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Cigarette smoking is widely described as the greatest preventable cause of morbidity and mortality. I have always found this a rather tortured definition of "preventable" – after all, if it is so preventable, why do U.S. smoking rates remain high, with the total number of smokers in the world increasing? It is reasonable to say that smoking is *theoretically* preventable. But the current methods – education, warning, regulating sales and advertising, prohibiting smoking in many places, and pharmaceutical nicotine replacements – despite their effectiveness over the last half century, seem to have had most of the effect as they are going to. Even if those methods become even more effective at discouraging people from taking up smoking, the tens of millions of current smokers in the U.S. remain at risk.

Last year, I was retained by U.S. Smokeless Tobacco Company to analyze and give my opinion on what the scientific research had to say about the health risks of using smokeless tobacco (ST). As a professor of public health (Assistant Professor, University of Texas School of Public Health and University of Texas Medical School) specializing in methods for interpreting data and study results, I had much to say about the science. As a public policy analyst (Ph.D. in public policy from Harvard University and Masters in Public Policy from the

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<sup>1</sup> This statement is the scientific opinion of the author, and does not necessarily represent the views of the University of Texas School of Public Health, the University of Texas Health Science Center at Houston or the University of Texas system.

Kennedy School of Government at Harvard), I find myself particularly interested in the potential life-saving policy of harm reduction.

Like most everyone who has not personally reviewed the science, I believed that ST was a major risk factor for life-threatening illness, perhaps not as risky as cigarettes, but of similar magnitude. It quickly became clear to me that the risk from smokeless tobacco was tremendously lower than that from cigarettes. Indeed, even for the one disease most commonly linked to ST, oral cancer, the evidence of any risk at all was highly equivocal. I was distressed that the public health community, a community I am part of, had perpetuated such misinformation. More than that, I was impressed by the potential to reduce the devastating health effects of cigarettes by encouraging smokers to switch to ST. I came to consider this one of the greatest untapped resources for improving the health of the U.S. population, and have made ST my major substantive area of academic research.

Many areas of health research offer large speculative payoffs, but it is not clear what will really be discovered. Many potential interventions offer great health benefits in theory, but it is not clear they could really be implemented. ST has scientifically proven potential to reduce harm from cigarettes and a proven track record in Sweden, where ST consumption has increased while smoking has dropped dramatically. It is difficult to imagine any other policy as likely to further reduce the health costs of smoking in the U.S., if only policy makers and public health leaders will let it work. This would require no complicated and expensive intervention; it would probably be enough for the government to tell the truth about the risks or allow ST manufacturers to do so.

Much less harmful than cigarettes

The potential of ST use to reduce harms from smoking follows immediately from its role as an alternative source of nicotine and its relative safety. Despite the popular belief to the contrary, there is no genuine scientific disagreement with the claim that ST is much less harmful than cigarettes. Biology and chemistry would tend to predict this (for example, ST does not produce carbon monoxide buildup or cause chemical insult to the lungs), but it is the study of actual results for actual people (the science of epidemiology) that makes it clear. Of the various cancers, cardiovascular diseases, and other life threatening diseases that smoking has been shown to cause, the only persistent claim about risk from ST is for oral cancer (OC). The elimination of clearly smoking-specific hazards – lung cancer and other lung diseases, fires, and environmental ("second hand") tobacco smoke – alone reduce the risks by half. But there has also been no conclusive link to cardiovascular disease and most other cancers. Even for OC, which account for about 1% of deaths attributable to smoking, smoking is associated with greater risk than the worst plausible claims about the risk from ST.

The bottom line is that a cigarette smoker who switches to ST reduces his risk of disease from tobacco use by more than 90%, and quite possibly more than 99%. There is legitimate scientific uncertainty about whether the reduction is 98%, 99.9%, or some other value, but it is clear that it is better than 90%. The remaining uncertainty should not dissuade us from acting immediately. One of the most important points I teach my students in my health policy classes is that if you perform a careful scientific analysis of a proposed policy, you will often find that you do not need to resolve the remaining uncertainty about some values. Even though they are somewhat uncertain, you know enough to know that any plausible value leads to the same policy recommendation. In the case of ST, if the reduction in risk of life threatening disease was possibly as low as 50% or even 75% compared to cigarettes, the question might be more

difficult. But our current information, that the risk of using ST is much less than 10% of that from smoking, is sufficient to show that telling the truth about ST is a promising harm reduction strategy

### How do we know?

The scientific literature fails to establish a link between ST use and any life threatening disease. Scientifically demonstrating that something does not exist, such as showing there is no substantial health risk from ST, is usually more difficult than demonstrating that it does exist. A common observation is that "the absence of evidence is not evidence of absence." This is an important point when evidence is absent because there has been little attempt to find the evidence. But when researchers have looked hard for evidence of a health risk and have not found it, we have compelling evidence that the risk is close to zero. This is the case for ST. This does not mean that the risk from ST for any particular disease is exactly zero – such a thing can never be proven – but it does give the best possible evidence that it is either zero or very low.

The active effort by many organizations and researchers in the health community to show that ST is unhealthy has created attitudes that are a barrier to the suggested harm reduction strategy. But that same active effort is very helpful for drawing scientific conclusions, because we can be confident that if there were any clear associations to be found, they would have been found. The health science literature contains only a few papers that look at risk of diseases other than OC from ST use. One reason for this might be that no one has looked for such associations. However, there are many well-studied datasets that would allow such analyses and there is huge demand for findings that ST is associated with disease. Given that there is demand and potential supply, we can conclude that the lack of findings is not for lack of trying to find something. It is

not surprising that there are not a lot of published papers that show a lack of association, because such findings tend to not get published (the phenomenon is called "publication bias"). We can further conclude that if there was a large risk for a disease from ST, it would be noticed; large effects are difficult to miss. Finally, we can observe that the opponents of ST focus almost entirely on the risk of oral cancer, and energetic advocates can usually be counted on to come up with the strongest possible case for their claims, suggesting that even they do not think there is support for the claim that ST causes other diseases.

But even the case for OC risk is not very strong. It is widely reported that there is a causal link between ST and OC, most notably in a Surgeon General's Report [1986]. There is evidence that smokeless products that contain other major ingredients (particularly betel nut in South Asia) are risk factors for OC. There is one large U.S. study [Winn et al., 1981], that found an association between the use of early- and mid-20th century *dry* snuff and oral cancer. (The Surgeon General Report conclusions hinged largely on this study.)

But the dominant product in the industrialized world, modern *moist* snuff, has not been associated with OC. The two major published studies on the topic [Lewin et al., 1998; Schildt et al., 1998] did not find an association, and provide convincing evidence that there is no strong association. Furthermore, my own research (which I will present this June at the Society for Epidemiologic Research meeting, the major U.S. epidemiology meeting) shows that Winn et al. and most others of the few modern studies that purport to find an association of ST and OC have reported their results in ways that tend to exaggerate the association, or make it appear that there is an association in the data when there really is not. In particular, they picked out subgroups of their population (such as only reporting results for nonsmoking women, or certain individuals who had used ST for more than 50 years), and reported numbers for them, omitting numbers for

other groups who had much lower association or even showed reductions in cancer rates. The conclusion from all this is not that modern American and Swedish ST is proven to not cause oral cancer, but there is clearly no proof that it does cause it.

#### A (so far) missed opportunity for harm reduction

Even if we accept the main finding from the Winn et al. study about OC risk, the worst case scenario there is any evidence to support, and allow for some small risk of others diseases (so small that it has not been detected), the risk from ST is only about 1% of that from smoking. Our current scientific knowledge allows us to be *fairly confident* that ST has about 99% less risk of life threatening disease than smoking. We are *as confident as is ever possible* in health research that the reduction is greater than 90%. The implication of that is clear: Anyone who uses ST rather than cigarettes will be much safer, eliminating almost all the risk of life-threatening disease from his or her tobacco use.

Having learned this in the last year, I have found myself thinking about my grandmother, a lifelong smoker, who died a few years ago following a series of smoking-related cancers. She tried to quit using tobacco and failed. The message from the public health community to her and to current smokers was "quit or die." She could not quit. As an Appalachian woman of her age group, the use of ST would not have been unusual or socially unacceptable. Had she gotten the message that she would have been so much safer using ST rather than cigarettes, she might be alive today.

Health authorities in other countries are starting to come around. Most notably, the United Kingdom's oldest medical organization, the Royal College of Physicians [2002], issued a report on tobacco regulation that acknowledged that ST is "10-1000 times less hazardous than

smoking" and suggested that a harm reduction strategy might be appropriate. Many public health advocates and researchers are speaking up in favor of using ST as part of a harm reduction strategy. The changes in policy attitudes will come too late for millions who have already died, but millions of others can be saved.

### Misleading the public

Why did my grandmother never learn that ST offered such a huge reduction in risk? Why do tens of millions of literate and well-informed smokers not know it now? Why did I, a well-read expert in public health not know this a year and a half ago? The consistent message from public health authorities, including state and federal government agencies, advocacy groups, and medical organizations, is that ST is as unhealthy as cigarettes. Sometimes this claim is stated in so many words, despite being clearly false. More often, the message is that ST is not a safe alternative to cigarettes. When this message is presented without further qualification, people tend to assume that the two products have comparable levels of risk, making the claim clearly misleading.

My colleagues and I just completed a review of the over four hundred public-service-oriented Web sites that were found with a Google search for statements about the health risk from ST. Less than 1% of these say anything about ST offering a major risk reduction compared to smoking or acknowledge that it has not been shown to be very harmful. Many sites contain specific numbers that make their claims more misleading, while giving the appearance of greater accuracy. A fairly common claim is that ST "can lead to a 50-fold increase in oral cancer risk." This result traces to one number reported in Winn et al., for extremely high exposure among a small subgroup of the population, and is not meaningful out of context. This number, the largest

reported in the paper for any subgroup or exposure definition, clearly does not summarize the results from Winn et al. Furthermore, having re-analyzed the original unpublished Winn data, I found that the specific statistical choices used to produce that number appear to have been chosen to produce the largest number possible, which is a scientifically invalid method of analysis.

Our major finding from our analysis of the Web sites (which we will also be presenting at the epidemiology meetings) is that most of them repeat the same overstated or false claims, reporting the same few numbers from Winn and the Surgeon General, and ignoring the substantial scientific literature that contradicts these claims. When they attribute their claims to any source, they cite the Surgeon General, the American Cancer Society, and a few other sources, all of which trace their claims primarily to pre-1980 research, which is not up to modern methodologic standards and studies people who used a different product from modern moist snuff. Furthermore, with the exception of two Web sites that deal with harm reduction, the sites that showed up in our search provide no absolute risk number that would allow readers to realize that, even the worst case scenario, ST is tremendously safer than smoking. What looks like a huge amount of mutually-confirming information about substantial risk turns out to be a lot of groups citing each other and repeating the same small body of misleading and often incorrect information.

Given these patterns of systematic misinformation, it is not surprising that when people learn the truth about the risk of ST, they are almost always extremely surprised. Of the hundreds of people, usually highly educated and often health professionals, that my colleagues and I have told this information to, only one (my dentist) already knew the truth. It is little wonder that the harm reduction message, as strong as it is, has not taken off on its own.

### Attempts to justify the misinformation

The health advocates who defend the misinforming of the public offer several arguments, all of which seem difficult to defend. No one who hopes to preserve any credibility will deny that using ST rather than cigarettes leads to a dramatic risk reduction. Instead, other arguments are usually offered. They turn out to be equally unconvincing, but more subtly so.

Advocates sometimes argue that honest information about ST should be denied to the public because it might cause tobacco nonusers to take up ST, and their increased risk could exceed the benefit experienced by smokers switching to ST. Simple arithmetic shows this to be wrong. If ST offers a 99% reduction compared to smoking, it would be necessary for 99 tobacco nonusers to take up ST for every smoker who switches. Even if the reduction were as little as 90%, it would require 9 for every 1. It is implausible that such a large increase in tobacco use could occur.

An occasional retort to this arithmetic is that there is an ethical concern when one person experiences a benefit (the smoker who switches to ST) and another suffers a health cost (the nonuser who takes up ST upon learning it is relatively safe – assuming, of course, that ST does create some risk). But a much clearer ethical argument is that it is unacceptable in a free society for public officials to filter information to protect people from their own free choices, especially when someone else (the smoker who never learns the value of switching) pays a high price for it.

A second argument used to justify the misinformation is that even though it is arithmetically implausible that increased ST use could directly cause an increase in the total health impact of tobacco, honest information about ST would lead to more tobacco users, and some of them would take up smoking. If this phenomenon – that ST would act as a "gateway" to

smoking – did occur, the net benefits would indeed be reduced. However, even though this possibility can be stated, there is no reason to believe it would actually occur. Several studies have attempted to show that there is a tendency to switch from ST to cigarettes, but they have merely shown that many of the same people who might use one form of tobacco might use another, just as we would expect. But even if a pattern of switching from ST to cigarettes does exist in the U.S. currently, it would say nothing about what would happen if people had good information. Believing that the two products are comparably unhealthy, people might be equally likely to switch in either direction. But when people learn that ST is much less harmful, they will increase their switching from cigarettes to ST and decrease their switching from ST to cigarettes. To claim otherwise is to say that tobacco users do not care about their health, which is clearly not the case.

Furthermore, the logic of the gateway argument is fundamentally flawed. The argument requires that there is a group of tobacco nonusers who are avoiding tobacco because of health concerns, but who would start using ST if they knew it was not very risky. But then, these same people – who were originally motivated to avoid tobacco due to health concerns – somehow decide to switch to cigarettes, which they know are much less healthy. Thus, since honest information about ST would tend to reduce the switching from ST to cigarettes, and it is difficult to imagine any new ST users switching to smoking, honest information about ST would tend to *decrease* any role that ST plays as a gateway to smoking. Anyone concerned with the gateway effect should be in favor of honest information about the lower risk from ST.

When the preceding arguments are shown to not hold up, anti-tobacco advocates sometimes offer a third argument that does not depend on logic or science: the goal of our society should be to eliminate all tobacco use, and telling the truth about ST is not compatible

with this goal. It is not clear exactly whose goal this is and what justification they have for imposing it on the rest of society. The legitimate goal of health advocates is to improve health, and denying people a great harm reduction opportunity clearly does not do this. It is certainly true that eliminating all tobacco use would improve health (almost all the gain coming from eliminating cigarettes), but this goal, whether legitimate or not, will be unrealistic for many decades.

### Conclusions

Advocating the use of ST to reduce the harm from cigarettes is a minority position in the U.S. But scientific truth and ethical duties are not decided by counting votes. The science is clear: ST is much less harmful than cigarettes, and there is no realistic scenario that leads to any increase in health risks by telling the truth. In my opinion, health officials have an affirmative ethical duty to make the truth known, both because it is the truth and because it would save lives. It is difficult to justify keeping the truth from people, even when it might be harmful; it is clearly unjustified when it would be beneficial. In other countries these points have been appreciated at the highest levels in the health community. And many other American health researchers, notably including Professor Lynn Kozlowski of Penn State University, who has presented the ethical arguments in greater detail than I can here, have come to the same conclusions.

It is not clear whether those who would prevent this harm reduction strategy are motivated by an unrealistic vision of eliminating all tobacco use in the short term or by something else. Whatever their motives, there should be a strong burden on them to present some logical argument, based on realistic scientific claims and clearly stated ethical positions, that we should deny people truthful information that could save their lives. In my extensive

studies of the scientific and popular literature, I have found no such argument. We are not faced with a need for more scientific information. We have enough information to know that the harm reduction strategy responds to a huge health problem, has the potential for substantial reduction of risks, is likely to be implementable, and has not been shown to be costly or likely to have major unintended consequences. It is difficult to imagine a more compelling case for harm reduction.

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