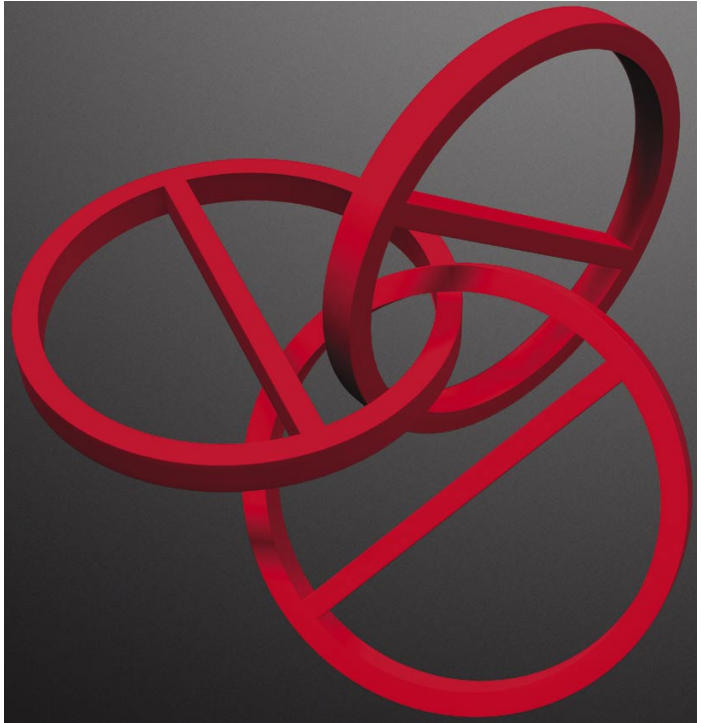


NIH State-of-the-Science Conference Statement on Tobacco Use: Prevention, Cessation, and Control



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NIH State-of-the-Science Conference on Tobacco Use: Prevention, Cessation, and Control

June 12–14, 2006

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National Institutes of Health
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Policy Perspective for Tobacco Risk Reduction

Lynn T. Kozlowski, Ph.D.

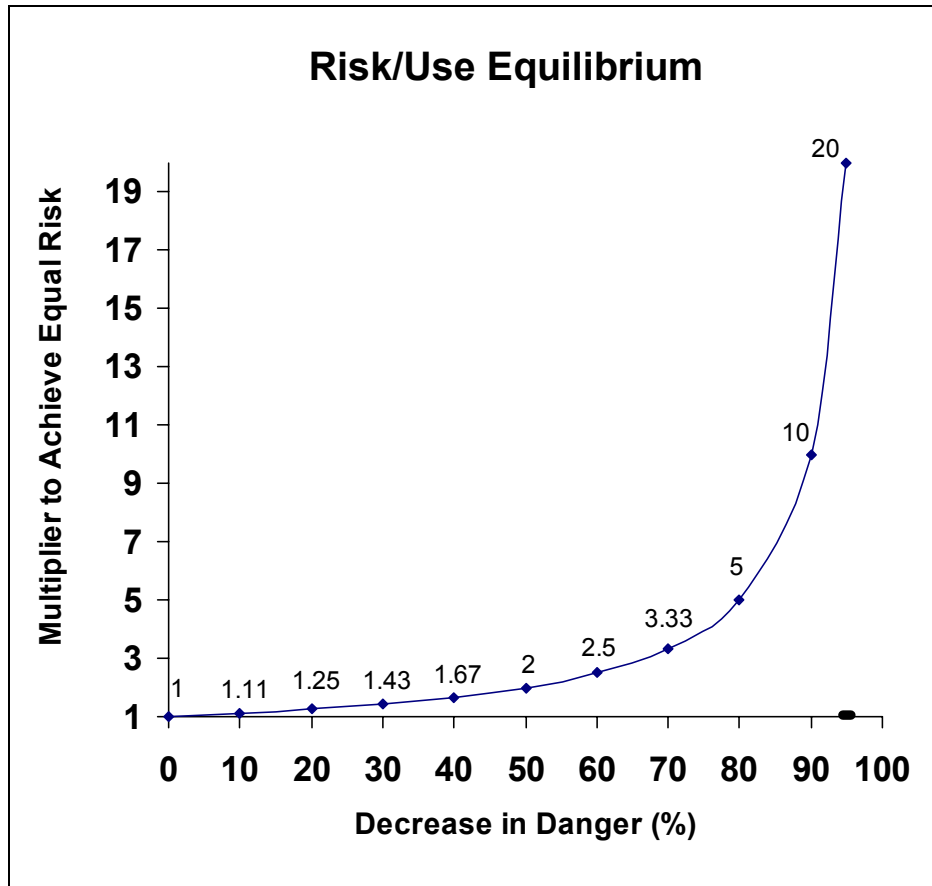
Leashing the “Pussycat” While the “Lion” Runs Free: The Problematic Mismatch of Regulations and Product Risks

In the United States, the least dangerous (and not very dangerous) form of nicotine delivery system, nicotine replacement therapy products (NRTs, or “medicinal nicotine”), has been subject to close, science-influenced oversight by the U.S. Food and Drug Administration (FDA), while the most dangerous (and extremely dangerous) nicotine delivery system, the cigarette, has been exempted from FDA and even Consumer Product Safety jurisdiction. Furthermore, cigarettes are advertised widely in magazines, their makers can add to their reputation in national advertising campaigns on television in prime time, and cigarettes can be readily, though illegally, bought at relatively low cost by even the marginally enterprising 12-year-old. Smokeless tobacco products, especially those with high levels of cancer-causing nitrosamines, are also exempted from drug and product laws. Much to the chagrin of many anti-tobacco advocates, the risks of manufactured smokeless tobacco products in the United States or Sweden, especially those with low nitrosamine levels, are much closer to the risks of NRTs than they are to cigarettes.^{1,2} Smokeless tobacco products are dangerous (NOT SAFE) products, but they are undoubtedly less dangerous (SAFER) products than cigarettes.

Population Harm and Smokeless Tobacco—Using the Risk/Use Equilibrium

Even though smokeless tobacco is *less* dangerous to individual users than cigarettes, if many more people start using the product, is it likely to produce a net loss for public health? This has become a frequent question when considering the population effects of less dangerous products for individuals. To get a sense of scale for the possible problems caused by increased use of a less dangerous product, we employ what we call *the risk/use equilibrium*—an equilibrium achieved by increasing use as risk decreases.³ Figure 1 plots the equilibrium line—the level at which a decrease in risk is made equal to the initial risk by virtue of an increased number of users. If the level of use rises faster than risk is decreased, public health would be hurt. If risk levels are decreased faster than use rises, public health would be helped. Figure 1 plots the relationship between level of risk and the increase in the number of users (as a multiplier) needed to achieve equilibrium, or, in other words, no increased population-level risks.

Figure 1. The Risk/Use Equilibrium



Each point on this curve indicates the multiplier needed to achieve a constant level of population risk, given specific levels of decreased danger per user. For example, if 100 individuals used a product with full danger (e.g., killing 100% of users), 10 times that number (1,000 individuals) would need to use a product that had 90% decreased danger, to achieve an equal health problem (100 dead in each instance). The formula is $Y=100/100-X$, where Y =Multiplier and X =Decrease in Danger, expressed in percentages. If danger is 0.1%, use would have to increase by 1,000 times to produce a problem of the same magnitude as the full-risk product (not plotted on figure). For a given risk on the curve, use that is increased by a smaller multiplier represents a public health benefit, and use that is increased by a larger multiplier represents a public health (population-level) cost.

Kozlowski LT, Strasser AA, Giovino GA, Erickson PA, Terza JV. Applying the risk/use equilibrium: Use medicinal nicotine now for harm reduction. *Tobacco Control*. 2001;10:201–203.

In 2003, a British Royal College of Physicians expert committee concluded that smokeless tobacco is from about “10–1,000 times less hazardous than smoking, depending on the product.”⁴ While it is difficult to determine the precise level of risks to health from smokeless tobacco products, it is likely to be substantially less dangerous than cigarettes, especially for low nitrosamine products.² It is reasonable to assume that very low nitrosamine products could be about 1,000 times less hazardous than smoking, which, according to the risk/use equilibrium would indicate very little chance for net public health harm.

The Specter of Smokeless Tobacco as a Causal Gateway to Cigarettes

Another concern has been that, even if smokeless tobacco is less dangerous than cigarettes, if smokeless tobacco use *leads to* (is a *causal gateway*) to cigarettes, then the reduced risk is, in a sense, only transitory. A “correlational gateway” between smokeless tobacco and cigarettes is easy to find evidence for, but a “causal gateway” in which prior use of smokeless tobacco causes an increased probability of smoking is much more challenging to prove. Some experts have argued that smokeless tobacco use in youth may lead to subsequent cigarette smoking;⁵ others have argued that smokeless tobacco may even act to prevent cigarette smoking in high-risk youth, and that much of the association between smokeless and smoking is not causally linked.^{6,7} But it is also true that marketing and prevention efforts to reduce cigarette smoking should be able to decrease the possible progression from smokeless to cigarettes. Mistaken public health information that smokeless tobacco is *as* dangerous or even *more* dangerous than cigarettes (see below) may actually promote the movement to cigarettes by smokeless tobacco users.⁸

Health Communication Issues on Smokeless Tobacco Products

The health communication practices on comparative risks of tobacco products on some major Web pages have improved recently in the United States. A few years ago, for example, in 2001, the Centers for Disease Control and Prevention’s (CDC’s) Surgeon-General’s Report for Kids asked the question “Is smokeless tobacco safer than cigarettes?” and answered “NO WAY!” and the Web page of the Substance Abuse and Mental Health Administration’s (SAMHSA’s) National Clearinghouse for Alcohol and Drug Information² contained this passage: “Q. Isn’t smokeless tobacco safer to use than cigarettes? A. No. There is no safe form of tobacco.” (accessed August 14, 2002).⁸ Kozlowski and O’Connor⁸ raised issues about the science base of such prominent public information on smokeless and questioned the ethical justification for this disinformation on comparative risks of smoking and smokeless tobacco use. There was also a formal complaint under the Data Quality Act that resulted in the National Institute of Aging changing the information on its Web site on smokeless tobacco.⁹ And in 2005 there was an analysis by Philips, Wang, and Guenzel on the “misleading and harmful public message about smokeless tobacco”¹⁰ to be found on the Internet. Accessing (or trying to access) these pages on March 28, 2006, however, demonstrated some major positive changes in the sites mentioned above and, for example, in the American Cancer Society’s Web page. It seems to have become less controversial to indicate the established risks of smokeless tobacco products and to forgo hyperbole.

“Not Safe” Is Not Enough

Health communications should also do more than inform that “there is no safe tobacco product.”¹¹ The congressionally mandated rotating warning that “WARNING: This product is not a safe alternative to cigarettes” is, in effect, a “not safe” message. At present there is an alignment of the basic message from the National Cancer Institute¹² and from the Philip Morris Tobacco Company¹³ (on their Web site and in national advertising) that there is no safe tobacco product. This message is of course true, but it is also a truism, in that “nothing is completely safe,” and it is of limited value in that the public largely knows that there is no safe tobacco product.¹¹ One of the lessons of the low-tar-cigarette disaster is that, while the public understands

that “low-tar” cigarettes are “not safe,” a public health tragedy has resulted from the simultaneous, non-contradictory belief that low-tar cigarettes were “safer” (when they are not).¹⁴ Given the years of mistaken information about the comparative risks of smokeless and cigarettes in the United States, there may also be an active need to correct the belief that smokeless tobacco is more dangerous than cigarettes.

Policy Questions

How important is it to make more dangerous products harder to get?

Would it be good for population health to adjust the expense (e.g., by taxation), the marketing/promotion, and the availability of tobacco/nicotine delivery systems, such that it is harder to get more dangerous products and easier to get less dangerous products? Would such efforts reduce the sales of the most dangerous products?

How should cross-product comparisons be done to assess health risk differences?

Based on mortality, smokeless products are less dangerous than cigarettes. It is less common to compare on the basis of morbidity or quality-of-life differences. Premature death is part of the tragedy of chronic obstructive lung disease; but long-suffering, behaviorally impaired years of life are also part of the tragedy. More complete assessments of disease- *and* disability-risk differentials are needed and may help motivate smokers to turn away from cigarettes.

What is the best way to communicate risk differences?

Research is urgently needed to develop ways to communicate science-based risk differentials in ways that minimize deception and maximize the likelihood of choices that benefit public health. For example, is it better to avoid speaking of “safer” products and better to describe them as “less dangerous” or “less harmful”?

Why aren't all smokeless tobacco products sold in the United States meeting a very low nitrosamine standard?

If the United States ever were able to establish a strong, science-based, public-health-concerned regulatory authority, low nitrosamine levels would likely be required in all smokeless tobacco products, to help reduce cancer risks. Even without regulatory oversight, one wonders why more manufacturers are not voluntarily reducing levels of nitrosamines in their products. Given that some products on the market now contain extremely low levels of nitrosamines, might health communication campaigns related to levels of toxic ingredients in smokeless tobacco help discourage the use of the more toxic products and even have an effect on the manufacturing of such products?

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