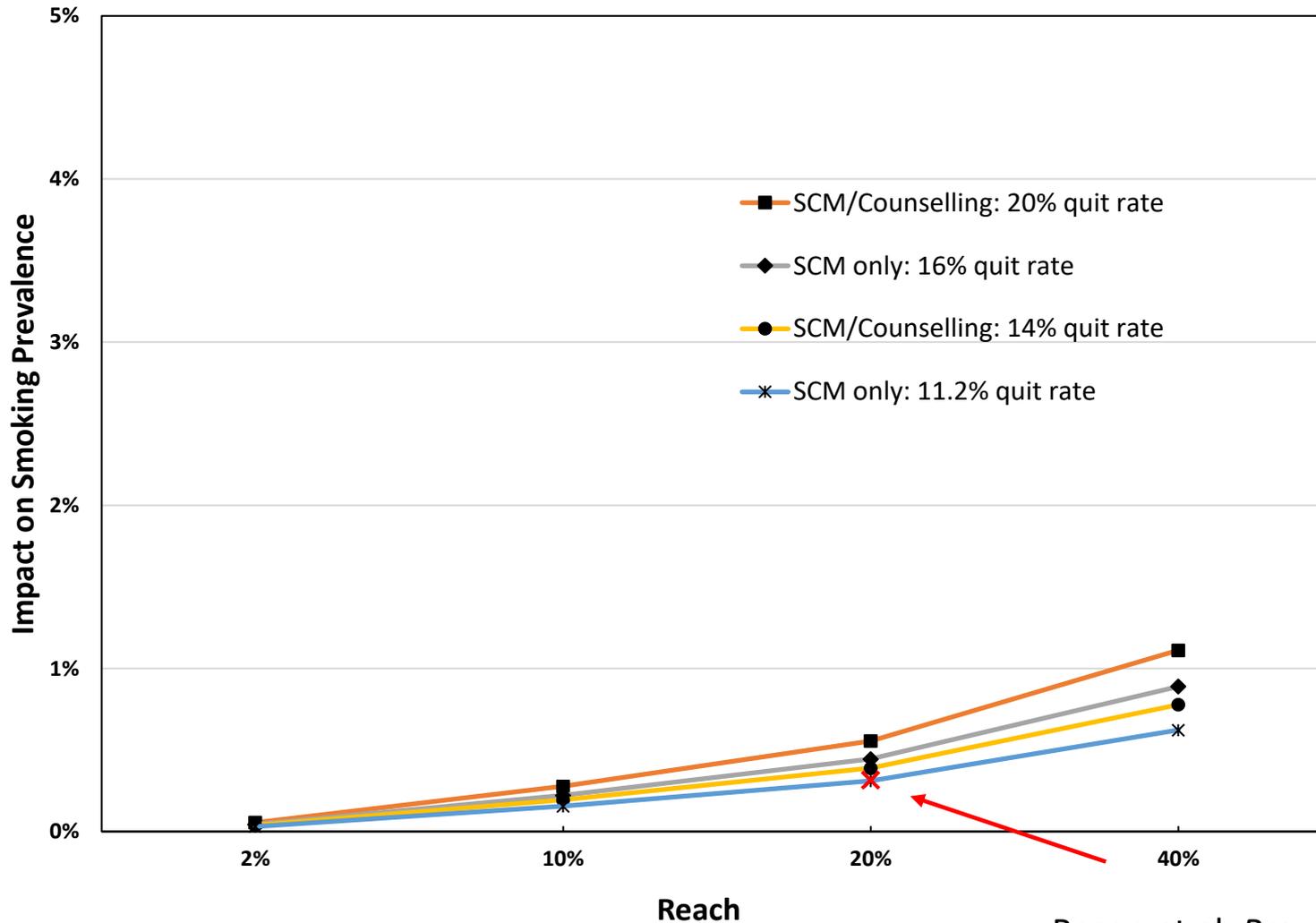
Keywords:

Population impact
Reach
Efficacy
Smoking cessation
Smoking cessation medications
Pharmacotherapy
Nicotine replacement therapy
Behavioral support

ABSTRACT

Smoking cessation medications (SCMs) are an evidence-based cornerstone of comprehensive tobacco control programs globally. However, the impact of SCMs on population smoking prevalence is controversial, with inconsistencies between randomized controlled trials (RCTs) and population-based observational studies. We estimated SCM impact on permanent cessation and population smoking prevalence by extrapolating efficacy estimates from meta-analyses of RCTs, using the standard population impact formula: efficacy*reach. We calculated the potential SCM impact under a range of assumptions for permanent cessation (20%,14%), behavioral support (yes/no), reach (40%–2%), and underlying smoking prevalence. Assuming behavioral support for all, depending on reach, 8%–0.3% of smokers are expected to quit permanently. Without behavioral support, permanent cessation is estimated to be 6.4%–0.2%. Assuming an underlying population smoking

Impact of first-line treatments on smoking prevalence



Tobacco Industry have exploited this opportunity ...

As demand for combustible cigarettes wanes...

- Low social acceptability
- High perceptions of health risk
- High desire to quit

Developed a new generation of non-combusted tobacco products

- Implicit claims for cessation
- Address the perceptions about smoking health risks
- Promote corporate social responsibility
- Maintain market share, profits

Reduced exposure products

- US FDA: Modified Risk Tobacco Products (MRTPs)
- European Union: Tobacco Products Directive Article 28
- E-cigarettes or Electronic Nicotine Delivery Systems
 - Ciga-likes, pen, tank & pod systems
 - JUUL (*Altria*); Vuse (*Reynolds*)
- Heated tobacco products (HTP)
 - Heat sticks, IQOS (*PMI*)
- Snus
 - Smokeless tobacco, pasteurized, pouches
 - Camel Snus (*Reynolds*), Taxi (*BAT*), Lyft (*BAT*)



The problem

Tobacco manufacturers have used the harm reduction narrative to subvert cessation opportunities

The major problem is dual use

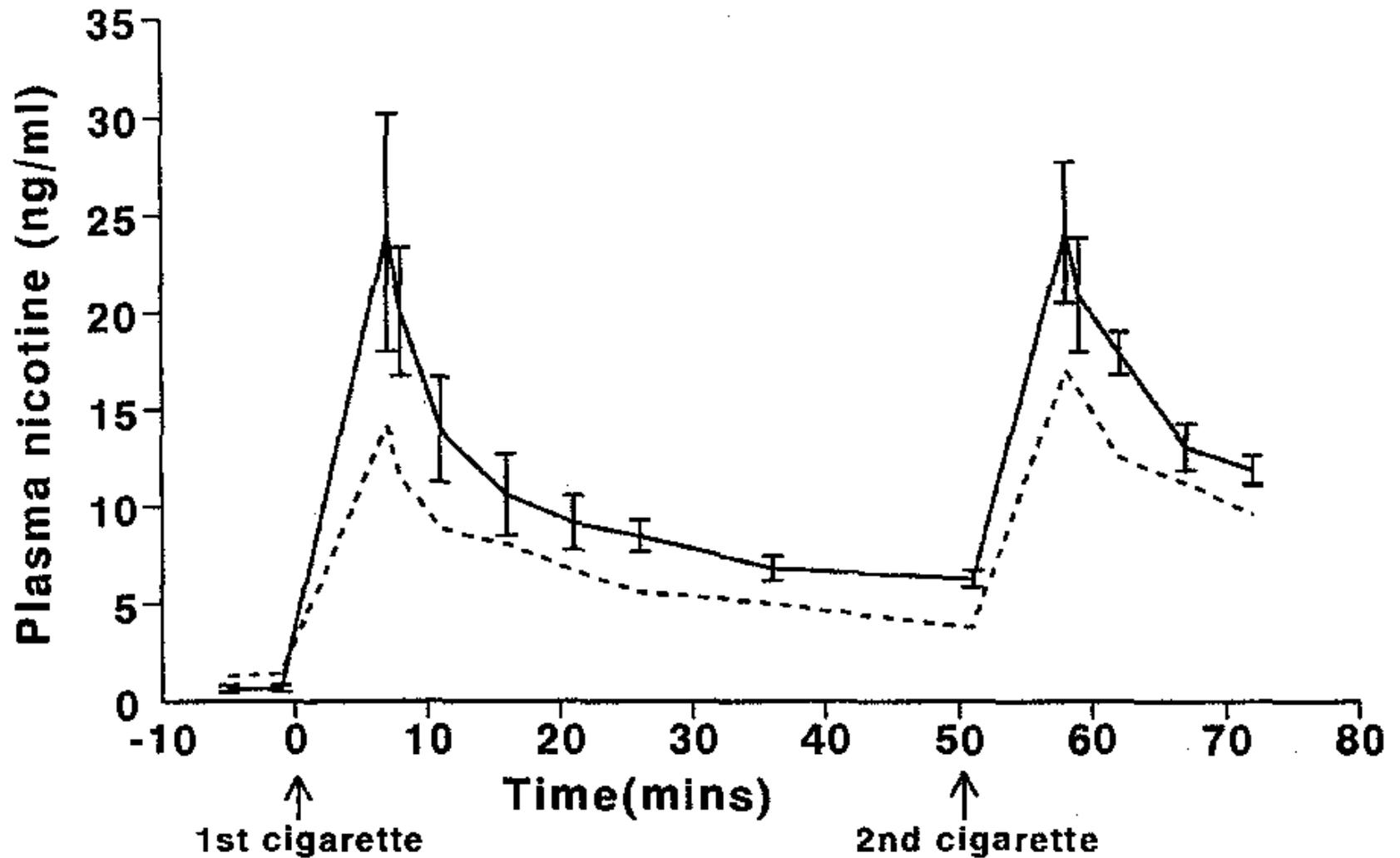
Products with low abuse liability are not as “satisfying” to smokers

Smokers cannot easily transition to products that do not deliver nicotine effectively

Promote dual use – smokers use the novel product *and continue smoking*

*****Dual use yields no net health advantage*****

Tobacco Product Abuse Liability: Nicotine Pharmacokinetics



The problem is compounded by marketing

Manufacturers of alternative devices have targeted youth

- *Target should be adult smokers*



1. E-cigarettes

E-cigs have generated attention among youth as a novel nicotine delivery device

Convenience of use:

- No smoke, limited emissions
- Concealed use, convenient
- Socially acceptable
- Cost advantage

NASEM Report: Lower health risks

Conclusions: Complete Switching

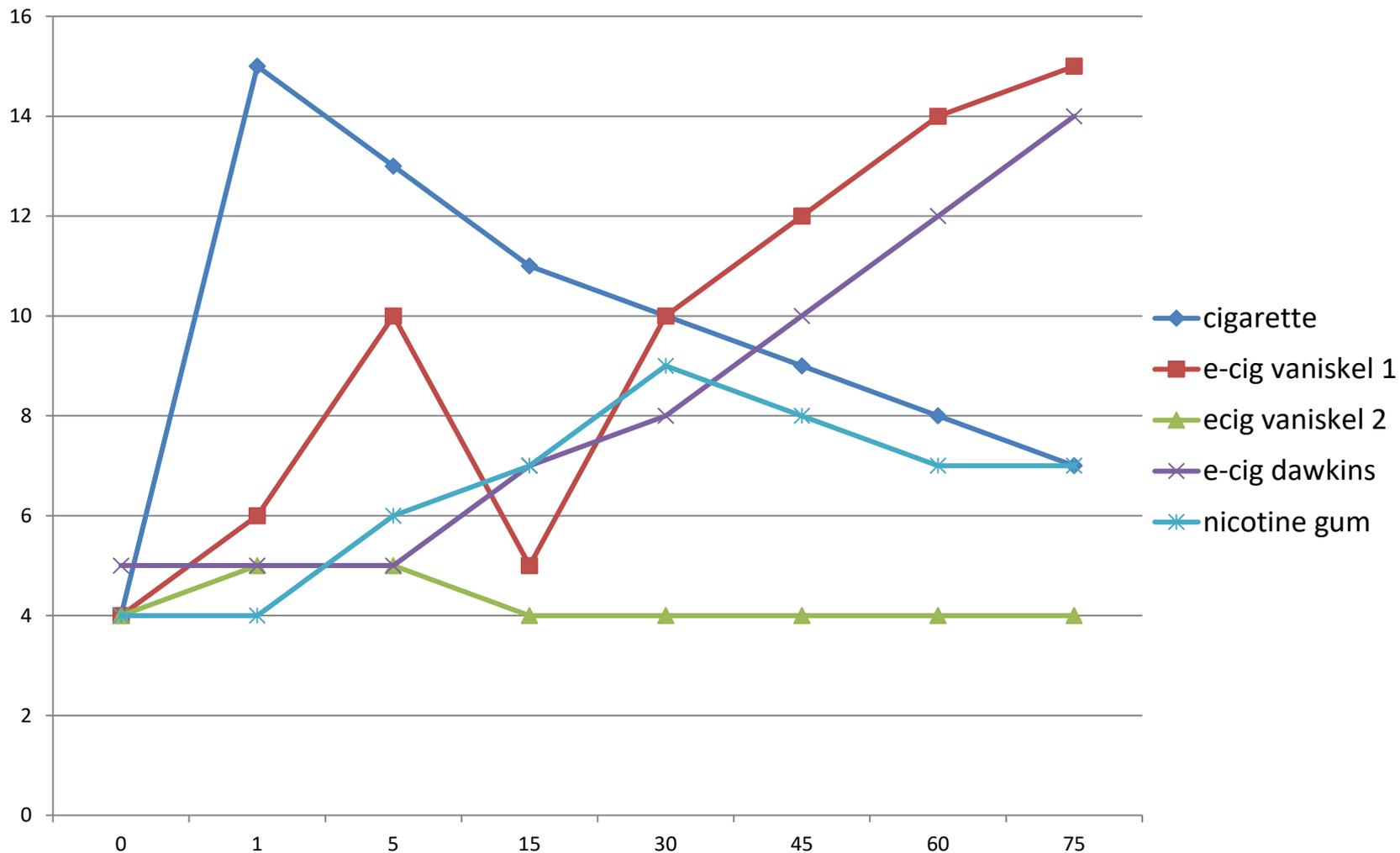
• **Conclusive evidence** that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes [18-1]

• **Substantial evidence** that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems [18-2]

Public Health Consequences of E-Cigarettes



Low Abuse liability of early gen e-cigarettes: Blood Plasma Nicotine Levels (ng/ml)



Data from multiple papers

JAMA Pediatrics | Review

Youth and Young Adult Use of Pod-Based Electronic Cigarettes From 2015 to 2019 A Systematic Review

Stella Juhyun Lee, PhD; Vaughan W. Rees, PhD; Noam Yossefy, MPH; Karen M. Emmons, PhD;
Andy S. L. Tan, MBBS, MPH, MBA, PhD

IMPORTANCE The use of electronic cigarettes (e-cigarettes) has rapidly increased among youth and young adults, but knowledge gaps exist on the potential health effects of using recently introduced pod-based e-cigarettes.

OBJECTIVE To conduct a systematic review of recent peer-reviewed scientific literature on pod-based e-cigarettes.

+ Editorial

+ Supplemental content

Summary: JUUL & pod-mods

High abuse liability:

- **High nicotine content and delivery**
- **Concerns about addiction**

Low toxicant delivery (compared to smoking)

Insufficient public knowledge:

- **Addiction, health risks**

P form of e-cigarettes named from their replaceable pod-style nicotine cartridges. Pod-based e-cigarettes have prompted this epidemic and its consequences for population health. A comprehensive review of research to date should

Smoking Cessation

A Report of the Surgeon General



U.S. Department of Health and Human Services

US Surgeon General: 2020 report on cessation

Evidence inadequate to infer that e-cigarettes...
increase smoking cessation

However:

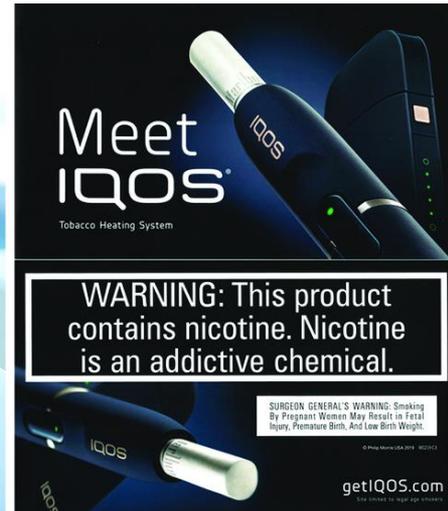
Evidence is suggestive but not sufficient to infer that the use of e-cigarettes **containing nicotine** is associated with increased smoking cessation compared with the use of e-cigarettes not containing nicotine

Evidence is suggestive but not sufficient to infer that **more frequent use of e-cigarettes** is associated with increased smoking cessation compared with less frequent use of e-cigarettes

2. Heated Tobacco Products (HTP)

2016: Applied to FDA for pre-market approval to market as a modified risk product

THIS CHANGES EVERYTHING



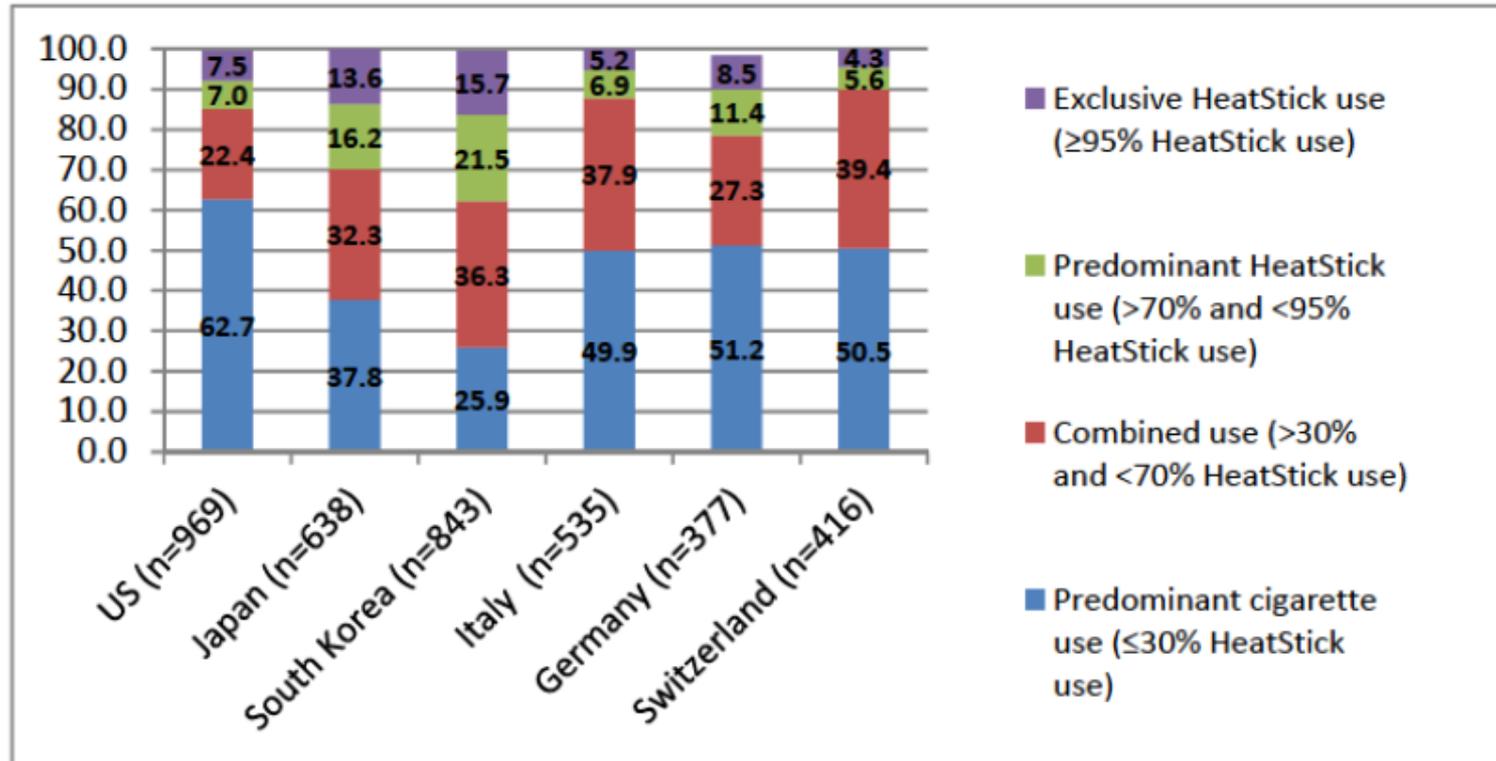
The evidence:

- Substantially reduces key toxic constituents in the smoke
- Human exposure to a number of toxic constituents lowered

BUT:

- Nicotine levels substantially lower than a conventional cigarette

Figure 6. Percent of all participants in each main IQOS use category at the end of the PBA-07 and Whole Offer Test (WOT) studies, by country



“Dual use with combusted cigarettes is the predominant pattern of IQOS use, whereas exclusive use was relatively less prevalent”

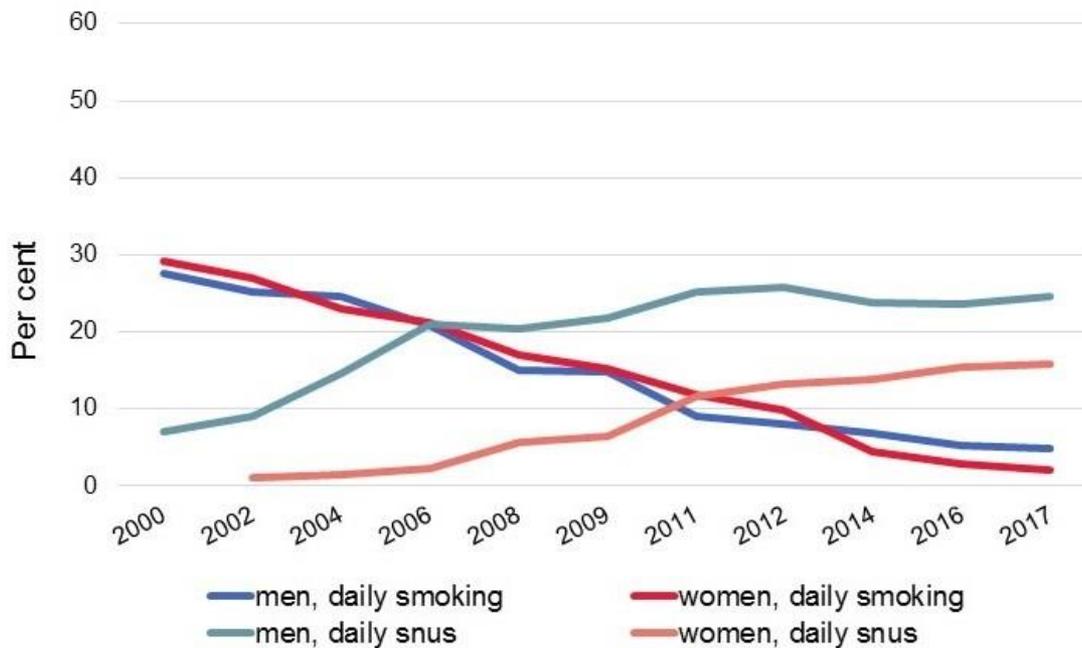
2020: Approval as modified exposure product granted by FDA

3. Snus

Low carcinogen, smokeless product

Delivers nicotine, with fewer toxicants

Associated with decline in smoking in Scandinavian countries



The advertisement features a blue background with the word 'CAMEL' in large, stylized letters. A central image shows a pack of Camel SNUS Frost tobacco pouches with a single pouch being pulled out. The text 'FROST THE FIRE' is prominently displayed in white, followed by 'GO SMOKE-FREE THIS THURSDAY'. Below this, a smaller text block reads: 'Smokers, on November 17th switch to Camel SNUS and enjoy smoke-free, split-free, great-tasting tobacco packed in a pouch. Camel SNUS—it just might change the way you enjoy tobacco.' The Camel logo and 'BREAK FREE' slogan are also visible. At the bottom, a warning box states: 'WARNING: Smokeless tobacco is addictive.'

Brief report

Characteristics of “American Snus” and Swedish Snus Products for Sale in Massachusetts, USA

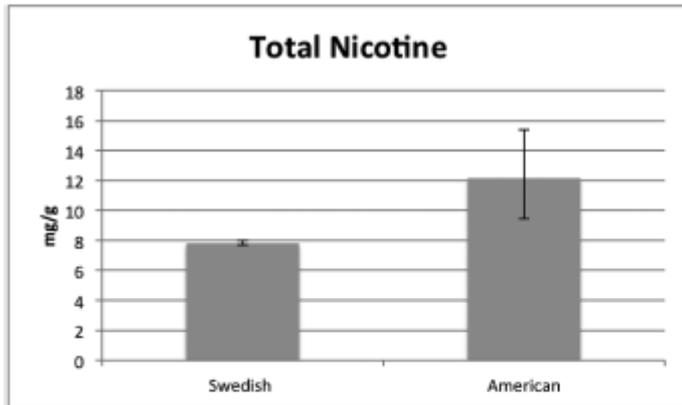
Andrew B. Seidenberg MPH¹, Olalekan A. Ayo-Yusuf BDS, MSc, MPH, PhD^{2,3}, Vaughan W. Rees PhD³

¹Department of Health Behavior, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC; ²Office of the Director, School of Oral Health Sciences, Sefako Makgatho Health Sciences University, Pretoria, South Africa; ³Center for Global Tobacco Control, Department of Social and Behavioral Sciences, Harvard T. H. Chan School of Public Health, Boston, MA

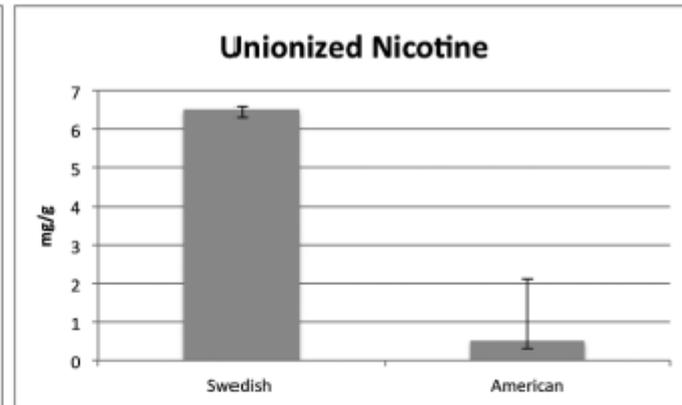
Corresponding Author: Andrew B. Seidenberg, MPH, Department of Health Behavior, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA. Telephone: 919-966-5771; Fax: 919-966-2921; E-mail: aseiden@live.unc.edu

Abstract

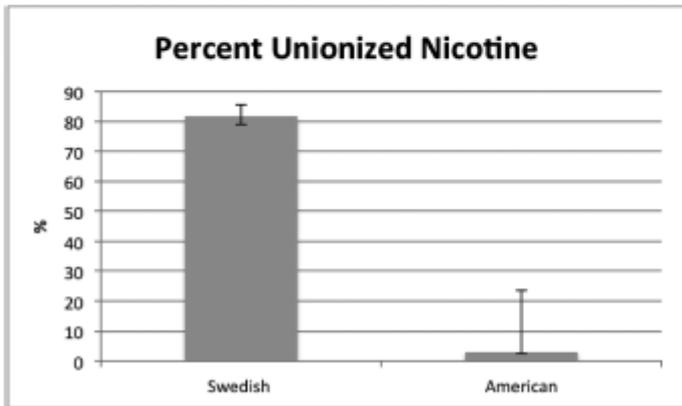
Introduction: Snus may present lower health risks than cigarettes, but its harm reduction potential may be undermined if used dually with cigarettes. The likelihood of exclusive snus use compared with dual use may depend in part on the capacity of snus to deliver nicotine in doses that are satisfactory to smokers. We examined characteristics of “American snus” products, including nicotine levels, and compared to snus products that are more typical of Sweden.



C



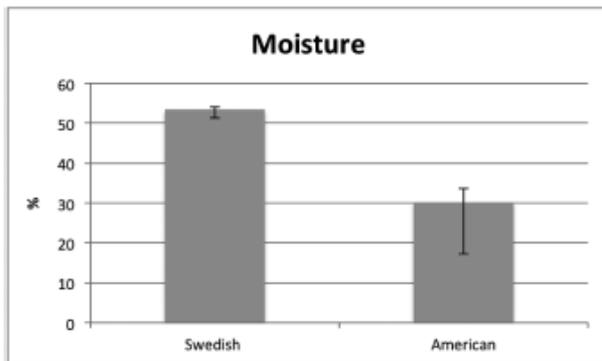
D



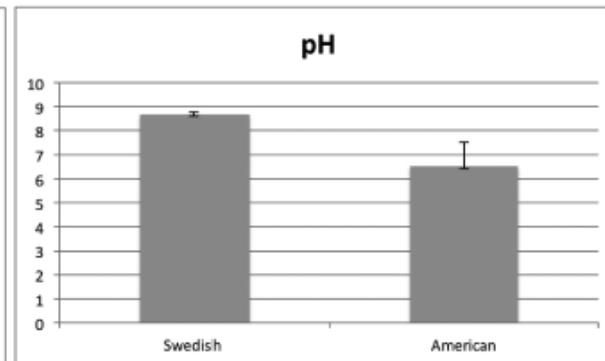
F

“American Snus” is designed to deliver nicotine in doses too low to support complete switching

The result is *dual use*: smokers continue to smoke



A



B

Where to From Here?

Tobacco manufacturers will seek to expand their product base

- Target different populations

Product regulatory standards are urgently required

- Regulate performance and toxicity of low exposure products
- Reduce the appeal and addictiveness of combusted cigarettes
- Permanently shift the gradient of appeal in favor of less risky products

Particular concern for developing countries, emerging tobacco markets

The tobacco “end game”:

- **Focus on the *elimination of combustible cigarettes?***
- **Eventual elimination of nicotine delivery devices?**
- **Or can we live with properly regulated, low-risk nicotine products?**



Contact:
Dr. Vaughan Rees
vrees@hsph.harvard.edu



HARVARD
T.H. CHAN

SCHOOL OF PUBLIC HEALTH
Department of Social and
Behavioral Sciences