

**FDA-TPSAC Meeting on
Dissolvable Products
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**”The Swedish Tobacco Harm
Reduction Experience”**

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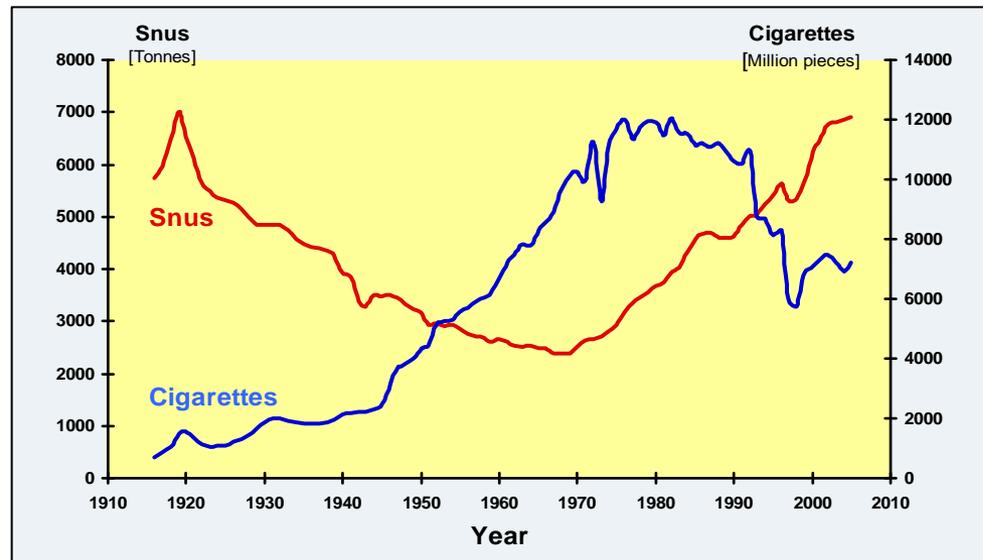
Key messages

- Tobacco consumption in Sweden is comparable to other countries
- Sweden has the lowest smoke-related deaths and diseases
- Snus is the predominant tobacco product among men
- Scientific basis is provided by several seminal articles based on information derived from cohort studies of Swedish groups.
- Government, industry, and media contributed to the “experience” but it was largely a grass roots phenomenon.

History: A Fairly Recent Experience

- Snus is the traditional Swedish tobacco product, but had lost its market share to cigarettes in the 1950s
- The “experience” began in the 1970s as the health effects of cigarettes were acknowledged and Swedes turned to snus as a less risky alternative.

Sales of cigarettes and snus in Sweden 1916-2010

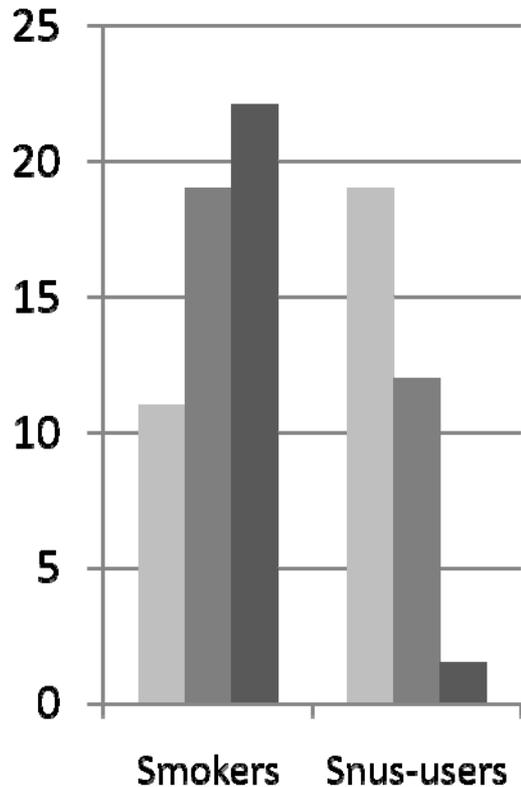


- The experience was not well documented until the 1990s when research based on Swedish cohorts was published in scientific journals.

Smoking, snus prevalence, cancer rates: Scandinavia

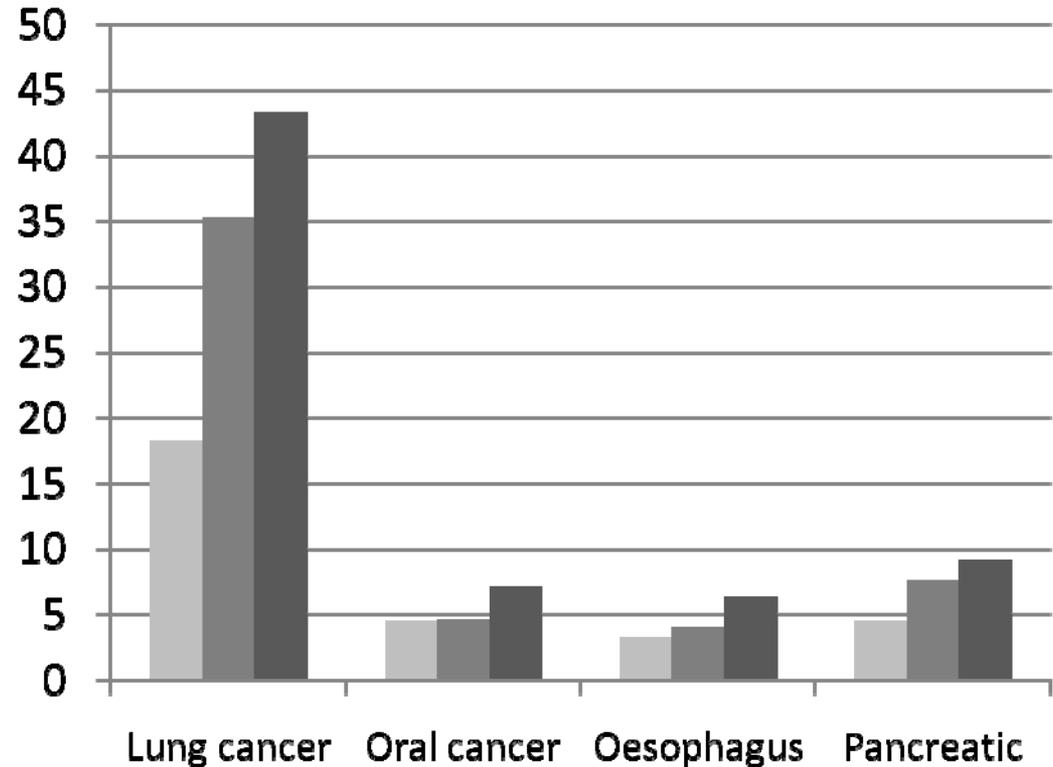
Use of tobacco males (%)

Source: Statens Folkhälsoinstitut 2010, Statistisk Sentralbyrå 2010, Sundhedsstyrelsen 2010



Incidence of cancer per 100.000 males 2008

Source: WHO International Agency for Research on Cancer (IARC) 2011



■ Sverige

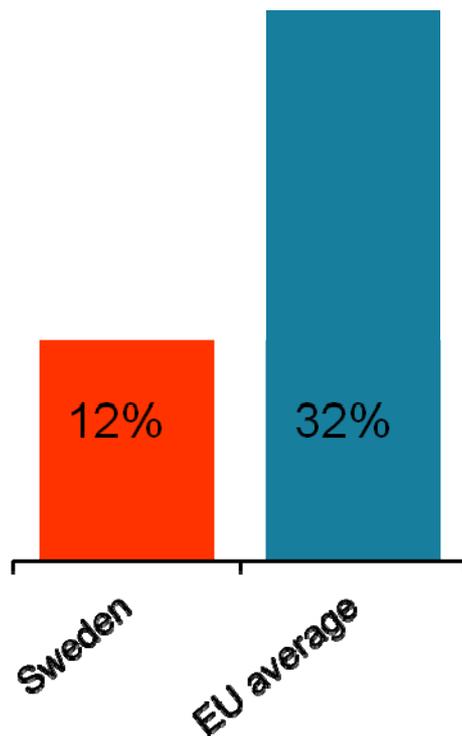
■ Norge

■ Danmark

Smoking prevalence, cancer rates: Sweden vs EU

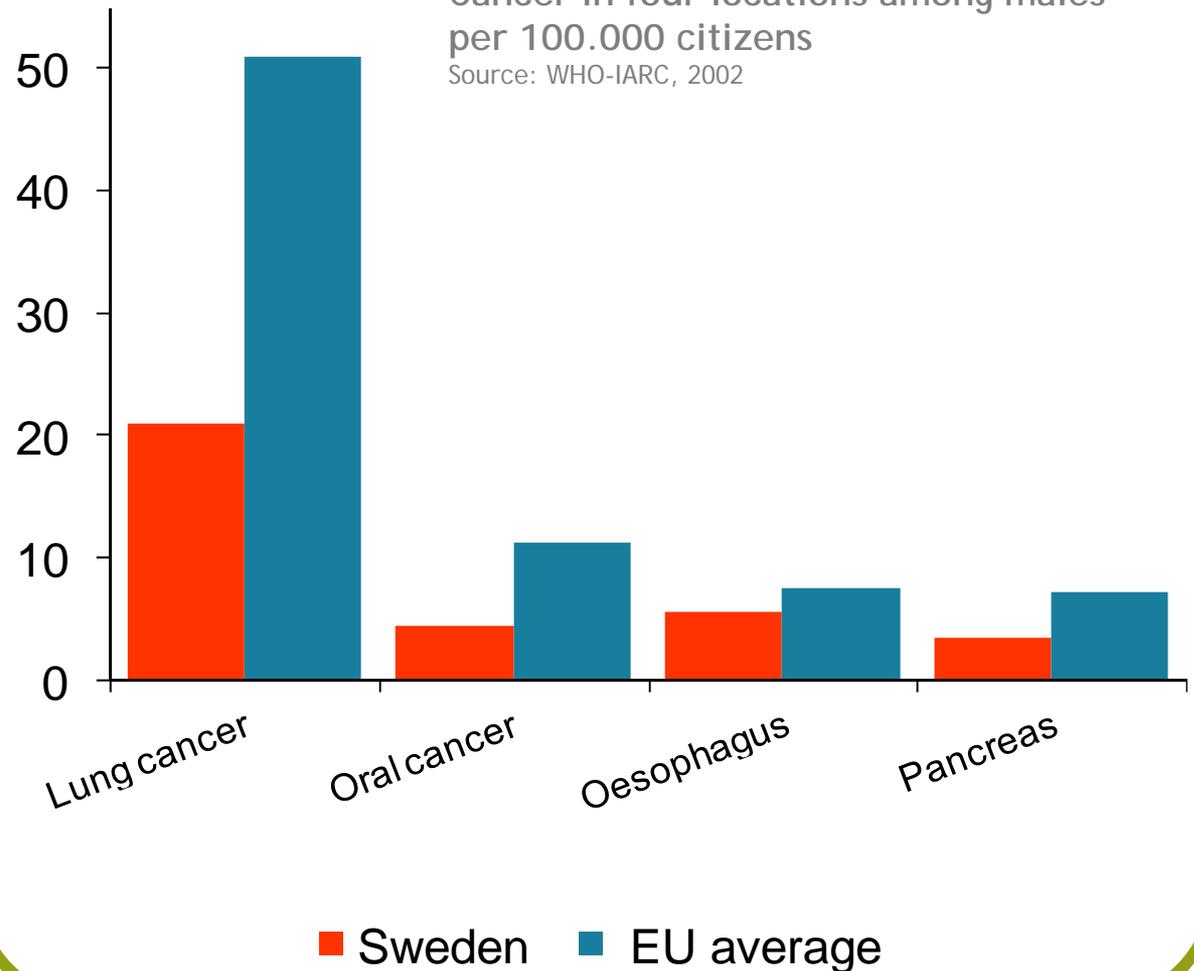
Smoking prevalence, males

Source: Eurobarometer 2009,
FHI 2007



Cancer in four locations among males per 100.000 citizens

Source: WHO-IARC, 2002



The Swedish Way

- Highly regulated country; citizen's habits are well documented
- Government commitment to public health
- Public is mostly health conscious
- Continuous national records on tobacco manufacturing and consumption dating to 1780
- Close relationship between industry and government

Cohorts

- Swedish Construction Workers
 - Data collected over a 24 year period (1969-1993)
 - Large size (over 340,000 men)
 - High prevalence of snus use (28%)
- BROMS (Children's Smoking and Environment in Stockholm County)
 - Surveyed over 3000 fifth graders during the 1997-1998 school year and conducted annual follow-up survey until 2005.
 - Series of questions relating to snus use: ever tried oral snuff, age at initiation, symptoms at first use, progression to regular use, quit attempts, circumstances of tobacco use, and preferred brands.
- MONICA (Northern Sweden Monitoring of Trends and Determinants in Cardiovascular Disease)
- Swedish Twins Registry
- Malmö Diet and Cancer
- Uppsala County Cohorts (2)
- Swedish Annual Level-of-Living Survey; Swedish Survey of Living Conditions

Swedish Public Health and Snus

- Swedish National Board of Health (SNBH) issues a Public Health Policy Report every 5 years
- 2005 report included section on snus; addressed:
 - Use patterns (snus is used by 23% of men and 3% of women)
 - Between 1996-2004 percentage of daily snus user rose from 10.3% to 13%
 - Socio-economic background of snus users
 - Health implications and snus as a gateway to smoking
 - Stated that snus does not increase risk of myocardial infarction morbidity
 - Cited research suggesting snus may be associated with some forms of cancer and may have adverse effects on pregnancy outcomes
 - Concluded that it should always be assumed that snus is not harmless

SNBH 2005 Report

- Poses the question– but leaves unanswered– whether officials should suggest to smokers they switch to snus
- Concludes that apparently many people have used snus as a means to give up smoking
- Concludes that the risk young adults will progress from snus to smoking is far smaller than the risk that a non-smoker will take up smoking

The Public Debate in Sweden

- Between 2000 and 2009 there were 5,000 articles in the Swedish media that addressed snus
- Health effects of snus has been debated in Läkartidningen, the official journal of the Swedish Medical Association
- EU trade restriction on snus are routinely addressed in the political, financial, and mainstream media
- Health impacts of snus vs. smoking is a common topic among friends and family members

Snus Regulated as a Food Product

- Regulated since 1971 by the National Food Act implemented by the Swedish Food Agency
- Currently (2011) considering more comprehensive and precise regulations
- Would treat snus as any other food product: additives, flavorings, new ingredients, vitamins, mineral substances, water, labeling, contaminants.
- Close relationship between Swedish Match and Swedish Food Agency

- The SM-government relationship lead to the establishment of the voluntary quality standard GothiaTek
- GothiaTek provides for requirements on the following:
 - Maximum permitted levels of suspected harmful elements that occur naturally in tobacco
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 - The manufacturing process
 - Qualified product information to consumers

GothiaTek Goals

- To continuously reduce or eliminate alleged harmful components in Swedish snus and to increase the knowledge about our snus products and its impact on users
- Closely follow independent research with relevance for the aims of GothiaTek
- Conduct own research and development work directed at continual improvement of products.
- Cooperate with legislators and authorities about products so that legislation and regulations shall be based on all available knowledge.

Tobacco Governance in Sweden

- Recent IOM Committee Report includes the chapter: "Governance and Conduct of Studies"
 - Address the relationship between FDA, industry, and academia
- Sweden faces similar challenges, but significant progress has been made
 - GothiaTek standard
 - Close relationship between Swedish Match and the regulatory authority (Swedish Food Agency), public health community, including the National Institute of Public Health (NIPH)
- Role of the Karolinska Institutet (KI), a leading medical university, is particularly significant
 - Various research groups at the KI has conducted seminal tobacco research, faculty have been influential in governmental policies

Industry (Swedish Match) Communication

- Website features a combination of science and business-related information.
- Science portion includes sections on snus and health, harm reduction, research on snus, tobacco use in Sweden, and GothiaTek.
- Intended to compliment other sources; industry's role is limited due to understandable public concerns about the credibility of such information.
- Thus, site presents factual, well referenced information, and only offers analysis and conclusions from credible sources such as the World Health Organization, Royal College of Physicians, and the Swedish National Board of Health

Swedish Match Communication

- Site is representative of Swedish Match's approach to communicating harm reduction and health effect information
- Statements must be backed up by research and should be consistent with findings stated by governmental agencies and the scientific community.
- Site is “pro snus,” but the company is careful to make the site science, not advocacy- based.
- Approach is correct from an ethical as well as business standpoint. If company overstates its case it runs the risk of losing all credibility with consumers and thereby not serving any useful purpose.

Marketing

- Snus has never been marketed as a harm reduction product or a smoking cessation aid.
- Snus is marketed as a "traditional" product with historic brand names
- Health effects information as presented on the website likely works best among consumers who value, and can make decisions based on scientific information.
- These consumers, educated, typically economically well established, may also be health conscious, and appreciate the GothiaTek goal of using the best available raw materials and manufacturing practices.

Conclusions

- The Swedish experience is widely viewed as a positive public health story. More than any other country, Sweden has been able to reduce the percentage of smokers, and thereby benefit public
- Many factors contributed to the phenomenon, but most importantly is the underlying sense of reasonableness behind government and industry statements and actions
- Public health authorities have been precautionary in characterizing snus as a potentially harmful product; but they have always been careful not to equate snus with cigarettes, and have presented the facts regarding tobacco use and resulting disease
- Swedish Match markets snus, but does so in a responsible manner and continuously strives to produce a clean a product as possible
- These actions are representative of, and provide a context for the Swedish experience

- Thank You -