

THE 2006 U.S. SURGEON GENERAL REPORT ON THE CLAIMED RISKS OF ENVIRONMENTAL TOBACCO SMOKE, AND THE EPIDEMIOLOGIC STUDIES ON WHICH IT IS BASED, REPRESENT A MASSIVE CASE OF DELIBERATE SCIENTIFIC MISCONDUCT, MISREPRESENTATION, FABRICATION, AND FALSIFICATION.

Premises

Studies claimed to be scientific, and presenting quantitative conclusions in precise statistical terms, by necessity and by definition must have derived those conclusions from primary data that have been measured with comparable accuracy. The studies also must warrant the authentic identity of those data and their relevance to the conclusions.

The same studies must warrant that conclusions are not corrupted by experimental or observational confounders, nor by data collection and interpretive biases. When reproduced by different investigators, the studies must yield consistent results.

Background

While there is agreement that cigarette smoking, like most pleasures, is risky, the zealous people who wish to abolish smoking could not have mounted the antismoking crusade without inventing the risks of environmental tobacco smoke (ETS).

Under the flag that the end justifies the means, those risks have been used to force draconian regulations to criminalize and marginalize lawful citizens, pitting children against parents, spouses against spouses, and people against people to the point of having raised homicidal animosities against smokers in some extreme cases – and those cases can be documented upon request.

Such policies are justified as being grounded on scientific findings and conclusions. The most recent of such justifications is the ostensibly authoritative report on the claimed risks of ETS, released on June 27, 2006 by the US Surgeon

General.¹ The report is not a primary epidemiologic study of ETS effects, but the summary of a selection of such studies published in the open literature.

At the press conference introducing the report, the Surgeon General personally asserted that “There is no risk-free level of secondhand smoke exposure”, that “Breathing secondhand smoke for even a short time can damage cells and set the cancer process in motion”, and that for children exposed to secondhand smoke “Eventually, they’ll develop cardiovascular disease and cancers over time.”

Such assertions are not sustained by the studies reviewed, and by the analytical methods of 2006 Surgeon General’s report on ETS. On the assumptions that The Surgeon General and the compilers of the report are competent professionals; those assertions are deceptively grounded on data that the compilers of the report and the Surgeon General knew to be fictitious.

Evidence of fraud

For brevity, the documentation of this complaint focuses on the alleged risk for lung cancer, although the arguments that are directly applicable to the alleged risks for other diseases. The 2006 Surgeon General’s report (SGR) describes ETS risks with a precision of two decimal points: for instance RR=1.21 for lung cancer. Such a precise assessments of risk must fulfill the inescapable requirement that the primary data utilized were indeed what it was claimed to have been measured; that measurements were accurate within an explicit and testable margin of error; that the results could not be explained by spurious experimental, observational or interpretive interferences; and lastly, that repeated studies yielded consistently reproducible results.

In assessing ETS risk it is necessary to find groups of non-smokers that have been variously exposed to ETS. Exposure alone, however, could not be the basis of risk estimates, because risk could be determined only in relation to the biologically effective doses that people internalize, a necessity that the SGR recognizes in Figure 1, page 18.²

¹ *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. June 27, 2006. <http://www.surgeongeneral.gov/library/secondhandsmoke/>*

² See 1, Figure 1 at page 18.

Figure 1.1 The determinants of exposure, dose, and biologically effective dose that underlie the development of health effects from smoking

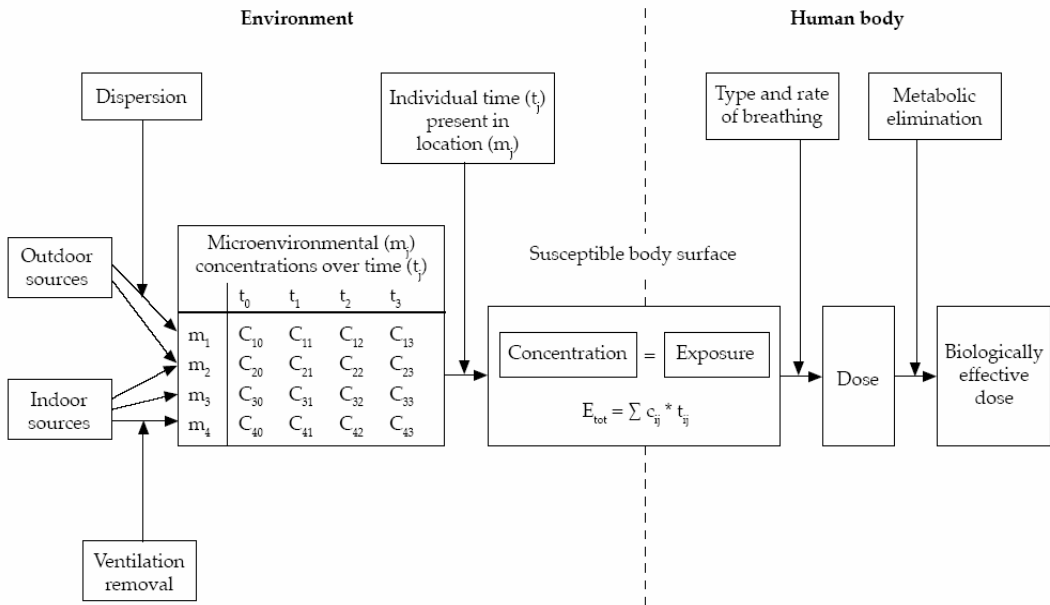


Figure 1 of the SGR clearly identifies that actual internalized doses cannot be derived from exposure data without knowing the simultaneous rates of individual inhalation and metabolic transformations. Effectively, those rates cannot be measured and cannot be known because rates vary continuously and independently from location to location, moment to moment, day to day, year to year. The changes are rapid and chaotic and make it impossible to obtain actual and cumulative measures over time. Although recognizing the problem, the SGR avoids any substantive discussion of the issue, with the tacit admission that, in fact, the absolutely crucial measurements of biologically effective doses are impossible. Such an admission is alone sufficient to disqualify any pretence of scientific representation of the risks claimed by the SGR and by epidemiologic studies of ETS risks.

Indifferent to this capital impediment, the SGR insists on exposure as a determinant of risk, despite describing in some detail the many insurmountable obstacles to its assessment. The report openly admits that studies directed at validating exposure reports “showed a high degree of repeatability for questions

concerning whether a spouse had smoked, but a lower reliability for responses concerning the quantitative aspects of an exposure. “³

Besides issues of dose and exposure, over two dozen widespread lung cancer risks other than smoking have been reported.⁴ Thus risk assessment studies must also determine whether the lung cancers observed are caused by those other risks rather than ETS. In reality, epidemiologic studies of ETS and lung cancer could not and did not cope with such fundamental problems.

Nonexistent Measurements of Exposure

Lung cancer develops slowly and generally manifests at advanced ages after cumulative lifetime experiences. It means that even if ETS exposure could measure risk – and it cannot - it should be measured as the sum-total of exposure episodes over the lifetime of individual non-smokers. Yet, as noted, the myriad momentary changes of exposure over lifetimes would be impossible to track, and therefore cumulative assessments of individual exposures are materially impossible.

Still, this is what ETS studies falsely claim to have done and what the SGR endorses, for it could not have been an actual continuous measure of exposures starting from any person’s birth through the 60-70 years needed for lung cancer to develop, as the studies claim. So truly impossible are those assessments that no epidemiologic study has ever measured the ETS exposures of study subjects. Instead, all epidemiologic studies of ETS shifted the burden on individual study subjects, falsely pretending they were capable of measuring their own lifetime exposure. This pretense has been doubly deceiving, first because it falsifies the conclusions of the studies, and second because it deceived study participants, who likely would have objected to the use of their extremely vague recalls as precise measurements of their lifetime exposures.

Typically, 60-70 year old self-declared non-smokers were asked to recall how many cigarettes, cigars or pipes might have been smoked in their presence during lifetime since early childhood, how thick the smoke might have been in the rooms, were the windows open, and similar vagaries. The resulting answers, elicited in a few minutes usually over

³ See 1, p.19

⁴ Gori GB, Mantel N. Mainstream and environmental tobacco smoke. *Regul Pharmacol Toxicol* 1991;14:88-105.

the phone - or by proxy recalls provided by relatives of deceased persons – have been recorded by all studies as precise numerical measures of lifetime exposures, as if taken by identical metrics and error and bias free.

As an example of these contrived absurdities, Appendix A of this complaint reproduces the questionnaire used by the International Agency for Research on Cancer, an agency of the World Health Organization. Based on the questionnaire, the agency conducted a series of studies presented as the best of epidemiologic studies of ETS and risk.

In reality it is well known how difficult it is to remember what one ate a week ago, never mind 40 years ago, 4 times a day, and during childhood. Psychologists also know how adaptive memory recalls can be in response to leading inducements.⁵ Thus it is transparently impossible to summarize from a few momentary and vague recalls, and with an absurd expectation of precision, the total exposure to smoke over the 40-50 years of a prior lifetime. The plain truth is that no reliable measure of ETS exposure was ever possible or ever performed. Therefore, epidemiologic studies of ETS have produced statistical estimates of risk based not only on improper exposure data, but also on exposure data that are indisputably illusory.

Fatal Flaws

Even assuming that ETS exposures could be measured to assess risk – and they cannot -, the 20 per cent lung cancer risk elevation claimed by the Surgeon General as a summary of epidemiologic studies, is also not credible because the studies have not accounted for the likely interference of a whole series of known lung cancer risks, and for prejudices and biases that are inevitably present.

For instance, the SGR acknowledges that people with lung cancer are more prone to amplify their recall of ETS exposure than those who are disease free, and that many study subjects will fib about being non-smokers and thus will contaminate the results. More than two dozen independent risk factors for lung cancer are reported in the professional literature.⁶ For coronary diseases the literature reports almost 250 independent risk factors.⁷ The SGR acknowledges

⁵ Schacter DL, Addis DR. Constructive memory: The ghosts of past and future. *Nature* 2007;445:27

⁶ Gori GB, Mantel N. Mainstream and environmental tobacco smoke. *Regul Pharmacol Toxicol* 1991; 14:88-105.

⁷ Hopkins PN, Williams RR. A survey of 246 suggested coronary risk factors. *Atherosclerosis* 1981; 40:1-52.

that all such interferences have not been credibly measured and controlled for in studies of ETS and risk. The SGR also mentions a publication bias, whereby studies reporting an elevation of risk have been preferentially published, with disregard for studies reporting no risk or risk reduction. Thus, the claimed small risks of ETS for lung cancer – and for other diseases - are doubly fictitious because of interferences that were not and could not be calculated and corrected.

Inconsistent outcomes

It is no surprise, therefore, that different studies have produced contrasting results. Of the 75 published studies of ETS and lung cancer, some 70 percent did not report statistically significant differences of risk and are moot, approximately 17 percent claim an increased risk, and 13 percent imply a reduction of risk.⁸ Thus, reported studies do not offer consistent results, and overall cannot be interpreted for or against risk.

Absurd Methodology

The overwhelming majority of ETS studies are of the case-control kind, and do not claim risk on the basis of higher or lower frequency of lung cancer in relation to higher or lower exposures to ETS. Rather, groups of self-declared non-smokers all with lung cancer and exposed to ETS have been compared to groups of self-declared non-smokers without lung cancer, and also exposed to ETS.

As a generic example, some studies may have found that non-smokers without lung cancer recalled ETS exposure at a standardized rate of 100, while non-smokers with lung cancer recalled exposure at a standardized rate of 120. The epidemiologic studies on ETS and the SGR adopt the incongruous assumption that a reported 20 per cent excess of exposure recall represents a 20 per cent excess risk.

⁸ http://www.data-yard.net/ets_summary/index.htm

The mirror implication is that a 20 per cent difference in exposure recall – which is impossible to verify or measure in the first place – is responsible for all the lung cancer of the non-smokers with the disease, while non-smokers who remember only slightly less exposure remain incredibly and totally immune from that cancer.

To complete the absurdity, a number of studies also reported the reverse, namely that non-smokers with lung cancer recalled less ETS exposure than non-smokers without the disease. Should such reports carry the equally absurd implication that ETS exposure protects from lung cancer?

Conclusion

No epidemiologic study has ever measured actual lifetime doses of ETS, nor lifetime exposures to ETS. No study has determined the recall bias of people with lung cancer. No study could guarantee that some self-declared non-smokers were in fact or had been smokers. No study could exclude that the lung cancers observed might have been caused by many known lung cancer risks and thus not by ETS. Plausible publication biases were not accounted for. Most studies did not report statistical differences of risk, and some implied a reduction of risk. In a nutshell, the primary data, their statistical analyses, and the claimed lung cancer risks of epidemiologic studies of ETS are illusory-, and by extension the ETS risks claimed by the SRG are equally illusory.

Implicit in the SGR, the professional prominence of epidemiologists and their technical resources and expertise exclude that the misrepresentations just described were the product of naïve incompetence. In the Spring of 2006, the obviously competent Oxford epidemiologist Sir Richard Peto – a leading intellect of the campaign against ETS - was called to testify to the UK House of Lords Select Committee on Economic Affairs, which was inquiring about government policy on the management of risk, including the claimed risks of ETS.

Asked to quantify the hazards of ETS, and confronted with his own reputation and honesty, Sir Richard replied: “I am sorry, I know that is what you would like to be given, but the point is that these risks are small and difficult to measure directly....I am sorry not to be more helpful; you want numbers and I could give you numbers..., but what does one make of them?...These hazards

cannot be directly measured.”⁹ He declined any quantification of ETS risks, with the clear implication that quantification is impossible.

The anachronism of the tobacco culture and economy may be slated for extinction in a nurturing civilization, but why must it happen under the tyranny of a deception falsely disguised as scientific fact? The deception is doubly grating, when the wilfully flawed SGR runs against the US statutory requirements of “ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by a government agency”¹⁰

Violation of research integrity is reprehensible enough at the hands of individual researchers. It becomes much more grating and reprehensible when perpetrated by public authorities for whatever reason, where not only science and truth are violated, but the sacred trust of a democratic government is irreparably breached.

⁹ <http://www.publications.parliament.uk/pa/ld200506/ldselect/ldconaf/183/6021405.htm>

¹⁰ Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554) Sec.515. <http://www.fws.gov/informationquality/section515.html>

