



International
Scientific Committee

A CRITIQUE OF:

Invernizzi G, et al. Real-time measurements of indoors particulate matter originating from environmental tobacco smoke: a pilot study. *Epidemiology and Prevention* 2002; 26:30-34.

Epidemiological premises

The paper accepts uncritically a causal connection between urban atmospheric particulate and increased overall mortality, as well as morbidity for a variety of respiratory conditions. Although summary assessments by the Italian government and WHO are referred in the paper, the original epidemiological studies were conducted in the USA, where to this date they have not been utilised by the Environmental Protection Agency to regulate airborne particulates as the Italian government seems to have done (for a review of the studies see: Krewski, D., et al. Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate Air Pollution and Mortality. Cambridge, MA: Health Effects Institute. 2000. www.healtheffects.org). In the USA the credibility of those studies is very much disputed and still under scrutiny. An additional blow to the credibility of those reports came in early June 2002 from the very authors of the studies, who revealed a gross error in their use of the statistical software used to analyse the data, admitting that the original and tenuous correlation values had been overstated by over 100%. Greater reduction is likely to be announced after additional consideration of the true impact of parameter setting in the statistical software program (Statistical error leaves pollution data in the air. *Nature*. 2002; 413: 677; Software glitch threw off mortality estimates. *Science*. 2002; 296:1945-6).

Besides this recently revealed statistical error, the epidemiological studies in question suffer of irremediable structural problems. In the first place, they assume that all particulates are identical in their influence on mortality and morbidity, and that any control would be beneficial (For a critique see: Lippmann M, Schlesinger RB. Toxicological bases for the setting of health-related air pollution standards. *Annu Rev Public Health*. 2000;21:309-33; Lipfert F W, Wyzga R E. Air pollution and

mortality: Issues and uncertainties. *J Air Waste Manag Assoc*. 1995;45(12), 949-966; Phalen R F, McClellan R O. PM- 10 research needs. *Inhalation Toxicology*.1995;7: 773-779; Phalen R F. Uncertainties relating to the health effects of particulate air pollution: The US EPA's particle standard. *Toxicology Letters*. 1998; 96-97, 263-267).

The studies are of the questionable ecological type, and have defined particulate exposure as machine measured averages, rather than actual measures at the level of individual persons, the latter being influenced in many ways that do not pertain to the measurements taken by machines in fixed locations. The correlations are very weak, close to 1.0 and below 1.0 in some studies, suggesting a contrary protective effect (See: Lipfert FW, et al. The Washington University-EPRI Veteran's Cohort Mortality Study: Preliminary Results. *Inhalation Toxicol*. 2000; 12(4): 41-73).

The studies pretend to raise regulatory concern by focusing on airborne particles of 2.5 µm (PM_{2.5}) in diameter, regardless of their chemical composition, although in reality any PM encompasses a bewildering variety of substances and origins. The studies make no distinction of even such elementary differences ad soluble or not, reactive or inert, acid or alkaline, biodegradable or not, etc.

Finally it is clear that mortality and morbidity depend on a host of factors that need to be accounted for and were not accounted in any of the studies (See: Green LC, Crouch EAC, Lash TL. What's wrong with the National Ambient Air Quality Standards (NAAQS) for fine particulate matter (PM_{2.5}). *Regul. Toxicol Pharmacol*. June 2002).

The report by Invernizzi et al. - classified as a pilot study - suffers fatally from a variety of methodological problems, from results that are manifestly not interpretable, and hence from conclusions that are erroneous. Besides, the title

is misleading because the study did not attempt to distinguish what was the fraction of smoke-derived particulate within the generic particulate that was measured.

The single room, single cigarette set-up.

The Materials and Methods section lacks fundamental information. It does not indicate whether windows and doors were present, and whether they might have been open or closed during the experiment. It states that the aeration in the test room was common with other rooms, that the ventilation rate was 2x/hour, but does not indicate the makeup rate, namely whether the incoming air is all fresh air from outdoors or whether it is fully or partially recirculated. This is important because baseline readings were conducted at 9:00 AM, the time when people start working in other rooms, generating particulate that could enter the test room unless the makeup is 100% fresh air filtered below PM_{1.0}, if the air-conditioning inlet intakes air from a Milan's urban air that cannot be free of particulates. In Figure 1 the PM count in the experimental room is stated to have been essentially zero at the beginning of the experiment: a remarkable reading. Indeed such a value is surprising (incredible?), unless the room was a unidirectional flow clean room. Any way, essential to a correct experimental set-up would have been a continuous monitoring of particulate at the room air inlet, synchronous with the particulate measurement in the room itself.

The paper states that the reading instrument was situated at 1.5m height at the centre of the room, with the notation "a parete" which is Italian for "on the wall" and equivocally interpreted as in vertical position. The smoker was positioned at 2m distance from the instrument, but no indication is given of the position relative to the room airflow. No mention is made of the all-important geometry of the experimental set-up, and of the location of air intakes and exhausts.

The results in Figure 1 are a clear indication that the experimental set-up was inadequate to determine the PM contribution of one smoked cigarette in a room of 30m³ volume and 2x/hour ventilation. This is because the average cigarette produces 15 mg of particulate (See: Nelson et al. Composition of environmental tobacco smoke (ETS) from international cigarettes and determinations of ETS-RSP: particulate marker

ratios. *Environment International*. 1997;23:47-52; Nelson et al. Composition of environmental tobacco smoke (ETS) from international cigarettes part II: nine country follow-up. *Environment International*. 1998;24:251-257). Thus, 15mg in a 30m³ volume would produce a maximum of 500µg/m³ of particulate when appropriately mixed. This figure would be considerably reduced by the 2x/hour ventilation if the incoming air were particulate-free, and by the absorption of particulate to environmental surfaces in the room. Indeed the results in Figure 1 are in stark contrast to published studies, whereby in an unventilated and sealed room of 45m³, six smokers smoking six Italian cigarettes produced a maximum particulate level of 1600µg/m³ (see: Nelson et al., 1997, 1998 above).

Missing is the information of how the cigarette was smoked. Assuming it was smoked by a person, the maximum PM reading was reached 10 minutes after the first puff, namely at the time that the smoker stopped smoking, given that a cigarette is normally smoked within 10 minutes. Within and additional 20 minutes the PM measurement approached zero again. The kinetics of the reported measurement are inconsistent with a dispersion in a 30m³ volume at 2x-ventilation rate. Assuming a mixing of medium dispersion efficiency, the peak concentration would have been reached some 30-40 minutes after the cigarette had been smoked. Instead the results in Figure 1 are consistent with poor air mixing in the room, with a geometry that creates local unidirectional air-flow conditions, and with the positioning of the monitoring instrument exactly downwind from the smoker.

The results of the study also are in contrast with the conclusions of the US Environmental Protection Agency, which agrees that the particulate concentration attributable to cigarettes in real life room-level environments average below 50µg/m³ (See: Respiratory health effects of passive smoking. Lung cancer and other disorders. United States Environmental Protection Agency, Office of Research and Development, Washington, DC. 1992).

The restaurant set-up

The Materials and Methods section gives no information as of continuous PM measurements

at outdoor air-intake during the experiment, filtration efficiency, fresh air makeup rate, ventilation rate, airflow direction, continuous PM measurements at the room air inlets during the experiment, geometry and density of furniture, curtains, carpeting, etc. No information is given as of occupancy rates, smoking frequency versus time, type of food served, etc. Lacking this basic environmental information, the set-up is not a controlled one and therefore the results are not interpretable. Further impediment to interpretation is a presentation of data of the smoking and non-smoking sections that are not synchronous, but derived from sampling at different times.

By any reasonable appraisal the reported set-up is not experimental nor scientific, and even as an observational set-up is lacking fundamental structure and information.

The PM level in the non-smoking area at 21:25 PM is higher than the level in the smoking section at 21:45 PM. Between 21:45 and 23:05 PM, the average level in the smoking area is barely above the peak concentration in the non-smoking area at 21:25 PM, suggesting a difference of less than $50\mu\text{g}/\text{m}^3$, in line with the assessment by the US Environmental Protection Agency, as noted above. About the only generic indication to be garnered from the numbers reported is that by far the main contribution to PM must come from sources other than smoking.

OVERALL CRITIQUE

The authors seem unaware of the international disputes about the validity of epidemiological studies of outdoor air PM and morbidity and mortality. Above all they take for granted that environmental tobacco smoke is a major health risk, likely basing their conclusion on a 1992 review by the US Environmental Protection Agency (USEPA. Respiratory health effects of passive smoking. Lung cancer and other disorders. United States Environmental Protection Agency, Office of Research and Development, Washington, DC. 1992). They

The conclusions of the study

The authors appear to accept their results at face value as if correct and sufficient to invoke stringent air quality regulations. They attempt to corroborate their single-room/single-cigarette results by misquoting Nelson et al. (Studies of environmental tobacco smoke generated by different cigarettes, *J Air & Waste Managem Assoc* 1998;48:336-344), a study in which 6 cigarettes were smoked in a sealed and unventilated room, not 1 as the authors of the paper misrepresent.

For the restaurant observations, the authors seem oblivious to the fact that the observations reported cannot establish the contribution of smoking to the PM levels in the smoking section. The authors state that in the smoking section the PM levels are orders of magnitude above what is permitted outdoors by law. The implication is that the law is correct, when in fact it is clear that the Italian law must have been written without a critical analysis of the epidemiological evidence.

The authors seem to make the same absurd assumption made by the epidemiological studies, namely that all PM is the same. The authors conclude (p.9) that “the data demonstrate much elevated concentrations of fine particles from cigarette smoke in public establishments that citizens frequently visit”. Such a statement is not sustained by any of the observations presented in the paper where, besides the set-up shortcomings noted above, no attempt has been made to distinguish cigarette-generated particulate from the generic particulate that was measured.

seem oblivious that such a report has been declared fraudulent and was voided by a US Federal Court (Osteen WL: Order and Judgment in: Flue-cured Tobacco Cooperative Stabilization Corporation et al. V. United States Environmental Protection Agency and Carol Browner, Administrator, Environmental Protection Agency. U.S. District Court, Middle District of North Carolina, Winston-Salem Division. July, 17, 1998). The Court order has not been changed to this day, even though the unwarranted conclusions of USEPA are still used invalidly in creating Draconian but Utopian regulations in many countries.

The authors appear unfamiliar with the literature about the contribution of environmental tobacco smoke to indoor and outdoor air PM.

The observational measurements reported do not deserve to be qualified as “data”, given the absence of elementary experimental precautions that even a pilot study requires. That the study was actually published, speaks of the weakness

of the peer review system. The study fails as a pilot exercise, and is deplorable even as an amateurish attempt. The authors are obviously scientific dilettantes, and as a minimum the National Tumor Institute of Milan should hastily retract the study.

The FORCES International Scientific Committee ^[*]

[*] The FORCES International (www.forces.org) Scientific Committee includes scientists, researchers, analysts, technicians, medical doctors, and engineers. These people still exercise their professions in universities, laboratories, or as free professionals in several nations. Because of the environment of intimidation, moral, and financial lynching by the international “health” establishment against those who expose antismoking frauds, the direct exposure of the above-mentioned people would almost certainly represent professional and economic damage for them and for their families, as has already happened for those who have come forward in the past.

Notwithstanding that, all the members of the International Committee share a love for the truth, and a hatred for frauds and disinformation turned to political and commercial ends. They express disgust and concern for the deep corruption of the institutions of “public health”, which has great social repercussions on our and future generations. The members of the Committee contribute their work either for free, or for a very modest compensation for live expenditures by FORCES International.

To these people, FORCES offers the protection of guaranteed anonymity, and expresses the greatest admiration and gratitude of its readers and members in the world – and the appreciation of all those who have the fight against the healthist corruption at heart.

However, it is impossible to ignore that those who still have the courage to denounce frauds and deceit are now reduced to circumspection and hiding. That should be a clear warning for those who still insist on believing in the honesty of the “health” movement.