

# Tobacco – the greatest untapped potential for harm reduction

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## 1. Rationale for tobacco harm reduction

### Nicotine - the benefits, popularity, and unfortunate delivery method

Nicotine is one of the most popular drugs in the world. It is most commonly acquired by smoking tobacco, though there are many alternative delivery methods. In addition to its purely recreational attraction as a mild stimulant that simultaneously has calming effects, many consumers find nicotine useful for improving productivity, combating anxiety, and aiding mental focus. Many people who suffer from clinical and subclinical levels of depression, attention deficit disorders, schizophrenia, and other conditions find relief in smoking, presumably mostly or entirely due to the nicotine delivery. Some of these benefits are similar to those from one of the other most popular drugs, caffeine, though many people (apparently as much as 1/3<sup>rd</sup> of the population) find the benefits from nicotine to be particularly appealing. Given the substantial benefits, it is not surprising that once nicotine consumption (in the form of tobacco use) becomes established in a population, it has never been reduced to below about 1/5<sup>th</sup> of all adults, despite massive campaigns to convince consumers to stop, draconian taxes, restrictions on usage, and social vilification.

The benefits and desirability of nicotine consumption are not widely recognized, a rather odd situation given how many people experience them. This lack of awareness appears largely due to anti-tobacco activists' success in establishing the notion that people only use nicotine because they are "addicted". Closer examination reveals that this claim is made without actually explaining what "addicted" means, other than the question-begging, "so beneficial that someone chooses to not give it up, despite the costs." Indeed, some commentators have suggested that calling nicotine addictive dilutes the concept so much as to render it meaningless (e.g., Atrens 2001). However, for present purposes the existence or absence of addiction, and whether it is well-defined, is not important. Equally unimportant are debates about whether there are "inveterate" smokers who could never be persuaded to quit no matter what the incentives. Instead, it is sufficient to observe that many people continue to use nicotine, despite the high financial and health costs of the most common delivery method, as well as the existence of every anti-smoking measure that is considered practical and effective. The number of smokers in the world continues to increase, and despite much rhetoric to the contrary there is no evidence that suggests that all nicotine users will eventually quit entirely.

Though nicotine itself is fairly benign (and so is similar to caffeine consumption in this respect as well), most users choose an extremely hazardous method for delivering it. Few realize that inhaling smoke from burning plant matter, and not the desired chemical being delivered, is the cause of almost all the health problems. While exact numbers are much more elusive than is often implied, it is safe to conclude that at least 1/3<sup>rd</sup> of long-term regular smokers living in communities with Western-level life expectancies will suffer major disease or a substantially hastened death due to their habit of inhaling smoke. Most everyone with access to education or mass media understands that smoking is extremely hazardous. Indeed, there is a bias toward overestimating its hazards (perhaps because of the habit of activists of exaggerating the risk, a strange behavior given how high the risk is in reality).

Yet many people choose to smoke nevertheless, largely to get nicotine, and the number of smokers continues to grow, dramatically and most places in the world. The trumpeted reductions in the prevalence of smoking in some Western populations are largely offset by population growth, such that the total number of smokers stays about the same. Meanwhile in the majority of the world's populations both smoking prevalence and population increases are increasing, dramatically increasing the number of smokers. We can expect that prevalence will eventually drop in populations as people become educated about the risks; historical evidence suggests that such education reduces consumption prevalence by about half, usually down to the 20%-30% range. But there is no evidence that nicotine use will drop below that range, no matter what policies are implemented, and predictions to the contrary appear to be based on little more than wishful thinking. Thus, separating nicotine delivery from smoke inhalation, has the potential to be one of the greatest improvements in human welfare and public health.

#### Failure to understand that smoke causes the damage

The way in which the "smoking is deadly" message is typically presented results in people thinking that nicotine use, exposure to the tobacco plant itself, or chemicals added to cigarettes by manufacturers cause most or all of the health risk. Anti-smoking messages almost never emphasize that the danger is breathing concentrated smoke (Phillips Heavner Smokeless Tobacco: the Epidemiology and Politics of Harm 2008 presentation, article in peer review). Instead, most of the communication about the dangers of smoking (sadly including most of the ostensibly scientific literature) misrepresents the relevant exposure as being tobacco or nicotine rather than smoking.

Tobacco, of course, is a plant, not an exposure. Exposure to it can take any number of forms, including smoking, non-combustion oral use, and occupational exposures, each of which have radically different health implications. Nicotine itself is also often conflated with smoking in ways that imply that it causes most or all of the health risks. There is ample evidence that these messages prevent people from learning that the risks from smoking cigarettes come from inhaling the concentrated smoke from burning plant matter. Smoke inhalation exposes the lungs, and thereby the bloodstream and rest of the body, to a huge number of particles (the "tar" that is often identified as part of what is harmful about smoking) and gasses. The salient factors are neither that the particular plant matter being smoked is tobacco leaves (possibly of some small consequence, but not definitively so and

clearly of minor importance), nor that nicotine is being consumed. As discussed below, the misleading communication often begins with claims by trusted anti-tobacco advocates, who are either lying or pretending to expertise that they lack. However, most appears to be well-meaning people unknowingly perpetuating myths by blindly repeating the ostensibly authoritative claims. Clinicians, health educators, and other health professionals are barely less ignorant than laypeople on these points and are substantially responsible for perpetuating the misinformation. Whatever the explanation, the failure to understand this difference and act on its practical implications dooms countless smokers to premature disease and death.

### The potential of tobacco harm reduction

The combination of highly-desired consumption and a needlessly dangerous technology creates an obvious potential for harm reduction. Discussions of the potential of reducing harm by substituting Western smokeless tobacco products (ST) for cigarettes trace back more than three decades, and the potential is now universally known to anyone with expertise in the area. However, understanding outside of the community of experts, as well as policy changes, have severely lagged this understanding.

Almost all efforts to reduce the harm from smoking have focused on eliminating nicotine use, rather than the harm from nicotine use. This represents an anomaly in public health practice, since it is generally accepted that we are better off making common beneficial activities safer rather than assuming we can reduce or eliminate them. For example, we encourage seatbelts and other transportation safety improvements, but do not even bother to encourage reducing travel. Even for hazardous behaviors that are not generally socially accepted, if eliminating the behavior is clearly impractical then risk reduction is encouraged. For example, we discourage all injection of recreational drugs, but we also try to provide clean needles for those who continue to use them. In cases like illicit drug use, large segments of the public and government may object to harm reduction on puritanical grounds (often mislabeled as "moral" grounds), but public health practitioners almost universally accept it. Yet many public health actors join those for whom purity is more important than protecting people from disease, and actively fight against reducing harm for tobacco consumers.

This contrast is especially odd given that the only substantial difference between harm reduction for smokers (hereafter, "tobacco harm reduction" or THR) and others engaged in risky behaviors is the magnitude of the potential benefits: First, the risks from smoking are greater than those from almost any other voluntary exposure, and when multiplied by the number of smokers totals up to a far greater public health impact than any other voluntary exposure. Second, and even more important, is that the potential reduction in risk for each individual dwarfs the reductions available from seatbelts or needle exchanges. Some sources of nicotine have been shown to be about 99% less harmful than smoking, and others probably have similar low risks. The implications of this can hardly be overstated: Switching from smoking to a low-risk source of nicotine is so close to being as healthy as quitting that it is hardly worth worrying about the difference.

Despite the widespread misperception about the risks from tobacco or nicotine, anyone with a basic knowledge of environmental health, or who notices that about half the health burden from smoking involves lung disease, would predict that getting nicotine without inhaling smoke causes less harm than smoking. There is ample evidence to confirm this hypothesis for one class of nicotine products, modern Western oral smokeless products. ST use includes snuff dipping (holding shredded tobacco, sometimes loose and sometimes in a teabag-like sachet, between the gum and lip or cheek) and tobacco chewing. (For pictures and more information about the products see: Ballin S. "Smokefree" tobacco and nicotine products: Reducing the risks of tobacco related disease. 2007. (Available at: [http://www.tobaccoatacrossroads.com/2007report/071128\\_Ballin%20Report\\_final.pdf](http://www.tobaccoatacrossroads.com/2007report/071128_Ballin%20Report_final.pdf)) or Rodu B, Godshall WT. Tobacco harm reduction: an alternative cessation strategy for inveterate smokers. Harm Reduct J. 2006;3:37. (Available at: <http://www.harmreductionjournal.com/content/3/1/37>)). Some newer products include powdered tobacco in hard lozenges or dissolvable strips.

Traditional ST products have been sufficiently popular in Sweden and the United States to provide substantial epidemiologic evidence about their effects. (Epidemiology is the science of quantitatively analyzing the occurrence of diseases in humans, usually with a focus of identifying their causes.) Epidemiology studies are possible because many people have used ST products for decades, and so we can observe whether they have a greater risk of disease or death than non-users. The evidence shows that the risk for any life-threatening disease from ST use is so low that it cannot be reliably measured or even definitively established. This does not mean that ST is completely harmless, since the limits of the science mean that we can never rule out small health risks. Based on best estimates of the magnitude of these small risks, it is estimated that the overall risk is about 1%, or perhaps 2%, of that from smoking. Most of that risk is based on the assumption that the mild stimulant effects of nicotine cause some small risk of cardiovascular disease.

Pharmaceutical nicotine products are produced by removing nicotine from tobacco and attaching it to an alternative substrate. Widely available pharmaceutical nicotine products include nicotine gum, patches, lozenges, and inhalers. (For more information about these products see: Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007 (Available at: <http://www.rcplondon.ac.uk/pubs/contents/bbc2aedc-87f7-4117-9ada-d7cdb21d9291.pdf>)) Pharmaceutical nicotine products are sometimes called "nicotine replacement therapy" in the context of using them as a short-term clinical intervention to wean people off of nicotine entirely, though this label tends to distract from their potential for long-term, self-administered, non-clinical use, and thus is best avoided when discussing THR. These products probably pose the same low risks that have been demonstrated for ST, since they are fairly similar in terms of being smokeless nicotine delivery systems

The oft-repeated claim that pharmaceutical nicotine products cause even less disease risk than ST is not actually supported by the scientific evidence. ST contains chemicals other than nicotine that are potentially harmful, but there is no evidence that doses acquired by users of popular Western ST products cause actual human disease. ST also contains

chemicals that are potentially beneficial and pharmaceutical products involve exposures other than nicotine intake, so without evidence it is not possible to conclude that the risks from pharmaceutical nicotine are even lower than the low risks from ST. There have been few studies of long-term pharmaceutical nicotine users, so that evidence does not currently exist. Whatever we eventually learn about the risk from pharmaceutical nicotine, it seems very likely that the risk is low, and since the risk from ST is clearly very low, it seems safe to conclude that they offer practically the same health benefits as substitutes for smoking.

Novel products containing either tobacco or pharmaceutical nicotine further expand THR options. Some of the emerging products are devices that mimic cigarettes but where users inhale heated pharmaceutical nicotine or tobacco rather than smoke. Because these products re-introduce airway involvement and inhaled chemicals other than just nicotine, we should probably hesitate assume that the risks are as low as those of ST use. However, for products where the non-nicotine inhaled chemicals have been shown to be benign in other contexts, it seems likely that the products offer reductions in risk for smokers similar to those from other non-combustion source of nicotine. Many smokers cite the appeal of social, ritual, and time-and-motion aspects of smoking rather than pure nicotine delivery, and imitation cigarettes might satisfy those aspects, increasing their appeal.

The evolution of the use of more common ST products is discussed in detail below. For context, most discussions of THR have focused on moist snuff, particularly the form contained in teabag-like sachets because it can be used discretely and without chewing or spitting. Such products are often referred to using the Swedish word for snuff, *snus*.

It is often claimed that the snuff from Sweden, which is manufactured using different processes than some other ST products, particularly chewing tobacco and American moist snuff, is less harmful than those other products. While it is plausible that there is some small risk difference because the Swedish-style product has somewhat lower levels of a few chemicals (called tobacco specific nitrosamines or TSNAs) that are suspected (though not definitively established) to be human carcinogens in sufficient doses, this situation is similar to the claims about pharmaceutical products: There is no evidence of differences in actual human health effects, there is very little room for difference given that all the risks are immeasurably low, and the greatest health risk seems to be the mild stimulant effect of nicotine which is similar across products. Moreover, the levels of TSNAs in modern products are quite low compared to historical levels, and the epidemiology does not show that any currently popular form of Western ST causes cancer. Nevertheless, manufacturers and marketers seem to have concluded that marketing new ST products as snus outside of Sweden, and claiming that they are substantially different from existing products, is a good response to the misinformed beliefs about the risks from ST. Since people are more likely to accept a "new and improved" claim than being informed that they were badly mistaken in their previous beliefs, this strategy might prove useful for THR, even though it might tend to perpetuate scientific illiteracy.

As discussed below, several demographic groups have adopted ST use, demonstrating the viability of switching as a THR strategy. Men and, to a lesser extent, women in Sweden have largely switched from smoking to snus use, (Rodu, Stegmayr, Nasic, et. al. 2002; Rodu,

Stegmayr, Nasic, et. al. 2003; Stegmayr, Eliasson, Rodu 2005) as have Norwegian men (Kraft 1997; IARC 2007; Wium, Aarø, Hetland 2008; Directorate of Health and Social Affairs 2007) and some men in the U.S. have also shown a willingness to switch (Rodu Phillips 2008). There is some concern that the cultural specificity of ST use to Scandinavia and particular subpopulations in North America limit its potential. But manufacturers are making concerted efforts to expand ST-based THR to other populations, and THR advocates have generally focused on ST as the most promising alternative to smoking. Some of that focus by industry and advocates appears to be shifting toward a broader variety of THR products.

## **2. Scientific basis and historical evidence for tobacco harm reduction**

### Scientific evidence of the low risk from smokeless tobacco

The potential of THR, at least in the form of substituting ST for cigarettes, is demonstrated by ample epidemiologic evidence. The popularity of ST in Sweden, and to a lesser extent in the U.S., Norway and Canada for many decades, resulted in hundreds of studies that have looked at the relationship between ST use and numerous diseases.

Perhaps more important, though usually overlooked, is the evidence from unreported results and descriptive epidemiology about the average disease risk in a population. Because public health studies typically collect data on all uses of tobacco, not just smoking, there have probably been thousands of other studies of disease risks that collected information on ST use. An unfortunate unscientific practice in public health research known as "publication bias", the tendency to publish only those results from a study that are "interesting" or conform to the political bias of the day. In this case, that means that studies of diseases that have data on ST use that find no association will likely not even mention the ST data because it is not interesting, and those that find the "wrong" association (i.e., a chance finding that people who use ST have a lower risk for a particular disease) are likely to not publish it because their result would be viewed as wrong (Phillips 2004 PBIS). Thus the absence of hundreds of reports that show a positive association between ST use and disease strongly suggests there are hundreds of studies that found there was no such association.

In addition, ST use among Swedish men is so common that any substantial health risk from it would appear in the descriptive epidemiology (i.e., basic population health statistics) for that population (Rodu 2004). However, Swedish men have among the lowest levels of all diseases that are sometimes thought to be caused by ST use.

Unfortunately, a non-expert who attempted a casual assessment of the evidence would likely be misled. In addition to not recognizing the important points above, a non-expert looking at the headlines or the anti-THR publications would find what appeared to be evidence that ST causes substantial disease risk. For example, in contrast with the ample evidence that the popular Western ST products do not cause a measurable risk for oral cancer, there is some evidence that dry snuff products that once were popular in parts of the U.S. caused a measurable risk for oral cancer (Rodu, Cole 2002), but these products are

no longer commonly used. In addition, tobacco-containing oral products that are popular in parts of Asia and Africa may cause substantial risk of oral cancer, though the epidemiology is of such low quality it is difficult to draw clear conclusions. These observations about non-Western products and older dry snuff are used as the basis for recent anti-THR activists' claims that ST causes oral cancer (IARC 2007; Boffetta, Hecht, Gray, Gupta, Straif 2008). These authors assume (probably quite accurately) that readers will not understand the difference and so believe that the claims are relevant to the modern Western ST products being proposed for THR.

The increasing interest in THR seems to have generated a spate of recent publications by anti-THR activists that purport to show harm from ST use, but still fail to present convincing evidence that ST causes any life-threatening disease. Many of these studies have been demonstrated to misrepresent the data and otherwise overstate the risks of ST (Heavner, Heffernan, Phillip, Rodu 2008; Rodu, Heavner accepted for publication; Phillips. American Cancer Society 2007). Furthermore, even if all of these exaggerated claims were accurate, the risk from ST use would still be a small fraction of that from smoking. But the anti-THR authors make sure never to mention the comparative risk and assume (probably quite accurately) that readers will not understand the difference between a large risk and a small risk, let alone learn of the dubious nature of their analysis.

It is biologically plausible that ST can cause acute cardiovascular events. It is a mild stimulant that temporarily increases blood pressure, and most such mild stimulants are believed to trigger incipient strokes and heart attacks. It is plausible that ST may occasionally cause cancer based on some of its chemical content, though the risk must be low or it would be detectable in the epidemiology. Some individual epidemiologic studies, considered in isolation, suggest risks for stroke, myocardial infarction, oral cancer, esophageal cancer, and pancreatic cancer. However, the evidence taken as a whole does not support these claims. (It is inevitable that when there are several epidemiologic studies, some of them will show higher results and some lower. It is sometimes effective propaganda to identify the most extreme study result and pretend that it represents the overall evidence, but proper science calls for considering all the evidence.) Thus, it is not possible to definitively conclude based on the current scientific literature that ST kills anyone. Given the biologic plausibility of risks and the impossibility of distinguishing zero risk from low risk, however, it seems safe to assume there are some small risks and some people die from using ST. We are aware of no one (not THR advocates, manufacturers, nor anyone else) who claims that that ST or any other THR product causes no risk of disease or death.

#### How much less harmful is smokeless tobacco?

It is tempting to just focus on the very low best point estimate of the risk, but the potential for THR is perhaps best illustrated by the worst-case scenario. Based on the epidemiology, it is completely implausible that, compared to smoking, ST causes 10% as much risk for serious disease or death. Indeed, only the most extreme interpretation of the evidence can get this figure as high as 5% (Phillips, Rabi, Rodu 2006). Even this pessimistic case represents a huge potential reduction in risk. The claim that ST is at least 90% less harmful is commonly repeated (e.g., Levy, Mumford, Cummings et. al. 2004; Royal College of

Physicians; Savitz, Meyer, Tanzer 2006). Although this is conservative to the point of being figure misleading, even a 90% reduction represents a huge potential for THR – much greater than the benefits of most harm reduction measures, to say nothing of other public health interventions.

Calculating a best estimate of the risk reduction, rather than a worst-case ceiling, depends largely on what estimate of risk for cardiovascular disease is chosen. Despite the anti-ST rhetoric that emphasizes cancer risk, the maximum plausible cancer risk adds to only a fraction of 1% of the risk from smoking. Plausible estimates put the total mortality risk in the range of 1% or 2% of that from smoking (Phillips, Rabi Rodu 2006). ST has not been linked to serious non-life-threatening diseases, unless such conditions as transient blood pressure increases are included in a broad definition of disease. ST sometimes causes superficial sore spots or lesions in the mouth, which some might consider a disease, though they are not life threatening or particularly harmful.

#### Misleading claim that ST causes cancer

There are widespread claims that ST causes substantial cancer risk, but this is an unfortunate red herring in terms of assessing its suitability for THR. Importantly, for non-smokers in Western populations, oral cancer is very rare (Department of Health and Human Services 2000). Thus, even if this risk were to be increased by, say, 50%, it would represent very low total risk. This usually comes as a complete surprise to non-experts -- including most clinicians, public health officials, and educators who incorrectly believe they are knowledgeable. More importantly, despite most non-experts' belief that the scientific evidence shows a substantially increased risk of oral cancer among ST users, the evidence shows that even a 50% increased risk is not plausible. The risk is actually so small as to be undetectable (RCP 2007; Rodu, Jansson 2004; Rodu, Cole 2002).

In the last few years, after it became clear that claims of a substantial risk for oral cancer were false, it became fashionable for anti-THR activists to claim that ST causes a substantial risk for pancreatic cancer. This claim is based on less evidence than the now-discredited claims about oral cancer were originally based on before further evidence contradicted it, and the data has clearly been interpreted in a biased fashion to exaggerate the association (Phillips 2006 Working paper; Heavner, Heffernan, Phillip, Rodu 2008). But even if the relative risk claims are accurate, the total absolute risk is small because the baseline risk is quite low, and so would represent extremely low risk compared to the total risk from smoking.

#### The benefits are clear

Disentangling the biases and misleading interpretations that litter the research is beyond the present scope, but fortunately it is not necessary. Nor is it necessary to resolve the genuine uncertainty about the exact magnitude of the actual risks of non-smoked nicotine products. There is ample evidence that the risks are very small compared to the risks from smoking, and no one with any scientific credibility claims otherwise.

While many readers might find it surprising that the reduction in risk is so great, it is not actually difficult to verify most of the reduction based on casual knowledge: About half the



disease risk attributed to smoking comes from lung diseases that no one claims are caused by ST use. Most of the rest of the risk comes from cardiovascular diseases, and even the worst plausible case scenario puts the risk for these at well less than half that from smoking. Thus, even without delving into the details of over diseases, it is clear that the vast majority of risk is eliminated.

In addition, ST and other non-combustion sources of nicotine eliminate the harm that users impose on others. This includes eliminating the health risks from second-hand smoke and fires, as well as the aesthetic impact of smoke. Since it eliminates all the costs to innocent bystanders, THR is the perfect solution for anyone who believes in the rights of individuals to make their own health-affective decisions, but wants to protect other people from the negative externalities from smoking.

#### Toxicology as a distraction from the wealth of epidemiological evidence

Some confusion about the risks from ST has been created by activists who try to distract from the good news from the epidemiology with studies of "toxins" or "carcinogens". As with any plant matter (dietary vegetables, etc.), tobacco contains thousands of chemicals, some of which (when removed from their context and concentrated in huge doses) have been shown to cause cancer and other toxic reactions in laboratory experiments on cells or non-human animals. A few chemicals that are believed to be harmful are found in tobacco in greater quantities than in other plants. ST users may receive higher doses of some these chemicals than smokers.

But anyone familiar with health science will recognize that since the epidemiology fails to show actual human health risk from ST, it must be that these chemicals, in the form and concentrations found in ST, do not cause measurable levels of disease, irrespective of what they might do under certain laboratory conditions. After all, if a particular chemical that entered the body due to an exposure caused disease to a substantial degree then the exposure would cause that disease to a substantial degree. Studies of chemistry or laboratory exposures are sometimes useful in helping us guess what health impact something might have when we do not have actual epidemiology, or in exploring the possible mechanisms involved in an effect that has already been determined, but using it to predict what might happen when we already know that actually does happen is obviously useless.

#### Other lower risk nicotine products

The epidemiology on pharmaceutical nicotine products is very limited. Data exist about the immediate effects of use, as well as effects over a several month course of use. However, this is of little value in assessing the disease implications of a lifetime of exposure by someone who uses them instead of smoking, the type of information we have for ST. It is estimated that despite being designed, tested, approved, labeled, and marketed only for short-term weaning off of cigarettes about half of all pharmaceutical nicotine users at any given time are long-term users (Hughes Hughes, Pillitteri, Callas, et. al. 2004). Many, possibly about one-third, of all users use pharmaceutical nicotine without quitting smoking, during periods of temporary abstinence (often due to restrictions on smoking) or

as means to lower but not eliminate cigarette consumption (Hammond, Reid, Driezen et. al. 2008).

However, for several reasons, there have not been epidemiologic studies of long-term users. This does not mean we have no useful information, since in public health science we rarely have a measure of exactly what we want to know (the exact exposure, population, etc. we are interested in) and so need to draw conclusions based on data from the most similar analog we have. In this case, the analog that has been studied is ST. Since: 1) the acute cardiovascular effects are similar because they are caused by nicotine; 2) ST does not seem to cause measurable levels of cancer and; 3) we believe that any risks caused by the non-nicotine aspects of pharmaceutical products are minor, it seems safe to estimate the health risks to be about the same (though, of course, actual epidemiology about the pharmaceutical products could discover that this is wrong). Given the lack of epidemiology, and only speculation about the effects of differences between the delivery systems, there is no basis for concluding that ST is a bit less harmful than pharmaceutical nicotine, or vice versa. However, no such conclusions are necessary to recognize that they are both much better than smoking, but probably cause a bit more risk than not using nicotine at all.

#### Redesigning cigarettes, smoking and smokeless

Attempts to make cigarettes less hazardous have a mixed history. Some changes have clearly offered health improvements, while others have failed spectacularly. One particular failure to improve the health impact of cigarettes, so called "light" cigarettes, may be responsible for some of the resistance to THR (Fairchild, Colgrove 2004; U.S. House of Representatives 2004) though exactly the opposite lesson should be drawn: In that case, health improvements that were predicted but not supported by any epidemiology did not occur. The unfortunate naïve conclusion by some observers was that since this attempt failed, harm reduction is not possible, and therefore abstinence is the only worthwhile goal. However, the actual lesson is that we should favor alternatives that have been proven low-risk and practical, like ST, over purely speculative hopes like expecting that everyone will just quit using nicotine.

Minor variations on cigarettes that still consist of burning tobacco ought to be able to reduce risks somewhat (e.g., by lowering levels of carbon monoxide levels or reducing the number of atoms of heavy metals or other hypothesize particularly unhealthy components of the smoke). But given the many harmful aspects of breathing smoke, it is difficult to imagine anything more than minor improvements. If the choice is simply to implement these changes or not, obviously a bit less harmful is better, but such changes should not be seen as substitutes for a radical change to non-combustion products.

Major product reengineering might prove more promising. Cigarette-like devices that heat the tobacco, volatilizing the nicotine and some other constituents, rather than burning it and creating all the constituents of smoke seem likely to reduce the risks, though presumably some of the hazards of exposing the airway to many chemicals remain. There has been no epidemiology on these products, and to date they have been a failure in the marketplace. (For a more detailed description of one of these products see: Fagerström KO, Hughes JR,

Rasmussen T, Callas PW. Randomised trial investigating effect of a novel nicotine delivery device (Eclipse) and a nicotine oral inhaler on smoking behaviour, nicotine and carbon monoxide exposure, and motivation to quit. *Tob Control*. 2000;9(3):327-33.)

A presumably low-risk variation on the cigarette appears that it might be on the verge of exploding in popularity at the time of this writing. These devices resemble and are handled like cigarettes, but use pharmaceutical nicotine in aerosolizable chemicals that produce an imitation of smoke that is inhaled by the user when heated (for more details see: Laugesen 2008). These have gained popularity as a smoking-like experience that does not violate indoor smoking prohibitions allow, for example, bar patrons to "smoke".

### 3. Adoption of THR

#### Scandinavia: Population level evidence of the viability and effectiveness of THR

The viability of ST use as a smoking cessation strategy, and the predicted dramatic reduction in morbidity and mortality from nicotine use it will cause, has been demonstrated in Sweden. Snuff use in Sweden dates back almost to the introduction of tobacco in Europe and became widespread by the 19<sup>th</sup> century before declining between 1920 and 1960, when cigarettes became popular in Sweden and throughout the West. In the mid-20<sup>th</sup> century, snuff use was most common among older male farmers, fishermen and lumberjacks but subsequently it became more common among other young men (Nordgren, Ramström 1990; Stegmayr, Eliasson, Rodu 2005; Furberg, Lichtenstein, Pedersen et. al. 2006). This trend is generally attributed to social factors rather than recognition of the benefits of THR.

But the THR benefits did occur, and then became recognized. Now more men use snus than smoke, with smoking prevalence about half that of men in even the Western countries with the most aggressive abstinence promotion policies. Snus use rates have been increasing and smoking rates have been decreasing among both Swedish males and females (Stegmayr, Eliasson, Rodu 2005), and many of the snus users switched from smoking (Rodu, Stegmayr 2003). Smoking is still the most common form of tobacco use among Swedish females, though the trends are positive (Stegmayr, Eliasson, Rodu 2005). Sweden is the only population where smoking became established but dropped to substantially less than 20% of the population. As a result, Sweden has the lowest rates of tobacco related (i.e., smoking caused) mortality in Europe (Rodu, Cole 2004).

There is also a long history of snus use in Norway, where snus use is increasing and is now common among males (Kraft 1997, Wiium 2008). There is evidence of a transition from smoking to snus use among men since, like in Sweden, snus use increased as smoking prevalence decreased from the mid 1980s to 2006 (Directorate of Health and Social Affairs 2007).

#### United States: History of niche popularity and a promising future for THR

Outside of Scandinavia, the U.S. is the country where modern western ST products are the most popular. Like Sweden, North America has a centuries old tradition of ST use (it pre-dates European arrival in the Americas). In the U.S., ST was the most popular method of

use before cigarettes became a mass-market commodity. By the mid-20th-century, usage was largely limited to niche markets, particularly among rural males, though popularity increased toward the end of the century. While less than 5% of the adult populations used ST at the beginning of the 21st century (though this represents a large and growing absolute number of users), it remains much less than the smoking prevalence of over 20% (CDC 2008, SAMHSA 2006).

Importantly, the U.S. has had among the most aggressive anti-smoking campaigns, including education, legal restrictions, high taxes, and other measures, which probably contribute to smoking rates being a bit lower than elsewhere in the West. But despite this, nicotine use, mostly in the form of smoking, remains popular, illustrating the importance of THR. There is evidence of American men switching to ST as a method for quitting smoking (Rodu, Phillips 2008), and THR is increasingly being discussed in the scientific literature, and is gaining acceptance in the medical community (Nitzkin, Rodu, 2008).

The U.S., long home to the biggest ST manufacturer and the biggest market, has recently been flooded by new ST product lines from several manufacturers. These are typically marketed as "snus", and often with low-key THR messages. This includes the two major cigarette makers introducing snus products marketed under their flagship cigarette brands. Increased public awareness of the availability of ST products likely occurred as a result of popular press coverage of the introductions of new products (e.g., Landler, Martin 2007). Widespread adoption of THR in the U.S. would likely be followed by implementation of THR policies in other countries. Unfortunately, as discussed below, there is a concerted effort to keep Americans (and others) from learning about the benefits of THR.

### Hurdles to THR elsewhere

Unfortunately, outside of Scandinavia and the United States, there has been little tendency toward THR. Smokeless products that include tobacco have a long history elsewhere, particularly in South Asia and parts of Africa, but the trend is toward increased smoking, perhaps replacing those products.

Anti-THR efforts are directly responsible for the lack of success in non-Scandinavian Europe. Due to some unfortunate history, the E.U. actually bans snus-style ST products. (Sweden demanded and received an exception to this rule when it joined the E.U. and Norway is not a member of the E.U.) However, smoking is legal and quite popular. At the beginning of the 21<sup>st</sup> century, more than 30% of adults in most E.U. countries smoked (Statistical Office of the European Communities). This bizarre combination of banning low-risk forms of tobacco while allowing the high-risk form is possibly the most costly anti-public-health regulation that exists in the world today. Though there is a growing constituency that favors eliminating the ban (e.g., Royal College of Physicians 2008), the conventional wisdom is that a removal of the ban is, at best, several years off.

Similarly, New Zealand and Australia ban ST (though, again, cigarettes remain legal and popular). There is some limited interest in changing this, though no specific signs of progress (Gartner, Hall, Vos, et. al. 2007; Laugesen 2007). However, since these

governments are much smaller and thus more responsive than the E.U.'s, the situation could change much more rapidly.

Canada, like the U.S., has a history of ST use in small niche markets, particularly in the rural west. In 2007, Canada's major cigarette company began test marketing a snus product under its flagship brand, explicitly marketing it as a reduced harm alternative to cigarettes, an approach that had not been previously used in North America. (ST products were already widely available in Canada, but not marketed in this way.) There was evidence that smokers in the test market area were quite interested in trying low risk nicotine products (Geertsema, Phillips, Heavner 2008; Heavner, Phillips, Rosenberg 2008). It appeared that Canada might emerge as a leader in THR. However, an anti-THR crusade, seems to have ended this hope. For example, when the research group that includes the authors of this paper started promoting THR locally, the local tobacco control groups shifted most of their emphasis to being anti-ST rather than anti-smoking (including the anti-tobacco unit of the provincial government and even groups that were explicitly anti-*smoking* and not anti-tobacco); apparently they were more worried about THR than about smoking. Canada lacks free speech protections, and various restrictions on free speech have made it almost impossible to educate smokers about the availability of the low-risk option (Heavner, Hu, Phillips under review; Heavner, Rosenberg, Tenorio, Phillips under review). In addition, Canadians hear only anti-harm-reduction messages from the supposed authorities and they have a tendency to defer to authority. Thus they are particularly unlikely to learn about THR, and so despite demand and supply, there is little hope of THR happening in Canada until after it has succeeded in the U.S. and trickles over the border.

In the non-Western world the barrier to THR is more lack of interest than anti-public-health actions by governments or activists. Attempts to introduce ST products in Japan and South Africa have been largely unsuccessful, apparently largely due to the difficulty of marketing a product line unlike anything used locally, though perhaps also due to some poor choices in design and marketing strategy. However, the persistent belief that there were no risk differences among tobacco products resulted in government requiring the same warnings as are on that graced cigarette packets be on to snus packaging, and regulations forbade communication to potential consumers about harm reduction (University of Stellenbosch Business School 2006).

The emergence of guerrilla-marketed imitation-cigarette inhalers might render some of the barriers to ST use moot. Before snus is decriminalized in Europe or becomes popular elsewhere in the world, non-smoked cigarette-like devices might occupy much of its niche. These devices emerged in China, a population that for cultural reasons is unlikely to adopt ST. They are used locally (it is not know exactly how much, but presumably they have made only tiny inroads into the massive Chinese cigarette market) and exported to the West. It is possible that regulators will declare these new products to be pharmaceuticals and thus subject to regulations that would drive them out of the market, or otherwise restrict their availability. Bans have already been implemented in some jurisdictions (Turkey, Finland), though the usual easy access to the much riskier products, cigarettes, remains unchallenged.

#### **4. The politics of THR**

The above is intended to describe the potential for and reality of THR with minimal reference to the politics and disinformation that surrounds the issue (though the dominance of politics and misinformation makes complete separation difficult). To fully understand THR requires answering the question, "why does such a promising public health intervention have such strong opposition, and why do so few people even know about it?"

The first thing that is necessary to understand is that many people and organizations in the anti-tobacco industry are not actually pro-health, but are merely anti-tobacco. (Given the huge budgets that come mostly from the public coffers and taxes paid by smokers, careerism, and institutionalization of anti-tobacco organizations, calling them an "industry" is the most polite accurate description. Others have proposed "racket.") Once this fact is recognized it becomes clear that the apparent paradox – that many in the "public health community" are opposed to improving public health by reducing the harm from a popular behavior -- is based on the incorrect premise that the anti-tobacco industry is all part of the public health community.

Part of the explanation for this is that the "public health community" in North America and parts of Europe evolved partially from various "purity"-based (and largely paternalistic and puritanical) social movements directed at modifying people's behaviors. While there was often a strong overlap between purifying behavior and improving people's health, particularly many decades ago, health concerns have often served as a stalking horse for attempts to purify people's minds and bodies, not their welfare or even health. To see the most salient example of this, one only needs to notice that much of the anti-smoking (and other anti-tobacco, anti-nicotine, and anti-drug) rhetoric focuses on product use being dirty or somehow sinful, rather than it being biologically unhealthy. Purity movements often condemn any dependence (chemical or otherwise) as a moral failing or even a disease, regardless of actual health effects. This explains why addiction itself is sometimes misconstrued as a disease, often without any attempt to defend the claim, or even define what addiction means. From such a perspective, the argument against smoking has little to do with the diseases it causes, so merely eliminating those diseases is not a substitute purifying the world of tobacco. Moreover, smokers are not treated as welfare-maximizing consumers whose lives could be improved by offering a safer way to do what they are doing, but rather as impure sinners who need to be cleansed of nicotine, not aided.

Many anti-smoking activists are generally anti-nicotine and anti-drug. However, many others have close ties to the pharmaceutical nicotine industry or support balanced and rational policies in other areas of drug use, so puritanism alone can only provide a limited explanation. (One could, perhaps, extend the reach of the puritan explanation: Clean, fancy, modern pharmaceutical products seem less dirty than actual plant matter. Or perhaps that the politics of self-identity of many activists requires them to treat the most destitute members of our society, such as illicit drug users, as innocent victims but smokers get no such deference.)

A second explanation for the disconnect between anti-tobacco and pro-health is a hatred of tobacco companies. This is a particularly costly attitude since the industry is currently far ahead of the public health community and pharmaceutical industry in assessing and promoting THR. If public health advocates were to support industry efforts rather than fight them, we would be years closer to widespread adoption of THR, saving countless lives in the process.

Animosity toward the industry is often attributed to past corporate behavior, but this clearly is either not the full explanation or is based on gross irrationality: The oft-cited bad behaviors were primarily committed by cigarette companies decades ago, and yet anti-tobacco-company bias makes no exceptions for companies that make ST and not cigarettes, or companies that did not even exist at the time of the worst offenses. Indeed, it obviously makes little sense to try to punish, or even to despise, an abstract entity whose shareholders, leaders, and employees have almost completely turned over since it committed most of the acts that are considered to warrant punishment. A partial explanation for the irrationality might be the general anti-big-corporation bias of some political activists, though since some targeted companies are not large, and since the bias does not generally extend to pharmaceutical companies, this explanation also falls short.

Probably the most convincing explanation for the anti-tobacco-industry bias is that it provides some relief from the cognitive dissonance that results from "knowing" you are doing everything right but observing that you are failing. It appears that most anti-tobacco activists genuinely believe, despite all evidence to the contrary, that the actions they are advocating will eliminate the demand for tobacco and that the world will eventually be free of nicotine use. When the reality of persistent tobacco use contradicts their hypotheses, they tend to seek a *deus ex machina* rather than revising their hypotheses as scientists would.

The cognitive dissonance results from obviously erroneous beliefs. When someone has an unshakable belief that smoking has no benefits, then rational cost-benefit analysis cannot explain the choice to smoke. If one assumes everyone wants to maximize their longevity at whatever cost, then it is difficult to explain how education about the risks from smoking does not cause everyone to quit. If it is assumed that higher taxes will only result in decreased consumption, it might be difficult to recognize that smuggling and more efficient smoking are obvious rational responses. Most importantly, the assumptions that every smoker really wants to quit, and various tools make quitting easy, mean that it cannot be the case that 1/5<sup>th</sup> of the population chooses to keep smoking. Though the rational response to these observations would be to revise the assumptions, if the assumptions have become religion rather than scientific hypothesis, it is easy to see the temptation to blame one's failure on (usually unspecified) evil acts of some opponents. The tobacco industry is the usual target, though non-industry advocates of THR and any researchers whose analyses point out errors in the anti-tobacco conventional wisdom are also targets of this frustrated fury (Enstrom 2007, Phillips EP&I 2007, Siegel 2007).

Puritanical anti-smoking activists are likely disturbed by the reasonable expectation that when people learn that there are low-risk ways to consume nicotine and tobacco, then the

incentive for purification will be tremendously diminished. Similarly, activists with an anti-corporate bias realize that tobacco companies will thrive if they can switch to low-risk products that consumers will have less reason to quit using. THR probably guarantees that the goals of driving tobacco companies out of business and eliminating self-administration of nicotine will never be realized. Perhaps even more frustrating to them, the health costs of smoking will be eliminated, but not due to the success of the anti-tobacco industry, but rather in spite of the actions to which the activists devoted their careers. Thus, it is not difficult to understand why this generates hostility toward THR efforts. Of course, none of these outcomes are bad from the perspective of public health, let alone overall human welfare.

The profound disconnect between the anti-tobacco industry and actual promotion of public health goals is so difficult for many observers to understand that they grant the anti-tobacco activists the benefit of every doubt. This makes it easy for the activists to obscure their real motives with disinformation.

### Misinformation and disinformation

The great potential for THR has been discussed for decades, has been clear beyond a doubt for at least one decade, and is now universally known by anyone with real expertise in tobacco science or policy. This makes the near-universal lack of knowledge about the potential for THR beyond a small community of experts especially remarkable. The ignorance extends beyond the lay public to include most clinicians, health policy makers, and even many health researchers. What is worse, most of them are very confident in their false beliefs. Surveys show that the vast majority of the public thinks that ST is at least as harmful as smoking (Geertsema, Phillips, Heavner 2008; Health Canada 2006; Broome County 2006; ITPC 2004; O'Connor, Hyland, Giovino, et. al. 2005; Smith, Curbow, Stillman 2007) and the limited data on health professionals shows almost as much ignorance (Prokhorov, Wetter, Padgett, et. al. 2002). Those of us who educate about THR can confirm these results based on experience. The typical conversation (with lay people, professors of public health, or others) follows the pattern "really, it is not as bad?", "no, not even close," "what about mouth cancer?" The last question is typical of even those who should know that even a high relative risk for oral cancer would result in a trivial absolute risk compared to smoking. The assertion that ST does not cause lung disease so could not possibly be as bad as smoking is usually followed by a surprised expression, then tentative acceptance of this obvious fact. Similar ignorance exists about the risks from pharmaceutical nicotine products, with many people believing that they are at least as hazardous as smoking and many smokers thinking that they will increase their risk or become "addicted" to these products, even when using those them for short periods while trying to quit.

To fully appreciate the magnitude and importance of this ignorance, it is necessary to remind ourselves that this is not a matter of some rare and obscure behavior -- smoking is often considered the most important issue in public health. Nor is there any genuine scientific doubt on the huge differences in risks. Failure to understand that alternative sources of nicotine are orders of magnitude less harmful than smoking is akin to believing that wearing a seatbelt is more dangerous than not, or that common vaccines are more



dangerous than they are beneficial. Granted a few people actually believe the former of these, and many lay people believe the latter, but these are generally seen as cases of unforgivable ignorance, and a health professional making such a claim would be guilty of malpractice. But a comparably absurd – and possibly even more deadly -- misunderstanding exists for THR, and clinicians and opinion leaders are guilty of actively perpetuating it.

Part of the confusion stems from the aforementioned conflation of smoking, tobacco, and nicotine, which is sometimes used innocently (though still quite inaccurately) as a shorthand. Some of the confusion stems from the tendency of most people to think of a health exposure as merely good or bad, without understanding the immense differences in magnitude among the harmful exposures. But ultimately, such a major and important error can only exist with the complacency of the subject matter experts. In this case, there is not merely complacency but complicity, an active campaign to mislead.

Several studies (e.g., Phillips, Wang, Guenzel 2005; Phillips, Bergen, Guenzel 2006; Boehm 2005) have documented the claims made by the anti-tobacco industry that are designed to convince non-experts (including clinicians and policy makers) that ST is roughly as hazardous as smoking. Even a casual observation of "educational" materials about ST and other alternative sources of nicotine reveals that anti-tobacco (or anti-nicotine or anti-drug) activists are intent on obscuring the known differences in risk and the fundamental difference between smoking and non-combustion exposures. The claims range from out-and-out lies about the risks from ST, to conflation of all types of tobacco, to trying to take advantage of scientific ignorance with impressive sounding, but ultimately meaningless, technical claims. The latter tactics include a wide variety of claims based on toxicology, such as pointing out that ST contains various chemicals that (under particular laboratory circumstances and in very high concentrations) are "carcinogens" or "toxins." This takes advantage of the widespread public fear of "chemicals," the lack of understanding that thousands of chemicals can be found in all plants, that low dose exposures do not have the same effects as high doses, and that epidemiology trumps toxicology. Experts in other areas of harm reduction might find a familiarity with the anti-tobacco tactics and "reefer madness"-style campaigns or the attempts to convince teenagers that using condoms is a bad idea. All represent triumphs of puritanical politics (at least temporarily) over overwhelming scientific evidence.

What pass for scientific studies are often little better than the broadsides that are aimed at laypeople. The dominance of the anti-tobacco industry in scientific research and publication in the field, as well as the inherent weaknesses of health science research (Phillips 2003; Phillips 2004; Phillips 2007; Phillips 2008), mean that almost any study can be construed to show that tobacco or nicotine use is unhealthy, and most any report that draws that conclusion will be published no matter how low the quality or absurd the conclusions.

To cite one recent example, a study by a major anti-tobacco organization (and, sadly, not actually pro-health, at least in this arena), the American Cancer Society (ACS), found that switching from smoking to ST is extremely beneficial (Henley, Connell, Richter et. al. 2007).

This article, based on the same large cohort study that produces some of the most often quoted statistics about the effects of smoking, provided some of the best evidence for the value of THR ever produced (Phillips. American Cancer Society 2007). But the ACS chose to completely obscure this finding by glaringly avoiding comparing the health outcomes of those who switched from cigarettes to ST to those who continued to smoke. Instead, they only compared those who switched to those who quit using nicotine entirely, claiming (incorrectly, it turns out) that their results showed that switching was worse than quitting entirely. The ACS then tried to convince the popular press that this showed that THR was a bad idea (ACS 2007) and their propaganda was so effective that some press reports actually told smokers that it was better to continue to smoke than to switch to ST (e.g., Spangler, 2007). ACS made no attempt to correct this misconception.

Another recent study by anti-tobacco activists (Hecht, Carmella, Murphy et. al. 2007) found that the concentration of a few particular chemicals that are suspected to cause cancer (though there is no actual human data to support this) in the urine of ST users is greater than in the urine of smokers. This study, obviously far too limited and technical to be useful to the public, was nevertheless touted to the popular press as showing that ST use was harmful, even though it actually provided absolutely no information about health outcomes. Again, the propaganda was effective, and the press were misled into reporting that the study showed that ST was more harmful than smoking (e.g., American Association for Cancer Research 2007; Bakalar 2007; Fox news 2007; Snuff not safe 2007; Tasker 2007).

Particularly of interest is that these two examples are part of a large number of quasi-scientific reports about the health effects of ST use that have recently been published, after decades in which there was relatively little interest in the topic. The increased interest, and the efforts to overstate the risks from ST, coincide with the growing acceptance of THR and the real possibility that ST might be actively promoted as a tool of helping smokers reduce their risks. What is equally interesting is that there are often clear discrepancies between what researchers or organizations report in their scientific papers and how they then report those findings (or allow others to inappropriately extrapolate from those findings). In both of the above examples, the most misleading claims were found only in press releases and other communication to the public and not the original journal articles.

More telling is that since several researchers started to document the inaccurate claims made about THR by anti-tobacco organizations, many of those organizations have changed the explicit false claims so that they are literally true but equally misleading. One common example is: instead of saying that ST is not safer than smoking they now say it is "not a safe alternative", a claim that communicates the same message to the reader, but is actually vacuous since nothing is "safe." Such careful re-crafting makes it especially clear that the authors are aware of the truth, and do not want to be caught making clearly false claims, but are still intent on misleading the public.

Efforts to prevent people from learning about THR are clear violations of the most fundamental tenet of modern health ethics, that individuals have a right to be given information so that they can make autonomous decisions about their own health. The

paternalism and puritanism that dominate nicotine and tobacco policy result in both deadly consequences and a fundamental violation of people's rights. What is often called *misinformation* about the potential for THR should be recognized for what it is: *disinformation*, a concerted effort to mislead people. Because of misplaced trust, this disinformation campaign has been hugely successful. Since information is the key to reducing the needless harm from using a deadly delivery system for a beneficial and relatively innocuous drug, the disinformation has been very effective at killing people. Fortunately, this may finally be starting to change.

## **5. The future of THR**

Despite the obstacles of widespread ignorance of critical facts and active opposition by the rich and powerful anti-tobacco industry, widespread adoption of THR seems inevitable. Good ideas do not remain secret forever and smokers are interested in low risk alternatives to cigarettes. The real question is how many more people will die from smoking before they learn about the alternatives.

Some pro-THR advocates have focused on trying to convince the anti-tobacco industry to endorse THR. Since the popular belief persists that anti-tobacco activists are honest and pro-health, many other organizations and policy makers take their cues from them. Thus it is very frustrating to try to educate the public, health care providers, and policy makers in the face of their anti-THR campaigns. However, since there has been little doubt about the potential value of THR for over a decade, but during that time anti-tobacco activists have only become more hardened in their opposition to THR, it is difficult to be optimistic about this approach. While converting the purity activists is not promising, many respected organizations that are genuinely pro-health and not beholden to the anti-tobacco forces have come out in favor of THR, providing adequate political cover for those who require such endorsement before supporting THR. Britain's Royal College of Physicians recently issued a report (Royal College of Physicians 2008) that actively supported THR, and the American Association of Public Health Physicians also recently endorsed THR (Nitzkin, Rodu, 2008). The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks reported on the benefits of THR, and thus the harm caused by the EU ban (SCENIHR 2007), though someone who read only the political documents surrounding the actual scientific report, and not the report itself, might not have noticed that this was the message.

The clear scientific consensus on the benefits of THR, coupled with some organizational endorsement, will likely lead to increased uptake of THR. The combination of freedom of speech, easy legal access to products, and an extremely compelling message make it inevitable that educated people will eventually get the message and lead the way for others. Each smoker who learns about the potential of THR can adopt it themselves (no policy action or social infrastructure is needed). Moreover, each person who is educated about THR will ratchet the progress of THR, since it is unlikely that those who spread disinformation will be able to cause someone to unlearn the truth.

With the most promising ST products banned in the EU and elsewhere, adoption is difficult for consumers and education is also severely hindered. In countries without adequate

education or free speech, information dissemination may be very slow, despite the availability of products. The U.S. is probably the best near-term hope for promoting THR. The litigious climate surrounding corporate actions has made major manufacturers nervous about exercising their free speech rights in the U.S. but smaller companies and some individuals are trying to educate the public about THR.

Legal restrictions like the EU ban on ST will stifle the adoption of THR. However it is possible that when the ban is lifted it will be sufficiently dramatic that there will be a highly teachable moment that causes education about THR to vault ahead of U.S. levels. More subtle restrictions in less open societies, like Canada's restrictions on free speech or the almost complete dominance of unscientific anti-THR messages in less educated populations, might actually delay uptake of THR longer than bans, assuming the bans are eventually lifted. In societies that are even more closed or where there is very limited education – a substantial majority of the world's population, with a majority of its smokers -- there is probably little hope for major inroads until THR is established in the West. The possible exception to this pessimism is that if corporations with major marketing clout (be they cigarette companies marketing snus, or otherwise) might actually be able to promote THR in unexpected places where there is no ST tradition. While such efforts are extremely costly, at least one major company has proven willing to accept the necessary losses to try to build knowledge of THR in new population, and they might eventually find a government that is willing to help rather than hinder their efforts.

An alternative scenario for the uptake of THR is an adoption of imitation cigarettes. These products currently have lower consumer awareness than ST. However, this is the type of product that can explode into popularity in a community if it becomes stylish. Indeed, the origination of such products in China makes that country a dark-horse hope for advancing THR. With hundreds of millions of smokers, a free-wheeling marketplace, an increasingly educated population, and free speech in the marketplace (though obviously not in many other arenas), China could emerge as the leading market for THR.

Adoption of THR seems likely to be a critical mass or tipping phenomenon (Schelling 1978), since each adopter is likely to increase the rate of knowledge dissemination and recruitment. The question then becomes, is there a way to push the positive but slow progress toward critical mass? Assuming that government and major health organizations remain part of the problem rather than the solution, marketing by ST manufacturers, targeted and localized enough to produce local critical mass may be the most promising alternative. It is possible that before ST use reaches critical mass, imitation cigarettes or other devices could become comparable contributors to THR. Such devices could provide the impetus for a lot of switching (followed by education about the advantages of switching).

It might seem surprising to see switching leading, rather than lagging, education about reduced harm, but this is actually not an unusual pattern for behavior change. The current impetus for using imitation cigarettes is time-and-place restrictions; in the West they appear to be primarily marketed to patrons of bars and restaurants, or to those worried about second-hand smoke, serving an obvious consumer demand that has nothing to do

with the user's health risks. Indeed, there is little evidence that consumers are aware of the much lower health risk, even though some suppliers have included a THR message in their marketing. However, knowledge often follows behavior. It is often difficult for people to internalize the message that their actions are needlessly harmful, even smokers who intellectually know the risks (i.e., people resist cognitive dissonance), but we become interested in learning once our actions have changed (i.e., people are curious about and become invested in rationalizing the actions they have chosen).

The irony here is the subtext of time and place restrictions. Such laws and regulations are almost always justified as ways to protect nonsmokers from the risks from an involuntary exposure (notwithstanding that the risks from second-hand smoke exposure have been grossly exaggerated and the bans increasingly include places where being there is highly voluntary). This is the only way to sell the restrictions to the public in societies that respect individual liberty. However, most anti-tobacco activists have other goals and clearly, often quite openly, argue that an intentional "benefit" of the restrictions is that they make smokers so miserable that they are more likely to quit (c.f., claims about the expected reduction in risks among smokers thanks to the bans, as well as advocating forbidding not just smoking but also ST use on airplanes, prisons, and other confined venues). But misery is the mother of invention, and so the restrictions cause invention of products and innovative consumption patterns for the long-term, low-risk use of tobacco that these same activists want to eliminate.

Were it actually that nicotine use was just the result of unwanted addiction and smokers really preferred to quit entirely, they might thank the regulators for making smoking less appealing. As it is, smokers are being driven to the economically rational choice of obeying the regulations with minimal cost to themselves, and so are driven to the rational decision to reduce their health risks. Having inadvertently reduced their risk, they will soon learn they have done so, and will probably help educate others. Harm reduction is always about maximizing welfare, usually by facilitating rational individual decisions. It should come as no surprise that smokers are rational actors who want to lower their costs without eliminating their benefits. When they are finally given the opportunity to do so, it will likely be the greatest public health triumph of our generation.

*For additional information about tobacco harm reduction, including to scientific information and popular educational materials, please see our website, [TobaccoHarmReduction.org](http://TobaccoHarmReduction.org).*

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