

## January the 16<sup>th</sup> Eternit Hearing

by

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" *Asbestos exposure causes lung cancer and mesothelioma, as well as cancer of the ovary and the larynx and asbestosis. Asbestos is the most important occupational carcinogen worldwide with about 125 million people exposed to asbestos in the workplace.*' The statement is reported in the '*Azzolina et al.* article', published in November 2022 in the authoritative journal *Thorax* and focuses on the '*Rate advancement measurement of lung cancer and pleural mesothelioma rates in asbestos exposed workers*' using 12,578 asbestos cement workers in Italy. It was the subject of a lively exchange between prosecution and defense expert witnesses at the Monday 16 December hearing of the Eternit Bis trial, which is being held in the Novara Court of Assizes against the defendant Stephan Schmidheiny [...].

Another quote from the *Azzolina et al* paper: '*According to global estimates, at least 107 000 people die each year from asbestos-related lung cancer, mesothelioma and asbestosis resulting from occupational exposures. Malignant mesothelioma is one of the worst legacies of asbestos exposure, causing an estimated figure of 27 000 deaths in the year 2017 worldwide.* In this case we are referring to occupational exposures; environmental exposures have to be added such as the ones in the Casale Monferrato area. '*The epidemiological evidence indicates that the frequency of asbestos-related lung cancer, mesothelioma and asbestosis increases with increasing cumulative exposure to fibres*'.

Such is the general picture. The main impact is that mortality rate is advanced and the more the higher the cumulative exposure – cumulative exposure corresponds to the sum of all exposures during a person's working life and is measured as the product of concentration (number of fibres per millilitre of air, f/mL) and duration (in years); its unit of measure are, thus, fibre-years per

millilitre, f-y/mL). Comparing workers with the highest and lowest exposure 40 years after first exposure, an anticipation of 26.6 years was observed for lung cancer and 33.8 for pleural mesothelioma.

The study offers quantitative estimates of the acceleration of mortality from lung and pleural cancers with increasing cumulative exposure to asbestos in the occupational setting for the first time.

The issue is one of the most challenging dilemmas that will face the judges of the Assize Court (Chief Justice Gianfranco Pezone, with judge Manuela Massino and the six members of the Jury, aka *giudici popolari*), when they will have to rule on the liability of the Swiss entrepreneur for the 392 victims of the Casale case.

The question is: does a greater exposure to asbestos simply increase the number of deaths, which is the effect commonly observed by employing standard methods of data analysis in epidemiological studies, or does it also lead (at the same time) to an earlier onset (advance) of pleural mesothelioma? That is, compared to a 'low' cumulative exposure, does an increase in cumulative exposure accelerate, anticipate death from mesothelioma?

This is the firm opinion expressed by epidemiologists Prof Corrado Magnani and Dr Dario Mirabelli, expert witnesses for the prosecutors Dr Gianfranco Colace and Dr Mariagiovanna Compare. The Azzolina study confirms that the higher cumulative exposure to asbestos the sooner mesothelioma deaths occur. As shown in Figure 1, panel B of the paper, for workers exposed to the intermediate category of asbestos exposure (54-620 f-y/mL) reaching a hazard of 0.00001 (corresponding to a death rate of 1 per 100.000 per year) requires an average latency of 37 years, whereas it takes only 32 years for those at the highest exposure level (above 620 f-y/mL). Other examples of disease or death advancement parallel to an increase of the relevant causal exposure

can be found in the scientific literature, but this has been the first study to report on such findings for lung cancer and mesothelioma among asbestos workers.

Prof Magnani and Dr Mirabelli had already given the scientific evidence in support of the anticipation when previously examined on November the 29<sup>th</sup>, 2021, and cross-examined (13 December 2021). They had not mentioned the Azzolina study at the time, because the work had not yet been published.

The defense expert witness Prof Canzio Romano was of an obviously opposite opinion. He said: *'The Azzolina study does not go beyond what we already knew, namely that greater exposure to asbestos fibre corresponds to a higher incidence rate. In other words: the greater the exposure to asbestos, the greater the number of people falling ill with mesothelioma.* What Prof Romano denies is *'that there is an anticipation'* (i.e. that these people with high exposure develop the illness sooner than those with low exposure, thus further curtailing their life expectancy they would have had if they had not been exposed). The tone is provocative: *'I don't know how Prof Magnani can prove it, if he proves it to me I am willing to believe it'.*

According to Professor Romano (and other previously examined defense expert witnesses), either greater exposure to fibres corresponds to an increase in incidence or there is a shortening of the expected latency (i.e. the time lapse between first exposure and death): it is either one or the other.

According to the prosecution expert witnesses Prof Magnani and Dr Mirabelli, increase and anticipation of incidence are two sides of the same coin: the same thing measured in two different ways.

The defense expert witness answered another of his theses: he insists that the role of epidemiology is to observe and analyze the behavior of groups of people, under similar conditions, but the results obtained would be average and probabilistic data; therefore, he believes this type of science cannot be considered valid and cannot be applied to individual cases.

However, Prof Magnani and Dr Mirabelli pointed out this is what is always done: for instance in drug trials, comparisons are made between a group of patients given a new drug to be tested and another group given the standard treatment or a placebo. If the new treatment is shown to be more effective in group A than the old one given to group B, the new treatment is then adopted and, of course, administered to individual cases. Prof Romano disagreed: 'I stand by my idea: epidemiology gives us information about a group, not an individual'. He speaks of 'probabilistic assessments' and rule of thumb.

The prosecution expert witnesses replied to these accusations about epidemiology being regarded as a patchwork of observations on groups and populations, already made in previous hearings:

*"Epidemiology is based on the observation and analysis of actual cases of individuals who have developed the disease".* Moreover, Prof Magnani insisted: *'All studies have a margin of inaccuracy, but the work we have done was carried out in an attempt to avoid systematic errors (i.e. caused by incorrect measurement methods) that would cause the estimated risk to deviate from the actual risk'*. Therefore, *'the average figure obtained is an unbiased estimate, and the results are consistent, repeatable with analyses conducted with different methods'*.

Since the trial against Schmidheiny concerns 392 specific cases of murder, since the beginning the effort the defense has been to raise doubts rather than being aimed at proving something which challenges the Prosecutors. In this case, questioning whether the results of the multiple epidemiological studies can be applied to individual deaths.

## **PLAINTIFF'S EXPERT WITNESSES**

President Pezone also questioned the plaintiffs' expert witnesses Dr Gino Barbieri and Dr Edoardo Bai.

Dr Barbieri was keen to clarify and point out that he had been questioned by the defense concerning 'unknown exposures', i.e. people who developed mesothelioma and whose exposure to

asbestos could not initially be ascertained. "*Research over the years then made it possible to identify the sources, so that now we can classify cases as 'certainly' exposed and not 'probably'.*"

In mesothelioma records (such as the Mesothelioma National Registry *ReNaMs*), it is very difficult to distinguish between 'actual non-exposure', 'probable absence of exposure', 'inadequate retrospective reconstruction of exposure history' or 'total lack of data' among persons for whom no previous exposure to asbestos can be demonstrated.

The question is whether mesothelioma would develop without asbestos exposure? In a debate held at the Afeva headquarters in Casale, in October last year, the Italian epidemiologist Prof Benedetto Terracini (author of the first studies conducted in Casale) asked the American occupational physician Dr Arthur Frank precisely this question, namely whether non asbestos related mesotheliomas exist. Professor Frank said that, if such a possibility exists, it would be an exceptional occurrence.

Dr Bai criticized the fact that Schmidheiny's consultants cited in support of their thesis a study carried out in 2012 by epidemiologists Carlo la Vecchia and Paolo Boffetta. The study content and conclusions matched those of the expert testimony they had given for the defense of former managers of [the chemical company] Montefibre and had been accused of conflict of interest. Dr Bai recalled that 'La Vecchia and Boffetta had stated they had conducted the study with the contribution of AIRC (Italian Association for Cancer Research) but 'AIRC itself had immediately denied this, explaining, among other things, that Prof Boffetta, who works abroad, had never applied AIRC for contributions, also because the association, by statute, can only fund researchers working in Italy'.

## **NEXT HEARINGS**

This part of the Eternit Bis trial before the Novara Assize Court is practically over. The Chief Judge will formally close it in the hearing of January the 30<sup>th</sup> , to allow the parties to produce the last documents. Dates for the discussion were then agreed and fixed.

Monday, January the 30<sup>th</sup> and Friday, February the 10<sup>th</sup> the PPs' closing speeches; Monday, the 20<sup>th</sup> of February and, February the 17<sup>th</sup> , arguments by the plaintiffs' lawyers; Friday, March the 10<sup>th</sup> and Wednesday, March the 29<sup>th</sup>, closing arguments by the defense. The court will schedule a further hearing, probably between the end of April and May, for replies, before withdrawing into chamber and then will announce their verdict.

### **THE JURY MEMBERS PROTESTS**

The jury members, and one in particular voiced their disappointment, first in the courtroom then in the corridor at the end of the hearing: 'Since the beginning of this trial we have not yet received any compensation or refund of expenses. We have waited, but now we have been told that there is no more money for 2021 [nor for later] ! Those of us who are not from Novara, but come from other places and have covered travel expenses as well as suffering inconveniences to balance their work commitments have not received anything'.

When questioned, the Chief of the Assize Court, Dr Pezone, clarified that the administrative-economic issue is a matter for the Turin Court of Appeal. In any case, he hopes that any inefficiency can be quickly clarified and defined.

<https://www.silmos.it/le-esposizioni-piu-elevate-allamianto-accorciano-la-vita-anche-di-oltre-trentanni/>

the Italian version linked above includes photos