Tobacco Harm Reduction – A Public Health Perspective

A statement by

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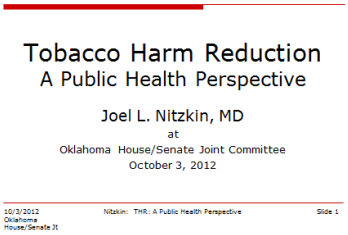
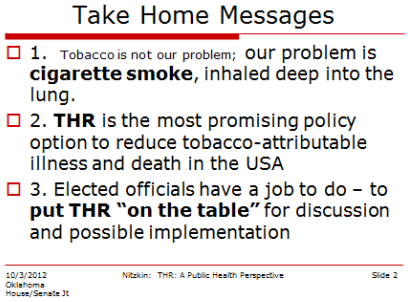
Introduction

This document is adapted from a presentation I gave to a joint committee meeting of the Oklahoma House and Senate, October 3, 2012. The first five pages present my remarks and images of my slides. The next seven pages present brief narratives relative to the most common objections raised by opponents of Tobacco Harm Reduction (THR), with selected bibliographic references.

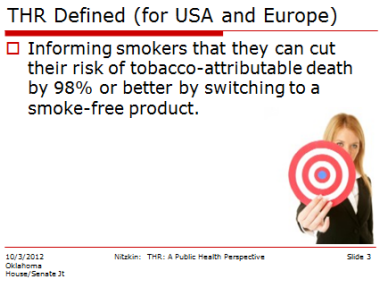


This document is intended to impart three take home messages:

1. When dealing with tobacco-attributable illness and death, "tobacco" is not our problem. **Our problem is cigarette smoke**, inhaled deep into the lung.
2. Tobacco Harm Reduction, which I will refer to as "**THR**," is the most promising policy option to reduce tobacco-attributable illness and death in the USA.
3. Together, we have a job to do – to **put THR "on the table"** for discussion and possible implementation.



THR, in operational terms, is education and counseling to encourage smokers who are unable or unwilling to quit, to switch to a much-lower-risk smoke-free tobacco/nicotine product to reduce their risk of cancer, heart and lung disease. THR differs from smoking cessation in that the hopefully ex-smoker continues to use nicotine for as long as he or she feels the need to do so.



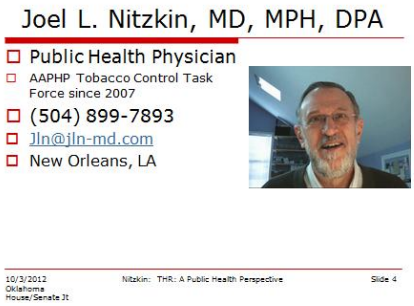
Having defined THR in operational terms, what I hope to do, over the next fifteen minutes, is to discuss why we should all promote THR, and address at least one of most common arguments against it.

I would like to bring your attention to the handout before you. The first half covers this verbal presentation. The second half of the handout presents the scientific case in favor of THR, complete with bibliographic references. I urge at least a superficial scan of these materials.

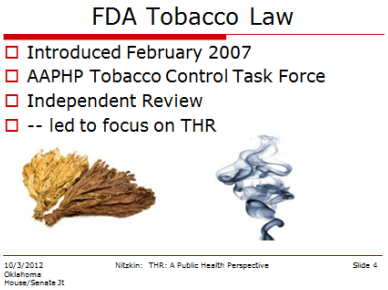
Personal Introduction:

But, first, a personal introduction is in order.

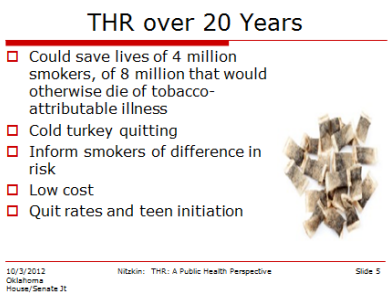
I am Dr. Joel Nitzkin. I am a physician, board certified in Preventive Medicine. I have been a local health director, state health director, and President of two national public health associations. Since the mid-1990's I have been in the private practice of public health as a policy consultant.



I have been involved in tobacco control since the 1970's.



The story that brings me here, today, began in February of 2007 when the FDA Tobacco bill was introduced into Congress. At that time I was serving as co-chair of the Tobacco Control Task Force of the American Association of Public Health Physicians. In response to what we saw as flaws in that bill, our AAPHP Task Force did an independent review of the tobacco control literature. We did this to determine the best possible approach to reducing tobacco-attributable illness and death, in the USA. It was this review that drew our attention to tobacco harm reduction.

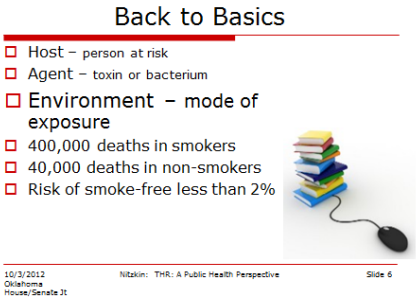


Our research, since that time, led us to the conclusion that **a well-coordinated tobacco harm reduction initiative, added to current tobacco control programming, could save the lives of 4 million of the 8 million current adult American Smokers who will otherwise die of a tobacco related illness over the next twenty years.** The two actions needed to secure this public health benefit are 1) to actively promote cold-turkey quitting and 2) to inform smokers who are unable or unwilling to quit, that they could reduce their future risk of tobacco related illness by 98% or better by switching to one of a number of much-lower-risk smokeless tobacco products or E-cigarettes. **Such a tobacco harm reduction initiative could be done at remarkably low cost while increasing quit rates and while decreasing the numbers of teens initiating tobacco use.**

Conflict of Interest Statement

Neither I, nor AAPHP has ever received any governmental, pharmaceutical or tobacco company support for any of the work we have done in the tobacco control arena. This work has been done on a voluntary basis.

Back to Basics: How Tobacco Causes Illness and Death



Back to Basics.

For a toxin or bacterium to cause illness, three things must be present. The first is the Host – the person at risk of illness. The second is the Agent – the chemical or bacterium capable of causing illness. The third is the Environment that enables the agent to enter the host in a way that will result in illness and possible death.

We have no idea as to which of the toxins, or what combination of toxins in cigarette smoke, cause the cancer and lung disease and most of the heart disease. What we do know is that, in the USA, 400,000 deaths per year in cigarette smokers, and 40,000 deaths in non-smokers are due to exposure to cigarette smoke. We also know **that the risk of potentially fatal illness posed by smoke-free tobacco/nicotine products currently on the American market is less than 2% the risk posed by cigarettes.** This means that the key factor

in causing illness is not the chemical profile of the tobacco product, but the means by which the Host is exposed**. Our problem is not "tobacco." Our problem is cigarette smoke.**

THR is based on this simple observation. If an American smoker switches to a smoke-free tobacco product, he or she can eventually cut his or her risk of potentially fatal tobacco-attributable illness by more than 98%.

The Case in Favor of THR

Why THR?

THR can save lives.

According to CDC, the numbers of smokers in the USA and the numbers of tobacco-attributable deaths each year have been remarkably stable over the past decade. The slight reductions we have seen in percentages of people who smoke have been matched by population growth, leaving the numbers about the same. THR stands out as the only feasible policy option that could rapidly and substantially reduce the numbers of smokers and deaths, and do so at remarkably little cost.

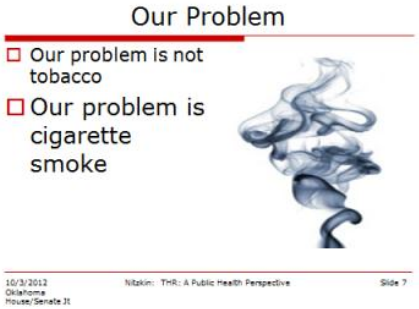
As pointed out by Dr. Rodu, there are very substantial differences in risk, comparing different classes of tobacco products. While all are addictive, one, the cigarette, kills one third of the people who use it regularly, while others, such as snus, and probably dissolvables and e-cigarettes, cause little or no potentially fatal illness.

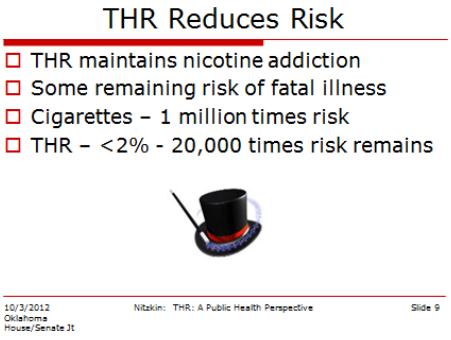
THR reduces, but does not eliminate harm. First there is the issue of nicotine addiction. THR continues and maintains this addiction. Second, THR reduces, but does not eliminate all risk of potentially fatal tobacco-attributable illness.

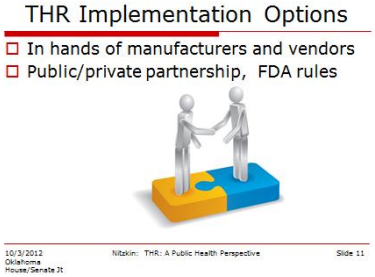
At the risk of a very crude analogy, let's put it this way. If cigarettes, which kill about 1/3 of the people who use them on a regular basis may be considered 1 million times more hazardous than acceptable in other consumer products. Reducing the risk by 98%, still leaves the reduced risk product 20,000 times more hazardous than other consumer products. While deaths may be few and far between, the low-risk tobacco/nicotine products still pose a level of risk not accepted in other consumer products.

Thus, from a public health perspective, the secret to success will be to effectively market the lower-risk smoke-free tobacco/nicotine products to current smokers, while not encouraging their use by non-smokers.

This will be exceedingly hard to accomplish if, as is currently the plan, all communications relative to risk are left in the hands of manufacturers and vendors. If, however, THR is pursued as a joint







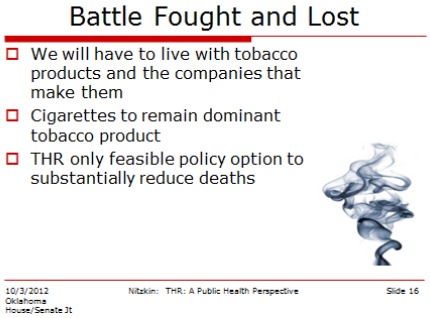
public/private venture, under rules established by the FDA – it should be possible to concentrate use of these products on recalcitrant smokers without adversely impacting initiation or quit rates.

"Tobacco-Free Society"

I would like to address the issue of a "Tobacco-Free Society."

Congress, and two administrations, one Republican and one Democrat, in their infinite wisdom, have decided that we, as a society, will not ban tobacco products. For ten years, public health authorities tried to get FDA authority to essentially ban tobacco products. This did not happen. We did not get an FDA-Tobacco law until Matt Myers of Tobacco Free Kids collaborated with the leadership of Altria/Philip Morris to craft a law that our largest cigarette maker would approve. The law basically grandfathers in all of the major cigarette products and currently marketed smoke-free products while putting nearly insurmountable barriers to the entry of new products and nearly insurmountable barriers for any product to claim it is lower in risk than cigarettes. When AAPHP and others proposed amendments that would strengthen the law from a public health perspective, we were told by Tobacco Free Kids, the Heart, Lung and Cancer associations, Waxman's office and others that the bill was the result of secret negotiations with Altria/Philip Morris, and that any such amendment would be considered a "poison pill" that might kill the proposed legislation.

What does all this mean?



1. We have fought valiantly for a "tobacco-free society" and lost. We will have to live with tobacco products and the companies that make them.
2. In the absence of a THR initiative, cigarettes – the most addictive and the most hazardous of all tobacco products will continue to be the dominant tobacco product on the American market.
3. THR presents the only feasible policy option by which the public health community can join forces with at least some within the tobacco industry to reduce tobacco-attributable illness and death in American Society.

Next Steps

If we are to move ahead to reduce tobacco-attributable illness and death in American Society, we need to do the following:

1. Place THR "on the table" for research and likely implementation.
2. Carefully consider the promise of Tobacco Harm Reduction and the means by which it could be

implemented with maximum possible public health benefit and minimal harm.
3. Open a dialogue between public health authorities and the tobacco industry to explore the means by which we might be able to work together in pursuit of public health objectives.
4. Reconsider the bans which currently prohibit major universities from accepting tobacco company research dollars.

Resource Material

Differences in Risk, Comparing Smoke-Free Tobacco Products to Cigarettes

The evidence that smoke-free products pose substantially less risk of death than cigarettes is based on studies done in the United States and Scandinavia. American risk data relative to smoke-free tobacco products, dating from the mid-1980's, reflect risks posed by **chewing tobacco and moist snuff**, with Scandinavian data mainly based on **Swedish snus**.[1-11]

Dissolvables (sticks, strips, orbs and lozenges) and E-cigarettes have only been on the market a few years, so there are no long-term epidemiologic studies documenting their impact on tobacco-attributable illness or death. These are included as low-risk alternatives to cigarettes because of their physical and chemical similarities to snus and the NRT products.

Smoke-free products that are low-risk alternatives to cigarettes also include **pharmaceutical nicotine replacement therapy (NRT) products** (gum, lozenges, patches etc) when used on a long term basis. It is important to note that none of the NRT products have been approved by FDA for long term use.

Relatively little data on long term risk are available for **pipes, cigars, hookahs** and other combustible products. Given that they all involve inhalation of products of combustion; they are not recommended for tobacco harm reduction (THR) because they are expected to confer risks substantially higher than the smoke-free options. In hookahs, also known as shishas or water pipes, charcoal is burned, with the hot smoke being drawn through flavored tobacco and water. Charcoal fumes have excessive carbon monoxide and a wide range of carcinogens and other toxins.

Many still believe that smokeless products currently on the American and Scandinavian markets present a risk of **oropharyngeal cancer** far in excess of the risk posed by cigarettes. This belief is incorrect. This issue was dealt with in a definitive manner in a review of 62 US and 18 Scandinavian studies by Lee and Hamling in 2009.[5] A minimally elevated risk of oropharyngeal cancer was evident in American epidemiologic studies prior to 1990, but not in more recent American or any Scandinavian studies. Smoking and alcohol consumption are the major risk factors for oropharyngeal cancer. More recent studies with better control for these confounders have concluded that the risk of oropharyngeal cancer posed by smokeless products is minimal to nonexistent.

The question of the **cardiovascular risk** posed by smokeless tobacco products was explored in a 2009 review by Piano et al.[9] This review found that smokeless tobacco users experience little or no excess cardiovascular mortality when compared to non-tobacco users.

Older reviews estimated that the risk posed by smokeless tobacco products is less than 10% of the risk posed by cigarettes, and possibly, less than 1%.[1-4] More recent reviews[5-11] provide relative risks for cancer and cardiovascular diseases that are in the extreme lower end of this range**. While smokeless tobacco products pose unacceptable cancer risk according to toxicological assessments.[12] such risk has not been borne out in epidemiologic studies.**

Thus, in both absolute and relative terms, smoke-free tobacco/nicotine products in the United States and Scandinavia present a remarkably small risk of cancer and cardiovascular disease, no perceptible risk of lung cancer or other lung disease, and no risk to non-users.

Risk Posed by Smokeless Tobacco Products in the USA

While much lower in risk than cigarettes, no tobacco or nicotine product is risk free. Thus, the term "harm reduction." If the current 46 million American smokers had been using smoke-free tobacco products instead of cigarettes, we would likely be seeing **between 800 and 8,000 tobacco-attributable deaths per year** among tobacco users**, instead of the current 440,000**. Eight hundred to 8,000 preventable deaths per year are much better than 440,000; but they would still constitute a significant public health problem. The smoke-free products that presented a significant risk of mouth cancer in the USA, prior to the 1980's are no longer on the market.

Risk Posed by Smokeless Tobacco Products in Asia

International data showing a high risk of mouth cancer from smoke-free tobacco products are based on highly contaminated and crudely made tobacco products widely used in Asia, Selected smokeless tobacco products, popular in Asia, pose high risks of oropharyngeal cancer. This risk is probably related to high concentration of contaminants or to ingredients other than the tobacco.[13] Since these products are not generally available in the United States, the risks they pose are not considered in this study.

Misleading Warnings Mandated for Smokeless Tobacco Products in the USA

The perception that smokeless products present the same risk as cigarettes is amplified by the misleading warnings currently mandated for smokeless tobacco products. These four warnings date from the early 1980's, and were written into the 2009 FDA tobacco law.

1. "not a safe alternative to cigarettes:" This warning has left more than 80% of smokers with the erroneous impression that smokeless products present the same risk of potentially fatal illness as cigarettes.
2. "mouth cancer" – risk is so low as to be barely detectable.
3. "tooth and gum disease" – risk is for relatively minor abnormalities, much of which will resolve after discontinuing use of the tobacco product.
4. "addictive" – this is the only accurate warning.

Thus, if one is to promote smoke-free tobacco products as an alternative to smoking – one must point out the misleading nature of three of the four mandated warnings on smokeless tobacco products.

Dual Use

Many opponents of tobacco harm reduction oppose THR on the basis that smokers will simply add smokeless tobacco use to their current cigarette use, and not reduce their use of cigarettes. This, in turn, is based on the marketing of smokeless products that encourages their use in places where smoking is prohibited. Data available to date suggest that dual use is a natural transition state between cigarette smoking and abstinence from cigarettes. The one reasonably comprehensive study to explore this issue showed that dual users smoke fewer cigarettes than exclusive smokers.[14]

Reduced Quit Rates:

Getting current smokers to quit has been a mainstay of tobacco control programming in the United States for more than a half-century. Results have been disappointing. Annual quit rates hover around 3% per year. Available pharmaceutical therapies only increase these rates to about 7%, when abstinence is measured six to twelve months after completion of therapy.[15] In other words, currently available cessation therapies fail 93% of smokers who use them as directed.

Rodu and Phillips,[16] utilized American 2000 National Health Interview Survey data to compare smokeless tobacco to NRT products as an aide to quitting cigarettes. They found that smokeless tobacco had the highest proportion of success (73%), compared to 0% to 35% for the various NRT products.

Using a one-year follow-up to the American 2002 Tobacco Use Supplement to the Current Population Survey, Zhu et al[17] found that "men quit smokeless tobacco at three times the rate of quitting cigarettes (38.8% vs. 11.6%; $p<0.001$)." These findings are not unexpected, given the perception that, addiction to cigarettes is substantially enhanced by habituation to the cigarette-handling ritual.[18-20] and the emotional appeal of advertising themes.

Thus, THR could substantially increase cigarette quit rates without adversely impacting overall tobacco/nicotine quit rates.

Increased Numbers of Teens Initiating tobacco/nicotine use

Critics of THR believe that it will lead to increased teenage smokeless tobacco use, which will function as a "gateway" to smoking.[21] However, there is no evidence for this in Sweden, where smokeless tobacco use has been high for many decades. A 2008 study of 3,000 adolescents from the Stockholm area by Galanti et al. found that "the majority of tobacco users (70%) started by smoking cigarettes" and "the proportion of adolescent smoking prevalence attributable to a potential induction effect of snus is likely small."[22] That same year the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks concluded that "The Swedish data…do not support the hypothesis that…snus is a gateway to future smoking."[23]

In the U.S. teenagers who use smokeless tobacco are more likely than non-users to subsequently smoke.[24,25] However, other American studies have concluded that smokeless tobacco is not a gateway to smoking among teenagers.[26-28] O'Connor et al. commented that "Continued evasion of the [harm reduction] issue based on claims that smokeless tobacco can cause smoking seems, to us, to be an unethical violation of the human right to honest, health-relevant information."[27]

The major benefits of smoking, as seen by teens, include a rite of passage to adulthood – a way to "be grown up," a way to be popular, glamorous, sexy, charming, tough, independent, and strong; and a way to feel at ease in a group or crowd.[29] These themes are unlikely to apply to smoke-free products which are less visible to others while in use. They also seem unlikely to apply to the e-cigarettes which teens are likely to see as imitation cigarettes.

Thus a well-managed THR initiative is not likely to attract teens or others who would not have initiated tobacco use.

Lack of Proof

The final major reason that opponents of THR refuse to even consider a THR initiative that would promote use of non-pharmaceutical smokeless tobacco products is lack of proof that such an initiative would yield substantial public health benefits and could be done in a way that would not decrease quit rates or increase teen initiation rates. In this context, "proof" is taken to mean demonstration of safety and efficacy by means of a **randomized placebo-controlled clinical trial**. The problem here is that such a trial would be **ethically impermissible** and would be **physically impossible** to conduct. First, it would be ethically impermissible to require that those randomized to the "control" arm of the study smoke cigarettes. This is because we know that such smoking will cause serious illness and death in that cohort. Second, placebo control will be impossible because the subjects and investigators will know the arm of the study for each subject. Third, the study-assigned behaviors would have to be maintained for 15-20 years, the "incubation period" for onset of the potentially fatal cancer heart and lung diseases that would be the objective of this study. Finally, prevention of decreasing quit rates or increasing teen initiation rates would require participation by both governmental authorities and voluntary health organizations to control vendor advertising and to provide supplemental health education messages.

This last point requires further discussion. Advertising a tobacco product as 98% less hazardous than cigarettes would likely tobacco quit rates and increase teen initiation rates, in the absence of countervailing measures. This is where participation by both governmental authorities and voluntary health organizations comes in. The countervailing health education and strict control of advertising content cannot reasonably be done by the tobacco companies. Effective health education relating to the harms of nicotine addiction and the residual cancer and heart disease should be able to prevent the unwanted changes in quit and initiation rates.

In other words, for THR to be implemented as a public health initiative, federal authorities will have to reconsider what they will or will not accept as "proof," and public health authorities will have to actively participate in the program.

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The literature reviews that lead Dr. Nitzkin to the conclusions noted above are posted on the Tobacco page of the AAPHP web site at www.aaphp.org/tobacco. This page is open to the public, without fee or registration.

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