A dissection of what passes for scientific review and policy analysis among anti-Tobacco-Harm-Reduction researchers; An annotation of "Is Smokeless Tobacco Use an Appropriate Public Health Strategy for Reducing Societal Harm from Cigarette Smoking?" by Scott L. Tomar, Brion J. Fox and Herbert H. Severson from International Journal of Environmental Research and Public Health 2009, 6:10-24.

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May 2009

Just as empirical reports are expected to follow certain norms of scientific conduct, an analytic paper must be more than a random collection of the authors' opinions. The latest piece by Scott Tomar et al. is presented as if it is a review and analysis of arguments against tobacco harm reduction (THR). It fails as both review and analysis. There are so many errors and problems that deserve comment that a letter to the editor would be extremely long and hopeless to try to read. An annotated version seemed most useful, and so appears below, with our analysis interleaved with the original content of Tomar et al.

Someone might argue that annotating this particular paper gives it far more credit and attention than it deserves. But we argue that this is exactly the attention that these anti-harm-reduction arguments deserve. There need to be direct responses to arguments in this area, rather than unchallenged monologues. By annotating an article, we are clearly responding to an argument that was actually made, and cannot be accused of mischaracterizing what was said to make it easier to respond to.

Someone might argue that responding to this particular paper represents a straw man because the argument presented is so weak. But this paper is quite typical of the genre, and so seems representative. Moreover, it is not just some random student's term paper. Tomar is among the most vocal activists against THR, and seems to be involved in most every major anti-THR meeting and document; he is consistently hired a consultant for the plaintiffs in consumer lawsuits against smokeless tobacco manufacturers; and he has been writing and re-rewriting versions of most of this content for a decade. While perhaps this paper cannot be credited with being the best anti-THR argument, the content of Tomar's repeated arguments over the last decade clearly has been read by and discussed with much of the anti-THR activist community. Thus it seems fair to conclude it is considered acceptable quality for anti-THR arguments by the anti-THR political community.

**OPEN ACCESS** International Journal of

Environmental Research and Public Health ISSN 1660-4601 www.mdpi.com/journal/ijerph

Review

# Is Smokeless Tobacco Use an Appropriate Public Health Strategy for Reducing Societal Harm from Cigarette Smoking?

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Received: 22 November 2008 / Accepted: 20 December 2008 / Published: 23 December 2008

The title invokes two key concepts that never appear in the analysis. The first is "appropriate", a word that vaguely invokes some sense of rightness, goodness, or morality. Since this paper purports to be analytic, rather than an extended voicing of the sentiment "I just don't like it!", this word needs to be defined in the present context. To be able to draw a conclusion about THR, the authors need to provide the reader with some idea of what characteristics would make a public health policy or practice appropriate or not. They do not do so, though they make a few implicit suggestions which are noted (and criticized) below. Instead they merely invoke the vague word again in their conclusions. This is a common tactic of political activists, to talk as if they are assessing a policy in relation to some clear and obvious standard, but to avoid ever stating what that standard is. This avoids the embarrassment of having it pointed out that if we adhered to their standards we would have to make other policy decisions that would be generally recognized as absurd.

The other key word is "strategy", which is absent from the analysis and the conclusion. No strategy is ever defined. This is critical because it allows the authors to muddle together arguments that would apply only to an unspecified massive expensive intervention, together with those that apply only to a "strategy" of merely allowing smokeless tobacco (ST) to exist, and a remaining few that would apply to any realistic policy intervention that has ever been proposed.

Additionally, the failure to specify a strategy lets the authors inaccurately imply that there is substantial support in THR for promoting only ST. While ST was considered uniquely promising for THR for many years, proponents of THR almost always pointed out that pharmaceutical nicotine products, which pose similarly low risk, are a good choice if a smoker finds them satisfying. (The problem was never that their risks were much different, but because they do a poor job of delivering a satisfying dose of nicotine.) Moreover, this article was

strangely archaic at the time it was submitted since "electronic cigarettes" (e-cigs) had by then come to play a large role, arguably dominant, in North American discussions of THR, and most THR proponents are now emphasizing their potential. By implying that THR advocates do not recommend pharmaceutical products, let alone e-cigs, as a low-risk alternative to smoking is a serious mischaracterization. However, the content can still be read partially as arguments about THR in general and partially about the inclusion of ST as part of a THR strategy, and thus is still relevant.

**Abstract:** Four arguments have been used to support smokeless tobacco (ST) for harm reduction: (1) Switching from cigarettes to ST would reduce health risks; (2) ST is effective for smoking cessation; (3) ST is an effective nicotine maintenance product; and (4) ST is not a "gateway" for cigarette smoking. There is little evidence to support the first three arguments and most evidence suggests that ST is a gateway for cigarette smoking. There are ethical challenges to promoting ST use. Based on the precautionary principle, the burden of proof is on proponents to provide evidence to support their position; such evidence is lacking.

Keywords: Smokeless tobacco, harm reduction, smoking cessation, smoking initiation.

When claiming to offer someone else's list of arguments, particularly those that that one vehemently opposes, making them credible is challenging. It requires careful study of the actual arguments being made, good and relevant citations, and an attempt to present all the arguments as effectively as possible. Failing that, there is a reasonable accusation that all that has been created is a straw man, a misrepresentation of arguments by one's opponent intended to make it easy to respond to them. This list does not effectively present the arguments, and no attempt is made by the authors to justify it as the arguments that pro-THR advocates use. However, it is not so clearly an effective straw man either (though there is no shortage of straw man arguments in the text). As much as anything, this just seems naive and sloppy, as if the authors have never really paid much attention to the actual pro-THR arguments even as they fancied themselves capable of debating the issues.

Argument 1, along with 2 and 3 (which when the arguments are actually made are typically combined into a statement like "some smokers would substitute ST for cigarettes if they knew the truth about the comparative risks") form the core arguments that encouraging THR will improve public health outcomes: It will reduce some smokers' risks by almost as much as quitting tobacco/nicotine entirely. But improvement in public health outcomes is just one of the arguments that are commonly made; an accurate completion to the sentence that begins "arguments have been used to support..." would include the multiple arguments, not just one of them (and would not actually include point (4)). If Tomar et al. wanted to claim "We think that the best arguments are..." then perhaps this list would be accurate (though it would indicate that they do not really understand the best arguments), but to claim that these are the arguments THR proponents use is simply wrong.

A key argument that Tomar et al. chose to ignore is the argument from rights, that people have a right to accurate health and risk information and to make their own decisions based on it, and thus the authorities have a responsibility to provide important information. This reflects the leading tenet of modern public health ethics in Western society, established as such about 60 years ago and seldom seriously questioned [see, e.g., the Declaration of Helsinki [http://www.wma.net/e/policy/b3.htm] and the Nuremberg Code

[http://www.ushmm.org/research/doctors/Nuremberg\_Code.htm]]. Many pro-THR statements emphasize this argument, often explicitly arguing that it is compelling regardless of the health benefits: We have an obligation to make sure that smokers (and everyone else) know that ST is approximately 99% less harmful than smoking so that they can make their own best choices. By largely ignoring this key argument, the authors avoid having to respond to what many consider the most compelling ethical argument for THR, even as they claim to be offering an analysis of ethics. Tomar et al. actually acknowledge that they are aware of this argument, but gloss over its substance with some non sequiturs (see below). Ignoring this point also makes it easier to avoid defining what strategy they are analyzing, since this ethical argument calls for simply providing accurate important information to people rather than lying to them, a strategy that is difficult to criticize.

(Note for readers who do not know: What is currently done is exactly the opposite of what an ethic of informed autonomy demands. Anti-THR activists, including Tomar, have conducted a very effective disinformation campaign that has most Americans convinced that ST use is as harmful as smoking. See Phillips, Wang & Guenzel, You Might as Well Smoke [http://www.biomedcentral.com/1471-2458/5/31] for more details. Knowing this is critical for recognizing the fundamental flaws in some of the points below.)

An additional argument in favor of THR ignored by Tomar et al. focuses on the welfare improvement from THR. Many advocates of harm reduction, including THR, note that not only do reduced harm alternative behaviors/products offer the possibility that some people who will not become abstinent will still reduce their risk, but that the alternative is welfare-enhancing compared to abstinence. Thus, only the most puritanical activists advocate that adults should avoid having sex (the best way to reduce the risk of sexually transmitted disease); most everyone recognizes that people's welfare is much greater if they have sex but try to reduce the risk (condoms, limiting number of partners, etc.). No one ever advocates motorized transport abstinence (though that is the best way to avoid the risk of trauma from a crash); everyone recognizes that harm reduction is better. What might be called the "health promotion pseudoethic" holds that public health policy should maximize health outcomes, regardless of welfare cost. From this perspective, harm reduction is only needed because those annoying humans that someone is trying to manipulate are going to choose, for example, to have sex even though we tell them it entails some risk. Thus, because people will not do what is "right", they will reluctantly try to make it safer. Obviously this is a position that few outside a puritanical minority would support.

In the case of THR, the argument is that offering a low-risk alternative to a behavior that people choose even when it is extremely high risk (consuming nicotine) will be better than either continuing the high-risk behavior or quitting entirely for many such consumers. Some THR proponents apparently buy into the health promotion pseudo-ethic, as evidenced by observations that someone who would have quit entirely, but prefers using a low-risk product to either smoking or quitting, represents a downside of promoting THR rather than an upside. But many of us recognize that a welfare based ethic should count such people on the benefit side, since they freely chose the new option and thus must be made better off by it. By ignoring the welfare argument, Tomar et al. are thus able to try to implicitly claim that complete nicotine abstinence is always best for everyone, without ever trying to justify that claim. As weak as their arguments are, they would be weaker still if they did not pretend either that there are no welfare benefits of using nicotine or that welfare should be considered part of judging a policy's "appropriateness". These authors are not unique in treating the health promotion pseudo-ethic as the indisputable goal even though no serious analysis of ethics would ever support it. It is relatively common in the many normative public health statements written by authors who do not understand ethics. But in this case, since the authors purport to be offering a scholarly

ethical analysis and to be presenting the arguments that are made in favor of THR, ignoring this key argument cannot be excused.

Note that merely including all the actual arguments in favor of THR would not mean that Tomar et al. could not then offer a refutation of them. But since they chose to simply pretend those arguments do not exist suggests that this is unlikely.

Their argument 4 is a rather different point that should not be on the same list. First, it is simply wrong: It should be obvious to the reader none of the arguments in favor of THR require that there be no "gateway" effect, including the one of the three that Tomar et al. acknowledge. After all, there could be some gateway effect but not enough to overcome the net health benefits. This is one component of many that need to be quantitatively analyzed to assess the effect of promoting THR on public health, not one of the major arguments for THR promotion, let alone a necessary argument. As pointed out below, Tomar et al. utterly fail to provide the necessary analysis to make sense of this claim.

#### 1. Introduction

There is increasing interest and controversy within the public health community about smokeless tobacco (ST) [1]. Some proponents believe that, given the enormity of the health problems associated

with cigarette smoking, a viable alternative is harm reduction, i.e., use of nicotine-containing products with lower mortality and morbidity risks [2, 3]. This has resulted in recommendations for cigarette smokers to switch to ST products [4-7].

A recent review article claimed "there is a strong scientific and medical foundation for tobacco harm reduction, and it [ST use] shows great potential as a public health strategy to help millions of smokers [4, p. 17]. One group of advocates for ST-based harm reduction characterized their opponents' position as "health professional's authoritarian insistence that the only valid choice for smokers is to quit or die as an addicted cigarette user." [8, p. 363].

What are the arguments put forward by proponents of ST use and is there sufficient evidence to support them? We had three purposes for this paper: (1) to identify the major arguments used by those who support ST as a tobacco harm reduction strategy; (2) to summarize and critique the scientific evidence behind those arguments; and (3) to consider the ethical and practical implications of promoting ST use for population harm reduction.

It should be clear from this annotation that they do not actually accomplish any item on this list.

In this paper, we will be focusing mainly on research from the United States and international findings that may or may not be relevant for ST use in the United States, keeping in mind that the context and products from other countries may not necessarily be transferable to the current situation in the United States. We will be addressing arguments that have been made about the use of ST, as well as describing some recent events and behaviors by U.S. tobacco companies.

#### 2. Background

The common feature of smokeless tobacco products is that they are not burned when used. In North America and parts of Europe, ST most commonly comes in the form of snuff (dry or moist) or chewing tobacco. Moist snuff, used orally, is the most popular form of ST [9]. Although having a much smaller market than cigarettes, ST products account for about \$2.6 billion in sales annually in the United States [10]. ST use in the United States occurs predominantly among males, with higher prevalence among younger-aged whites, rural residents, and in some Native American and Alaska Native tribes [9]. Similarly, ST use in Sweden and Norway occurs largely among males [11, 12]. In 2005, an estimated 6% of men and less than 1% of women in the United States used ST [13].

There is scientific consensus that ST use increases the risk for cancers of the oral cavity and pharynx, oral soft tissue lesions, gingival recession, and nicotine addiction [14-18].

This is the first of several places where Tomar et al. imply that they have done some kind of comprehensive review and are offering a summary conclusion based on it but they (a) have not done any kind of systematic review, (b) clearly omit key well-known analyses, and (c) draw a conclusion that is not supported by what they do cite.

There is clearly no such consensus (except, perhaps, about inconsequential soft tissue lesions). Numerous authoritative authors and documents have explicitly argued that the products being proposed for THR have not been shown to cause some of these diseases. Indeed, at this point in the paper, the Tomar et al. have already cited some of these. The references that Tomar et al. do cite are a curious collection. A reader who noticed that there were five references for the claim of consensus would presumably expect that they represented systematic reviews of either the scientific consensus or the science itself. In fact, references 14, 15, and 18 are basically opinion pieces about the wisdom of THR that, among them, represent the opinions of only five authors, one of whom is Tomar. The first of these includes a nonsystematic collection of references, but nothing that could be seen as a legitimate basis for assessing what the evidence shows, let alone a scientific consensus. The other two are even less legitimate as references for the sentence. Reference 16 is an old review of some of the scientific literature, and contradicts what Tomar et al. say in this sentence (it concludes only that the rather different ST-like products used in South Asia cause oral cancer, but that this claim is not supported for the American products they emphasize in this analysis). Reference 17, a particularly odd choice, explicitly denies the claim that modern American ST products cause oral cancer.

Recent Swedish, Norwegian, and U.S. studies found an increased risk for pancreatic cancer from using ST [19-21]. ST has been classified as a human carcinogen by the International Agency for Research on Cancer [22, 23], the U.S. Surgeon General [24], and the National Toxicology Program [25]. Some ST proponents suggest that the health risks associated with ST use are greatly exaggerated [4], particularly for moist snuff products with lower levels of tobacco-specific nitrosamines (TSNAs) such as Swedish snus [26].

Tomar et al. ignore the much more important point that THR proponents also point out that even if all the exaggerated worst-case claims about ST were true, it would still be more than 90% less harmful than smoking.

Indeed, this entire paragraph appears intended to distract rather than provide useful background. Since the phrase "harm reduction" is invoked to explicitly point out that not all risk is eliminated, arguing that ST causes some health risk offers no information. What would be informative is pointing out that that risk, all totaled, is usually estimated to be about 1/100th

the risk from smoking. This is relevant because some of the arguments in favor of THR are substantially strengthened by the observation that the reduction in risk is so close to complete that there is little point in distinguishing it from risk elimination. Again, Tomar et al. avoid presenting the actual case in favor of THR despite claiming that this is what they are responding to.

It is also interesting that Tomar et al. mention diseases that are now generally regarded as not being caused by Western ST (oral cancer) and those where there is only a bit of information but rampant speculation (pancreatic cancer), yet ignore the risk that is best supported by available science. The mild stimulant properties of nicotine clearly cause acute cardiovascular changes which probably increase the risk for fatal events (stroke, heart attack), as other mild stimulants have been shown to do. There is a bit of epidemiology that tends to support this also. The risk is clearly small, but is likely nonzero. Perhaps Tomar et al. left this out because this best argument that ST causes some risk requires admitting that pharmaceutical nicotine products also cause that risk, and they want to claim that the pharmaceutical products are less risky (even though there is absolutely no scientific evidence to support that claim -- see below).

The United States currently has no regulatory framework or standards for levels of TSNAs or other toxins in ST products, and their levels are substantially greater in most U.S. moist snuff products than in products sold in Sweden [27, 28].

#### 3. Current situation

Two recent circumstances have increased attention on ST. First, there is growing consideration of ST use within the public health community. Several recent publications indicate that ST is being taken more seriously by scientists as a harm reduction strategy [3, 17, 26, 29].

Second, the two largest U.S. cigarette manufacturers have entered the ST market. In 2006, Reynolds American purchased Conwood, a major ST manufacturer with 32% of the U.S. moist snuff market, and began test-marketing Camel Snus [30]. Also in 2006, Philip Morris USA began test-marketing Taboka, an ST product in a pouch [31], and began test marketing Marlboro Snus [32]. In 2008, Philip Morris USA acquired U.S. Smokeless Tobacco Company, the country's major manufacturer of moist snuff (64% of the US moist snuff market), and expanded test marketing of new moist snuff products. Promotions for these newer ST products focus on their being "spit free" and their use in indoor areas where smoking is not allowed [33, 34].

While it does not directly bear on the quality of the authors' arguments, it testifies to the care of their analysis that they get dates and company names wrong in this paragraph.

A reader might expect that the two references at the end of the paragraph are studies of how promotions for new ST products are focused. In fact, they are just images of two apparent ads by one company ("apparent" because they are not even accompanied by references that show they were ever published). Obviously two examples, with no information about whether they ran at all, let alone how much, cannot establish a "focus". Even more interesting, the images are both dated 2005, which pre-dates everything that is referred to in the paragraph.

Some tobacco companies disseminate statements by those who favor ST for tobacco harm reduction, and criticize opponents as being unprincipled in their resistance to harm reduction [35].

This is a rather broad statement to make without evidence. The single cited reference does not make any such claim and is not even an example of what is being claimed (the reference is to a brief article in an industry specialty publication about some of the politics surrounding THR; it was not disseminated by a tobacco company). Also, we monitor the literature quite closely and recently completed a review of companies' public statements, and are aware of no case where a tobacco company openly criticized THR opponents as being unprincipled. Indeed, anyone familiar with the area would recognize this claim as completely absurd, given that the industry has been extremely timid in their public statements for the entire period that anti-THR activism has existed.

Moreover, it is not even clear what this statement or paragraph has to do with the ostensible analysis in this paper. Perhaps the subtext is one that is common in parts of "scientific" literature in this area: "Those evil tobacco companies did something bad, and therefore we are excused from doing legitimate analysis."

#### 4. Arguments used to support ST as a harm reduction strategy

Proponents present four major arguments for ST as a harm reduction strategy, each of which is reviewed below.

### 4.1. Smokers Reduce Their Health Risks by Switching to Smokeless Tobacco

The first argument is that, although ST has health risks, the risks are considerably lower than those associated with cigarette smoking. Two broad lines of research are needed to support this argument:

(a) exclusive ST users who never smoked cigarettes experience fewer health risks than exclusive smokers; andb) exclusive smokers who switch to only using ST experience reduced health risks compared to those who continue to smoke.

There is substantial evidence that lifetime ST-only users have lower health risks than lifetime cigarette-only smokers [15, 16, 36, 37]. For example, unlike smoking, ST products do not appear to increase the risk for lung cancer or chronic obstructive pulmonary disease. Some have attempted to quantify the reduced level of health risks among ST-only users compared with cigarette-only users [4, 38].

Proponents also stress that not all ST products are the same.

The reader might think that Tomar et al. reviewed pro-THR statements and concluded that most or all "stress" these points. In fact, very few do. Often it is emphasized that some products are more likely to be socially acceptable, but typically the observation is that any widely-available Western ST product is a low-risk alternative to smoking, so smokers should switch to whichever appeals to them.

They argue that moist snuff, particularly lower-TSNA products, has fewer health risks than dry snuff or chewing tobacco [4]. Population-based data from men in Sweden, a country with a high prevalence of ST and a low prevalence of daily cigarette smoking, are cited to demonstrate lower rates of smoking-related cancers compared to men in other European countries with different patterns of tobacco use [39, 40].

The reader might think that a sentence that refers to what proponents cite and includes two references would actually cite the proponents. In fact, both of those references are general overviews of disease rates and, unlike other papers that Tomar et al. could have cited had they actually been trying to present the pro-THR arguments, do not try to emphasize the success of THR in Sweden.

We found little evidence that lifetime cigarette-only users who switch to ST reduce their health risks compared to continuing smokers, although it is very unlikely that smokers who completely switched to using ST would increase their health risks.

As anyone remotely familiar with the science knows, there is overwhelming evidence to support the conclusion that smokers who switch dramatically decrease their health risks; this is easily inferred from the fact that smoking is high risk and ST use is low risk. Tomar et al.'s statement is like saying "there are no studies that directly support the claim that drug users who switch from huffing solvents to smoking cannabis reduce their health risks, though switching to it probably does not hurt them too much." The bald rhetoric would be funny if it were not so destructive (to both scientific discourse and public health).

Only one published study compared mortality rates among smokers who permanently switched to ST with those who quit smoking entirely. An analysis of data from American Cancer Society's second cancer prevention study (CPS II) cohort [37] found that men who switched from cigarette use to using only ST had higher death rates from all causes combined, lung cancer, coronary heart disease, or stroke compared with those who had quit smoking completely. Mortality rates from all causes among "switchers" appear to be lower than for continuing smokers in CPS-II [41].

The results that Tomar et al. describe as "appear to be lower" are actually so clearly and overwhelmingly lower that we normally only dream of such clear results in epidemiology. The only reason that this is not completely obvious and well known is that the ACS who published these studies is not so much a scientific organization as a powerful activist political organization which is for some reason dedicated to anti-THR activism. They reported results from the same data about the risks of continuing to smoke and the risk for those who switch to ST, but avoided ever making the obvious direct comparison of them. But any interested readers can make the comparison themselves. Having done so, they will find that the evidence is, in fact, exactly what Tomar et al. claim does not exist (see our mock press-release-that-never-happened on this point at http://www.tobaccoharmreduction.org/papers/phillips-henleycomments-maro7.pdf).

An extension of the "ST is safer" argument is that individuals should be provided with information on the comparative health risks of products, weigh the risks, and decide for themselves [42]. Proponents recommend providing "objective scientific data," and criticize health organizations and governmental agencies for exaggerating ST health risks and implying its use is "just as dangerous as smoking" [4, 43]. Unfortunately, smokers may substantially underestimate their current risks [44] and decades of research indicates that scientific number-based messages alone are not effective in changing smoking or other behaviors [45, 46].

This paragraph presents some interesting non sequiturs, some of which are a bit random and bear no relation to the claim being putatively addressed.

It starts with a vague statement of the key ethical argument that Tomar et al. largely ignore (as discussed above), about the obligation to honesty and the right to informed autonomy. This is a logical non sequitur in this section, since that is a fundamentally different point from the point that switching lowers a smoker's risk. They are, in fact, incommensurate, since one is consequentialist and the other is deontological, which anyone qualified to analyze ethical arguments would recognize immediately.

Moreover, Tomar et al. pretend to acknowledge the deontological argument while actually completely ignoring the substance of it and its basis in widely accepted ethical principles. Instead, the authors seem to be implicitly arguing that honesty and individual autonomy do not impart any duty when there are popular misconceptions. While it is true that care must be taken in providing honest information for autonomous decision making when the information is potentially difficult to interpret, no serious ethical analysis claims that the possibility of misinterpretation means that we should give up on informed autonomy and instead blatantly lie to people.

Moreover, in the case of THR there seems to be little worry of misinterpretations that lead to mistaken choices. Tomar et al. claim that smokers may underestimate their risks and cite one study, though the weight of all the evidence tends to suggests that smokers overestimate the risks from smoking. But even if smokers did underestimate their own personal risks somewhat (which there is some evidence to support), it is not clear what relevance this has to the practicality of THR, let alone the ethics of providing honest information. The accuracy and potential usefulness of a message that switching products reduces risks by about 99% seems little affected by a smoker misjudging his baseline risk by 20% or, for that matter, by 75%. This sentence is thus a complete non sequitur in what is already a non sequitur paragraph about the ethics of honesty and autonomy.

The last half of the sentence wanders still further away from the points, since it is relevant only to the practical effects of a straw man version of the never-stated strategy. Even if the statement were true, it would merely be an argument against holding out much hope for the specific strategy of merely proving numbers "alone", not against all strategies to encourage THR and not against providing the information for autonomous choices in some form other than numbers alone. Moreover, even the empirical claim is misleading. Scientific messages about the risk from smoking, which often included quantification, caused the initial Western reduction in smoking from about half the population to about one quarter, making it one of only two interventions that have been proven to reduce smoking more than a small amount (the other being the switch to ST that started among Swedish men and has extended to Swedish women and Norwegians). Moreover, any evidence about what numbers alone can do is only relevant if the number that was studied was in the order of a 99% reduction in risk, something that most anyone can understand and would find quite compelling.

As a minor aside, we have to point out the inaccuracy on the suggestion that "Proponents recommend providing 'objective scientific data". We (particularly CVP), who surely must be counted among the most active proponents of THR, are sufficiently educated in the philosophy of science that we would never naively use the word "objective" to describe science. We and anyone else with a modicum of knowledge about communication would also never suggest that consumers be provided with data rather than the results of analyses of data.

In short, someone reading this paragraph quickly might think that an argument against THR had been offered, when it is really a vacuous wandering across several unrelated points. To make sure that we are not accused of using a straw man argument ourselves, we will point out that most of the rest of the paper is not nearly this nonsensical, but it is significant since it represent Tomar et al.'s only attempt to argue one of the key pro-THR arguments.

Although health risks from using only ST are lower than those for exclusively smoking, this comparison of health risks is true for virtually any consumer product. Proponents do not compare ST risks with risks associated with FDA-approved smoking cessation pharmaceuticals or with the lower risks associated with quitting tobacco entirely [37]. If these types of risk comparisons were made, the health risks for ST would not seem small.

One might think that if the authors had any support for the latter claim they would have mentioned it, rather than blatantly omitting any quantification of comparative risks.

The first sentence here is just kind of funny; the relevance of the comparison is obviously not just that one product has lower risk than another, but that the former could be considered by many users to be a close substitute for many users of the latter. The second sentence is a combination of nonsense and false (and, keeping with their usual citation practice, cites an article written by anti-THR activists which does not say anything about whether proponents make such a comparison). We and other THR proponents often estimate the risk from using ST compared to abstinence, and put it in context. Reporting that switching products reduces risks by about 99% is obviously equivalent to saying that using low-risk alternatives is about 1% as bad as smoking compared to abstinence. Putting that in context, it substantially lower than the risk from motorized transport and in the same range as the risks from drinking coffee or eating french fries. And pretty much any time it is relevant, we point out that products that deliver nicotine that has been extracted from tobacco and delivered on another substrate (whether FDA-approved or not -- this is a random red herring in the text) apparently also have very low risks, indistinguishable from those from ST.

No one can actually compare the health risks from using ST with those from using pharmaceutical nicotine because there is no good way to estimate the risks from long-term use of pharmaceutical nicotine (which would be the relevant comparison), except by assuming that it is basically the same as that from ST. Thus, the third of the above sentences is nonsense, since the only available comparison to be made across product categories is "we have clear evidence that ST is low risk and since most of the estimated risk comes from the nicotine itself, we have no reason to believe that other nicotine products are much different". Comparing one number to another, when all you know about the latter is you surmise it is similar to the former, obviously gets you nowhere.

In addition, proponents do not address the health effects of multiple tobacco product use, although the prevalence of ST used in combination with other tobacco products may be substantial. U.S. national data indicate that 40% of men who occasionally used snuff and 19% who used snuff daily also smoked cigarettes [47], and 26% of male cigarette smokers in 10 states also used other forms of tobacco [48].

This is the first of several claims that can either be interpreted as another non sequitur or as suggesting that the strategy being analyzed is whether to invent and start selling ST (or perhaps whether to implement an anti-THR strategy by banning ST). That is, the effect of the existence of ST is only relevant if the policy in question were not promoting THR but changing the availability status of ST. Obviously this is not relevant to the American market that Tomar et al. explicitly say they are analyzing, since ST exists and is universally available. Whatever the health risks are from using multiple products, they will occur if multiple products are available whether or not THR is promoted. Indeed, promoting THR would encourage dual users to shift

more or entirely to ST which would undoubtedly be healthier, so Tomar et al. are presenting an argument in favor of promoting THR, not against it.

In summary, we conclude that exclusive use of ST confers fewer health risks than exclusive cigarette smoking. However, ST use has important health risks that are substantially greater than those associated with not smoking. We identified one study demonstrating that smokers who switched to using only ST reduced their risks for fatal health outcomes, although that study also found slightly higher mortality rates among lifetime cigarette-only smokers who switched to ST compared with those who quit tobacco use entirely.

Though they work hard to obscure it with the rhetoric, what the authors say in this paragraph is that the original claim, that smokers reduce their risk by switching, is correct. They concede that smokers who switch have only slightly higher risk than those who quit entirely, which is exactly the core of the THR argument. They assert that ST has risks that are "substantially greater" than "not smoking" (presumably they meant to say "not using any nicotine product"), but they never actually present any evidence to support this claim or indicate what they mean by "substantially". Similarly, they continue to avoid quantifying just how much lower the risks from ST use are compared to continuing to smoke.

#### 4.2. ST Use is Effective for Smoking Cessation

The second claim is that the ST is an effective smoking cessation aid.

This statement fundamentally mischaracterizes the actual pro-THR argument using subtle linguistic games, specifically the verb tense and the implicit universality. The actual argument is that switching ST would be an effective smoking option for many smokers if they knew the truth about the comparative risk. Thus, the actual claim is not that ST has already been effective for many smokers given that most people believe that ST poses high health risks, similar to those from smoking. This is the result of a very effective anti-ST propaganda campaign (it predates most discussions of THR, but it is now an anti-THR propaganda campaign). Arguing that THR cannot work because it has not previously been adopted by many smokers, is thus like saying that an antibiotic that has never been released for use cannot cure diseases because it has not cured many yet. (Indeed, it is quite remarkable quite how many people have quit smoking by switching given the effective disinformation.) This observation means that almost all the content of this section is pure straw man.

The implicit universal appeal of THR is also a common straw man argument. If many smokers are not interested in switching, or find it less appealing than some other method of quitting, does not mean that promoting THR has no benefits. It is only necessary that some smokers benefit from it or, at most, that enough smokers benefit to justify the (presumably very low) costs of whatever the unspecified strategy is.

Various approaches have been used to estimate the extent to which ST has been used as a smoking cessation method from survey data: specific questions about cessation methods used; the proportion of current ST-only users who were former cigarette smokers; reconstructed birth cohorts using serial surveys; and comparative population trends in prevalence for cigarette smoking and ST use.

ST proponents cite the experience in Sweden to support use of ST (snus) for smoking cessation. Although overall tobacco use has changed little over the past 20 years in Sweden, smoking prevalence among men and

women declined while ST use by men increased, with the implication being that some of the reduction in smoking prevalence resulted from smokers switching to using ST [4, 49-51]. However, that pattern has not been found in other countries. In Norway, for example, the prevalence of ST use among males aged 16-24 years increased from 9% in 1985 to 21% in 2002, while the prevalence of cigarette smoking remained relatively constant [52].

Even the data from Sweden underestimates the potential of actively promoting THR. Sweden has experienced the benefit of THR, but there has not actually been a concerted effort to promote THR. Indeed, Sweden too has aggressive anti-ST activists who inaccurately represent themselves as being pro-health rather than anti-tobacco, and thus make the official "public health" strategy there far from pro-THR. Even as ST has became popular for cultural reasons, about half the population still thinks it is as hazardous as smoking. This is much better than the United States, but still makes one wonder how much more progress would result if everyone knew the truth. As for Norway, it is too early to judge what will happen, but it is also largely irrelevant to whether or not to promote THR: With no substantial public health THR strategy in Norway, we can learn almost nothing about how effective promoting THR would actually be. Tomar et al. are thus using the common anti-THR straw man that we should not try it because the results (from having not tried it before) have not proven as good as we might want. This is especially absurd given that THR has, in fact, been remarkably successful even though it has never been promoted as a public policy.

Survey data on the use of ST as a method for quitting smoking are available from the U.S. and Sweden. An estimated 7% of men in a 1986 U.S. national survey who were former cigarette smokers used ST for quitting [53]. In a 2001-2002 national Swedish survey, ST was reportedly used in the last quit attempt by 24% of men who smoked cigarettes, making it the most common cessation aid used by that population [51].

The U.S. result a rather amazing success rate for THR given that almost everyone believed that there was no reduction in risk from switching, and there was no social support for switching. The Swedish result speaks wonders for the potential of THR.

Analyses of U.S. data from the 1998 National Health Interview Survey (NHIS) found that about 6% of daily snuff users reported having quit cigarette smoking within the preceding year, suggesting that they had switched to ST [52]. Two groups of researchers used data from the 1987 and 2000 NHIS and offered contrasting interpretations [54, 55]. Kozlowski *et al.* [54] found that among men aged 22-34 years, those who smoked cigarettes but became snuff users were twice as likely as never users of snuff to have quit smoking. On the other hand, Tomar and Loree [55] analyzed male birth cohorts and found that about 1% of former cigarette smokers aged 36-47 years had used snuff or chewing tobacco to quit smoking, although about 19% had been regular ST users at some time.

Tomar et al. try to imply in this section that they conducted some kind of systematic review rather than cherry picking a few results. Among the studies that they seem to have overlooked is the latest one, by Rodu and Phillips [http://www.harmreductionjournal.com/content/5/1/18] that provided further evidence that many American smokers had quit by switching to ST in spite of the anti-ST disinformation.

The last Tomar self-citation deserves comment since, while intentionally analyzing data in a way that produces a result that the authors prefer is woefully common in epidemiology, it is seldom that it is done quite so baldly (this study typically makes researchers laugh out loud when told about it). Reporting a result only for ages 36-47, a range no one would ever think of analyzing or reporting, makes it quite clear that it was done to cook up a result they liked.

Intervention trials provide more direct evidence of the effectiveness of ST use for smoking cessation. To our knowledge, only two trials have been conducted in which ST was used for cessation. An uncontrolled U.S. trial reported results for one- and seven-year follow-ups [56, 57]. Sixteen of 63 subjects (25%) had used snuff and successfully quit smoking at the 1-year follow-up; at the 7-year follow-up, 12 of 16 persons who had used ST remained abstinent from smoking (an overall quit rate of about 19%). A recently reported open label randomized trial conducted in Denmark included smokeless tobacco and group support in the intervention arm and only group support in the control arm [58]. That study found significantly greater point prevalence and continuous abstinence rates in the ST group than in the control group at 7 weeks, but no significant difference between groups in 6-month point prevalence abstinence rates (23.1% vs. 20.8%). The authors concluded that the trial demonstrated short-term efficacy of ST in combination with group support for smoking cessation but no long-term efficacy.

There is a common misconception that clinical trials provide particularly useful information about the potential of THR (this may be another intentional straw man, but it is sufficiently common among clinicians is such that it may represent genuine ignorance -e.g., [http://caonline.amcancersoc.org/cgi/eletters/58/1/4]). This again brings up the question of what THR promotion method Tomar et al. are supposed to be analyzing. Clinical trials can tell us what happens when we gather a few smokers who are inclined to volunteer for a cessation trial about THR, randomly assign some of them to try an alternative product, and then send them out into a society where ST use is unusual in most social circles and almost everyone volunteers the (completely erroneous) advice that ST use is terribly risky and makes oral cancer very likely. THR proponents do not usually advocate this "strategy". Almost all visions of promoting THR focus on educating the population about the comparative risk and letting some smokers self-select into switching to whichever alternative product appeals. Thus, the results of standard clinical experiments provide very limited useful information. THR proponents generally hypothesize that if smokers were educated and encouraged to switch the results would be clear, and thus the fiddly comparisons of small differences that can sometimes justify carefully controlled studies would be unnecessary.

In summary, while data from Sweden suggest that ST is a cessation aid for some cigarette smokers, findings from U.S. studies are inconsistent; it is clear, however, that ST is not widely used for smoking cessation in the United States. The only known randomized trial of ST use for smoking cessation found no long-term efficacy. We conclude that, at present, there is insufficient evidence for ST as an effective cigarette smoking cessation aid.

Tomar et al. claim that the study results are inconsistent, though the studies actually consistently show some success of THR and with the exception of Tomar's own gerrymandered study, the degree of success is actually rather astonishing given the effectiveness of the anti-THR disinformation campaign. Apparently without having conducted any systematic or comprehensive review, Tomar et al. conclude there is insufficient evidence. They draw this conclusion after finding some evidence of THR being adopted by American smokers (and

claiming to not know about other such evidence which they are almost certainly aware of), without giving any hint of how much evidence they would consider sufficient. They would, of course, be correct if they observed that there is no evidence about what happens when THR is actively encouraged in a population, since we cannot know that until we try. In short, this entire section offers almost no useful information, and certainly does not respond to the argument that it purports to respond to.

# 4.3. ST is an Effective Nicotine Maintenance Product for Highly Nicotine-dependent ("Hard Core") Smokers

The third argument is based on two assumptions: ST use has lower risks than cigarette smoking, and some people who are unwilling or unable to quit using tobacco by evidence-based approaches [59] could use ST for long-term nicotine maintenance.

As noted above, what they characterize here as the third argument is actually part of the single argument that they address in this paper. It is the other half of the claim that ST could be an effective substitute for some smokers -- after having quit smoking by switching, they can stay quit by continuing to use ST. Tomar et al. muddle their description of this point rather badly, however, bundling in the lower risks claim that they already addressed as if it were part of the point and making a random reference to unspecified and undefined "evidenced-base approaches". Worse, they imply that this point is relevant only to an undefined "hard core" subpopulation of smokers, when actually the point applies to any smoker who switches. As usual, they are limiting their analysis to the "THR will improve longevity" version of the argument, ignoring whether THR will improve welfare compared to complete cessation, by restricting the discussion to smokers who will not otherwise quit. Moreover, this restriction also misses some of the longevity benefit of switching, since switching sooner is far healthier than quitting much later.

The rationale is similar to that used for reducing harm from the abuse of other substances: long-term substitution of a less dangerous product is more desirable than continued use of a more dangerous product. A model similar to this is the long-term treatment of heroin addiction with methadone [60]. ST proponents note that FDA-approved nicotine-containing products for smoking cessation are not approved for long-term nicotine maintenance, and that the bioavailability of nicotine from ST is greater than that achieved for FDA-approved nicotine products [4].

The suggestion that all ST proponents consider the lack of FDA-approval for long term use of pharmaceutical nicotine to be important is false. Many, probably most, THR proponents recognize this as being entirely inconsequential, and recommend that smokers consider switching to long term use of those products if that appeals to them. The characteristic poor delivery of nicotine of these products is more important, though e-cigs have offered the solution to this problem, leveling the nicotine-delivery playing field between tobacco and extracted-nicotine products.

They point out that opponents of substituting ST for cigarettes offer no help for "hard core" smokers who want to reduce their health risks, i.e., the only choices are to "quit or die" [8].

Proponents of nicotine maintenance believe that ST would provide a "middle way" to help smokers reduce

their health risks [4]. The argument continues that, although at some point persons using ST for nicotine maintenance ideally would decide to quit ST use entirely, even if they never quit ST use their health risks would be lower than if they continued to smoke cigarettes.

The last sentence is not generally true; many proponents of THR would suggest that continuing to use the low-risk product indefinitely is fine if it is welfare enhancing (again, Tomar et al. ignore people's welfare, including their psychological health). None of these characterizations present the argument that smokers who switch will keep using with ST which is the point they go on to implicitly respond to. Once again, Tomar et al. pretend to be responding to one argument, but actually respond to something entirely different.

There are three problems with this argument. First, unlike methadone, we found no studies that examined the rates of relapse to cigarette smoking for person using ST for long-term nicotine maintenance, either alone or in comparison to FDA-approved pharmacotherapies. Thus, the relative effectiveness of ST as a long-term nicotine maintenance strategy is unknown.

This is another, albeit somewhat less typical, version of the "it has not been proven to have already worked before it was ever tried and therefore we should not try it" argument. As with the previous point, no study about what happened with switchers in the past could tell us much about what would happen if people knew the truth. Needless to say, it is difficult to serious doubt that enough smokers are sufficiently concerned about their health that those who switch would not switch back once they became accustomed to using a low-risk alternative.

Second, harm reduction treatments for heroin use are managed and monitored under the guidance of health care professionals, as these treatments require prescriptions. In contrast, ST products are available "over-the-counter," are still heavily marketed to young males and have a high potential for abuse, and have levels of bioavailable nicotine that vary widely by product [61, 62]. Third, the mechanism by which methadone works is completely different from ST: methadone operates to reduce or eliminate withdrawal symptoms by blocking receptors [60] In contrast, ST contains the same addictive substance (nicotine) as cigarettes, which may continue nicotine addiction and perpetuate relapse.

This point is a further straw man. Apparently Tomar et al. are trying to imply that THR advocates base their position on its similarity to methadone-based harm reduction, though this analogy is seldom offered by the leading proponents. The better analogies to other harm reduction approaches are condoms and seatbelts. Moreover, Tomar et al. do not even explain why the contrasts they claim exist would be arguments against THR even if anyone did try to justify THR based on methadone. On top of that, the authors apparently have limited knowledge about methadone too: Methadone is also a psychoactive drug that has high potential for abuse. Indeed, a common complaint that sometimes arises about methadone regimens is that the dosage given is too small to have enough effect to be satisfying (i.e., to get high), causing some users to relapse (which does offer a pretty good analogy to pharmaceutical nicotine products, but not to ST).

There is strong support for the statement that some people are more addicted than others to nicotine, which makes smoking cessation more difficult for them [15]. Some ST products have higher and more rapid nicotine dosing than some FDA-approved nicotine replacement products [4]. Although ST proponents may intend to

help smokers who "have tried everything" but have been unable to quit, encouraging ST use for long-term nicotine maintenance may delay or prevent persons who would otherwise end their nicotine addiction from doing so [63]. We conclude there is currently no evidence on the effectiveness of ST for long-term nicotine maintenance.

Once again the authors conclude that there is no evidence without even suggesting they conducted any serious search for it, let alone defining what would constitute evidence. Obviously there will be no evidence about what happened when THR was widely encouraged until after THR is widely encouraged. Yet Tomar et al. ignore the experience of the one population where THR has been widely adopted even though it was not strongly encouraged as an official public health measure, mentioning nothing about the experience of Swedish former smokers who switched to ST and stayed switched. In addition, they muddle together points about long-term use and about highly dedicated smokers, which are not the same, and throw in irrelevant observations about delaying the end of nicotine use even though THR proponents obviously recognize that this is inevitable.

# 4.4. ST use is not a "Gateway" Product for Initiating Cigarette Smoking

The final argument is that ST users are not at increased risk of initiating cigarette smoking, or that ST use may even prevent smoking initiation [8, 49, 51]. The not-a-gateway argument is crucial for ST proponents in order to support the first three arguments, because if ST use increased rates of smoking initiation there is no rationale for advocating its use as a harm reduction product.

As noted above, this is a fundamentally different point from what comes before, representing a concern that for some possible policies (there is that problem of not specifying any strategies again!), the health costs of promoting THR might exceed the benefits. Even setting aside the logical misplacement, they get the argument wrong. In fairness to the authors, there are some cases of THR proponents saying that it is necessary that there be no gateway effect to support the case for THR. However, it should be obvious that this is not the case. The relevant claim is not that the existence of ST causes any smoking initiation, but that the promotion of THR would cause substantial smoking initiation. It should be clear than if ST were shown to be a gateway to smoking, that this could theoretically contribute to an argument for banning ST or not allowing it to be introduced (which is not to say that it would be definitive in such an argument, of course). But it would say nothing about whether promoting THR somewhere ST is already well known and established (like North America) could cause smoking. Indeed, it is difficult to imagine how this could even be the case: How could telling people "we do not recommend using tobacco, but if you are going to use it, make sure it is smokeless because it is 99% less harmful than smoking" could lead to more smoking? And even if there were some such effect, it would have to be quite large to result in a net negative public health impact.

One might think that Tomar et al. actually recognize this, since they do not claim that arguing that ST is not a gateway to smoking is critical to THR proponents (which is clearly not the case), but merely to ST proponents (though who exactly those are is not clear). But this appear to just have been sloppiness, since they go on to claim that if ST leads to smoking initiation then there is no rationale for using it in THR, a statement that is clearly false for the two reasons cited above, as well as the fact that this argument only applies to the "maximize health" goal, not to arguments based on rights and not obviously to arguments based on welfare.

Research to support the not-a-gateway argument comes from several types of studies. Indirect evidence,

based on comparative prevalence trend data for cigarette smoking and ST use among adolescents and adults in Sweden over the past 20 years, are cited to support this position: if ST is a gateway to cigarette smoking, then smoking prevalence would not decrease at the same time ST use increased [4].

Comparative population-based prevalence trend data for ST use and cigarette smoking are not supported by data from countries other than Sweden. In the United Stated, trends in ST use and cigarette smoking among adolescent boys and men tended to parallel each other during the past two decades, with a drop in use of both types of tobacco products among boys since 1997 [64]. Norway, where ST use by young males has increased sharply during the past two decades, did not experience a decline in smoking initiation during most of that period [52].

If growing popularity of ST actually did lead to an increase in smoking in societies where the comparative risk was not known, it might constitute a strong argument for promoting the THR message. If ST users are making the serious mistake of switching to smoking -- because they are constantly being misinformed that since ST is as bad as smoking, they might as well smoke - the obvious solution is to inform them about how bad that switch is. However, no existing data actually suggests that ST is causing more smoking. Tomar et al. have again misunderstood the actual logic of what they are claiming: If the gateway claim were true, it would mean that high ST use causes more smoking, and thus should be associated with an increase in smoking. The preceding observations might be intended to mislead a casual reader into believing they had supported that claim, but obviously they have not.

Using data from the 1987 NHIS, Kozlowski *et al.* [54] examined age of first use by type and sequence of use of different tobacco products. More than three-quarters of males aged 23-34 were classified as non-gateway users; i.e., use of snuff did not precede use of cigarettes. However, several U.S. prospective cohort and cross-sectional studies of young males found that use of ST was predictive of cigarette smoking initiation [65-68].

More recent U.S. studies provide additional support for ST use as a predictor of cigarette smoking initiation. Using data from the 1989 and 1993 national Teenage Attitudes and Practices Survey (TAPS), Tomar [69] found that adolescent males who were ST-only users were more than three times as likely as never ST-users to become cigarette smokers within the following four years. A re-analysis of the TAPS data by O'Connor et al. [70] concluded that regular ST use was not a statistically significant predictor of current smoking when psychosocial risk factors were included in the models. However, those authors equated lack of statistical significance due to the small number of ST users at baseline and highly parameterized regression models with lack of effect [71]. In the TAPS data, the strength of association between ST use and subsequent smoking was on the same order of magnitude as many established psychosocial risk factors for smoking.

The studies of correlations between ST use and smoking initiation tend to show the unsurprising result that people who like nicotine, as demonstrated by using one nicotine product, are more likely than others to begin to use a particular nicotine product. (They also show the equally unsurprising result that people who engage in various risky behaviors are more likely to smoke and use ST and vice versa.) None of the studies show that ST is causing anyone to smoke who would not have smoked if ST did not exist. Or to put it another way, none of the studies indicate that there is someone who smokes who, if ST had never been available, would not smoke. Clearly none are showing that a concerted policy of promoting THR (which cannot be studied because it has not happened) cause people to smoke. It remains difficult to

imagine that such promotion would not discourage those who currently switch from low-risk products to smoking from doing so.

As an aside, it is interesting that Tomar et al. are inclined to argue that lack of statistical significance should be disregarded here, where they do not like the interpretation of the lack as equivalent to no association, but elsewhere in the paper they interpret lack of statistical significance as no difference between values.

Severson *et al.* [72] followed a cohort of adolescent boys in grades seven and nine who were ST-only users for two years. Among the ST-only users, 26% maintained their ST-only status, 17% switched and became cigarette-only users, and 41% became dual users of ST and cigarettes at follow-up. Among nonsmoking, non ST users, 24.0% maintained their status, 15.7% reported using cigarettes and only 8.3% reported using both products. They found that initiation of weekly smoking in grades nine and eleven was significantly associated with baseline ST use, even after controlling for other risk factors.

Haddock *et al.* [73] followed a cohort of almost 8,000 young adult male Air Force recruits who had not smoked in the past year. Both current and former ST users were more than twice as likely as never-users to begin smoking.

In summary, the preponderance of evidence suggests that ST use is a predictor of cigarette smoking in the United States. The findings in one country regarding temporal changes in patterns of tobacco use cannot be assumed to apply elsewhere.

Once again, Tomar et al. make claims about the totality of the evidence without attempting to review all the evidence, let alone explain what constitutes sufficient evidence to draw a conclusion. In this case, though, they claim that the limited evidence they cite is sufficient to draw a conclusion, whereas the comparable or greater amounts of evidence presented above were insufficient to draw the conclusions they wanted to avoid. At least they accurately phrased their conclusion: that ST use is a predictor of smoking, suggesting that they recognize that none of the evidence they cite supports the claim that it causal. It is interesting that they assert that these changes cannot be extrapolated from one country to another (without any substantiation of this claim, let alone any explanation as to why they can be extrapolated across subpopulations and time, yet there is an epistemic divide at the border), and yet cite Norwegian observations to support their conclusions about the United States. In any case, nothing in the section represents an argument that promoting THR would increase smoking initiation.

#### 5. Discussion

The primary evidence supporting ST use as a harm reduction strategy is that exclusive using ST has lower health risks than does cigarette smoking. There is some evidence that cigarette smokers who switch to ST use may reduce their health risks. There is little evidence that ST use is effective for smoking cessation; or that ST is an effective nicotine maintenance product. In addition, the available evidence suggests that ST use may be a gateway to smoking initiation in the United States.

Proponents of ST-as-harm-reduction argue for differential taxation and emphasis on differences in risk among tobacco products, on the grounds that the public should be moved from cigarettes to less harmful forms of tobacco [4]. Most major tobacco control organizations see all tobacco use as a harmful behavior that provides no net societal benefits, and prefer taxation policies and health messages that discourage the initiation

or continued use of any form of tobacco.

Anti-THR activists, and anti-drug activists in general, often subscribe to the "repeat something enough times and it becomes The Truth" school of mass persuasion. These paragraphs do not merely repeat as fact the arguments that were never actually effectively made in the paper, but explicitly endorse the "repeat something enough times" approach. They imply that because a particular political faction asserts something, the claim is somehow supported. It is also pretty humorous to consider the phrasing: Not surprisingly, most major anti-censorship organizations see all censorship as bad and most major anti-gay organizations see all homosexuality as bad; why, then, is it interesting or informative to point out that most major anti-tobacco organizations see all tobacco as bad?

Moreover, these authors, who purport to be conducting an ethical analysis and examining pro-THR arguments, should find it embarrassing that their political allies based their positions on the claim that nicotine/tobacco use has no benefits. (This ignores their use of the word "net", which is grammatical nonsense here; the balance of the article suggests that the authors do not actually understand this concept, since they never acknowledge net effects need to be considered – e.g., they claim that any gateway effect, no matter how small, means that THR does not benefit public health.) This is patronizing dismissal of the benefits that millions of people experience from smoking or otherwise using nicotine, including simply pleasure, stress relief, focus, social facilitation, and relief from psychological symptoms. In the present context, it also points out that the authors have simply ignored some of the most important pro-THR arguments that they claim to be addressing, since the observations about the benefits of smoking etc. are clearly represented in those arguments. They are effectively saying that the anti-THR position is premised on intentionally ignoring some of the strongest pro-THR arguments and making an empirical claim that any casual observer can identify as incorrect.

There are certainly some individuals who have successfully used ST as an aid to smoking cessation or for long-term nicotine maintenance. From a population-based public health perspective, however, there is a real danger of potential unintended adverse consequences of promoting ST for harm reduction.

In this statement, phrased as an aside, Tomar et al. admit that THR has positive effects and then try to suggest that the gateway effect (the only unintended adverse consequence they mention in their analysis) means that these should be ignored. Once again, they fail to recognize the concept of net effects.

Of greatest concern is that broader promotion of ST would result in an increase in ST initiation and simply add to or increase cigarette smoking among adolescents and young adults, as apparently was the case in Norway.

The previous sentence suggests that the authors expect their readers to fail to notice that this claim makes little sense and also contradicts what they wrote a page earlier about not being able to apply what happened in other countries to the U.S. It is undoubtedly the case that informing people of the low risk of ST use would increase its use as consumers learn the cost-benefit tradeoff was not what they thought it was. This is worth discussing, and is strangely absent from anti-THR activism. From any accepted ethical standpoint, this result is not problematic, but it is kind of surprising that anti-THR extremists have not latched on to it; perhaps they do not want to concede that economically rational behavior is relevant.

A second unintended consequence is that promoting ST for harm reduction may imply that tobacco prevention and control efforts have failed [74]. Although great strides have been made in reducing youth tobacco use, only a small proportion of the available resources are currently being used for tobacco control in most states [75].

This is a refreshing bit of candor! Tomar et al. admit that part of their motivation of anti-THR activists is that they want to try to hide the fact that their preferred methods have failed. After spending billions of dollars, sullying the good name of public health, and making millions of dedicated nicotine users miserable, American tobacco control activism efforts over the last two decades have had woefully poor success. Almost all the historical reduction from the peak smoking prevalence seems attributable to widespread dissemination of accurate information about the risks that dates to the 1960s. Only THR (in Sweden) has substantially improved on those results. If THR were promoted and succeeded, it would indeed highlight the inadequacies of other methods and perhaps even undermine the whole anti-tobacco industry. Moreover, since THR has been widely advocated for a decade, it would become obvious how many smokers died because of the delay that anti-THR activism caused. It is clear why career tobacco control activists might not want this to happen, but it is rare to see them admit it.

Needless to say, the claim that we should dismiss an effective public health measure because of how it might make others look makes it clear that these authors are making no serious attempt to based their ethical argument on ethical principles. Moreover, if they are really proud of what they are now doing then the scrutiny that might be caused by successful THR should not be a problem for them.

Substantial reductions in tobacco use could be achieved if tobacco control programs were fully funded. The promotion of ST for harm reduction by the public health community would divert the existing limited tobacco control resources, which may be better spent on practices demonstrated as effective in reducing smoking [76].

This vaguely invokes a posited disadvantage of promoting THR, that it would take funding away from other anti-tobacco efforts. By never defining what THR strategy they are talking about, Tomar et al. are able to make this claim without having to explain the causal pathway. If they tried to explain it, it would be obvious that any realistic implementation of THR promotion would cost little compared to the huge current expenditures. Indeed, many reasonable strategies would divert basically nothing from current expenditures. And, of course, the diversion argument implies that the marginal current expenditure on tobacco control is producing great value, a rather incredible claim that the authors imply but in no way support. (In keeping with the pattern of previous citations, the citation they include, which the reader might think is support for their assertion that there are other practices that would reduce smoking if they just had more funding, is actually an irrelevant opinion piece about THR.) Lamentations that "only a small proportion of the available resources" are being used (what does that even mean? all of society's wealth is "available") do not imply that useful approaches are being underfunded and would be more so if THR was promoted; it actually suggests that the marginal benefit of the current huge expenditures has been judged to be low enough that more funding is not justified.

Several ethical issues also must be considered. If products with fewer health risks are available and can perform a function similar to the original product, there is an ethical and, often, statutory or other legal requirement to use the substitute product [77, 78]. Product substitution is a long-recognized strategy in fields

such as consumer protection and occupational and environmental health; e.g., using synthetic plastics or cellulose in place of asbestos in building materials or automobile brakes. Although ST use has fewer health risks than does cigarette smoking, several FDA-approved and scientifically established pharmacotherapies are available for smoking cessation [59], which constitute safer substitutes for smoking. In addition, to our knowledge, the public health community has never advocated substitution of an unregulated toxin and human carcinogen when known safer alternatives existed.

Tomar et al. vaguely refer to the deontological ethical argument that they ignore in their list of pro-THR arguments, though they describe it incorrectly, presumably due to their commandand-control bias. For individual consumption decisions, there is no legal or ethical requirement to use a particular product, of course. The requirements are to inform the consumers and not interfere with their free choice. (It is, of course, often acceptable to go further, such as by banning the more dangerous product.) But even in the garbled form in which the authors describe the ethical argument, it is still a rather compelling argument for promoting THR products. Presumably because of this, they try to misdirect it with the tangential claim that other products are less risky still. As noted above, there is actually no evidence that pharmaceutical products are less risky (which is why Tomar et al. simply assert this claim without attempting to support it -- there is no way to support it). Moreover, even if it is true that pharmaceutical products are lower risk, this does not constitute an anti-THR argument. Contrary to what Tomar et al. have misrepresented about the pro-THR position, almost every advocate of THR argues that consumers should be told about the low risk from ST, pharmaceutical products, and e-cigs, and given the chance to choose. Despite what they assert about law and ethics, there is no requirement for the authorities to figure out which of these is a little bit safer for people and force them to choose it.

Searching the paper, the last sentence of this paragraph seems to be the closest thing Tomar et al. offer as a standard for what constitutes good public health policy or a definition for their vague term "appropriate" from the title. But it does not work out so well for their argument. In the time it took to read the sentence, three examples occurred to me of deadly exposures that are widely embraced in American public health because of the net reduction in risk they produced: chlorination of drinking water (exposing everyone to a carcinogen to dramatically reduce their risks of various diseases; clear alternative: household boiling or ozone treatment), the recommendation to eat somewhat less meat rather than radically less (leaving everyone exposed to more of a carcinogen than necessary; clear alternative: asking them eat almost none -- clearly impractical), and vaccinations. The latter might not quite fit because though vaccines clearly kill some people, it does not tend to be via cancer. However, they are a "toxin", though since everything is in the right dose, this gratuitous word is just random rhetoric and adds no content. Readers can probably add another ten examples to the list with a few minutes' thought.

It is interesting that authors trying to analyze "appropriateness" of public health policies are not sufficiently expert in public health to think about water chlorination or dietary recommendations. Presumably the real problem is that Tomar et al. claim to have conducted an ethical analysis without trying to define the ethical standard they think should be used. As a throw away line in the conclusion they recognized this fact, but did not think about it enough to formulate a coherent point and instead retreated into status quo bias: Anything that is currently done is ethical, while anything new should be feared. It is worth noting that such errors are not unique to these authors, and are quite common in the anti-THR literature. There are assertions that promoting something that entails any risk violates some imaginary version of a "do no harm" ethic, even though practice clearly demonstrates that no such ethic exists (acts that are somewhat harmful, and do more harm than good for rare individuals, are

common in public health, medicine, and all areas of public policy). There are claims that harm reduction cannot be justified when harm elimination can be envisioned, even though welfarebased arguments clearly show that this is wrong and virtually every intervention in public health reduces risks less than is theoretically possible. It is not clear whether the anti-THR activists are just trying to take advantage of naive public perceptions of ethics and practices, or whether they themselves are ignorant of these matters, but one of these is clearly true.

A second ethical dilemma could result if changes occurred in risk perception about using ST. Research has shown that "low or minimal risk" health messages, in the context of voluntary decision making or personal health behaviors, are commonly interpreted by the public as meaning "no risk" [79].

Here the authors introduce another potential disadvantage that they imply (but do not state) could outweigh the advantages of THR. However, the claim is empirically absurd and presumably the authors know it. Most Americans overestimate the risk from ST by a factor of about 100, and have been the targets of so much anti-THR propaganda that it is difficult to convince them of the truth. Anti-ST messages (and similar messages about e-cigs and other nicotine products) are extremely common and would not be expected to cease. People would still have unrealistic fears about "toxins" and chemicals. Every attempt to promote THR to the population that we are aware of has emphasized the caveat that the low-risk alternatives are not zero-risk. Thus, it is really grasping at straws to suggest that consumers would come to believe that ST poses zero risk.

Moreover, even if this were plausible, it is difficult to see how it constitutes an argument in favor of current policies compared to promoting THR. If we honestly told people that the risk is very low, they might think it was even lower than it really is, so instead we should lie to them and convince them that it is 100 times what it really is? What kind of ethical argument is that? It argues for ceasing to tell people that seatbelts make them safer because people might overestimate the benefits. It is difficult to find their point.

Also, once again, it is useful to notice what the referenced paper actually says instead of assuming that Tomar et al. have accurately represented it. It is a study of how people perceive public health messages, discussing the strengths and weaknesses of different messages, and how to improve their salience. The implication is that it is certainly possible to come up with a misleading way to communicate, but this is obviously a straw man. It does not suggest that we simply stop communicating or intentionally mislead people, as Tomar et al. seem to imply.

The history of the tobacco industry's development and marketing of filtered, "low-tar," and "light" cigarettes, which resulted in smokers' perceptions that these products were safer and reduced their desire to quit [80], should be considered a warning about potential unintended consequences of promoting ST for harm reduction.

This story is often invoked by anti-THR activists to confuse people about the case for THR. It describes a product development that manufacturers as well as tobacco control activists promoted as reduced harm despite the complete lack of evidence that it would lower users' risks somewhat; it turned out not to do so. This is certainly a warning -- about activists charging ahead with unproven technologies -- but one that in no way supports the claim that a proven much-lower-risk alternative should not be promoted. Perhaps this observation (which is almost ubiquitous in anti-THR screeds, though never actually logically linked to the arguments) would be a legitimate argument against promoting THR if the alternative products were highly untested or only reduced risk by 50% or 80%, and thus consumers might overestimate their

benefits. There is simply not much room to overestimate the implications of a 99% reduction in risk.

A third concern is that mixed messages from the public health and medical communities can be problematic. Lay audiences rely heavily on the expert heuristic when assessing information received from health or other experts [81], preferring consistent interpretations and recommendations about what scientific findings mean and what actions are recommended [82]. A message that encouraged people to "not initiate or continue ST use because of its adverse health effects" juxtaposed with "it's okay to use ST if you are a smoker and have been unable to quit" could result in confusion among the public.

In mining the paper for what the authors argue constitutes an "appropriate" policy, this might be included, though it is phrased in terms of empirical claims rather than ethics. As such, it is another attempt to grasp at straws to construct a disadvantage. The solution to their dilemma of mixed messages is quite simple, and presumably would be part of THR promotion: Tell the truth. If everyone is informed that ST causes some risk, but only 1/100th that from smoking, it is difficult to imagine that this would overtax very many consumers' cognitive abilities. (Readers are invited to insert their own snarky observation here about the apparent confusion this information causes for some activists.) Moreover, assuming that people should be denied such information because they cannot handle it further demonstrates the authors' unfamiliarity with public health practices: It is quite common to remind people that having sex with multiple partners poses some risk, but that using condoms dramatically reduces it, and people do not appear as baffled by this as Tomar et al. would have us believe. Similarly, there does not seem to be much hesitation to expect people to understand, "getting drunk is not good for you, but if you do, it is much safer to let someone else drive." Everyone understands that driving is never safe (and most probably realize that buses and trains are safer alternatives), but that driving legally is far safer than driving drunk.

Another observation follows from these claims, a confession that they are not concerned with rights or welfare: The authors think that lying to people is justified if telling the truth might cause them to not do what those who have power think they should (i.e., telling the truth about the risk from ST might lead people to ignore the advice from the powerful players in this arena that they should not use ST).

#### Probably the biggest ethical challenge concerns the potential role of tobacco companies.

This is a remarkable confession of the author's real motives. In Tomar et al.'s minds, the biggest ethical question is not whether we have a right to lie to people to prevent them from learning how to reduce their risk, nor whether longevity should be promoted at the expense of welfare. Instead, it is a purely political preference about the involvement of particular stakeholders in the policy debate. There is not actually an ethical question here in the sense of ethics that applies to the rest of this analysis; this is only an ethical question in the impoverished sense the word is used in the context of who has political influence.

Cigarette and ST manufacturers are in the business of helping people to develop and maintain nicotine addiction [83], and promotion of dual product use is one strategy to maintain addiction in the face of increasing smoke-free indoor air laws. This scenario is even more likely now that nearly the entire U.S. smokeless tobacco market is controlled by cigarette manufacturers. Many ST users also use other tobacco products, particularly cigarettes [44], and ST products are advertised to smokers for situational use when they cannot smoke due to

smoke-free policies [31, 32, 84].

This paragraph is a muddle of at least four distinct points, so it a bit difficult to sort out. One is the obvious point that manufacturers have a stake in selling their products, which is commonly presented in anti-THR screeds as if it were an argument in itself, though it obviously is not. A second is that most companies with a stake in cigarettes also have a stake in the ST market, though again it is not clear why this matters. Indeed, if a policy argument were to be built on these two observations (and the implicit subtext that the authors are unwilling to present for scrutiny), it would be the argument for tobacco prohibition; anti-tobacco activists tend to carefully avoid such arguments because they realize that they are socially unacceptable, and making them would call attention to other socially unacceptable positions and tactics. Obviously, ST manufacturers would be happy to sell their products to smokers who use them occasionally, even if those manufacturers do not sell cigarettes, contrary to Tomar et al.'s nonsensical claim. They even prove this point themselves with one of their earlier sloppy arguments, when they cited ads by a then ST-only company.

The main point of the first part of this paragraph seems to be that use of ST offers smokers a way of not suffering quite as much due to restrictions on where they can smoke. It is quite interesting that many tobacco control activists are so willing to volunteer this information that they support clearly unethical behavior: Bans on smoking in various indoor spaces are always justified to the public and policy makers as protection for nonsmokers, with the problems they create for smokers being necessary costs in order to achieve the benefits. This is the rhetoric that makes the loss of freedom socially acceptable. But the anti-tobacco activists then openly admit that they consider it an advantage, sometimes even the primary advantage, that these rules make smokers suffer and thus might torture them into quitting. Any policy of intentionally causing people to suffer to try to force them to do something "for their own good" in a free society requires some serious ethical defense since it violates basic tenets of liberalism, yet such arguments are never offered in this context. Even apart from that, to lie about one's real goals to get policies implemented is per se unethical. Yet tobacco control activists seem happy to admit this behavior.

Of course, the entire point, that tobacco companies are so evil as to deserve extermination no matter what, and that they make money from selling ST, has nothing to do with THR. This might constitute an argument in favor of prohibition, but in a society where ST is legal and widely available, it is in no way an argument against promoting THR. Indeed, if the anti-THR activists were genuinely worried that people who sometimes use ST also smoke, they would join the effort to make sure those consumers knew which of their two products posed almost all of the risk.

Although many proponents of ST for tobacco harm reduction have no financial relationship with the tobacco industry, it is clear that the industry provides financial support to scientists who favor their position on harm reduction, some of whom have been particularly vocal ST advocates [38, 43].

Woo hoo! The authors who claim to be responding to arguments of THR proponents finally, after 8 pages of claims about what THR proponents think and argue finally cite anything by me and my research group (ref 43). I just had to laugh out loud at this point. I am not suggesting that we are more worthy of citation than other proponents, but we are certainly among the most visible and vocal; our TobaccoHarmReduction.org website is the top result for most any web search someone might do on the topic, and it clearly lays out the arguments for THR, unlike most of what Tomar et al. cite. I cannot really judge objectively, but I have to figure that anyone wanting to characterize pro-THR arguments would find that the website is among the most

important sources to read and cite. Moreover, when Tomar et al. finally do acknowledge our existence, they cite one niche work that is largely irrelevant to the present context, instead of citing the website which is our most comprehensive and easily accessible work.

Moreover, the website shows up near the top of any search for my (CVP's) name, far higher than the article they cite, if they were simply looking to obliquely refer to me in this paragraph. It is difficult not to conclude that they were going to great lengths to avoid letting naive readers know where they can find the actual comprehensive arguments made by THR proponents that they claim to be responding to. This is not too surprising, since TobaccoHarmReduction.org includes refutations of most of the points that Tomar et al. make in this article. If they had acknowledged its existence, they would have had to make better arguments. (There is a source of doubt about this explanation for their behavior, however: If Tomar et al. expected people to actually read their references, they presumably would not have made the serious referencing gaffes that are noted above, so perhaps this theory assumes too much.)

As for the final point muddled together in this paragraph, it is the usual ad hominem attack on some researchers because they try to productively engage with the industries and other stakeholders rather than pretending they have nothing useful to offer. Such innuendo never constitutes a legitimate argument, of course, but it is particularly pathetic in the present context: Tomar et al. claim that they can respond to the pro-THR arguments. If that were true, it would not matter where those arguments came from and there would be no need to try to trick readers with innuendo about associations.

Reporting that various now-retired industry-funded researchers produced misleading science is presumably intended to suggest bad-science-by-association. I wonder what Tomar's or Fox's colleagues – perhaps the philosophy and economics departments – would think if someone suggested that the present paper (or Tomar's court testimony as a consultant expert witness) should be considered a reflection of all policy and ethics analysis from the Universities of Florida and Wisconsin?

It would be interesting to assess the psychology of this urge that anti-THR activists have to talk about industry funding. Such behavior is tantamount to admitting that one has no legitimate criticisms of the research, and in this particular context it is concession that the entire goal of the paper is a failure. Yet they just cannot resist the urge, even when it makes them look especially weak.

Findings from tobacco industry documents clearly demonstrate that the motivation for industry funding of extramural research is to serve their business interests [85-87]. For example, not only has it been shown that industry-funded scientists were less likely to conclude that secondhand smoke had adverse health effects [88], but the industry actively funded individuals and institutions for the purpose of creating divisions within the public health community [89].

A bill has been passed by the U.S. House of Representatives [H.R. 1108] and another is currently pending in the U.S. Senate [S. 625] that would grant the U.S Food and Drug Administration (FDA) the authority to regulate the manufacturing, marketing and sale of tobacco products. Among its provisions, the legislation would require FDA approval before the introduction of tobacco products that are claimed to be "reduced harm." Tobacco manufacturers would be required to provide scientific evidence that such products would reduce harm for individuals and for the population as a whole. The FDA also would have the authority to require changes in current and future tobacco products to protect public health. In the absence of a regulatory

framework, which is the current status in the United States, it is largely left to the tobacco industry to decide what products will be introduced, their contents and toxin levels, their marketing, and the implicit claims that can be made. Perhaps when such decisions are under the regulatory control of public health authorities and not tobacco manufacturers it may be appropriate to discuss promotion of reduced harm tobacco products.

This paragraph seems largely irrelevant to the theses of the paper. I will just observe that the authors' unquestioning faith in the honesty and effectiveness of the U.S. government is just precious.

It is clear that more research on ST is needed, particularly regarding health risks among smokers who switch to exclusively using ST and the effectiveness of ST for long-term nicotine maintenance.

Really? That is a rather bold statement, even apart from the meaninglessness of the key word, "needed".

Nevertheless, based on the precautionary principle widely used in public health [90], the burden of proof is on ST proponents to provide strong scientifically credible evidence to support their position.

The authors are wading into areas they do not understand again. First, there is no "the" precautionary principle. There are various statements to which that label is applied. Most of the time when someone invokes the phrase (the present case included) it is meaningless because it can be used to argue either side of the point: Compare "we should be cautious about promoting THR even though it seems promising because something might go wrong" with "we should be cautious about assuming that all smokers will just quit using nicotine, and thus assuming we can afford to forego THR" or with "we should be very cautious about lying to people to manipulate their behavior". What constitutes caution is in the eye of the beholder.

Second, to the extent that there is substantial agreement on one form of a principle of precaution, it is that someone who would introduce a novel exposure into a population has the burden of investigating its effects to show that it is unlikely to cause unwarranted risk, rather than the burden being on those who are worried about it to show that there is a risk. In particular, for a new industrial pollutant, the burden is on the polluter to prove that it is not too damaging, rather than on the public to prove that it is. That is a fair request, and so THR advocates have actively pursued it. Judging from the literature (not just the present paper), proponents seem far more aware of the genuine uncertainties and legitimate questions than are the opponents, and have responded to them (a fact that is ignored in the present paper). Obviously someone using "precaution" as a nihilistic tactic for denying all evidence, no matter how compelling, based on making up flimsy stories, can always find something to say. Cigarette companies used this tactic for decades, to argue that smoking did not cause disease, and anti-THR activists have proven adept at mimicking this behavior.

As we have outlined, such evidence currently is lacking, and it is therefore inappropriate at this time for the public health community to promote ST use as an evidence-based harm reduction strategy.

Actually, even this paper, as paltry as the review of the pro-THR arguments and evidence are, seems to have shown that there is quite a bit of evidence. Of course, the failure to make any attempt to define "inappropriate" or "evidence-based" means that the authors are not actually making any substantive scientific or ethical claim here, so are neither right nor wrong.

Those considering ST use for harm reduction need to consider the entire body of research, along with the many

practical and ethical challenges. We conclude that the implications extend far beyond the simple statement that "ST use is safer than cigarette smoking".

They conclude with an assertion that is ill-defined and does not seem to be related to their analysis.

Conclusion to the annotation

This article exemplifies what passes for ethical and scientific analysis among anti-THR activists, including those activists who publish in the scholarly literature and thus presumably represent the intellectual leaders in the field. Perhaps this paper has a denser concentration of random gaffes and non sequiturs than do other pieces, but the contrast is not dramatic. The practice of responding to only a few straw man arguments and relegating some of the most important arguments to minor asides that are dismissed without any actual refutation is quite common. So is the practice of asserting unsupported scientific claims as if they are facts, citing to others who themselves asserted the claims without support. Equally common is the suggestion that because THR has not been shown to work on a large scale (because no concerted promotion effort has ever been tried -- and yet has actually worked surprisingly well in spite of this), it must not work at all, so it should not be tried. This nihilism is especially interesting when contrasted with the claim that promoting THR has never been tried, like the gateway effect, even though promoting THR has never been tried.

If any reader of this thinks that I have picked a weak straw man of a paper to respond to, I strongly encourage you to point out what are the best anti-THR documents. I would be happy to give due credit to the better arguments and respond to them.

#### Acknowledgements

The authors would like to acknowledge Mr. Mitch Zeller, who read an earlier draft of the manuscript and provided us with many useful suggestions. We would also like to acknowledge the comments and suggestions from Dr. David Nelson and Dr. Linda Pederson, who provided us with invaluable comments and suggestions throughout the duration of the research and writing.

### References

1. Gartner, C.E.; Hall, W.D.; Vos, T.; Bertram, M.Y.; Wallace A.K.; Lim, S.S. Assessment of Swedish snus for tobacco harm reduction: an epidemiological modeling study. *Lancet* **2007**, *369*, 2010-2014.

2. Stratton, K.; Shetty, P.; Wallace, R.; Bondurant, S. *Clearing the Smoke: Assessing the science base for tobacco harm reduction.* National Academy Press: Washington, D.C., U.S., 2001.

3. Royal College of Physicians of London. *Harm reduction in nicotine addiction: helping people who can't quit.* A report by the Tobacco Advisory Group of the Royal College of Physicians. Royal College of Physicians of London: London, UK, 2007. Available at: http://www.rcplondon.ac.uk/ pubs/contents/4fc74817-64c5-4105-951e-38239b09c5db.pdf

4. Rodu, B.; Godshall, W.T. Tobacco harm reduction: an alternative cessation strategy for inveterate smokers. *Harm Reduct. J.* **2006**, *3*, 37.

5. Kozlowski, L.T.; O'Connor, R.J.; Edwards, B.Q. Some practical points on harm reduction: what to tell your lawmaker and what to tell your brother about Swedish snus. *Tob. Control.* **2003**, *12*, 372-373.

6. Whelan, E.M. Cigarettes: what the warning label doesn't tell you. The first comprehensive guide to the

*health consequences of smoking updated and revised for the 21<sup>st</sup> century.* American Council on Science and Health; New York, U.S., 2003.

7. Brinson, B. Relative benefits: smokeless tobacco is thought to present less of a health risk than cigarettes; but many health advocates remain unconvinced. *Tob. Reporter* **2006**, *March*, 30-32.

8. Bates, C.; Fagerstrom, K.; Jarvis, M.J.; Kunze, M.; McNeill, A.; Ramstrom, L. European Union policy on smokeless tobacco: a statement in favour of evidence based regulation for public health. *Tob. Control.* **2003**, *12*, 360-367.

9. Nelson, D.E.; Mowery, P.; Tomar, S.; Marcus, S.; Giovino, G.; Zhao, L. Trends in smokeless tobacco use among adults and adolescents in the United States. *Am. J. Public Health* **2006**, *96*, 897-905.

10. Federal Trade Commission. *Smokeless tobacco report for the years 2002-2005*. Federal Trade Commission: Washington, D.C., U.S., 2007. Available at http://www.ftc.gov/reports/tobacco/02-05smokeless0623105.pdf

11. Statistics Sweden. *Use of alcohol and tobacco. Official Statistics of Sweden. Living Conditions Report No. 114.* Statistics Sweden, Unit of Social Welfare: Stockholm, Sweden, 2007.

12. Braverman, M.T.; Svendsen, T.; Lund, K.E.; Aaro, L.E. Tobacco use by early adolescents in Norway. *Eur. J. Public Health* **2001**, *11*, 218-224.

13. Substance Abuse and Mental Health Services Administration. *Results from the 2006 National Survey on Drug Use and Health: National Findings.* U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Office of Applied Studies: Rockville, MD., U.S., 2007. DHHS Publication No. SMA 07-4293.

14. Hatsukami, D.K.; Lemmonds, C.; Tomar, S.L. Smokeless tobacco use: harm reduction or induction approach? *Prev. Med.* **2003**, *38*, 309-317.

15. Hatsukami, D.K.; Henningfield, J.E.; Kotlyar, M. Harm reduction approaches to reducing tobaccorelated mortality. *Annu. Rev. Public Health* **2004**, *25*, 377-395.

16. Critchley, J.A.; Unal, B. Health effects associated with smokeless tobacco: a systematic review. *Thorax.* **2003**, *58*, 435-443.

17. Savitz, D.A.; Meyer, R.E.; Tanzer, J.M.; Mirvish, S.S.; Lewin, F. Public health implications of smokeless tobacco use as a harm reduction strategy. *Am. J. Public Health* **2006**, *11*, 1934-1939.

18. Tomar, S. Is smokeless tobacco effective in reducing cigarette smoking and tobacco-related harms? Member commentary on the smokeless tobacco debate. *Soc. Res. Nicotine Tob. Newsletter* 2005, *11*, 2-3.

19. Luo, J.; Ye, W.; Zendehdel, K.; Adami, J.; Adami, H.O.; Boffetta, P.; Nyrén, O. Oral use of Swedish moist snuff (snus) and risk for cancer of the mouth, lung, and pancreas in male construction works: a retrospective cohort study. *Lancet* **2007**, *369*, 2015-2020.

20. Boffetta, P.; Aagnes, B.; Weiderpass, E.; Andersen, A. Smokeless tobacco use and risk of cancer of the pancreas and other organs. *Int. J. Cancer* **2005**, *114*, 992-995.

21. Alguacil, J.; Silverman, D.T. Smokeless and other noncigarette tobacco use and pancreatic cancer: a case-control study based on direct interviews. *Cancer Epidemiol. Biomarker. Prev.* **2004**, *13*, 55-58.

22. International Agency for Research on Cancer. *Tobacco habits other than smoking. IARC Monog. Eval. Carcinog. Risk Chem. Hum. Vol. 37.* International Agency for Research on Cancer: Lyon, France, 1985.

23. International Agency for Research on Cancer. *Smokeless tobacco and some tobacco-related Nnitrosamines. IARC Monog. Eval. Carcinog. Risk Chem. Hum. Vol.* 89. International Agency for Research on Cancer: Lyon, France, 2007.

24. U.S. Department of Health and Human Services *The health consequences of using smokeless tobacco. A report of the Advisory Committee to the Surgeon General.* U.S. Department of Health and Human Services, Public Health Service: Bethesda, MD, U.S., 1986. NIH Publication No. 862874.

25. National Toxicology Program. *Report on carcinogens*, 11<sup>th</sup> Ed.; Department of Health and Human Services, Public Health Service, National Toxicology Program: Research Triangle Park, N.C., U.S., 2005.

26. Levy, D.T.; Mumford, E.A.; Cummings, K.M.; Gilpin, E.A.; Giovino, G.; Hyland, A.; Sweanor, D.; Warner, K.E. The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes: estimates of a panel of experts. *Cancer Epidemiol. Biomarker. Prev.* **2004**, *13*, 2035-2042.

27. Richter, P.; Hodge, K.; Stanfill, S.; Zhang, L.; Watson, C. Surveillance of moist snuff: total nicotine, moisture, pH, un-ionized nicotine, and tobacco-specific nitrosamines. *Nicotine Tob. Res.* **2008**, *10*, 1645-1652. Stepanov, I.; Jensen, J.; Hatsukami, D.; Hecht, S.S. New and traditional smokeless tobacco: Comparison of toxicant and carcinogen levels. *Nicotine Tob. Res.* **2008**, *10*, 1773-1782.

29. Royal College of Physicians of London. *Protecting smokers, saving lives: the case for a tobacco and nicotine regulatory authority*. Royal College of Physicians of London: London, U.K., 2002. Available at http://www.rcplondon.ac.uk/pubs/books/protsmokers/index.asp.

30. Reynolds American Inc. Reynolds American CEO: 'Progress Continues, Profits Climb' [press release]. 27 April 2006. Available at http://www.reynoldsamerican.com/Newsroom/..%5Ccommon%

5CViewPDF.aspx?postID=1128. Accessed on 13 March 2007.

31. Altria Group, Inc. Remarks by Michael E. Szymanczyk, Chairman and CEO, Philip Morris USA Inc. at Prudential Consumer Conference. Boston, U.S., September 7, 2006. http://www.altria.com/media/press\_release/03\_02\_pr\_2006\_09\_07\_01.asp. Accessed on March 13, 2007.

32. Philip Morris USA. Marlboro Snus fact sheet. Available at http://www.philipmorrisusa.com/en/popup\_marlboro\_snus\_fact\_sheet.asp?source=home? Accessed on June 25, 2007.

33. U.S. Smokeless Tobacco Company. Magazine advertisement for Skoal® moist snuff: "Enjoy tobacco on a 4-hour flight? Absolutely." 2005. Available at http://www.trinketsandtrash.org/

tearsheet.asp?ItemNum=210630. Accessed on March 13, 2007.

34. U.S. Smokeless Tobacco Company. Magazine advertisement for Skoal® moist snuff:"Enjoy tobacco in a smoke-free sports bar? Believe it." 2005. Available at http://www.trinketsandtrash.org/ tearsheet.asp?ItemNum=210555. Accessed on March 13, 2007.

35. Luik, J.C. The truth that dare not speak: the moral case for smokeless tobacco. *Tob. Report.* **2006**, *March*, 22-28.

36. Bolinder, G.; Alfredssom, L.; Englund, A.; deFaire, U. Smokeless tobacco use and increased cardiovascular mortality among Swedish construction workers. *Am. J. Public Health* **1994**, *84*, 399-404.

37. Henley, S.J.; Connell, C.J.; Richter, P.; Husten, C.; Pechacek, T.; Calle, E.E.; Thun, M.J. Tobacco-related disease mortality among men who switched from cigarettes to spit tobacco. *Tob. Control* **2007**, *16*, 22-28.

38. Rodu, B.; Stier, J. Smokeout: not as easy as ABC. The Washington Times, November 13, 2005. p. B03.

39. LaVecchia, C.; Lucchini, F.; Negri, E.; Boyle, P.; Maisoneuve, P.; Levi F. Trends of cancer mortality in Europe, 1985-1989: II and IV. *Eur. J. Cancer* **1992**, *28*, 514-599; *28A*, 1210-1281.

40. Peto, R.; Lopez, A.D.; Boreham, J.; Thun, M.J.; Health, C. Jr. Mortality from tobacco in developed countries: indirect estimation from national vital statistics. *Lancet* **2006**, *339*, 12681278.

41. U.S. Department of Health and Human Services. *The health consequences of smoking: a report of the Surgeon General.* U.S. Department of Health and Human Services, Centers for Disease Control and

Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health: Atlanta, Georgia, 2004.

42. Kozlowski, L.T. Harm reduction, public health, and human rights: smokers have a right to be informed of significant harm reduction options. *Nicotine Tob. Res.* **2002**, *4*, S55-S60.

43. Phillips, C.V.; Guenzel, B.; Bergen, P. Deconstructing anti-harm reduction metaphors: mortality risk from falls and other traumatic injuries compared to smokeless tobacco use. *Harm Reduct. J.* **2005**, *3*, 15.

44. Weinstein, N.D.; Marcus, S.E.; Moser, R.P. Smokers' unrealistic optimism about their risk. *Tob. Control* **2005**, *14*, 55-59.

45. Petty, R.E.; Cacioppo, J.T. *Communication and persuasion: central and peripheral routes to attitude change*. Springer-Verlag: New York, U.S., 1986.

46. Slovic, P. Smoking: Risk, Perception and Policy. Sage, Thousand Oaks, CA, U.S., 2001.

47. Tomar, S.L. Association between smoking and snuff use in U.S. men: implications for harm reduction. *Am. J. Prev. Med.* **2002**, *23*, 143-149.

48. Bombard, J.M.; Pederson, L.L.; Nelson, D.E.; Malarcher, A.M. Are smokers only using cigarettes: exploring current polytobacco use among an adult population. *Addict. Behav.* **2007**, *32*, 2411-2419.

49. Foulds, J., Ramstrom, L., Burke, M., Fagerstrom, K. Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tob. Control* **2003**, *12*, 349-359.

50. Furberg, H.; Bulik, C.M.; Lerman, C.; Lichtenstein, P.; Pederson, N.L.; Sullivan, P.F. Is Swedish snus associated with smoking initiation or smoking cessation. *Tob. Control* **2005**, *14*, 422-424.

51. Ramstrom, L.M.; Foulds, J. Role of snus in initiation and cessation of tobacco smoking in Sweden. *Tob. Control* **2006**, *15*, 210-214.

52. Tomar, S.L. Epidemiological perspectives on smokeless tobacco marketing and population harm. *Am. J. Prev. Med.* **2007**, *33*, S387-S397.

53. Novotny, T.E.; Pierce, J.P.; Fiore, M.C.; Davis, R.M. Smokeless tobacco use in the United States: the adult use of tobacco surveys. *NCI Monogr.* **1989**, *8*, 25-28.

54. Kozlowski, L.T.; O'Connor, R.J.; Edwards, B.Q.; Flaherty, B.P. Most smokeless tobacco use is not a causal gateway to cigarettes: using order of product use to evaluate causation in a national

U.S. sample. Addiction 2003, 98, 1077-1085.

55. Tomar, S.L.; Loree, M. Errors in analyzing associations between use of smokeless tobacco and cigarettes. *Addiction* **2004**, *99*, 260-262.

56. Tilashalski, K.; Rodu, B.; Cole, P. A pilot study of smokeless tobacco in smoking cessation. *Am. J. Med.* **1998**, *104*, 456-458.

57. Tilashalski, K.; Rodu, B.; Cole, P. Seven year follow-up of smoking cessation with smokeless tobacco. *J. Psychoactive Drugs* **2005**, *37*, 105-108.

58. Tønnesen, P.; Mikkelsen, K.; Bremann, L. Smoking cessation with smokeless tobacco and group therapy: an open, randomized, controlled trial. *Nicotine Tob. Res.* **2008**, *10*, 1365-1372.

59. Fiore, M.C.; Bailey, W.C.; Cohen, S.J.; *et al. Treating tobacco use and dependence*. U.S. Department of Health and Human Services, Public Health Service: Rockville, MD., U.S., 2000.

60. Office of National Drug Control Policy. Methadone [fact sheet]. White House, Office of National Drug

Control Policy, Drug Policy Information Clearinghouse: Rockville, MD., U.S., 2000. Available at www.whitehousedrugpolicy.gov/publications/factsht/methadone/index.html. Accessed on 20 November 2007.
61. Djordjevic, M.V.; Hoffmann, D.; Glynn, T.; Connolly, G.N. US commercial brands of moist snuff, 1994. I. Assessment of nicotine, moisture, and pH. *Tob. Control* 1995, *4*, 62-66.

62. Henningfield, J.; Radzius, A.; Cone, E. Estimation of available nicotine content in six smokeless tobacco products. *Tob. Control* **1995**, *4*, 57-61.

63. Henningfield, J.E.; Rose, C.A.; Giovino, G.A. Brave new world of tobacco disease prevention: promoting dual tobacco-product use? *Am. J. Prev. Med.* **2002**, *23*, 226-228.

64. Johnston, L.D.; O'Malley, P.M.; Bachman, J.G.; Schulenber, J.E. *Monitoring the Future: national results on adolescent drug use. Overview of key findings, 2006.* U.S. Department of Health and Human Services, National Institutes of Health, National Institute on Drug Abuse: Bethesda, MD, U.S., 2007. NIH Publication No. 07-6202.

65. Ary, D.V.; Lichtenstein, E.; Severson, H.H. Smokeless tobacco use among male adolescents: patterns, correlates predictors and the use of other drugs. *Prev. Med.* **1987**, *16*, 385-401.

66. Ary, D.V. Use of smokeless tobacco among male adolescents: concurrent and prospective relationships. *NCI Monogr.* **1989**, *8*, 49-55.

67. Dent, C.W.; Sussman, S.; Johnson, C.A.; Hansen, W.B.; Flay, B.R. Adolescent smokeless tobacco incidence: relationship with other drugs and psychosocial variables. *Prev. Med.* **1987**, *16*, 422 431.

68. Glover, E.D.; Laflin, M.; Edwards, S.W. Age of initiation and switching patterns between smokeless tobacco and cigarettes among college students in the United States. *Am. J. Public Health* **1989**, *79*, 207-208.

69. Tomar, S.L. Is use of smokeless tobacco a risk factor for cigarette smoking? The U.S. experience. *Nicotine Tob. Res.* **2003**, *5*, 561-569.

70. O'Connor, R.J.; Flaherty, B.P.; Quinio Edwards, B.; Kozlowski, L.T. Regular smokeless tobacco use is not a reliable predictor of smoking onset when psychosocial predictors are included in the model. *Nicotine Tob. Res.* **2003**, *5*, 535-543.

71. Tomar, S.L. Smokeless tobacco use is a significant predictor of smoking when appropriately modeled. *Nicotine Tob. Res.* **2003**, *5*, 571-573.

72. Severson, H.H.; Forrester, K.K.; Biglan, A. Use of smokeless tobacco is a risk factor for cigarette smoking. *Nicotine Tob Res.* **2007**, *9*, 1131-1137.

Haddock, C.K.; Vander Weg, M.; DeBon, M.; Klesges, R.C.; Talcott, G.W.; Lando, H.; Peterson,
A. Evidence that smokeless tobacco use is a gateway for smoking initiation in young adult males. *Prev. Med.*2001, *32*, 262-267.

74. Myers, M. Statement of Matthew Myers, President, Campaign for Tobacco-Free Kids, on Smokeless (Spit) Tobacco Before the U.S. House Energy and Commerce Committee, Subcommittee on Commerce, Trade and Consumer Protection, June 3, 2003. Available at http://tobaccofreekids.org/ reports/spit/MyersTestimony.pdf. Accessed on April 24, 2007.

75. Campaign for Tobacco Free Kids. *A Broken Promise to our Children. The 1998 State Tobacco Settlement Eight Years Later.* Campaign for Tobacco Free Kids: Washington, D.C., U.S., 2006. Available at:

http://tobaccofreekids.org/reports/settlements/2007/fullreport.pdf. Accessed on April 24, 2007.

76. Gartner, C.E.; Hall, W.D.; Chapman, S.; Freeman, B. Should the health community promote smokeless tobacco (snus) as a harm reduction measure? *PLoS Med.* **2007**, *4*, 1703-1704.

77. Antonsson, A.B. Substitution of dangerous chemicals—the solution to problems with chemical hazards in the work environment? *Am. Ind. Hyg. Assoc. J.* **1995**, *56*, 394-397.

78. Fischer, K., Schot, J., Eds. *Environmental strategies for industry: international perspectives on research needs and implications*. Island Press: Washington, D.C., U.S., 1993.

79. Rothman, A.J.; Kiviniemi, M.T. Treating people with information: an analysis and review of approaches to communicating health risk information. *J. Natl. Cancer Inst. Monogr.* **1999**, *25*, 44 51.

80. National Cancer Institute. *Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine*. Smoking and Tobacco Control Monographs No. 13. U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute: Bethesda, MD, U.S., 2001. NIH Pub. No 02-5074.

81. Kahneman, D., Tversky, A., Slovic, P., Eds. *Judgment under uncertainty: heuristics and biases*. Cambridge University Press: New York, U.S., 1982.

82. Remington, P.L. *Communicating public health information effectively: a guide for practitioners*. Nelson, D.E., Parvanta, C., Eds.; American Public Health Association: Washington, DC, U.S., 2002.

83. United States District Court for The District of Columbia. United States of America *et al.* v. Philip Morris USA, Inc., *et al.* Civil Action No. 99-2496 (GK). Final Opinion. United States District Court for The District of Columbia: Washington, DC, U.S., 1999. Available at: http://tobaccofreekids.org/reports/doj/FinalOpinion.pdf. Accessed on June 25, 2007.

84. Ling, P.M.; Glantz, S.A. Tobacco industry consumer research on socially acceptable cigarettes. *Tob. Control* **2005**, *14*, 1-16.

85. Barnoya, J.; Glantz, S.A. The tobacco industry's worldwide ETS consultants project: European and Asian components. *Eur. J. Public Health* **2006**, *16*, 69-77.

86. Bero, L.A. Tobacco industry manipulation of research. Public Health Rep. 2005, 120, 200-208.

87. Parascandola, M. Science, industry, and tobacco harm reduction: a case study of tobacco industry scientists' involvement in the National Cancer Institute's Smoking and Health Program, 19641980. *Public Health Rep.* **2005**, *120*, 338-349.

88. Muggli, M.E.; Forster, J.L.; Hurt, R.D.; Repace, J.L. The smoke you don't see: uncovering tobacco industry scientific strategies aimed against environmental tobacco smoke policies. *Am. J. Public Health* **2001**, *91*, 1419-1423.

89. McDaniel, P.A.; Smith, E.A.; Malone, R.E. Philip Morris's Project Sunrise: weakening tobacco control by working with it. *Tob. Control* **2006**, *15*, 215-223.

90.. Cranor, C.F. Toward understanding aspects of the precautionary principle. *J. Med. Philos.* **2004**, *29*, 259-279.

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