Non-Smokers' Rights Association
Smoking and Health Action Foundation

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Harm Reduction in Tobacco Control: What is it? Why should you care?

POLICY ANALYSIS

Overview

The concept of harm reduction

Harm reduction is a widely accepted strategy in public health that recognizes that there will always be some people who engage in risky or illegal behaviours, including the use of licit and illicit drugs. Because abstinence is regarded as an unrealistic goal for some people, the goal of harm reduction is to mitigate the health risks associated with the risky behaviours rather than to eliminate the behaviour. Advocates of harm reduction see it as a pragmatic middle path between the polar opposites of the moral model—abstinence is the only valid goal—and the medical model—addiction is a disease requiring treatment.[1]

Needle exchange programs, safe injection sites, and methadone clinics are examples of harm reduction initiatives that accept that not everyone is ready, willing, or able to overcome a drug addiction. Rather than exhorting abstinence, these initiatives focus instead on reducing the related harms, such as HIV transmission from dirty needles.

Harm reduction in tobacco control

In tobacco control, harm reduction likewise acknowledges that a significant proportion of tobacco users are unable or unwilling to break their addiction to nicotine, at least for the foreseeable future. The goal therefore is to minimize harms and decrease total morbidity and mortality, without completely eliminating tobacco and/or nicotine use.[2]

Harm reduction can be achieved at the level of the individual and at the societal level. However, what constitutes harm reduction for an individual may not necessarily result in a net decrease in harm for society as a whole. If a product is only marginally less harmful but it is used by many more people, the end result could be an increase in societal harm. The opposite is also true. Where the reductions in risk are large, a public health benefit is likely even with a large increase in use.

The possible conflict between individual and societal harm reduction raises the question of whose interests should take precedence. According to Kozlowski and colleagues, "Public health concerns should trump individual rights only when there is clear and convincing evidence of harm to society. Lacking that evidence, individual rights should prevail."[3]

Total harm to society from a particular product depends on the harmfulness of the product, the number of users and their frequency of use.[4]

> Total harm = harmfulness of product (toxicity)
> x frequency of use (per user)
> x prevalence (number of users)

As the total harm equation suggests, harm reduction in tobacco control can be accomplished in a number of different ways:[5]

- Decreasing the risks of smoking through
  - product modification—modifying cigarettes to reduce smokers' exposure to toxicants
  - product substitution—switching smokers from cigarettes to smokeless tobacco products and/or to pharmaceutical nicotine replacement therapies (NRTs) or other nicotine-based products
- Decreasing the frequency/intensity of tobacco use per user through
  - reduced consumption
  - the use of NRTs for temporary abstinence
- Decreasing the prevalence of tobacco use through
  - reduced uptake
  - increased quitting.

For various reasons, this paper will address only product substitution — the merits of encouraging tobacco users to switch to less dangerous products, including pharmaceutical NRTs, smokeless tobacco products, and the new generation of alternative nicotine products. Product substitution is highly controversial within the tobacco control community, and therefore a thorough analysis of all facets of the issue is warranted. As well an examination of the issues is timely, given the recent introduction of a Swedish-style snus product on the Canadian market and the proliferation of alternative nicotine and tobacco products.

Product modification holds promise for the future, but the research is not conclusive enough to discuss related policy changes. The policy agenda with regard to decreasing the frequency and prevalence of tobacco use is already well advanced and is based on a solid body of research. It is worth noting, however, that some aspects of product substitution inevitably intersect with policies that promote quitting.

Continuum of risk

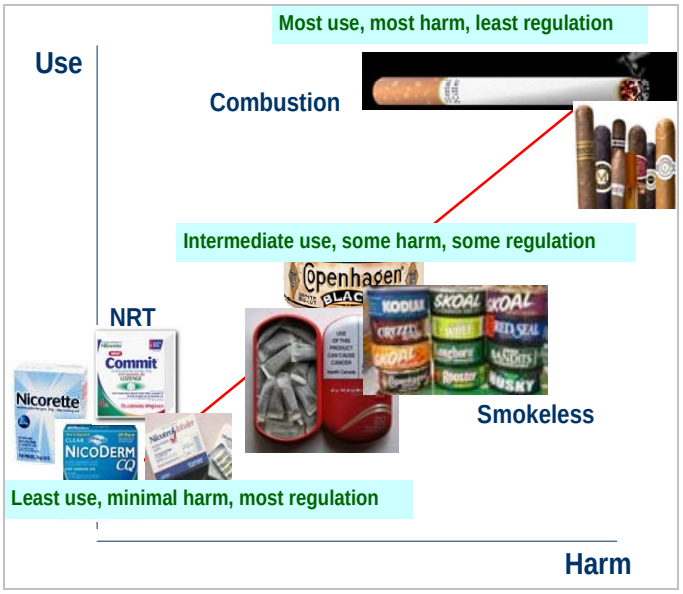
There is a wide array of tobacco products on the market, all of which contain nicotine, but for which the risk of use varies greatly, as illustrated in the graph below. The harmfulness of a tobacco product depends on many factors: the type of tobacco leaves in the product and the way they are grown, the method used to cure the tobacco, the way the product is manufactured, and the way the product is used.[6] The most serious health risks from tobacco use are not caused by nicotine but by the chemicals formed when tobacco is combusted for smoking.

In addition to tobacco products, a range of nicotine products is available, both pharmaceutical and consumer, that deliver nicotine but contain no tobacco and that are intended to be used as substitutes for tobacco products.

If nicotine could be delivered to addicted smokers in a purer form, without the deadly particles and gases formed by combustion, the disease and death now caused by cigarettes would drop dramatically. In Canada and many other countries, the perverse situation exists whereby the product that causes the most harm—cigarettes—is the

most widely used and the least regulated, whereas the safest products—nicotine replacement therapies—are the least used and subject to the most regulatory control. In brief, this is because tobacco products have been classified as unique consumer goods and as such are subject to their own regulatory regime, whereas NRTs and other non-tobacco nicotine products are classified as drugs and as such must comply with the requirements of the *Food and Drugs Act.*

Nicotine Delivery Devices[7]



The debate summarized

The debate over harm reduction in tobacco control basically centres on two opposing views. On the one hand are those who believe that encouraging people to switch to less hazardous products is the ethical choice, given the fact that most smokers are unwilling or unable to quit, at least not in the short-term, and that cigarettes kill one out of two of their long-term users. Proponents also see harm reduction as a necessary public health strategy, given the burden of disease and death caused by cigarettes and the fact that even in countries with advanced tobacco control policies, smoking rates and cigarette sales are declining by only 2-3% per year.

On the other side of the debate are those who believe that promoting tobacco and nicotine products that may be less hazardous serves to perpetuate addiction to nicotine, and addiction itself is a disease. Seeking to move smokers to other tobacco products rather than focusing on prevention and cessation likewise serves to prolong the tobacco epidemic. Because jurisdictions that have implemented effective tobacco control policies continue to experience reductions in prevalence, harm reduction opponents see no reason for other tobacco or nicotine products that may distract people from their goal of ending their addiction.[8] Moreover, opponents see a real risk that total harm may be increased because of the involvement of tobacco companies in developing and marketing these products. (See below for more detailed discussion on "The tobacco industry's role.")

More specifically, there are three principal aspects of the debate:

- The role of smokeless tobacco products, especially snus, and other new, non-combustible tobacco products.
- The extent to which NRTs should be promoted over 'cold turkey' or other non-pharmaceutical quitting supports. (Some are concerned that, like tobacco companies, the primary motive of pharmaceutical companies is profit. As well, there are concerns that the judgment of researchers and health organizations may be influenced by the fact that drug companies provide significant funding to them.)[9]
- The role of alternative nicotine products, other than pharmaceutical nicotine replacement therapies, such as the electronic cigarette and nicotine water.

The tobacco industry's role

What makes an assessment of harm reduction in tobacco control particularly problematic is the involvement of the tobacco industry as the manufacturers and promoters of many of these products and as the source of much of the research purporting that the products are harm-reduced. It is critical to bear in mind that the industry's goal is to maximize sales of tobacco products and hence profits, not to protect health.

It is equally valuable to recall the lessons of history, that is, previous attempts by the industry to market so-called 'safer' cigarettes. Tobacco companies knew decades before health authorities that "light" or "low-tar" cigarettes produced lower tar and nicotine emissions when tested by smoking machines but not when smoked by real people, who merely adjusted their smoking behaviour to get the desired dose of nicotine. Nonetheless, the companies continued to promote these products as safer alternatives to regular cigarettes. As a result, many health-concerned smokers switched to light cigarettes rather than quit. Despite widespread belief that these products were safer and despite widely anticipated public health gains, there was no reduction in morbidity and mortality from the use of these products.

This massive ongoing deception of the public and the government was one of the reasons for the landmark ruling by US District Court Judge Gladys Kessler in 2006 that tobacco companies have violated and continue to violate the *Racketeer Influenced and Corrupt Organizations Act*:

> "Defendants have marketed and sold their lethal products with zeal, with deception, with a single-minded focus on their financial success, and without regard for the human tragedy or social costs that success exacted…. Over the course of more than 50 years, Defendants lied, misrepresented and deceived the American public, including smokers and the young people they avidly sought as 'replacement' smokers about the devastating health effects of smoking and environmental tobacco smoke."

In Canada and other developed countries where smoking rates have been declining dramatically, tobacco companies have begun publicly championing the merits of "harm reduced" products and have positioned their efforts to bring such products to market as part of their corporate social responsibility initiatives. Internal company documents, however, give insight into their true motivation: to reap the benefits in terms of sales and profits from being able to market products that have been 'sanctioned' by government as being less risky:

> "Our aim is to present smokers with a choice of products, including cigarettes that might reduce the health effects of smoking. To help us reach that goal, we want governments to develop standards that establish exactly what constitutes a potentially reduced risk product and how to convey that information to smokers."[10]

Such sanction by a respected government authority would be a huge boon to their marketing efforts and could help shield the companies from future lawsuits, should the products prove more dangerous than anticipated.

In the meantime, the marketing campaigns for new snus and other new tobacco products have emphasized the advantage for consumers of being able to use these products where smoking is not permitted. The companies are seeking to keep their smoking customers in the market by promoting dual use of cigarettes and smokeless products.

Regardless of where one stands in principle on harm reduction, it is clear that vigilance and wariness are warranted regarding the involvement of tobacco companies in developing and

marketing potentially lower risk products. The lessons learned from the light and mild fraud must inform our consideration of the new generation of tobacco products purporting to reduce risk.

Other considerations: consumer acceptance

A key factor in the success of any harm reduction strategy is the consumer acceptance of alternative products. Consumer acceptance depends on a number of variables:

- The ability of the product to quell withdrawal symptoms—how quickly the product delivers an adequate dose of nicotine to satisfy a craving and how long the craving remains appeased
- The overall satisfaction derived from using the product (taste, physiological experience, etc.)
- Social acceptability
- Beliefs regarding the absolute and relative risks of use
- Cost
- Availability.

Here again there are opposing views. Some feel that the willingness of smokers to try new, less harmful products and their acceptance of these products will depend in part on how these products are promoted. The willingness of smokers to try snus, for example, may be enhanced if the snus bears the same brand name as a well-known brand of cigarettes and is given the same cachet through marketing. Others, however, believe that giving a smokeless product the same name as a cigarette brand merely serves as cross-promotion to encourage dual use.

Relative Risks of Nicotine Products

Smoked tobacco products

Cigarettes

Cigarettes are by far the most widely used form of nicotine/tobacco product and by far the most toxic. Cigarettes kill one out of two long-term users, half of them prematurely.[11] There are 4.9 million smokers in Canada, most of whom want to quit and most of whom are addicted.[12] Approximately 37,000 Canadians die every year from diseases caused by tobacco use.[13]

The most serious health risks from cigarettes are not caused by nicotine but by the chemicals formed when tobacco is burned. There are hundreds of poisons in tobacco smoke, of which more than 60 cause cancer.[14] For this reason, addiction experts call cigarettes dirty drug delivery systems, like dirty needles that transmit disease to addicts of illicit drugs such as heroin and cocaine.

Smoking damages almost every organ of the body. About 30% of all heart disease, 30% of all cancers, and 90% of all chronic obstructive lung disease are caused by smoking.[15] The major health risks from smoking cigarettes are as follows:[16]

- Addiction
  - Nicotine is highly addictive. It is even more addictive when delivered through the inhalation of cigarette smoke, since nicotine from tobacco smoke reaches the brain in less than 10 seconds, faster than if administered intravenously.[17]

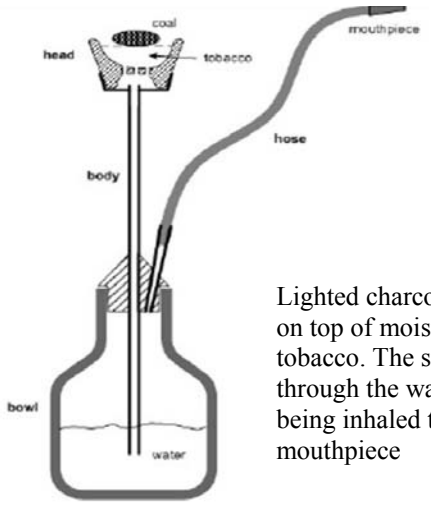
- Cardiovascular disease
  - heart attack—smokers are 2–4 times more likely than non-smokers to develop heart disease
  - stroke—smoking doubles risk of stroke
  - peripheral vascular disease—smokers are 10 times more likely than non-smokers to develop PVD
  - abdominal aortic aneurysm
- Cancers
  - Lung cancer—85-90% of all lung cancer deaths are attributable to smoking
  - Cancers of the bladder, oral cavity, pharynx, larynx, esophagus, cervix, kidney, pancreas, stomach, breast,[18] and acute myeloid leukemia
- Chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema
- Spontaneous abortion (miscarriage)
- Fertility problems (male and female)
- Erectile dysfunction (impotence)
- Peptic ulcers
- Osteoporosis
- Cataracts.

Although the federal government has had the authority under the *Tobacco Act* since 1997 to regulate the contents of cigarettes and other tobacco products, this power has gone virtually unexercised. Apart from having to adhere to regulations controlling the ignition propensity of cigarettes, cigarette manufacturers remain virtually unfettered in what they can put inside cigarettes—cigarette contents—and what comes out of cigarettes—toxic emissions.[19] A new tobacco product can be introduced to the Canadian market with virtually no regulatory oversight or approval. As Thompson puts it, "the most hazardous consumer product in widespread use is subject to less regulation than foods, cars, or toys."[20]

Waterpipes

Also called hookah, narghile, shisha, hubble-bubble, and gouza, waterpipes have been used for smoking for over 400 years, primarily in northern Africa, south east Asia, and the eastern Mediterranean. In recent years, the practice has been spreading to young adults in North America, Brazil, and Europe.[21]

In a waterpipe moist flavoured tobacco is burned in a bowl and the smoke is drawn through a water container before being inhaled through the mouthpiece.[22]



Lighted charcoal is placed on top of moist (flavoured) tobacco. The smoke passes through the water before being inhaled through the mouthpiece

Waterpipe tobacco is actually a special blend of tobacco leaves, fruit pulp, honey or molasses, and glycerin and is available in a wide variety of flavours, such as strawberry, apricot, mango, banana, grape, double apple, and mint.

There are several reasons for the growing popularity of the waterpipe in western societies.

Smoking a waterpipe is a social activity, since the waterpipe is often shared among a group of people. In addition, there is a widespread misperception that waterpipe smoking is safer than cigarette smoking because the smoke passes through water and because the tobacco is highly flavoured, masking its 'tobacco' taste. As well, packs of waterpipe tobacco often make misleading health claims such as "This blend contains only 0.5% nicotine and no tar."[23] In fact, no tobacco product contains tar, since tar is a by-product of burning the tobacco.

In general, hookah smoking carries the same health risks as cigarette smoking—addiction, cancer, heart disease, and respiratory diseases. However, the method of smoking, including the frequency of puffing, the depth of inhalation, and the length of a typical smoking session, means that hookah smokers absorb higher concentrations of toxins. A hookah smoker may inhale as much smoke from one session as a smoker would inhale from 100 cigarettes.[24] As well, second-hand smoke from the tobacco and the charcoal is as toxic as second-hand cigarette smoke.[25]

Smokeless tobacco products

A wide range of smokeless tobacco products is available that are all consumed without burning the tobacco. Oral smokeless tobacco products are placed in the mouth, cheek or lip and are sucked (dipped) or chewed. In North America, the most commonly used oral smokeless tobacco products are chewing tobacco (loose leaf, moist plug, plug), moist snuff (also called dip or spit tobacco), and snus (Swedish-style snus is moist, fine-ground tobacco that has been air-cured and/or sun-cured). Dry snuff is made from fire-cured tobacco that has been fermented and ground into a powder; it can be used orally or nasally, although the use of nasal snuff is now very rare in North America.[26]

Chewing tobacco: loose leaf

Moist snuff: loose leaf, long cut*

Moist snuff: loose leaf, short cut

Swedish-style snus

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Dry snuff

Not only do smokeless tobacco products vary widely in terms of their form and method of use but also in terms of their related health risks. For example, as the table below illustrates, there is almost a 50-fold difference in the amount of tobacco-specific nitrosamines in oral tobacco products (from 0.19 µg to 9.2 µg per gram of tobacco wet weight).[28,29] Tobacco specific nitrosamines (TSNAs) are the major cancer-causing chemicals in smokeless tobacco products.[30]

Nitrosamine Levels of Smokeless Tobacco Products ((per gram of tobacco wet weight)			
Product	**Company**	**Nitrosamine Level**	**Availability**
Ariva (compressed tobacco lozenge)	Star Scientific	▪ 0.19 µg	US drug store chains
Camel snus	R.J. Reynolds	▪ 1.12 µg	Test marketed in selected US cities 2006-09; US 2009
Copenhagen ▪ Snuff ▪ Long cut	UST (Altria/ Philip Morris)	▪ 4.8 µg ▪ 7.5 µg	US; Canada
du Maurier snus	Imperial Tobacco (BAT)	▪ 1.3 µg	Test marketed—Edmonton (Oct. 2006), Ottawa (Feb. 2007)
General snus	Swedish Match	▪ 2.0 µg	Online; select US states
Revel	UST (Altria/ Philip Morris)	▪ 0.99 µg	Test marketed—Colorado
Skoal ▪ Long cut straight ▪ Bandits	UST (Altria/ Philip Morris)	▪ 9.2 µg ▪ 1.3 µg	US; Canada

Because smokeless tobacco products do not involve combustion and inhalation into the lungs, their use does not cause two of the main health consequences of smoking—lung cancer and chronic obstructive pulmonary disease. Indeed, there is no disease and no form of cancer for which use of any type of smokeless tobacco carries a greater risk than the risk from cigarette smoking.[31]

When considering studies of the health risks of smokeless tobacco use, it is important to note which types of smokeless tobacco products were assessed, as the risk of use vary greatly among different products. For example, although the US Surgeon General, the American Cancer Society, and the International Agency for Research on Cancer (IARC) have all concluded that smokeless tobacco causes oral cancer,[32] a careful review of the evidence by the UK Royal College of Physicians led to a very different conclusion:[33]

> "The main evidence associating smokeless tobacco with oral cancer comes predominantly from studies in populations combining smokeless tobacco with other toxins (such as areca nut) or from populations using products that contain higher concentrations of carcinogenic compounds than are present in current moist snuff or new smokeless tobacco products available in the United States or Scandinavia."

In general, use of smokeless tobacco poses the following health risks:

- Addiction
  - Smokeless tobacco delivers quantities of nicotine comparable to those typically absorbed from inhalation of tobacco smoke, but nicotine is not delivered to the brain with the same speed or to the same peak concentration. For these reasons some researchers believe that smokeless tobacco may have relatively less addictive potential than cigarettes.[34] In contrast, the Royal College of Physicians has concluded that "smokeless tobacco is capable of delivering sufficient quantities of nicotine with sufficient speed to have reinforcing psychoactive effects and … is potentially dependence-forming in many users."[35]
  - The time course and symptoms of withdrawal from smokeless tobacco are similar to those of cigarette smokers, with the exception of depressed mood or negative affect. Daily snus users reported similar prevalence of withdrawal symptoms to cigarette smokers, including 85% reporting an urge to chew, 63% reporting irritability, and 41% reporting difficulty concentrating. In comparison only 9% of snus users reported "feeling sad, blue or depressed" compared to 26% of smokers. Withdrawal symptoms are reported to be stronger with some brands of smokeless tobacco that deliver higher levels of nicotine.[36]

- Oral cancer
  - The risk of oral cancer varies by type of smokeless tobacco product and is much greater for dry snuff than for moist snuff. The relative risk of oral cancer from use of dry snuff is 5.9 compared to 1.2 from chewing tobacco and 1.0 from moist snuff.[37] A meta-analysis in 2007 concluded that the type of smokeless tobacco used in America or Europe "carries at most a minor increased risk of oral cancer."[38] The Royal College of Physicians has concluded that "the risk of oral cancer associated with use of low-TSNA tobacco products such as Swedish snus is small, and possibly non-existent."[39]
- Pancreatic cancer
  - Most of the studies showing an increase in risk of pancreatic cancer among smokeless tobacco users fail to correct for the confounding influence of smoking. Some also do not correct for the possible confounding of alcohol use. A small case-control study of smokeless users who were never smokers found a small but not statistically significant increased risk of pancreatic cancer, with the risk being dose-related. The Royal College of Physicians nonetheless reached the conclusion that "smokeless tobacco, including the snus consumed in Sweden over the past half century, appears to be associated with an increased risk of pancreatic cancer."[40]
- Oral health problems
  - Smokeless tobacco use causes recession of the gums and increases the risk of periodontal disease, although to a lesser degree than smoking.[41] There is clear evidence that smokeless tobacco use causes leukoplakia, white lesions on the soft tissues in the mouth where the oral tobacco is usually placed. Precancerous changes in the leukoplakia cells are found in less than 3% of smokeless tobacco users compared to 20% of smokers and are usually found in earlier stages. Leukoplakia in smokeless tobacco users rarely progress to oral cancer.[42]
- Cardiovascular risks
  - Early studies of the risks of cardiovascular diseases from use of smokeless tobacco were primarily conducted in Sweden on snus users and produced inconsistent results. The evidence from more recent studies is also inconsistent, but three large studies have found increased risks of cardiovascular disease among smokeless tobacco users compared to never tobacco users. The risk, however, is lower than for smokers.[43] A meta-analysis published in 2009 of 11 studies, 8 from Sweden and 3 from the US, found a small but significant increased risk of death from a heart attack and stroke among users of smokeless tobacco products compared with non-users.[44]
- Reproductive effects
  - There are few studies that specifically examine the effect of smokeless tobacco use on fetal development. The findings from the existing epidemiological studies, however, are consistent with the evidence from animal studies that exposure to nicotine via smokeless tobacco causes a reduction in birth weight (about 20% of the reduction caused by smoking) and increases risks of pre-eclampsia and stillbirth.[45]

Snus[*]

Swedish-style snus is moist, fine-ground tobacco that has been air-cured and/or sun-cured. The ground tobacco is combined with water, salt, humectants, baking soda, and flavours. Snus is usually sold in pouches or as loose tobacco, which is placed between the lip and the gum. Unlike most other forms of smokeless tobacco, snus does not require spitting.[46]

Because snus is manufactured by pasteurizing the tobacco with steam, and not by fermenting, and because the product is kept refrigerated, Swedish snus is much lower in nitrosamines than other forms of oral smokeless tobacco, including other types of snus.[47] Since 1970, the Swedish government has regulated the manufacture of snus as a food product, imposing strict requirements to meet food safety standards related to the manufacturing process, ingredients, ingredient disclosure, and levels of various toxins.[48] The levels of carcinogens in Swedish snus have decreased significantly since the 1980s.[49]

The Gothiatek Standard, established by the largest snus manufacturer in Sweden, Swedish Match, sets maximum permissible limits for nine major toxins in snus. The limits meet or exceed the requirements of the Swedish government:

Gothiatek Standard	
Toxin	**Max. Permissible Limit**
Nitrate	3.5 mg/kg
TSNAs	5.0 mg/kg
N-Nitrosodimethylamine	5.0 µg/kg
Benzo(a)pyrene	10.0 µg/kg
Cadmium	0.5 mg/kg
Lead	1.0 mg/kg
Arsenic	0.25 mg/kg
Nickel	2.25 mg/kg
Chromium	1.5 mg/kg

When considering studies of the health risks of smokeless tobacco, it is important to distinguish between smokeless products such as traditional spit and chew (in Canada the most popular brands are Copenhagen and Skoal) and Swedish-style snus. Most studies of the health risks of smokeless tobacco use do *not* make the distinction between snus and other forms of smokeless tobacco.

- Oral cancer
  - The risk of oral cancer varies according to the type of smokeless tobacco. Two Swedish studies found no elevated risk of oral cancer from snus use, and the findings constituted the grounds for the removal of the oral cancer warning from snus products in Sweden in 2001.[50]
- Leukoplakia
  - There is a very high rate of leukoplakia development from snus use, much higher than with other forms of smokeless tobacco; however, the lesions are mostly due to irritation and only rarely progress to oral cancer.[51]
- Heart disease
  - There are very few studies of the risk of heart disease from use of Swedish snus that also correct for possible confounding variables, including smoking and exposure

[*] Throughout this report, unless otherwise stated, the term "snus" refers to Swedish-style snus as defined in this section.

to second-hand smoke. Of six studies of risks of heart attack risk among long-term Swedish snus users, only one found an increased risk, and five found no increased risk over never tobacco users.[52] A meta-analysis in 2009 of eleven studies, eight in Sweden and three in the US, provides consistent evidence of a small increase in risk of fatal heart attack and stroke, with no evidence of a difference in effect of the smokeless products consumed in Sweden vs. the US.[53]

Compared to cigarettes, snus is estimated to have significantly lower risks:[54]

- 9% of the risk of total (tobacco-caused) mortality, for users aged 35-49
- 5% of the risk of total mortality, for users aged 50+
- 10% the risk of heart disease
- 15-30% the risk of oral cancer.

The nicotine levels obtained from snus are about twice as high as those typically obtained from NRTs.[55] In Canada, du Maurier snus contains about 18 mg of nicotine per pouch, while nicotine gum has only 4 mg at most.* That means that du Maurier snus delivers 3-4 times more nicotine than nicotine gum, making it far cheaper than the cheapest NRT on the market on a milligram to milligram basis.[56]

In Canada, the first snus product to hit the market was launched by Imperial Tobacco in 2006 under the brand name of the top selling Canadian cigarette—du Maurier. To date, the product is still being test-marketed in two cities only, Edmonton and Ottawa. In its promotional material, Imperial described the introduction of snus as a fulfillment of the company's Corporate Social Responsibility commitment to "test market a reduced harm product" and emphasized the pasteurization process that reduces the formation of TSNAs. However, Imperial has not made public any information on the level of TSNAs or any other toxic ingredient in its snus.[57] As mentioned earlier, the introduction of a new tobacco product in Canada does not require any regulatory approval or verification of the manufacturer's claims.

In the two years since the launch, Imperial has focused its advertising on the benefits of using snus where smoking is not permitted. Clearly the company is promoting dual use, not the reduced risks from using snus rather than cigarettes.

New forms of tobacco products

In recent years a number of new forms of tobacco products have entered the market, in some cases narrowing the differences between pharmaceutical nicotine products and industry-based tobacco products.[58]

Small manufacturer Star Scientific has been selling two forms of dissolvable tobacco product for several years—Ariva, targeting cigarette smokers, and Stonewall, aimed at users of smokeless tobacco. Both products come in the form of a small pellet, slightly larger than a Tic Tac mint.[59]

* Note that the nicotine content is not the same as nicotine delivery. Typical moist snuff contains about 12.6 g of nicotine and delivers about 3.6 g, whereas the dose of nicotine from gum is about half its nicotine content, or about 2 mg from a piece 4 mg gum (Royal College, 2007)..

Ariva and Stonewall have levels of TSNAs similar to Swedish snus.[60] The company's principal marketing message, however, does not focus on the product's reduced risk but rather on its value as a bridge when smokers can't light up and its greater social acceptability.[61] Likewise, the company emphasizes the increased social acceptability of Stonewall for smokeless tobacco users, since the product is more discreet (there is no visible bulge in the cheek with the lozenge) and it does not require spitting.[62]

"Discreet tobacco alternative. No smoke. No mess. Enjoy real smoking satisfaction in all the places you can't smoke. Workplace. Restaurants. Airports. Sporting Events. More than 40% of American's 47 million smokers are looking for socially acceptable alternatives to cigarettes."

In 2009 RJ Reynolds became the first major tobacco company to sell a dissolvable tobacco product in the US, when it began test marketing several new products—strips, sticks, and orbs—all under the Camel brand name.[63] The company believes the products are a more socially acceptable form of tobacco, producing no spit, no second-hand smoke, and very little litter.[64] The products were developed in part because of feedback from users of Camel snus who did not like the loose tobacco or tobacco pouches and who objected to having to dispose of the pouches after use.[65]

Camel Strips resemble breath strips; they are sold in packs of 20 Fresh-flavoured strips. Each strip lasts 2-3 minutes and provides 0.6 mg of nicotine. Camel Orbs are lozenges that last 10-15 minutes, with each orb providing 1 mg of nicotine. They are sold in packs of 15 orbs, in two flavours, Fresh and Mellow. Camel Sticks are similar to toothpicks and last 20-30 minutes; they contain 3.1 mg of nicotine. They are sold in packs of 10 sticks, in one flavour only, Mellow.[66] The products are expected to be priced similar to a tin of Camel snus.

"Strips give you a fresh burst of tobacco pleasure. Just get a Camel Strip form its pack and put it on your tongue. That's it. You've just enjoyed a Strip. Strips will dissolve away completely in a couple of minutes."

"Sticks come in Mellow, which delivers a rich natural tobacco taste. To enjoy a Stick, just put one in your mouth like a toothpick or break off a piece and let it dissolve in your mouth a little at a time. Sticks are pretty flexible in how you enjoy them."

It is clear that both Star Scientific and Reynolds are marketing dissolvable tobacco products primarily as viable alternatives for smokers when they can't light up. They are also promoting the products as more socially acceptable alternatives to both cigarettes and smokeless tobacco. Other

than the level of nicotine, the manufacturers have not provided the public with any information regarding the ingredients, additives, and toxic constituents of these products.

The impact of these products and their aggressive marketing by a major tobacco manufacturer on consumer behaviour remains unknown. Will smokers use them as bridge products for occasions when they can't smoke, increasing total tobacco use and decreasing cessation? Will they become a gateway for young people into the tobacco market, and if so will they appeal to youth who would otherwise not have started smoking? The US Campaign for Tobacco-Free Kids believes that RJ Reynolds is overtly targeting kids with the new products, given their youth-friendly flavouring and packaging that mimics candy.[67] Harvard University Professor of Public Health and tobacco control advocate Greg Connolly is ardent in his opposition to these new tobacco products, calling them "nicotine on training wheels":[68]

> "R.J. Reynolds 'is just trying to expand the options for nicotine delivery products for the American public.' Smoking a cigarette for the first time, can be a deeply uncomfortable experience for a teenager…. By turning it into a mint-like product — in mint and cinnamon flavors — they've made nicotine addiction a more pleasurable experience."

Nicotine Replacement Therapies

Nicotine replacement therapies (NRTs) are medications that offer clean and therapeutic delivery of the drug nicotine intended to lessen the physical symptoms of withdrawal from nicotine experienced by most smokers who are trying to quit. NRTs are formulated to provide nicotine in controlled doses, allowing the smoker to reduce gradually the amount of nicotine in the body and thus manage withdrawal symptoms and cravings.[69] The U.S. Public Health Service Clinical Practice Guideline on *Treating Tobacco Use and Dependence* recommends that clinicians encourage the use of approved cessation medications by all patients attempting to quit smoking—except when medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness.[70]

NRTs are available in Canada in several forms and dosages, all of which are recommended by the U.S. Clinical Practice Guideline:

- Patch—16 hour, 24 hour; constant dosage or stepped dosage: 21 mg, 14 mg, 7 mg
- Gum—2 mg, 4 mg
- Lozenge—1 mg, 2 mg, 4 mg
- Inhaler—4 mg.

NRTs are much safer than tobacco products because they contain only the nicotine and none of the other chemicals in tobacco. Extensive research has been done on these products, including toxicity and safety studies, both pre- and post-market.[71]

The risks of NRTs have been found to be minimal; however, because these products are not risk-free, caution is needed with some populations.[72] As well, the risks of long-term use are not yet fully known:[73]

- Nicotine is potentially neurotoxic to the developing fetus. Nicotine may contribute to complications in pregnancy and to sudden infant death syndrome. However, the risks to both the mother and fetus are considerably lower from NRT use than from continued smoking, because the dose of nicotine is much lower and because nicotine is administered without all of the other toxins in tobacco smoke.[74]
- Nicotine has direct effects on blood vessels and may cause endothelial dysfunction.

However, numerous studies have found no increased risk of cardiovascular disease among cardiovascular patients who use NRT or among people who continue to smoke while using NRT.

- There is conflicting evidence regarding whether nicotine promotes the growth of cancerous tumours in humans. There is some indication that smokers who switch to smokeless tobacco may have an increased risk of lung cancer compared to smokers who quit tobacco use altogether. However, exposure to TSNAs from smokeless tobacco, as opposed to nicotine, could account for or contribute to the increase in lung cancer risk. As well, the fact that lifelong use of snus among Swedish men does not increase risk of any cancer except pancreatic argues against the role of nicotine in promoting tumour growth.[75]

- Nicotine can impair wound healing. However, clinical trials have found that surgical outcomes are much better among patients who use NRT than those who continue smoking.[76]

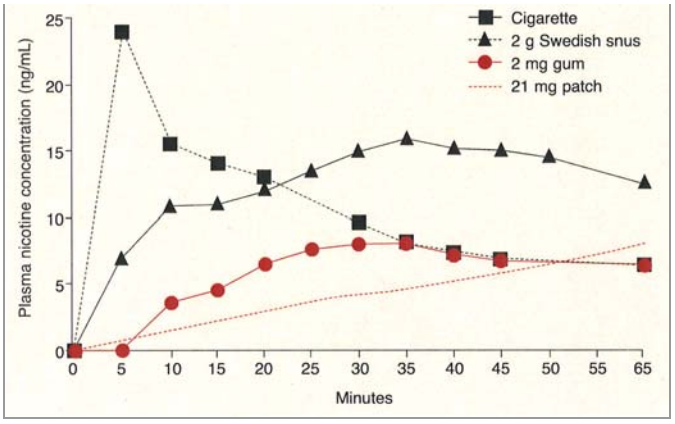
Despite the fact that they pose significantly lower health risks, medicinal nicotine products are at a substantial marketing disadvantage compared to tobacco products in both Canada and the U.S. This anomaly is largely because, as with other products considered drugs, they must undergo a rigorous federal approval process. These regulatory requirements inhibit innovation and slow the introduction of new products and/or formulations, as well as restricting the marketing of these products, including where the products may be sold.

In addition to the marketing restrictions, the warnings on NRTs contribute to the widespread misconceptions among consumers and even some health professionals about the absolute risks of use and the risks of use compared to continued tobacco use.[77] A survey for the American Legacy Foundation in 2007, for example, found that 80% are unsure whether or incorrectly believe that nicotine causes cancer, emphysema, and heart attacks. Two thirds are unsure whether or wrongly believe that the nicotine in NRTs is more dangerous than the nicotine in cigarettes and three-quarters do not know whether or wrongly believe that NRTs are more addictive than cigarettes.[78] These misconceptions inhibit many smokers from trying NRTs and prevent others from using these products in a manner that would maximize their potential to aid in quitting.

Why NRT isn't the answer for all smokers

NRTs have proven effective in helping smokers to quit.[79] However, for various reasons, NRT hasn't been and may never be the answer for all smokers who want to stop using tobacco:

- The nicotine in NRTs replaces only some of the nicotine that a smoker is used to getting and does so at a slower pace than cigarettes, as illustrated in the graph below.[80]



  - The patch releases nicotine the most slowly of all forms of NRT, achieving peak nicotine concentrations after 3-8 hours, but allows users to achieve a near constant level of nicotine in their system. The slow release of nicotine and the

passive administration, however, do not help smokers deal with sudden urges to smoke.[81]

  - The gum, inhaler, and lozenge release nicotine faster than the patch and therefore are most useful for dealing with acute cravings. However, peak concentrations of nicotine are not reached for about 20 minutes, much slower than cigarettes.[82]
  - While the inhaler comes the closest to mimicking the look and feel of a cigarette, it has some distinct shortcomings. When puffing on the thin, plastic cartridge, the user extracts nicotine vapor which is absorbed through the lining of the mouth; however, it takes at least 80 puffs to obtain the equivalent amount of nicotine delivered by one cigarette. Also, cooler temperatures reduce the amount of nicotine that is extractable from the inhaler.[83]

- For many smokers the cost of NRTs is a barrier to their use:
  - They are too expensive, and insurance plans either don't cover them or they provide inadequate coverage.
  - NRTs are sold in quantities requiring a much higher outlay of cash than cigarettes, which are sold in packs that for most smokers contain a 1-2 day supply.

- Access to the different NRT options is uneven across Canada, depending in part on what province/territory the smokers live in and whether it is an urban or rural community.

Other nicotine products

In recent years, several non-pharmaceutical, non-tobacco products containing nicotine have begun to appear on the market. These include the electronic cigarette, as well as nicotine water, gel, wafers, and lollipops.

E cigarette

Electronic cigarettes, called "e-cigarettes," resemble real cigarettes but are made of a stainless steel tube with a chamber that holds liquid nicotine. Powered by a rechargeable battery, the device produces a heated mist of nicotine that is absorbed in the lungs and a vapour resembling smoke that is exhaled.[84] Electronic versions of cigars, cigarillos, and pipes are also available.

[85]

Electronic cigarettes were first developed in China in 2004 and are now sold on the Internet and in countries around the world, including Brazil, parts of Europe, Israel, Lebanon, and the United Kingdom.

In March 2009, Health Canada issued an Advisory to consumers not to use e-cigarettes and to persons importing, advertising or selling electronic cigarette products in Canada to stop doing so immediately. Because e-cigarettes contain no tobacco, they are not regulated under the *Tobacco Act* but rather under the *Food and Drugs Act* and as such require market authorization before they can be imported, advertised, or sold in Canada.[86]

Health Canada warns that electronic smoking products have not been evaluated for quality,

efficacy, and safety and may pose health risks, including addiction and nicotine poisoning. As well, the inhalation of propylene glycol is a known irritant.[87] The World Health Organization states that "There are a number of chemical additives in the product which could be very toxic."[88] The US Food and Drug Administration is reviewing the data on e-cigarettes and will not allow their importation until they have been approved as a drug delivery device. The American Medical Association intends to study the potential role of electronic cigarettes in smoking cessation.[89]

The appearance of e-cigarettes on the market has raised several concerns:

- They contain nicotine and nicotine is highly addictive.
- They are being marketed as a safe alternative to smoking cigarettes, although the safety of these products for short-term and long-term use has not been independently tested by health authorities. Unlike NRT, there is no toxicity data, no safety data, and no pharmacokinetic (PK) data* for these products.[90]
- They are being marketed as an aid to quitting smoking, although there is no scientific evidence demonstrating their safety and efficacy as a cessation device. Furthermore, some manufacturers have included WHO's name or logo on their website, package inserts, or advertisements, implying an endorsement by WHO that has never been given.[91]
- They are being marketed as a way of circumventing smoking bans. Workplace and public place smoking bans have proven effective in getting smokers to cut down and to quit. The presence of people smoking electronic cigarettes in places where smoking is prohibited may complicate enforcement and may serve as a cue to smoke, undermining the reduction in consumption that normally follows smoking bans.[92]

On the other side of the issue are those who have been advocating for the development of a clean nicotine delivery device that would allow tobacco users to satisfy their need for nicotine without being exposed to the many noxious chemicals in tobacco smoke.[93] Safety testing for one brand of e-cigarette, Ruyan, conducted by Murray Laugesen, a former principal medical officer of health with the New Zealand health department, and funded by the manufacturer, concluded that the e-cigarette is a safe alternative to smoking:[94]

> "It is very safe relative to cigarettes, and also safe in absolute terms on all measurements we have applied. Using micro-electronics it vaporizes, separately for each puff, very small quantities of nicotine dissolved in propylene glycol, two small well-known molecules with excellent safety profiles, – into a fine aerosol. Each puff contains one third to one half the nicotine in a tobacco cigarette's puff. The cartridge liquid is tobacco-free and no combustion occurs."

Laugesen's research also concludes that there is no risk to others from breathing the exhaled mist from the e-cigarette. The exhaled mist is an odorless mixture containing no active ingredients and no products of combustion. The mist consists primarily of propylene glycol with a small amount of nicotine and no carbon monoxide.[95]

While the e-cigarette is not entirely risk-free, there is little doubt that it poses far less risk to health than tobacco products, particularly smoked tobacco products. Clearly the regulatory regime in Canada and many other countries runs counter to logic when a new tobacco product can enter the market with no prior testing or approval by a

* Pharmacokinetic or PK data determines the relationship between the dosing regimen of a drug and the body's exposure to the drug.

regulatory authority, and a much less harmful product may not be sold until approved by Health Canada following an extensive review of the scientific evidence of its safety and efficacy.[96]

Nicotine water

Sales of nicotine water began in the U.S. in 1998 but were halted between 2002 and 2006, because the product did not meet FDA criteria for an over-the-counter (OTC) dietary supplement. The product was reintroduced to the U.S. market in 2006 as a homeopathic formulation and in 2008 as a tobacco product.[97] According to one manufacturer, a bottle of nicotine water contains the nicotine equivalent of 2-3 cigarettes.

The description of the product's benefits on one manufacturer's website suggests that nicotine water is being marketed as a safer alternative to smoking ("contains no tar") and as an aid to quitting ("process of drinking keeps the hands occupied; "helps prevent weight gain"; "the safest nicotine product available since the volume of the water makes abuse difficult.") Another manufacturer, NicLite, promotes the water as "a quick, convenient and easy solution" for people "when they cannot smoke, should not smoke or choose not to smoke."[98]

Nicotine gel

Nicotine gel is a tobacco-based clear gel that purports to allow the user to absorb nicotine through the skin, providing that "cigarette satisfaction feeling" in about a minute. It comes in a 50 ml pump dispenser that contains the equivalent of 50 cigarettes.[99]

Nicotine lollipop

Nicotine lollipops contain nicotine, combined with a natural sweetener and flavorings, according to information provided on Internet pharmacy sites. The lollipops are available in 2 mg or 4 mg doses. Nicotine lollipops are promoted as an aid for smoking cessation.[100]

In Canada, products containing nicotine are regulated under Schedule F of the *Food and Drugs Act.* All products containing nicotine and its salts, except four permitted types of NRT, can only be sold by prescription and can only be imported by a pharmacist, practitioner, or manufacturer. As with the e-cigarette, at present these alternative nicotine products cannot be legally sold in Canada or purchased on the Internet and imported into Canada by an individual. Because products that contain nicotine but not tobacco are considered drugs, they must go through an extensive testing and approval process and be given a unique drug identification number (DIN) before they can be sold in Canada.

Discussion: Smoked vs. Smokeless

The science is clear that smokeless tobacco products, and especially Swedish-style snus, pose considerably lower health risks than combustion tobacco products, in particular cigarettes. The research provides conflicting evidence, however, regarding the impact of smokeless tobacco products on individual behaviour and public health. Most of the research comes from Sweden and Norway, the two countries with a history of both cigarette and snus use. Some research is also available from the US, where oral tobacco use has been increasing in the past decade. To determine whether or not the availability and marketing of smokeless tobacco, in particular Swedish-style snus, result in harm reduction at the societal level, several questions need to be answered related to the impact of snus on youth smoking uptake, smoking cessation, and total consumption.[101]

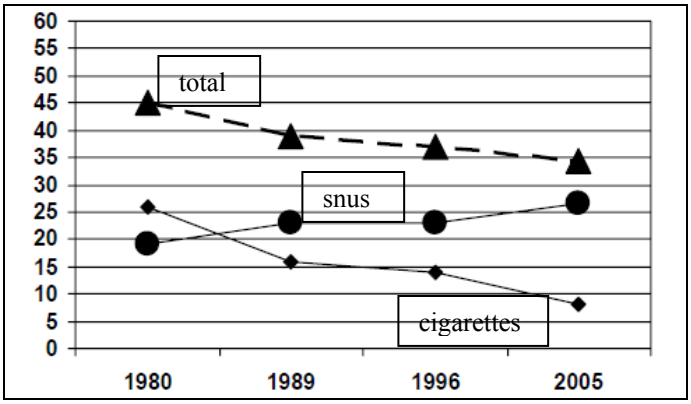
1. Does the availability of snus result in reduced smoking initiation among youth?

Or does snus serve as a gateway drug to cigarettes?

The data from Sweden do not indicate that use of Swedish snus is a stepping stone to smoking cigarettes. A survey of 2879 men found that 20% of primary daily snus users (daily snus use with no prior smoking) went on to become daily smokers compared to 45% of men who were not primary snus users.[102]

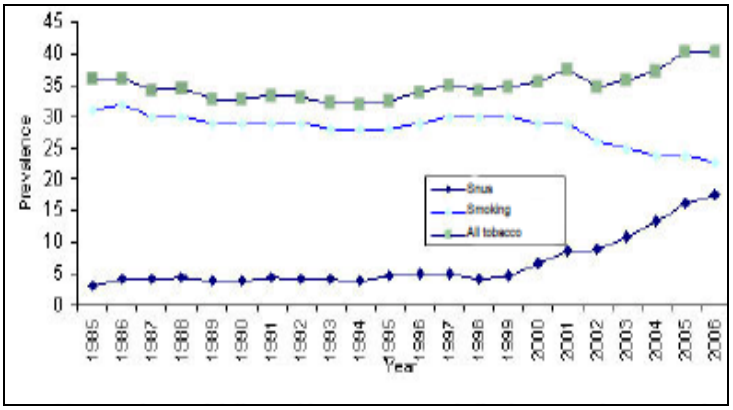
Among young men aged 16-24, daily snus use has risen slightly over the past decade from approximately 24% to 27%, while daily smoking has dropped from 25% to below 10%.[103]

Prevalence of daily tobacco use, Sweden, males age 16-24



The experience in Norway with snus is quite different. As the graph below illustrates, among young men in Norway aged 16-24, snus use has increased dramatically since 1999, whereas the prevalence of smoking has declined very gradually over the past twenty years. Total tobacco use among young Norwegian men is also increasing. Smoking prevalence is almost double that of young Swedish men, and the rate of snus use is approximately 30% lower.[104]

Prevalence of daily tobacco use, Norway, males, age 16-24



Researchers urge caution in translating the findings from Sweden and Norway to North America, given the significant social and cultural differences as well as the differences in smokeless tobacco products.[105] The limited research from the US experience with smokeless tobacco products reinforces the need for caution. There is some evidence from the US that youth who use smokeless tobacco (primarily chew, no snus) are more likely to progress to smoking.[106]

2. Does snus serve as a gateway to quitting smoking?

No randomized trial has been conducted on the use of snus as an aid to quitting. As well there has been no randomized trial comparing smokeless tobacco to nicotine replacement therapies as cessation aids. Although several observational studies have examined the use of smokeless tobacco to reduce smoking, these studies have produced inconsistent findings. As a result the European Commission Scientific Committee on Emerging and Newly Identified Health Risks reached the following conclusion:[107]

> "On the available evidence it is therefore not possible to draw conclusions as to the relative effectiveness of smokeless tobacco as an aid to smoking cessation in comparison with established therapies."

The significant differences between Sweden and Norway regarding changes in prevalence of smoking and snus use suggest that the association between snus use and smoking cessation is likely to be affected by cultural, societal, and other factors such as tobacco control interventions.[108]

Over the past 30 years, snus consumption has doubled among men in Sweden, while cigarette consumption has decreased steadily, with per capita consumption being cut in half.[109] The decline in daily smoking has been much greater among men (from 40% in 1976 to 15% in 2002) than women (from 34% to 20%). During the same period, male daily snus use increased from around 10% to 23%,[110] whereas female snus use increased from negligible to less than 5%.[111] Research by Rodu and colleagues of cessation among Swedish ever-smokers shows that a higher proportion of male ever-smokers than female have quit and that most of the men who quit smoking also used snus. Further research by Rodu found that 39% of men in Northern Sweden who were smokers (no snus use) at the time of the 1986–94 surveys had quit smoking by 1999. One-third of the ex-smokers had switched to snus use. In contrast, 30% of the women who were smokers at the time of the baseline surveys had quit by 1999, but only 10% had switched to snus. It is widely believed that the greater decline in smoking among men than women in Sweden and the concomitant greater increase in snus use "provide strong support for the role of snus in promoting smoking cessation among Swedish men."[112]

Several studies specifically examining the role of snus in quitting smoking have concluded that snus use is a gateway away from smoking. One study involving 2879 men, for example, found that 71% of smokers with a history of snus use quit smoking, compared to 54% of those who did not use snus. Among the men surveyed who quit smoking with the help of a single cessation aid, 62% reported having used snus, versus 38% who used NRT.

In Norway, male smoking rates have decreased by 50% over the past 30 years, from 52% to 24%. During the past decade, smoking prevalence has declined at the same rate in men and women, while snus use has increased substantially only among younger men. Snus use among males 16-44 years has risen to 17% daily and 9% non-daily. Since 2002, the rate of increase has been highest among males age 16-24.[113]

3. Does the availability of snus benefit or harm public health?

In assessing total harm, the impact of snus on total tobacco consumption is an important consideration. In Sweden, aggregate data show that over the past three decades, smoking rates among Swedish men have decreased, while prevalence of snus use has increased. Smoking rates among Swedish women also decreased markedly, but to a lesser extent than in men and with a much smaller increase in snus use.

The relationship between snus use and total tobacco consumption in Sweden has not been replicated in Norway. Despite the availability of snus, smoking rates among both men and women age 16+ in Norway are much higher than in Sweden. Daily smoking among men in Norway, at 25%, is also much higher than in Canada, at 15%. In general, total tobacco use among both males and females in Norway—snus use, smoking or dual use—is much higher than in Canada (see table below).[114]

Tobacco use (including smokeless) adults + youth; Canada, Sweden, Norway

	Men			Women		
	Canada, 2006	Sweden, 2005	Norway, 2006	Canada, 2006	Sweden, 2005	Norway, 2006
Age range	*15+*	*16–84*	*16-74*	*15+*	*16–84*	*16-74*
Daily Smoker	15	14	25	13	18	24
Occasional Smoker	5	12	11	4	8	11
Daily smokeless		23	11		3	
Occasional smokeless		4	7		2	
Used smokeless in past 30 days	2			<1		
Former daily Smokers	28	28		20	23	
Never Smokers	49	46		60	51	
Age range	*16-24*	*16-24*	*16-24*	*16-24*	*16-24*	*16-24*
Daily Smoker	16	9	23	13	13	22
Occasional Smoker	9	17	15	7	24	15
Daily smokeless		26	18		4	1
Occasional smokeless		7	17		6	
Used smokeless in past 30 days	2			<1		

Changes in total tobacco consumption, however, do not provide conclusive evidence of changes in total harm. Population changes in tobacco-caused diseases provide a more accurate indication of the impact of snus on public health. Since 2000, Sweden has a lower standardized rate of male lung cancer incidence than any other comparable developed country. As well, there has been a significant improvement in cardiovascular health among Swedish men. Sweden also has a low rate of oral cancer compared to international standards, and the rate has dropped over the past twenty years at the same time as snus use has increased. Although these changes could be due to other factors, the fact that the major health improvements have been experienced primarily by men, for whom a large reduction in smoking was accompanied by a large increase in snus use, strongly suggests that snus has played a direct role in the decline in male smoking and subsequent improvements in health.[115]

Recent research by Gartner and colleagues modeled the potential health impact of the introduction of snus in Australia at both the individual level, from snus use by smokers and non-smokers, and the societal level, from snus use by ex-smokers and never smokers. The researchers found little difference in health adjusted life expectancy between smokers who quit all tobacco use and smokers who switch to snus. Consistent with the Swedish experience, the authors conclude that significant health benefits could be achieved from smokers switching to snus:[116]

> "Current smokers who switch to snus rather than continuing to smoke can realise substantial health gains. Snus could produce a net benefit to health at the population level if it is adopted in sufficient numbers by inveterate smokers."

There is growing evidence that the availability of snus has the potential to increase overall tobacco use, as tobacco companies promote dual use. In many jurisdictions, snus is being marketed by tobacco companies as the solution to smoking bans. In Canada, for example, ads for du Maurier snus trumpet the product as "The handy tobacco option."[117] The website for General Snus by Swedish Match says "the best thing about it is that you can Snus anywhere."[118] Particularly disturbing is the new marketing campaign for Camel snus (see below), exhorting the sensory joys of using snus—in all the key places where smoking has been banned.[119]

"Taste: Bar Friendly. See: Stadium Friendly. Hear: Concert Friendly. Smell: Date Friendly. Feel: Travel Friendly."

Euromonitor International (a private company providing research and business intelligence on industries, consumers, and countries) concludes that the new interest in snus by major cigarette manufacturers, in particular the acquisition by Altria of UST in the US and the joint venture between Philip Morris and Swedish Match, is partly an attempt to mitigate the impact of smoking bans. Euromonitor further claims that the smoking ban in Norway led to a 20% increase in snus sales in 2008 alone.[120]

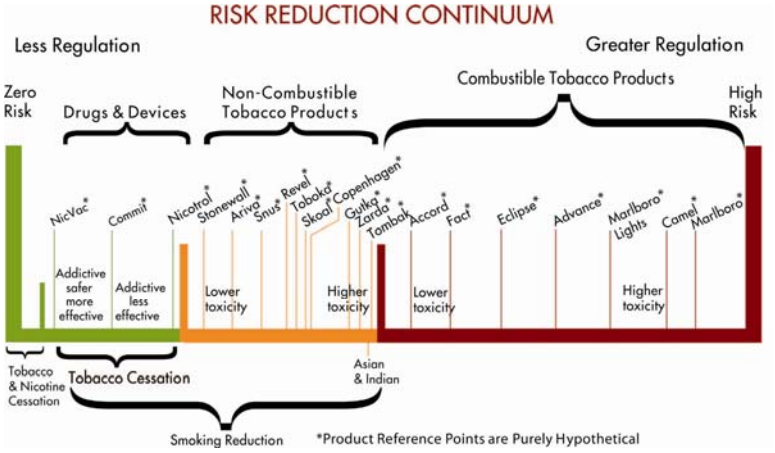
The potential for snus use to undermine the significant impact of smoking bans on smoking rates and public health is a valid concern. To put the concern in context, Gartner and colleagues modeled the conditions under which an increase in snus use would result in a net increase in societal harm. According to their research, 14–25 ex-smokers would have to start using snus to offset the health gain from every smoker who switches to snus. Likewise, 14–25 never smokers would have to start using snus to offset the health gain from every new tobacco user who uses snus rather than starting to smoke.[121]

Recommendations

1. Establish a regulatory framework for nicotine products

The federal government should develop a regulatory framework for all nicotine delivery products which would apply consistent criteria to evaluate whether these products should be marketed and sold in Canada and under what conditions. In general, the regulatory approval process to which these products are subject and their availability, price/taxation, and permitted forms of promotion should all be related to the level of risk inherent in their use.

An example of a risk reduction continuum under such a regulatory framework is shown in the graphic below.[122] Note that not all of the products listed are available on the Canadian market.



The need for a regulatory framework to regulate all products that contain nicotine is supported by numerous reputable tobacco control experts and organizations, among them the Royal College of Physicians and Surgeons, UK (2007), the American Association of Public Health Physicians (2008), and the Strategic Dialogue on Tobacco Harm Reduction Group (2009), which involved prominent US researchers such as Neal Benowitz, Dorothy Hatsukami, Kenneth Warner, and Mitch Zeller.

A regulatory framework for nicotine products would perform the following functions:[123,124,125]

- Monitor and disclose the constituents, additives, and toxicants in all products under its purview.
- Set maximum limits on the levels of nicotine and toxins in tobacco products and tobacco smoke emissions.
- Evaluate exposure and risk reduction claims on a pre-market basis and prohibit such claims in the absence of adequate scientific validation

of actual risk reduction that considers the impact on both the population as a whole and the individual consumer.

- Conduct post-market surveillance to re-evaluate the claims.
- Ensure that consumers are accurately informed about the relative risks of using the different types of nicotine products.
- Regularly monitor and publicly report on the prevalence and sales of both tobacco products and non-tobacco nicotine products, including how they are being used and by whom, as well as related morbidity and mortality. Assess whether any unintended consequences have arisen that call for changes in policy and/or practice.
- Ensure that research is conducted on the following key issues:
  - Methods to assess the levels of toxic constituents in tobacco, tobacco smoke, and nicotine products, as well as exposure levels and human toxicity.
  - Consumer risk perception, including consumer understanding of relative risk.
  - The impact of any risk reduction claim on consumption of that product, including the impact on initiation, cessation, and relapse.
  - Health risks of long-term use of non-tobacco nicotine products and population impacts.

2. Shift current tobacco users to the least harmful nicotine product—NRTs[126]

Pharmaceutical nicotine replacement products are the safest alternative to combustion tobacco products and are the recommended alternatives to cigarettes. There is widespread agreement that making therapeutic nicotine products more effective and acceptable to consumers is a key part of the harm reduction equation. This requires making the products more palatable by increasing the amount and the delivery speed of nicotine and by improving their taste and sensory appeal.[127]

Moving more smokers to this safer form of nicotine delivery also requires improved education of both the public and practitioners regarding the health risks of using nicotine replacement products. The misconceptions inhibit many potential users from trying NRTs and prevent many others from using NRTs in a manner that would maximize their chances of quitting the more dangerous forms of nicotine delivery.

An important component of any harm reduction strategy is the provision of full and factual information to the public. However, the current warnings on NRT products are believed to reinforce misconceptions about the appropriate use of NRTs and the inherent risk. Current Clinical Practice Guidelines likewise counsel NRT use that is too restrictive to benefit many smokers. Both the warnings and the Guidelines need to be revised to reflect the current science regarding the safety and efficacy of NRT use. Smokers need to be reassured of the safety of using a nicotine-based product, of the safety of using NRTs for a longer period than normally prescribed if they need longer-term help in quitting, and of the safety of using NRTs even if they are not able to abstain completely from smoking.

- Reassure smokers about nicotine replacement therapies (NRTs):
  - Improve risk messaging and public education to dispel current myths about nicotine and NRTs, so that the following key facts are widely known:[128]
    - Nicotine is *not* the harmful substance in cigarettes.
    - Nicotine in NRTs is *not* as toxic and addictive as the nicotine in cigarettes.

- Smoking while using the patch does *not* cause heart attacks.
- NRTs are *effective* in helping people quit.
- It is *cost-effective* for NRTs to be covered under health insurance plans.

– Broaden Clinical Practice Guidelines to reflect current scientific evidence on the safety and efficacy of NRTs:[129]
  - NRTs should be offered to a broader spectrum of smokers, including patients with cardiovascular disease and pregnant women who are unable to quit on their own.
  - NRT dosage should be modified to suit the smoker's needs.
  - Smokers should be encouraged to use NRTs for as long as needed to maintain abstinence.
  - Smokers should be encouraged to consider using various NRT products concurrently, and/or in combination with Bupropion, to control withdrawal symptoms.

– Health Canada should approve all forms of NRT (not just gum) for use in reducing consumption by continuing smokers.

- Make NRTs more affordable:[130]
  – NRTs should be covered under public and private health insurance plans.
  – The federal government should eliminate the GST on NRTs. The provinces/ territories should likewise eliminate the PST on over-the-counter cessation aids.
  – Pharmaceutical companies should closely match package quantity and price of NRTs to tobacco products. Ideally NRTs would be less expensive than tobacco products, providing a financial incentive for people to quit.

- Make NRTs more accessible:
  – Ensure that NRTs are available at every retail outlet where tobacco products are sold and are displayed prominently.

- Broaden community support for cessation:
  – All relevant health and allied health professionals should be trained in a proven basic intervention model (such as the 5 A's). They should routinely assess the smoking status of their patients and recommend quitting.
  – Cessation interventions should be available from a wide range of health and allied health professionals working in a variety of settings within communities, including family health clinics, community health centres, addiction services, social services, and asthma clinics.
  – Hospitals should include cessation medications in their drug formularies.
  – Hospitals should offer cessation support to all patients who smoke based on the Ottawa Model.*
  – Scheduled hospitalization should include the provision of cessation support, with NRT, before admission.

3. Shift smokers who are unable to quit or unwilling to make a quit attempt to a less harmful product—snus[131]

* The smoking status of all patients is recorded on their chart. All smokers are advised to quit by a trained nurse counselor and offered help, including NRT. Following discharge an automated voice messaging system tracks the patient's success in remaining smoke-free. If any response suggests the patient is having trouble, a nurse counselor calls the patient to review options. Patients are assessed again six months after discharge. (The Lung Association, *Making Quit Happen,* May 2008.)

The goal of moving smokers toward the least harmful form of nicotine delivery also suggests a role for snus, since existing NRTs cannot meet the needs of all smokers.

- Improve messaging about the relative risks of tobacco and nicotine products:
  - The public has the right under Canadian tort law to accurate information about the relative risks of using tobacco products and to make choices based on the facts. The current warning on smokeless tobacco products, "This product is not a safe alternative to smoking," is woefully inadequate as it provides no information regarding relative risks.
  - Governments and health organizations must improve messaging, both on the product and in other media, about the relative risks of cigarettes, smokeless tobacco products, and non-tobacco nicotine products to ensure that the public is better informed and does not rely on tobacco companies for risk information.
- Conduct research about the post-market impact of any new tobacco product:
  - Additional research must be done on the real-world impact of the introduction of snus to the Canadian market and of the promotion of snus and other forms of smokeless tobacco on smoking rates and total tobacco consumption.
  - This will require that tobacco companies share detailed marketing and sales data with Health Canada. Health Canada must make this information available to health groups to enable them to conduct necessary oversight of the impact of tobacco industry practices.
- Ensure that tobacco companies do not make unsubstantiated health claims about snus or other tobacco products:
  - Health Canada and/or other relevant government authorities must be vigilant in ensuring that tobacco companies do not make any unsubstantiated claims about the risks of smokeless tobacco products.
- Ensure that tobacco companies do not promote snus in a way that undermines the impact of smoking bans:
  - Tobacco companies must not be allowed to undermine the effectiveness of tobacco use reduction strategies, including smoking bans, by promoting smokeless tobacco products as an option when smoking is not permitted.

4. Monitor the impact of alternative nicotine products

- Conduct post-market surveillance of the promotion of alternative nicotine products:
  - Health Canada and/or other relevant government authorities must be vigilant in ensuring that the manufacturers of alternative nicotine products do not make any unsubstantiated claims about the risks of using these products.
  - Manufacturers of alternative nicotine products must not be allowed to undermine the effectiveness of tobacco use reduction strategies, including smoking bans, by promoting the use of these products as an option when smoking is not permitted.
- Conduct research on the health impact of alternative nicotine products:
  - Health Canada and/or other relevant government authorities should conduct ongoing monitoring to assess consumer

uptake of these products and the impact of their use on individual and population tobacco use and on consequent morbidity and mortality.

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