Experiences from the first country to reach the endgame of smoking. Swedish an example of harm reduction in practise.

Karl Fagerstrom Ph.D.

Relevant Disclosure:

I have received consulting fees from many companies that develop or market pharmaceutical and behavioral treatments for smoking cessation. In the year 2000, I started a company Niconovum that developed the first non-tobacco nicotine pouch that was licensed as a nicotine replacement therapy. I have received fees in the past from Swedish Match and PMP to assist their development of reduced-risk tobacco products.

TOBACCO USE IS AN IDEAL AREA FOR HARM REDUCTION

Tobacco products are used largely because of

nicotine.

Pure nicotine, and even unburned tobacco, is not the primary cause of tobacco-related morbidity and mortality.

Most negative health effects are caused when tobacco is burned.

Statement from FDA Commissioner Scott Gottlieb March 15 2018 on Harm Reduction

"nicotine, while highly addictive, is delivered through products on a continuum of risk, and that in order to successfully address cigarette addiction, we must make it possible for current adult smokers who still seek nicotine to get it from alternative and less harmful sources".

Statement from FDA Commissioners Scott Gottlieb and Mark McLellan April 2024

"For these currently nicotine-addicted adult smokers, the opportunity to convert to noncombustible products offering nicotine delivery without the combustion-related health risks should be a renewed part of the public health agenda".

JAMA April 11, 2024

Swedish Inventions

Non-tobacco nicotine pouches



Nicotine replacement







Significant Decline of Cigarette Sales in Sweden 5,6% daily smokers Volumes Sold Per Year In Sweden 700 (Million Packs/Cans) 600 500 Snus / Nicotine 400 Pouches 300 Cigarettes 200 100 1973: First portion Swedish snus launched 0 2910, 912, 912, 912, 913, 910, 912, 910, 912, 910, 910, 910, 910, 910, 910, 910, 980, 980, 991, 990, 200, 200, 200, 201, 202, 202

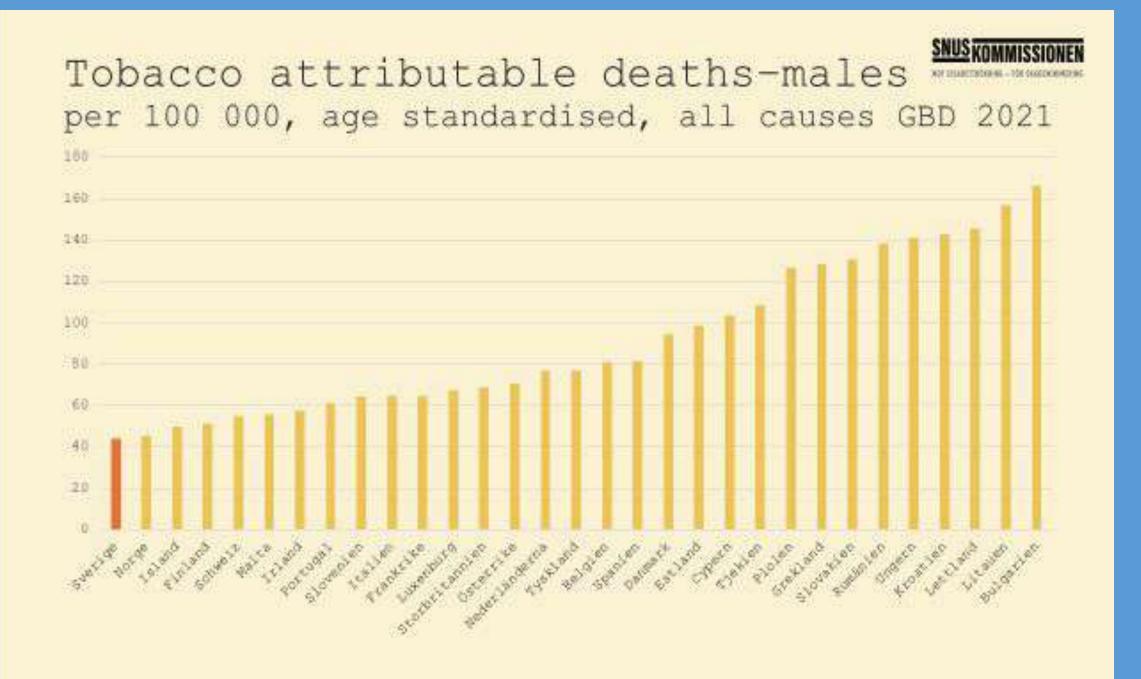
Note: Temporal associations do not demonstrate cause and effect and are subject to inherent limitations. Specific factors associated with changing cigarette sales volumes over time have not been fully analyzed. 20 cigarettes per pack; 21 estimated average pouches in can for snus and nicotine pouches Source: Swedish Match Estimates, SMD Logistics; <u>2019 TPSAC Meeting Materials and Information | FDA</u>. Investor Day 2023, presented September 28, 2023

SWEDISH MALES HAVE THE LOWEST SMOKING PREVALENCE AND TOBACCO-ATTRIBUTABLE MORTALITY IN THE EUROPEAN UNION



Male deaths per 100,000 attributable to tobacco, all causes, age-standardized (Global Burden of Disease study, 2019) Male smoking prevalence (2020 Eurobarometer)

Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettesGlobal Burden of Disease



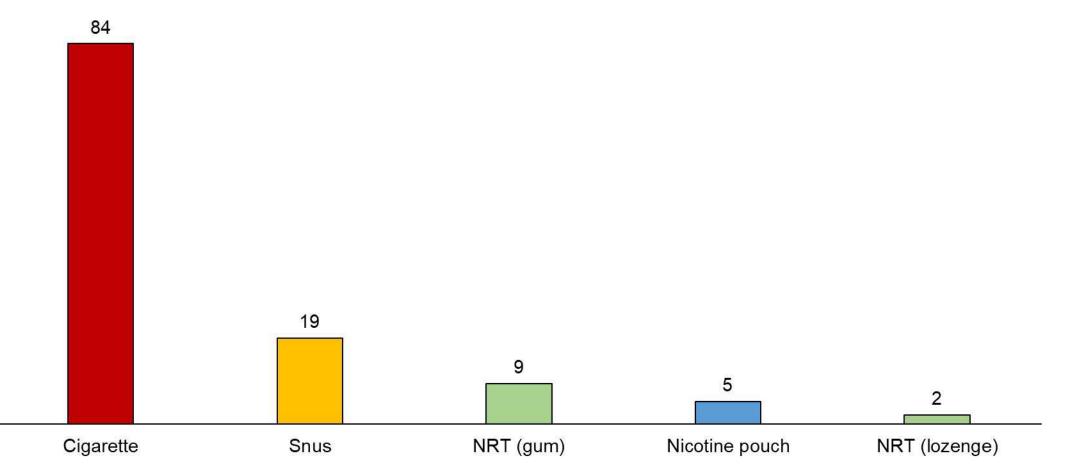
THE CONTENT OF A NICOTINE POUCH IS VERY SIMILAR TO NRT

ZYN (nicotine pouch)	Nicorette gum (NRT)	ZONNIC pouch (NRT)
Pharma grade nicotine	Pharma grade nicotine	Pharma grade nicotine
Microchrystalline cellulose Hydroxypropyl cellulose	Gum base Glycerine	Microchrystalline cellulose
Acesulfame potassium E950 Maltitol	Acesulfame potassium E950	Acesulfame potassium E950 Aspartame E951
Sodium carbonate Sodium bicarbonate	Sodium carbonate Sodium bicarbonate	Trisdium phosphate Ascorbyl palmitate
Flavorings	Flavorings	Flavorings

The health and adverse effects would be very similar to NRTs.

THE NUMBER OF HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS (HPHC) IN A NICOTINE POUCH IS SIMILAR TO NRT

Number of HPHCs



Back et al. 2023; US FDA

THE SWEDISH GOVERNMENT

- Secretary of Health endorsing a harm reduction perspective for nicotine products
- Lowered tax on snus by 20% and increased tax on cigarettes by 10% from Nov 1 2024.
- Sweden is at Endgame with 4,9 % smokers

Percent daily use of tobacco and nicotine products

	Total	Women	Men
Smoking	4,9	5,1	4,7
Snus + pouch use	17,8	11,5	23,8
Any tobacco	16,7	9,8	23,2
Any nicotine	22,5	16,7	28,0
Dual use	0,6	0,5	0,8

The Public Health Agency of Sweden 2024

A REGULATORY SYSTEM FOR TOBACCO/NICOTINE PRODUCTS

Alcohol	Low	High	
	Beer	Wine	Spirits
Tobacco/Nicotine	Low		High
	NRT E.g. gum Nicotine pouches		Cigarettes

Important features with the alcohol regulation:

Taxation and Availability according to harm and Minimum Age for purchase.

SAME SYSTEM CAN BE USED FOR TOBACCO/NICOTINE PRODUCTS

Thank you for your attention.