

SECOND-HAND TOBACCO SMOKE IN PERSPECTIVE

DRAFT May 21

INTRODUCTION

The claim that second-hand tobacco smoke is harmful to non-smokers has been a matter of public concern for a number of years. A lot of people have been persuaded that this claim is true.

We acknowledge that - for smokers - smoking itself is a risk factor for certain diseases. And, of course, some people find second-hand smoke unappealing and unpleasant. Therefore we support reasonable smoking policies that take the preferences of both smokers and non-smokers into account. But does second-hand smoke really present a meaningful health risk to people who have chosen not to smoke? Does the science justify the type of radical smoking bans prevalent in the United States and increasingly advocated by some in Europe? Not, we think, if you look at the evidence. This paper examines the epidemiological science dealing with second-hand tobacco smoke so that you can decide for yourself.

of lung cancer
- Rider 1

- Rider 2

THE SCIENTIFIC EVIDENCE ON SECOND-HAND TOBACCO SMOKE AND LUNG CANCER

Epidemiology

The scientific evidence on second-hand smoke is based principally on epidemiology. Epidemiology is the study of disease in the human population. Epidemiological studies use statistical methods to try to investigate possible links between a specific disease and factors which

2063794261

may cause the disease. Diet, occupation and family medical histories are other examples of factors investigated.

Epidemiological studies are statistical comparisons of the evidence of a specific disease in two groups: one group which was exposed to a possible suspected cause and another group which was not.

epidemiological

What does the science say?

as noted above, the EPA

Meaningful

Of over 40 epidemiological studies which address the issue of lung cancer and second-hand smoke in non-smokers, 32 report overall risk estimates that are not statistically significant, i.e. the results do not establish any association between second-hand smoke and lung cancer. Despite these findings, certain authorities have declared second-hand smoke to be a hazard to health. In 1993, the US Environmental Protection Agency (EPA) classified second-hand tobacco smoke as a "known human carcinogen". The inevitable media coverage was a key factor in fuelling public concern, and led directly to a wave of restrictions on smoking in public places in the United States and to a lesser extent in Europe.

the

recent

The EPA said that based on a compilation of 11 US epidemiological studies, non-smokers married to smokers had a "relative risk" of 1.19 for lung cancer - in other words, a 19% increased risk of lung cancer - compared to non-smokers with non-smoking spouses. A figure like 1.19 or 19% may sound meaningful. But epidemiological studies have attributed even higher relative risk numbers for lung cancer to drinking 1-2 glasses of whole milk per day

individual

2063794262

(1.62)¹, for heart disease to eating one biscuit a day (1.49)² and for rectal cancer to drinking chlorinated water (1.38)³.

Relative risk in perspective

What's going on here? Is everything dangerous? Let's step back a bit and talk about the science of "epidemiology". Scientists acknowledge that epidemiology is inexact and advise caution in interpreting relative risk numbers. When a 1995 study from the US National Cancer Institute found a relative risk of 1.5 associating induced abortion with breast cancer, the accompanying press release said: "In epidemiological research, relative risks of less than 2.0 are considered small and are usually difficult to interpret. Such increases may be due to chance, statistical bias, or effects of confounding factors that are sometimes not evident."⁴ The International Agency for Research on Cancer, part of the World Health Organisation, expressed similar reservations stating: "Relative risks of less than 2.0 may readily reflect some unperceived bias or confounding factor, those over 5.0 are unlikely to do so."⁵

CALCULATING THE RISK

The reason for this caution is due to the methodology used by epidemiologists to identify potential health risks. Epidemiological studies can take two basic forms - prospective studies and case control studies. 'Case control' studies are more common and investigate two populations - one population with a given

¹ International Journal of Cancer, Vol. 43, p. 608 (1989)

² Lancet, Vol. 341, p. 581 (1993)

³ American Journal of Public Health, Vol. 82, p. 955 (1992)

⁴ U.S. National Cancer Institute, Press Release, 26 October 1994

⁵ Breslow and Day, IARC Statistical Methods in Cancer Research, Vol. 1, p. 36, 1990

Suppose
statistical
10

disease and a 'control' population which does not have the disease. They compare the incidence of disease in individuals exposed to a possible suspected cause to the incidence of disease in non-exposed individuals. One can then, in principle, determine if there is an association between the exposure and the disease. Let's take an example. Research finds that of 100,000 people who do not drink whole milk, 10 of them die of lung cancer. Then it is found that of 100,000 people who drink 1-2 glasses of whole milk per day, 16 die of lung cancer. Therefore the relative risk for lung cancer from drinking 1-2 glasses of whole milk is 16 over 10, or 1.6.

Think back 30 years...

generally have not taken
and, sometimes, how much they smoked

But there are a number of factors which should be taken into account before drawing any firm conclusions. For instance, such a small increase could be due to one of the 20 or more recognised risk factors for lung cancer such as family history, diet, type of job and alcohol consumption. *Epidemiological studies on second-hand smoke cannot take all of these factors into account. In fact, they generally address very few if any of them. Also, epidemiologists use questionnaires to gather data. In the case of second-hand tobacco smoke, researchers question non-smokers who have contracted lung cancer and who lived or worked with smokers to ascertain how much their spouses or colleagues smoked in their presence.* Sometimes they ask the patients to think back 30 years and remember how many cigarettes were consumed around them. And often researchers question not the non-smokers concerned but their surviving relatives.

Unfortunately, human memory is far from perfect particularly if you are trying to remember what someone else did many years ago. This, and the

whether or not

2063794264

possible influence of other risk factors, explains epidemiologists' reluctance to draw firm conclusions based on relative risks of 2.0 or less. Many have raised serious questions about the validity of the EPA's classification of second-hand smoke as a known human carcinogen based on a relative risk of 1.19.

many

particularly involving infectious diseases with specific identifiable causes

THE LIMITS OF EPIDEMIOLOGY

dismissed

The science of epidemiology should not be minimized. Far from it, Epidemiology is a recognised tool for the identification of possible associations between specific factors and a human disease. It has served the cause of public health well in certain cases. Epidemiology played a role in solving the riddles of cholera and malaria. In those cases, epidemiology pointed researchers towards factors which biologists later established to be the causes of those diseases: contaminated drinking water for cholera and bites by infected mosquitoes for malaria.

Far from it

many factors singly or in combination may be responsible, and/or when

But epidemiology alone cannot establish causation, particularly when low-level relative risks are involved. According to Michael Thun, Director of Analytical Epidemiology for the American Cancer Society⁶, "With epidemiology you can tell a little thing from a big thing. What's very hard is to tell a little thing from nothing at all."

CRITICISMS OF EPA

2063794265

⁶ From "Epidemiology Faces its Limits", quoted in Science, Vol. 269, p. 164, 14 July 1995

Many scientists have contested the EPA's conclusions and criticised its misuse of epidemiology to achieve political ends. Dr. F. A. de Wolff of the University of Amsterdam's medical faculty warned of possible flaws in EPA science: "The reader of the EPA report gets the uneasy feeling that a certain selectivity cannot be excluded... This is a dangerous development against which the scientific community must actively defend itself."⁷

Journalists have been *taken to task* for accepting the EPA's conclusions at face value while rejecting independent science. In *Forbes Media Critic* magazine, Jacob Sullum wrote: "Despite serious questions about the report's assertion that ETS causes lung cancer and the process by which the EPA reached that conclusion, leading US newspapers have treated this assertion as scientific fact. In so doing, not only have they exaggerated what is known about the effects of ETS, but they have missed an important story about the corruption of science by the political crusade against smoking."⁸

Some other pertinent comments on the EPA risk assessment and on epidemiology in the area of second-hand smoke:

- Dr Jane Gravelle of the US Congressional Research Service testified to the US Senate in 1994: "The statistical evidence does not appear to support a conclusion that there are substantial health effects of passive smoking."⁹

⁷ Dr. F.A. de Wolff, Faculty of Medicine, University of Amsterdam, in "Nederlands Tijdschrift voor Geneeskunde, 5 March 1994

⁸ Jacob Sullum, *Forbes Media Critic*, Summer 1994

⁹ Dr. Jane Gravelle, et al., Senior Specialist in Economic Policy, Congressional Research Service, in testimony before a U.S. Senate Subcommittee, 11 May 1994

- **M. E. LeVois of Environmental Health Resources:** "The ETS lung cancer epidemiological data provide no scientific basis for government regulation of smoking in the workplace."¹⁰
- **Kent Jeffreys of the Alexis de Tocqueville Institution:** "The EPA has manipulated selected portions of the existing literature until it produced the desired result."¹¹
- **Dr. Gary L. Huber, professor of medicine at the University of Texas Health Center:** "In its report on ETS (second-hand smoke), the EPA did not comply with accepted principles of toxicology, chemistry and epidemiology, nor with its own guidelines for undertaking cancer risk assessment. In fact, the conclusions drawn are not even supported by the EPA's own statements."¹²

GOVERNMENT REGULATION

We have seen a wave of anti-tobacco regulation sweep the United States - including smoking bans in restaurants, in the workplace, in parks and open air stadiums, outside public buildings and in one town in Florida even in the home. In general, Europeans are far more tolerant when it comes to smoking, but in the 15 European Union member states there are already 40

¹⁰ LeVois, M.E. et al., Environmental Health Resources, 'Inconsistency between workplace and spousal studies of Environmental Tobacco Smoke and Lung Cancer', Regulatory Toxicology and Pharmacology, 1994

¹¹ Science, Economics and Environmental Policy: a Critical Examination', a research report by the Alexis de Tocqueville Institution, 11 August 1994

¹² Dr. Gary L. Huber, et al., Professor of Medicine at University of Texas Health Center in "Smoke and Mirrors: The EPA's flawed Study of Environmental Tobacco Smoke and Cancer", Regulation, Number 3, 1993

2063794267

laws on the books dictating when and where people can smoke. And in many countries, policy makers at local, regional or national levels are being asked to consider tougher restrictions.

There is no question that the vast majority of health scientists and experts are truly devoted to improving public health, but a rush to publicise relative risk statistics without due explanation of the limitations can lead to concern and unjustified regulation. Over time, a closer look at the evidence may produce conflicting and confusing information.

Margarine and apples under investigation

Consider some of the stunning reversals of public health conclusions of recent years:

- We were told several years ago to substitute margarine for butter, only to be told later that margarine's trans-fatty acids might be worse for our arteries.
- We were told that apple growers were causing cancer with a pesticide called Alar, which the EPA promptly banned. Later it surfaced that thousands of apples would have to be consumed daily for years on end to *possibly* result in cancer.
- Women were informed by a prestigious study that a diet heavy in fat would increase the risk of breast cancer. Now that has been contradicted by other studies.

2063794268

- *The May 1996 edition of the British Medical Journal published a study urging the government to cut the population's salt intake in the face of "overwhelming evidence" that excessive consumption was causing high blood pressure, heart disease and strokes. The May 1996 edition of the Journal of the American Medical Association published another study concluding that "dietary salt intake has little effect on blood pressure in the population at large."¹³*

Yet to be reversed are the perfume bans already in place in the California cities of San Francisco, Oakland and Santa Cruz, and at the University of Minnesota. These bans were enacted because of claims that a disorder known as Multiple Chemical Sensitivity (MCS) - involving symptoms ranging from headaches to heart attacks - can be triggered by everyday odours including after-shave lotions and perfumes. Time will tell.

RISK IN PERSPECTIVE

In this era of science, coupled with global information dissemination, it is difficult to keep life's risks in perspective. Every new health scare seems to demand our attention. But the latest scientific report is often presented by the media and mistaken by the layperson as the last word. Reality is otherwise. It is a process of debate - developing and testing hypotheses and then arguing about the results. That scientists disagree is all to the good. Without scientific debate progress would not occur. But today's competitive media ensure that we receive scientific findings in sequence. They announce a new study as if it were

¹³ Financial Times, 21st May 1996

2063794269

a fact, rather than what it is: a finding to be examined, then refined, and often disproven. Who is keeping track? The debate over second-hand smoke has been clouded by these forces. Science reporting, like crime reporting and political reporting, seeks out the negative side of stories. Reading the health pages of a newspaper, one might wonder, "Is everything bad for us?"

COMMON SENSE SMOKING POLICIES

Many adults choose to smoke. In the European Union, 97 million adults have made that choice. But we recognise that non-smokers *in particular* sometimes find tobacco smoke unappealing or unpleasant and common sense dictates that their preferences should be taken into account.

Accommodation works

Opinion polls show that Europeans prefer *policies* which accommodate non-smokers and smokers alike. Accommodation means smokers showing courtesy to those around them in public places, at work and in the home. It means non-smokers demonstrating tolerance when someone wants to light up. It means hotel and restaurant owners ensuring sufficient ventilation and, where necessary, providing separate sections for smokers and non-smokers. It means businesses having a sensible smoking policy, geared to balancing the preferences of both parties.

No one policy will fit every company or establishment. Each situation is different, the place is different and the people are different. Governments should avoid the temptation to regulate down to the finest detail and allow

2063794270

people and businesses the freedom to develop solutions suited to their own particular needs.

In summary, we believe the science does not demonstrate that second-hand smoke presents a meaningful health risk and that a crusade against it is unwarranted. Opinion polls show that Europeans want to decide for themselves when and where people can smoke. Clearly what they do not want or need are inflexible smoking bans.

contrary to the conclusion of the EPA that

of contracting lung cancer

2063794271