

Prepared Witness Testimony

The House Committee on Energy and Commerce

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## Can Tobacco Cure Smoking? - A Review of Tobacco Harm Reduction.

Subcommittee on Commerce, Trade, and Consumer Protection

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2123 Rayburn House Office Building

### Dr. Brad Rodu DDS

Professor, Department of Pathology  
University of Alabama at Birmingham  
LHRB 156  
Birmingham, AL, 35294

The Centers for Disease Control and Prevention report that 440,000 Americans die from smoking-related illnesses every year. However, even this enormous number does not adequately describe the extraordinary burden that cigarette smoking imposes on American society. Our research provides additional perspective: If smoking-related lung cancer did not occur, cancer mortality rates in the United States would have declined continuously since 1950 (Figure 1)(1). Thus, for the past 50 years the American cancer "epidemic" has primarily consisted of one disease, cancer of the lung, and has been due to one dominant lifestyle factor, cigarette smoking. It is compelling evidence that the anti-smoking campaign in the United States, now nearly 40 years old and of ever-increasing intensity, has failed to help adult smokers to quit.

Conventional approaches to cessation have failed because they offer smokers only behavioral therapy. An excellent example is a 1993 NCI smoking cessation manual, How to Help Your Patients Stop Smoking, which advises physicians to recommend coping tips such as "Keep your hands busy -- doodle, knit, type a letter;" "Cut a drinking straw into cigarette-sized pieces and inhale air;" "Keep a daydream ready to go."(2) Such advice has little effect on adult smokers because they need nicotine. Conventional programs also fail because they offer adult smokers only temporary nicotine replacement. But these products are expensive and provide low doses of nicotine at doses too low to prevent craving and withdrawal. A recent review of over-the-counter nicotine medications revealed that their success rate is 7% (3). The authors characterized this result as "efficacious" and

"modest." We characterize programs with 7% "success" rates as abject failures.

All these programs are failures because they require smokers to quit nicotine completely. This is incorrect, as well as ineffective. Over the past decade we published epidemiologic and clinical studies that provide the scientific foundation for a new smoking cessation strategy. It involves permanent nicotine maintenance using products other than cigarettes (4,5,6,7,8). Our strategy is based on the fact that nicotine, while addictive, is about as safe as caffeine, another widely consumed addictive drug. It is tobacco smoke, with its thousands of toxic agents, that leads to cancer, heart disease and emphysema. Eliminate the smoke, and you eliminate virtually all of the risk.

We recommend many types of nicotine delivery systems, including smokeless tobacco (SLT) products. These products are well suited to replace cigarettes because they have four key characteristics: 1) They provide nicotine levels similar to those from smoking; 2) They are vastly safer than smoking; 3) They are socially acceptable and are cost-comparable to cigarettes; and 4) there is evidence that they help smokers quit. No other products have this combination of features to help smokers quit now.

**Nicotine Delivery:** SLT rapidly delivers a dose of nicotine comparable to that from smoking (Figure 2). Thus, smokeless tobacco satisfies smokers, a necessary criterium for any agent intended as a permanent substitute. In comparison, nicotine medications provide only about one-third to one-half the peak nicotine levels of tobacco products, which is unsatisfying for many smokers.

**Safety:** SLT use has been the subject of intensive research for over 50 years. The only consequential adverse health effect from long-term SLT use is oral cancer. However, more than twenty epidemiologic studies over the past 50 years have established that this risk is very low (9). Our research documents that SLT use imposes only about 2% of the mortality risk of smoking (4,7). We found that the average reduction in life expectancy from SLT use is only 15 days (5). In contrast, the average smoker loses almost 8 years. For further context, the risk of death from long-term use of smokeless tobacco (12 deaths in every 100,000 users per year) is about the same as that from automobile use (15 deaths in every 100,000 users per year) (10).

**Social Acceptability:** Opponents of our strategy often argue that smokers will never use disgusting "spit" tobacco. That term is insensitive and inappropriate when used by health professionals. First, it is demeaning and degrading both to current SLT users and to smokers who may wish to try this strategy. Second, and more importantly, the term is incorrect, because new SLT products can be used invisibly and are more discreet than chewing gum.

Evidence that SLT products work: In 1998 we published the first trial assessing SLT substitution as a quit-smoking method (11). After one year 25% of inveterate smokers, most of whom had failed repeatedly to quit even with prescription nicotine gum or patches, had successfully substituted SLT for cigarettes. We have followed this group for seven years, and our results suggest that SLT substitution is sustainable (manuscript submitted).

Data from Sweden support the role of SLT in harm reduction at the population level. For 50 years men in Sweden consistently have had the lowest smoking rate and the highest SLT usage rate in Europe. The result: Rates of lung cancer - the sentinel disease of smoking - among Swedish men have been the lowest in Europe for 50 years. World Health organization statistics reveal that Swedish men have the lowest rates of lung cancer among 20 European countries (Figure 3). Not so for Swedish women, whose lung cancer rate ranks fifth highest in Europe (Figure 4). One of us (BR) is very familiar with tobacco use patterns in Sweden. He lived there for six months last year conducting research on this subject, resulting in two published studies with Swedish colleagues that demonstrate that SLT was primarily responsible for a decline in smoking among men from 19% in 1986 to 11% in 1999 (12,13)(Figure 5). This figure reveals the lower rate of smoking among men than among women for the entire period of study. We emphasize that this is the reverse of the pattern seen in virtually every other society in the world, where men invariably have higher smoking rates than those of women.

Our strategy has evoked criticisms that are inaccurate, irrelevant or both. The usual complaint is that providing risk information about SLT to adults will prompt children to use these products. We painstakingly point out that our strategy is tailored to adult smokers. This is not a children's issue. Eliminating children's access to tobacco is important, but the 10 million Americans who will die from smoking over the next two decades are now adults. Withholding life-saving information from these adults, in the name of children, is shortsighted, even immoral.

An extension of the children's theme is that SLT could serve as a gateway to smoking. This notion never had a sound basis, and current research shows it to be wrong. Furthermore, and most unfortunately, for twenty years the dominant public health message has been that SLT use and smoking are equally risky. In fact, this erroneous message is reinforced by the mandated warning on packages of SLT ("This product is not a safe alternative to cigarettes"). Regrettably, surveys show that 80% of smokers believe that smokeless tobacco is as dangerous as smoking, and continue to smoke. This message may also cause some SLT users to switch to cigarettes, an unfortunate and lethal behavior.

Finally, for ten years we have been portrayed as lone advocates of a flawed public health

strategy. But now good company has joined us. Last year Britain's Royal College of Physicians, one of the world's most prestigious medical societies, issued a report on tobacco regulation in the United Kingdom called "Protecting Smokers, Saving Lives"(14). This report marked the first time a major health organization acknowledged that products like smokeless tobacco are safer than cigarettes. The report stated "As a way of using nicotine, the consumption of non-combustible [smokeless] tobacco is on the order of 10-1,000 times less hazardous than smoking, depending on the product." The report continued with an even bolder statement, acknowledging that some smokeless tobacco manufacturers may want to market their products "as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community."

A growing number of public health experts now agree with our harm reduction strategy, because the antiquated quit-or-die strategy is increasingly recognized as a failure. Cigarette smoke is the problem for 48 million adult smokers. To answer the question posed by this hearing, smokeless tobacco can be part of the solution.

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### Financial Support

During the period 1993-1999 all of the developmental work for this harm-reduction strategy was completed with limited financial support from general university accounts and no external support. During that time Drs. Rodu and Cole established the scientific foundation of the strategy with publications in professional medical journals and in the general-interest press. Dr. Rodu's book, *For Smokers Only: How Smokeless Tobacco Can Save Your Life*, was published in 1995.

The publication of the first two articles in medical journals was followed by strong negative reaction from organizations that traditionally provide funding for tobacco related research. For example, in 1994 Dr. Rodu and colleagues sent a letter of inquiry to the National Cancer Institute with regard to obtaining support for tobacco harm reduction research ( Reference 15, above). The letter was never answered, but Dr. Rodu and the University of Alabama at Birmingham (UAB) were accused of possible ethical, legal and medical malpractice violations by the acting director of the NCI. This resulted in a year-long investigation of research by Rodu and others at UAB by the NIH Office for Protection

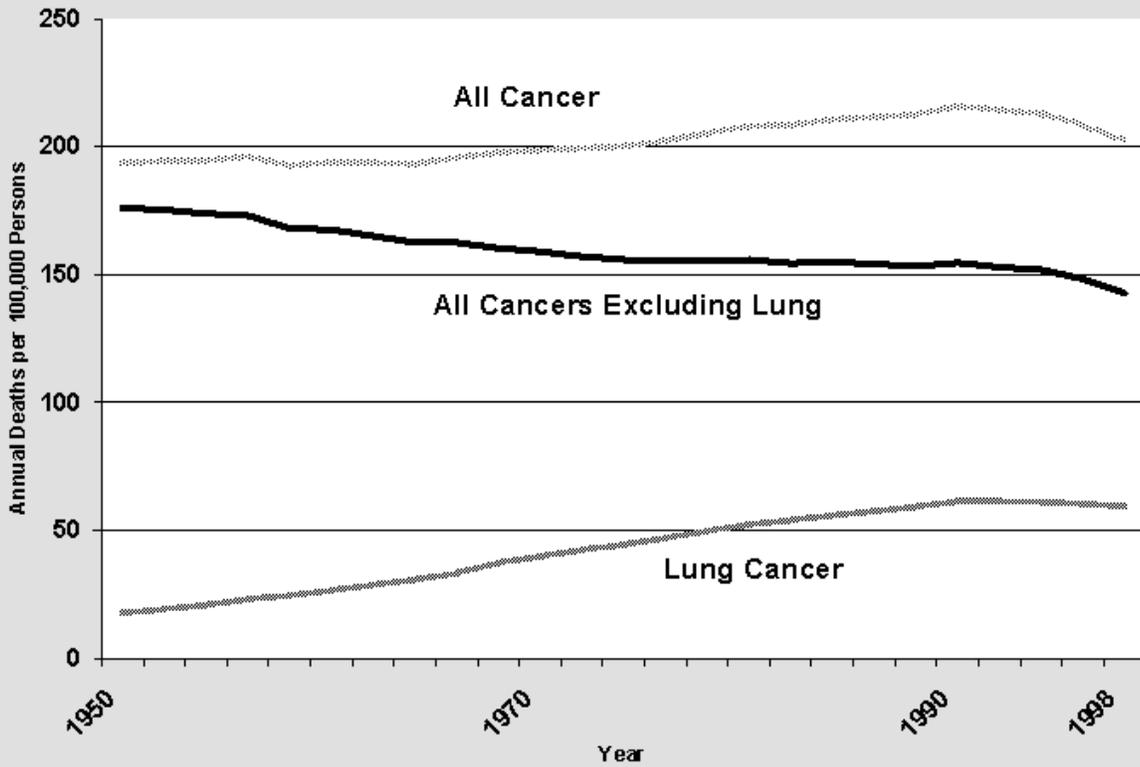
from Research Risks. This investigation concluded that the research was on a solid ethical and legal foundation, but the broad message was clear: The NIH and other organizations would not fund research in the area of tobacco harm reduction.

In 1999 the University of Alabama at Birmingham received a five-year \$1.25 million unrestricted research grant from the United States Smokeless Tobacco Company (USST) of Greenwich, Connecticut. The award supports the UAB Tobacco Research Fund (UAB-TRF), and the principal investigator is Brad Rodu.

The agreement between the USST and UAB broke new ground with regard to industry-sponsored university research. The award is completely unrestricted; the agreement specified that UAB has no obligation to USST regarding consequential work products. USST has no scientific input or other influence regarding the nature of the research projects or activities and does not have access to research reports prior to their publication. In fact, this agreement exceeds UAB's guidelines with regard to financial support from external sources, and it imposes no restrictions on academic freedom in the undertaking and communication of the research. A scientific advisory board oversees the program. The board consists of a former UAB associate dean, and a cancer center director and an epidemiologist from other universities.

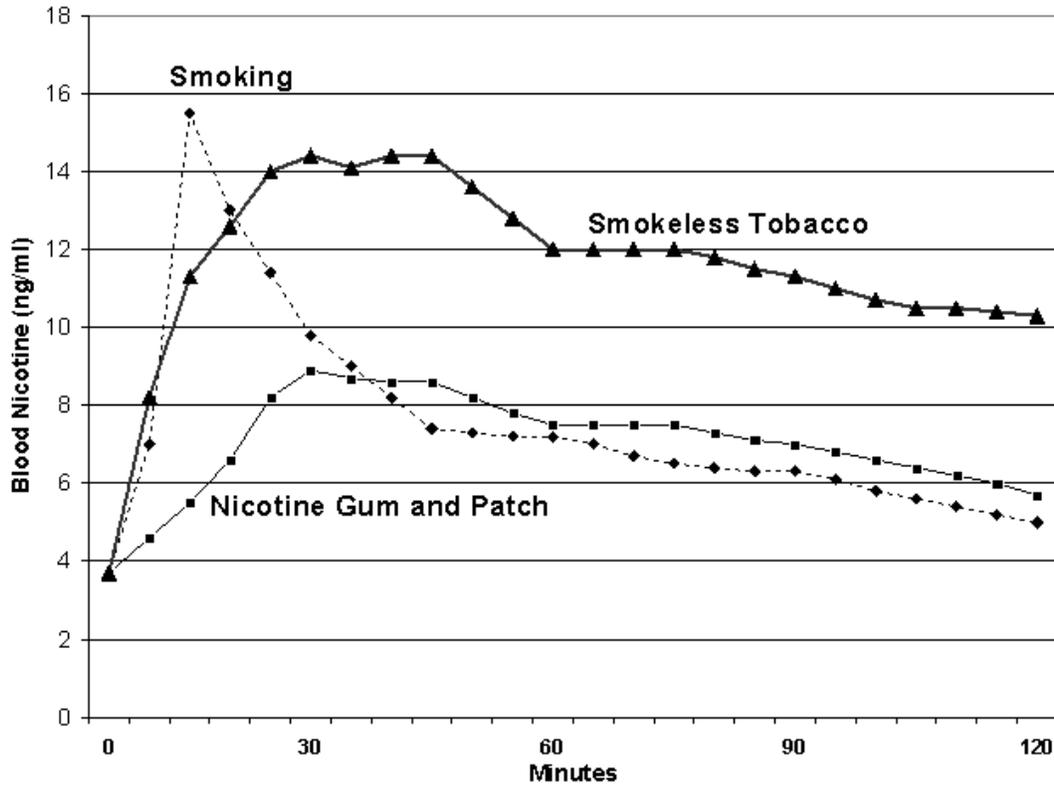
Research publications cited in this document that were supported by the Tobacco Research Fund are clearly marked by the notation (UAB-TRF).

**Figure 1. Mortality from Cancer, United States 1950-1998\***



\*Adapted from Rodu and Cole, Journal of Clinical Oncology, 2001

**Figure 2. Nicotine Concentrations Following Use of Tobacco Products and Nicotine Medications\***



(\*Adapted from Benowitz, N. NEJM 319: 1318-1330, 1998)

Figure 3. Lung Cancer Mortality Among Men Age 40+ in European Countries, 1996

WHO-IARC Worldwide Cancer Mortality Database

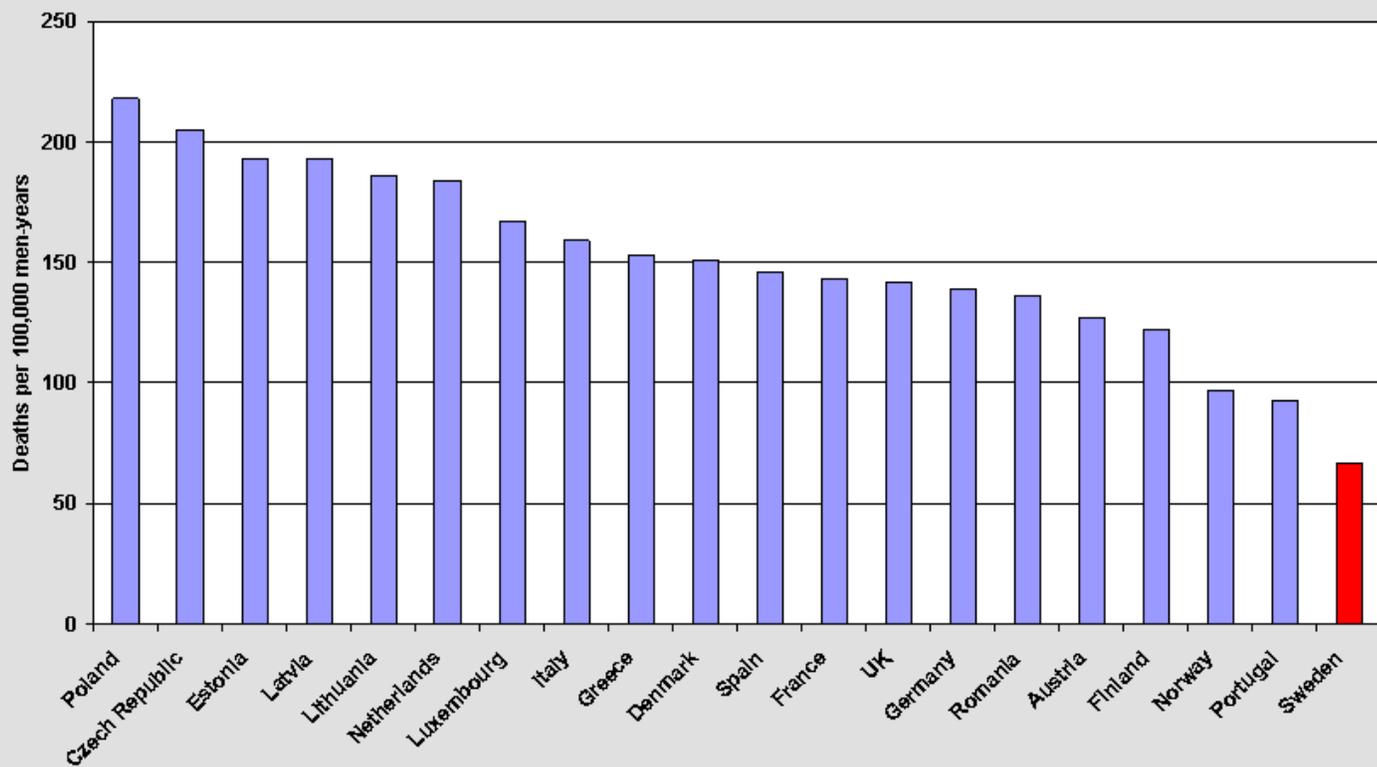
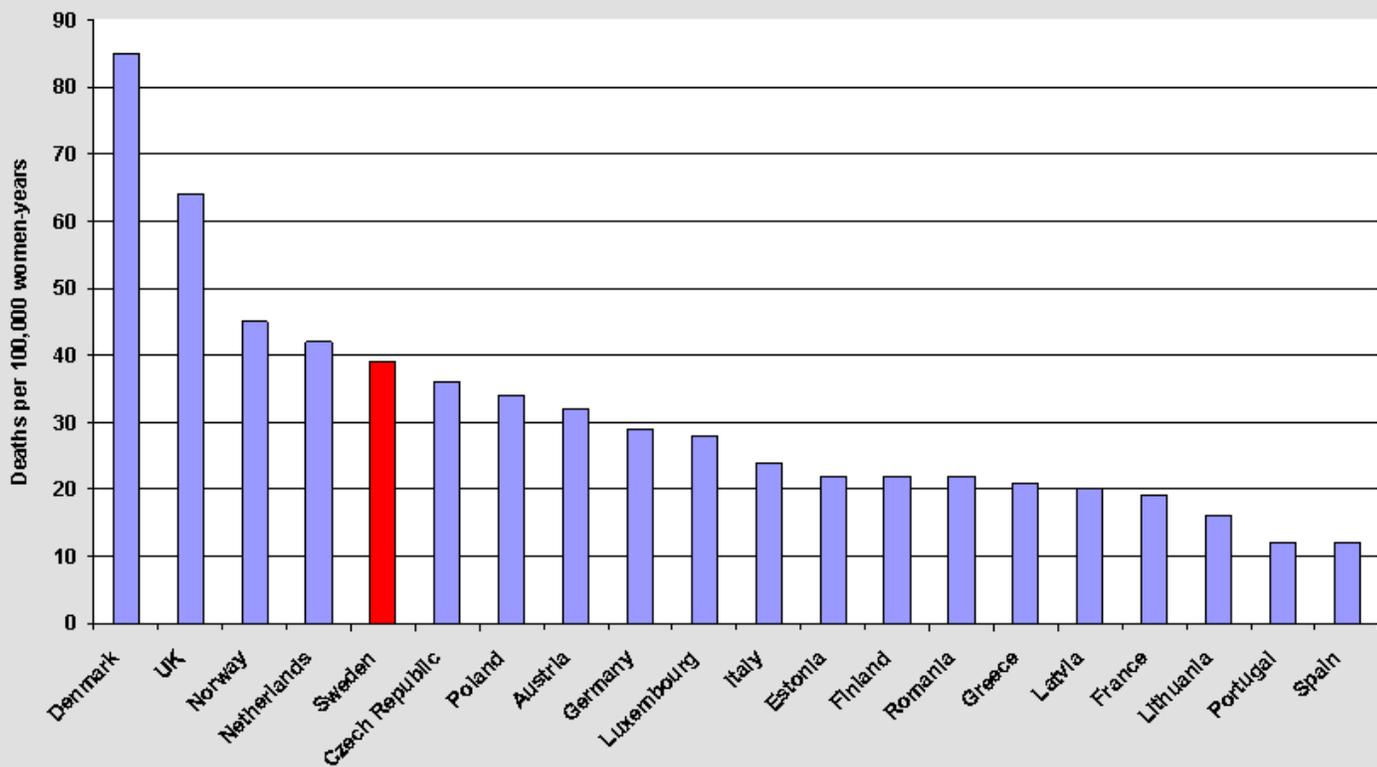
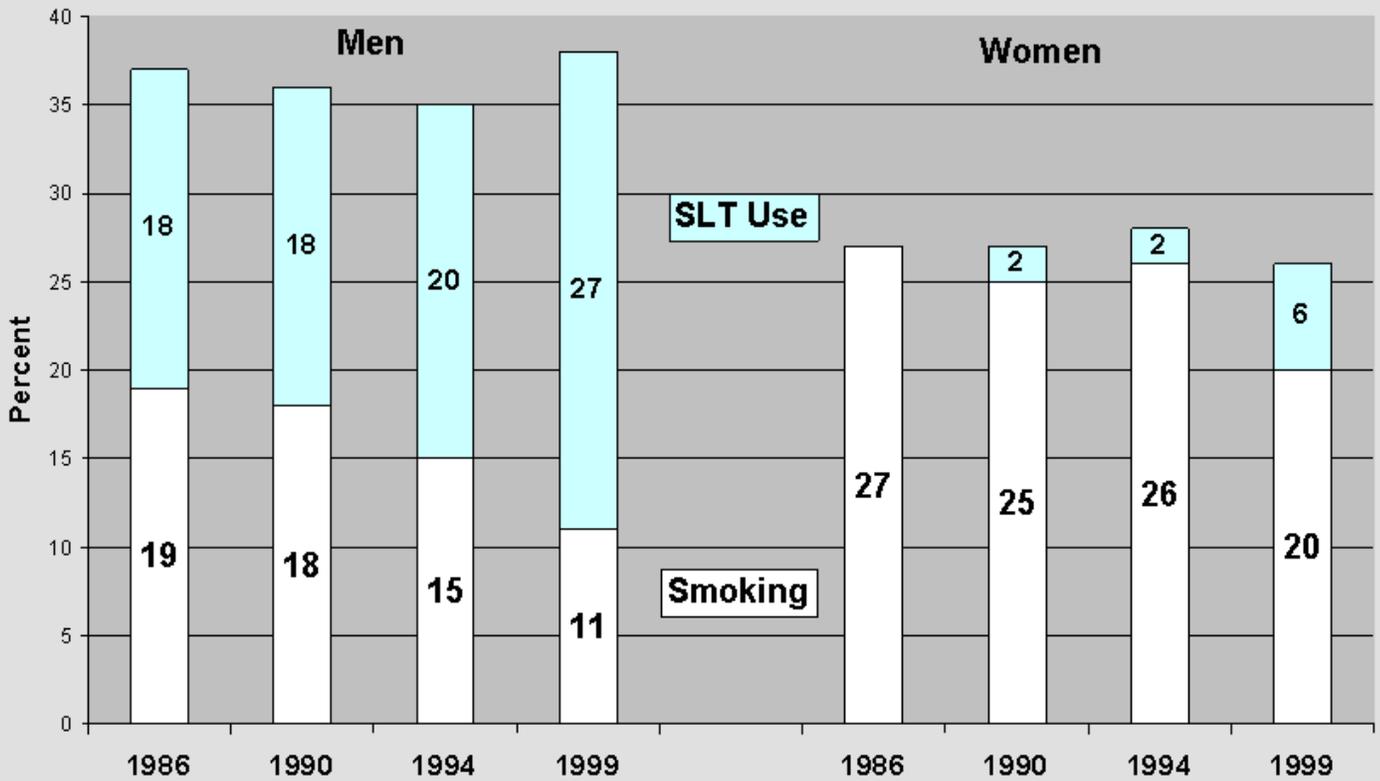


Figure 4. Lung Cancer Mortality Among Women Age 40+ in European Countries, 1996

WHO-IARC Worldwide Cancer Mortality Database



**Figure 5. Prevalence of SLT Use and Smoking in Northern Sweden\***



\*Adapted from Rodu et al, Journal of Internal Medicine, 2002

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