

Two recent reports from an independent Government research unit say the evidence on health effects of environmental tobacco smoke (ETS) is "weak" and "uncertain".

The Congressional Research Service (CRS) is an objective group, unlikely to be affected by either side in the smoking and health debate. They have published two reports on the health effects of ETS.

A report issued in March 1994 by Gravelle & Zimmerman was critical of the methods used by the EPA in their report on ETS and lung cancer. Some of the CRS conclusions (emphasis added):

— "Our assessment of the existing evidence on passive smoking was made as a basis for drawing conclusions about the efficiency justifications for an increase in the cigarette tax. Based on that evidence, as indicated in this testimony, **our evaluation was that the statistical evidence does not appear to support a conclusion that there are substantial health effects of passive smoking.**"

— "...[T]he epidemiological evidence for passive-smoking-related disease is **weak.**"

— "[T]he combination of the greater statistical uncertainty of passive-smoking epi studies and the potential inconsistency of those results with physical exposure models is responsible for our conclusion that the finding of increased risk from passive smoking is **'uncertain.'**"

— "The EPA study analyzed and summarized 30 studies of passive smoking lung cancer effects. Critics have questioned how a passive-smoking effect can be discerned from a group of 30 studies of which six found a statistically significant (but small) effect, 24 found no statistically significant effect, and six of the 24 found a passive smoking effect opposite to the expected relationship."

— "EPA attempted to standardize this diverse group of studies to account for statistically important differences in their methodologies. In this process, EPA reduced the standard for statistical significance from the usual standard, and the one generally used in the original studies. **It is unusual to return to a study after the fact, lower the required significance level, and declare its results to be supportive rather than unsupportive of the effect one's theory suggests should be present,** but our conclusion about the 'uncertainty' of the EPA results is not dependent upon this change in significance levels."

On 14 November a second CRS report was issued, authored by Redhead & Rowberg. This report concentrates on studies published after the EPA report, on the concept of increased responses at higher "exposures", and on potential health effects of exposure to ETS in the workplace.

The report warns: "As statistical studies, the interpretation of the findings in these studies are subject to many limitations of statistical inference, and these

limitations have been the subject of considerable controversy in the debate on ETS and lung cancer".

Some other conclusions from the second report:

— The new studies "complicated the interpretation of the evidence, since the two largest studies -- Fontham and Brownson -- found in one case a positive risk that was barely statistically significant and the other no risk at all."

— For the dose-response "... the results are not definitive. And even at the greatest integrated exposure level, the measured risks are still subject to uncertainty."

— For workplace, "a meta-analysis using all 13 occupational risk estimates ... found no association between workplace ETS exposure and lung cancer."

— The new report has an in-depth analysis of two major sources of uncertainty:

— Factors other than ETS which may affect lung cancer risks in nonsmoking women ("confounders"). "Women who consumed the highest amounts of saturated fat -- a mean value of 20 percent of their daily calories -- had a lung cancer risk value of over 6." This translates to a risk 25 times higher than that calculated by the EPA for spousal exposures to ETS.

— New data on the rates of different types of "misclassification", including that of smokers as nonsmokers. The report states that "smoker misclassification could explain all the measured risk even at high exposure levels even for studies such as Fontham and Brownson", noting that "it is clear that misclassification and recall bias plague ETS epidemiology studies."

— The second CRS report shows that ETS-lung cancer risks are definitely minute and may well be nonexistent. Using one set of assumptions the risk rate is less than that for drowning "and is in the neighborhood of risk from such causes as fires."

The results of the two CRS reports are in marked disagreement with claims from antismoking groups. Objective science simply does **not** support the concept of increased risk for lung cancer as a result of exposure to ETS.

External Analyses of the CRS Report

Since the CRS report was published, critiques have been issued by three prominent antismoking activists: Waxman, Banzhaf and Glantz. The following is an examination of those critiques.

In most cases, the activists have selected the same statements in the CRS report and have presented their own interpretations of them. The most common tactic has been to quote data referring to the Fonham study and to ignore data from the other studies (especially Brownson). Most of the quotes used come from the CRS's analysis of the Fonham study.

It is interesting that all 3 chose approximately the same areas, and that their critiques of a 75-page report were so short. Note also that 2 of the three posted their comments on the Internet (in one case, within a day of the report being issued). I have also described some areas which the three specifically chose to omit. Finally, I have not commented on the ad hominem statements made by each of the three.

Waxman

A short press release was issued on November 15 (the day after the CRS report was issued). The release begins *"A new study by the CRS has confirmed that ETS is a human carcinogen. The report also indicates that ETS may cause up to 5,500 lung cancer deaths each year"*.

— The first statement is an interpretation: the CRS report does not make any such claim.

— The second statement (note the conditional "may") is incomplete. The relevant section on page 2 of the CRS report reads *"Calculations based on data from the Fonham et al study ... result in a range of 470 to 5500 annual lung cancer deaths in the US from ETS... Data from the Brownson et al. study, on the other hand, produce no annual lung cancer deaths...."* (emphasis added).

Waxman continues: *"Since the release of the 1993 EPA report classifying ETS as a human lung carcinogen, there have been four major new studies of ETS. Three of the four studies report a statistically significant increase in lung cancer rates at the highest exposure level"*.

— Technically, the word "rates" should be replaced with "risks".

— The CRS report on page 2 does make the above statement, but it goes on to say *"While there is evidence of an upward dose response trend, the results are not definitive. And even at the greatest integrated exposure levels, the measured risks are still subject to uncertainty"* (emphasis added)..

In a repetition of an earlier statement, Waxman says *"Using data from the recently completed Fonham study, CRS calculated that the range of annual lung cancer deaths from exposure to ETS is 470 to 5,500 with a mean value of 2,780 -- virtually the same level of deaths estimated by EPA"*.

— The CRS report does make the statement, but it continues *"Data from the Brownson et al. study, on the other hand, produce no annual lung cancer deaths from ETS..."* (emphasis added).

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Waxman says "For a nonsmoker married to a smoker, the lifetime risk of dying from lung cancer is 1 in 500. For a nonsmoker who is not married to a smoker, but who is exposed to an average level of ETS outside the home, the lifetime risk is 1 in 1,500".

The figures quoted are derived from the statement made on page 57 of the CRS report: "Using the Fontham data, there is 7/1000 of one per cent chance of a person exposed to both background and spousal smoke dying from ETS in a given year, or about 2/10 of one per cent chance of dying in a lifetime. For a person exposed only to background ETS, the annual risk is about 2/1000 of one per cent and the lifetime risk less than one tenth of one per cent".

The Waxman statement excludes the reason why CRS made such a calculation, given by the CRS immediately before the selected quote: "Another way of expressing this risk is to compare it with the chance of dying in a given year, or in a lifetime, using some rough numbers. To take a major risk that is similar in nature, the chance of dying from any type of cancer in any one year is about 1/3 of one percent; assuming a life span of 70 years and an equal chance of dying in each year, there is a 20 percent lifetime chance of dying from cancer". **Thus, the lifetime lung cancer risk (2/10 of a percent) of the maximally ETS-exposed person is one hundred times less than is the lifetime risk (20 per cent) of dying from any kind of cancer.**

The Waxman quote also excludes this relevant sentence from the quote: "By comparison, auto accidents account for a lifetime risk about 1.5 percent and homicide about 1 percent". **Thus, the maximally ETS-exposed person over their lifetime is 5 times more likely to die in a homicide than to die from lung cancer.** The CRS report goes on: "Actually, the relative risk is even smaller, especially when compared to causes such as accidents".

Waxman also omits to mention that the lifetime lung cancer risk calculated from the Brownson study is zero.

Waxman ends by saying "... even under the threshold model advocated by the tobacco industry, ETS would remain a significant source of lung cancer in nonsmokers -- causing 440 to 530 lung cancer deaths each year".

The CRS on page 50 of their report clearly state "It is important to point out that the threshold illustration is a hypothetical example and does not mean that any lung cancer which might result from ETS exposure would actually exhibit a threshold dose response .. the use of a threshold model in these calculations is only to simulate the upper limit of possible dose response relationships".

Waxman omits the following statement on page 19 of the report: "The chemical similarities between mainstream and sidestream smoke and the association of active smoking with lung cancer are reasons for a possible relationship between ETS and lung cancer. But, they do not prove the relationship, since ETS is substantially diluted and aged compared to even low levels of active smoking". **This statement effectively negates the entire working hypothesis of the EPA report on ETS and lung cancer.**

Waxman also makes no mention of the workplace data presented in an appendix. These data clearly show **no elevation in risk for lung cancer as a result of being exposed to ETS at work.**

Glantz

Glantz apparently placed some comments on the Internet on 12 December 1995. He quotes verbatim a paragraph from page 2 of the CRS report (the same paragraph examined above by Waxman), and says *"given the uncertainties in computing these estimates, there is no practical difference between 2780 and 3300"* (from the Fontham study and the EPA report, respectively).

— The relevant point here is not that the two estimates are similar (the EPA figure is driven in a major way by a subset of the Fontham data, so one would expect the two figures to be close), but that another study of approximately the same size as Fontham (Brownson) arrives at zero annual lung cancer death risks.

Glantz then quotes in full the CRS paragraph on threshold models (page 50), considering that *"there is no evidence that there is a threshold for cancer induced by secondhand smoke."*

— The CRS states on page 52 *"A certain level of exposure is required to cause risk" and "the fact that no risk is found in the low spousal exposure case indicates that there is not enough exposure of any kind to induce effects"*.

— On page 53 the CRS states *"if there are any lung cancer deaths from ETS exposure [note the conditional "if"], they are likely to be concentrated among those subjected to the greatest, integrated exposure levels, and, as a consequence, primarily among those nonsmokers subjected to significant spousal ETS."*

Glantz quotes in entirety a paragraph from Page 6 of the CRS report, claiming from this that the *"CRS recognizes that the EPA report has received wide support from the scientific community and that all the criticism is coming from the tobacco industry"*.

— The CRS says on page 25 *"...the conclusions in the EPA study have generated considerable controversy. While receiving support from a segment of the scientific community, others have registered criticism focusing on the uncertainty in such low risk values and argued that there were potentially other explanations for these results if indeed they were not due to chance alone"*.

— In fact, the CRS itself has been very critical of the EPA, in their report of 8 March 1994 and in testimony to the House Committee on Energy and Commerce, Subcommittee on Health and the Environment, May 11, 1994. Other groups are mentioned in the footnote to the CRS paragraph quoted by Glantz.

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Glantz gives as his bottom line *"despite the weakness of the approach in the CRS report, it reaches essentially the same conclusions as the EPA and is certainly not a repudiation of the EPA"*. This is an opinion, not fact. Selected CRS statements on this summary:

— From the first report, quoted on page 7: *"the statistical evidence does not appear to support a conclusion that there are substantial health effects of passive smoking."*

— *"The risk estimate in the final Fontham study is similar to the original one included in the EPA study, but attains statistical significance because of its larger numbers of observations. The other three new studies show, in one case, no effect, in the other cases a positive effect that is not statistically significant..."* (page 23).

— Referring to the EPA's meta-analysis: *"Even when overall risk is considered, it is a very small risk and is not statistically significant at a conventional 95 percent level (page 25)."*

— *"Both the size of the effects measures and the lack of consistent, statistically significant data lead to considerable uncertainty"* (page 30).

— *"It is clear that misclassification and bias plague ETS epidemiology studies. It is also clear from the simulations that modest, possible misclassification and recall bias rates can change the measured relative risk results, possibly in dramatic ways"* (page 45).

Glantz makes the same **omissions** as Waxman above (biological plausibility, workplace exposures), plus he does not make any comments on the appendix on cardiovascular disease, an area where he has declared a major scientific interest.

Banzhaf

Banzhaf issued a three-page statement on 15 November 1995, also on the Internet.

In addition to comments which are very similar to those used by Waxman and Glantz, Banzhaf claims *"the number of lung cancer deaths from secondhand smoke is almost equal to all deaths resulting from surgery, and exceed those caused by X-rays, bicycles, home appliance accidents, commercial aviation, lightning, skiing and vaccinations"*.

— The data Banzhaf quotes come from Table 10 of the CRS report, where the estimated number of deaths for "surgery" is 2800 and 3728 for the selected combination. The range given in the table for ETS-lung cancer is 470 to 5500 for the Fontham data (Banzhaf has probably made an error in his comparisons of the data), but the figure for ETS-lung cancer **based on the Brownson data is zero**.

CRS REPORT RAISES DOUBTS ABOUT ETS/CANCER CLAIMS

In November 1995, the Congressional Research Service (an independent research arm of the U.S. Congress) released a report analyzing the potential health effects of environmental tobacco smoke (ETS). The CRS was asked to review the ETS issue in detail following Senate testimony in May 1994 by CRS staff members that, "The statistical evidence does not appear to support a conclusion that there are substantial health effects of passive smoking."

In the November report, the CRS made numerous findings that strongly support the earlier conclusions by the CRS staff -- that the risk of lung cancer from ETS exposure is very small, if, in fact, it exists at all.

The CRS examined a number of issues surrounding the alleged link between lung cancer and ETS. In many cases, their findings agree with the tobacco industry's views and conflict with those of various government and private agencies and organizations that have claimed that there is a proven association between ETS and lung cancer.

For example:

BIOLOGICAL PLAUSIBILITY DOES NOT PROVE ETS/LUNG CANCER RELATIONSHIP

"The chemical similarities between mainstream and sidestream smoke and the association of active smoking with lung cancer are reasons for a possible relationship between ETS and lung cancer. But they do not prove the relationship, since ETS is substantially diluted and aged compared to even low levels of active smoking."

MISCLASSIFICATION, BIAS AND CONFOUNDERS MAY INVALIDATE EPIDEMIOLOGICAL RESULTS

- "[S]imulated calculations indicate that misclassification can be a potent uncertainty in these ETS epi studies, and could account for the measured risk values. Further research on this issue appears called for."
- "The evidence from these studies appears inconclusive about whether confounders may be responsible for the measured ETS risk values, particularly those at the most extensive ETS exposure levels."
- "It is clear that misclassification and recall bias plague ETS epidemiology studies. It is also clear from the simulations that modest, possible misclassification and recall bias rates can change the measured relative risk results, possibly in dramatic ways. Aside from smoking

misclassification, however, attempts to correct for them have not taken place because there is currently no information available on how to carry out such corrections."

- "It is possible that any observed elevation in occupational risk is due to confounding or misclassification bias."

META-ANALYSIS OF U.S. STUDIES IS NOT STATISTICALLY SIGNIFICANT

"Even when overall risk is considered, it is a very small risk and is not statistically significant at a conventional 95 percent level."

ZERO THRESHOLD THEORY IS QUESTIONED

- "The pack-year studies also offer evidence that non-smokers exposed to lower levels of ETS -- below 40 pack-years -- have little or no relative risk of developing lung cancer from ETS."
- "Nevertheless, the possibility cannot be ruled out that a threshold level does exist if there is a real effect from ETS."

ETS EXPOSURE IN THE WORKPLACE IS NOT A PROVEN RISK

"If, on average, workplace ETS exposure is lower than residential exposure, then it is likely that relatively few workers would be exposed to sufficient ETS to be at increased risk for lung cancer."

- "[H]ad OSHA performed a meta-analysis, it seems likely that it would have found no increased lung cancer risk from occupational ETS exposure."
- "It is possible that any observed elevation in occupational risk is due to confounding or misclassification bias."

IT IS IMPORTANT TO PUT RISK IN PERSPECTIVE

- "To put estimates of possible lung cancer deaths from ETS in context, it is useful to compare them to other risks resulting in premature deaths."

- "Based on the Fontham study, the risk rate for those exposed to spousal smoke falls between rates from causes such as drowning, but below home accidents and homicide, and far below major causes. The risk for those not exposed to spousal smoke is much smaller, and is in the neighborhood of risks from causes such as fires. The average risk implied by the Brownson study, for either group, is negligible or zero."
- "Using the Fontham data, there is a 7/1000 of one percent chance of a person exposed to both background and spousal smoke dying from ETS in a given year, or about a 2/10 of a percent chance of dying in a lifetime. For a person exposed only to background ETS, the annual risk is about 2/1000 of one percent and the lifetime risk less than one tenth of one percent. By comparison, auto accidents account for a lifetime risk about 1.5 percent and homicide about 1 percent."

(This means that, based on the only U.S. study that found a statistically significant overall increase in lung cancer risk from ETS exposure, you are more than 10 times as likely to get murdered or more than 15 times as likely to die in an auto wreck as you are to die from lung cancer associated with ETS.)