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THE ASBESTOS INSTITUTE

sensible management of a natural resource

No Excess Lung Cancers Detected From Chrysotile Exposures Less Than 50 f/cc

Important Study Finds That at Exposure Levels Below a Threshold of 50 f/cc, Chrysotile Asbestos Is Not Linked to Any Increased Incidence of Lung Cancer.

Preliminary results from the largest cohort study of chrysotile workers ever undertaken were released this past September at the 9th International Symposium on Epidemiology and Occupational Health held in Cincinnati, Ohio. The study, conducted by Doctors F.D.K. Liddell, A.D. McDonald and J.C. McDonald of McGill University evaluated more than 11,000 chrysotile miners in Québec born between 1891 and 1926. Initiated in 1966, the study was designed to define as accurately as possible the quantitative relationship between exposure to chrysotile asbestos and the incidence of lung cancer. Cohort data has been collected five times since, the latest in May of 1992.

Based on exposure data gathered by the mines, and comparisons of Standard Mortality Ratios (SMR = observed mortality / expected mortality) the authors concluded that any excess cancer mortality was found only among workers exposed to more than 50 f/cc for a period of 20 years or more.

(see No Excess Lung Cancer on page 2)

Inside

Policy Considerations and Theory, Not Science Have Guided Asbestos Regulations

For years the linear model of risk analysis has been applied to the regulation of chrysotile asbestos exposure. Today scientists are questioning the validity of this approach.

The linear model of risk analysis holds that a substance which is toxic at extremely high doses can have a health impact at levels many orders of magnitude lower - even if there are no observable effects at these levels. The linear model maintain that effects may exist, yet are not detectable with current techniques. This model has traditionally served as a guideline for setting exposure limits and other regulatory action. In the face of mounting evidence that for many known carcinogens there appears to be a threshold level of exposure below

(see Policy Considerations on page 4)

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No Excess Lung Cancers ...

This landmark study confirms the findings of other less extensive research which has found no excess mortality risks resulting from low-level exposures to chrysotile asbestos. For example, Churg (1986) discovered that residents of chrysotile mining communities who were exposed to fibre levels from 200 to 500 times higher than those common in most North American cities showed no evidence of a higher incidence of asbestos-related disease. Other studies examining work place exposures have corroborated these findings. Newhouse & Sullivan (1989) conducted a 40 year mortality study in a factory producing chrysotile-based friction materials. They concluded that despite exposure levels substantially higher than those currently found, chrysotile asbestos was processed with no detectable excess mortality. Similar findings have also been observed in studies of chrysotile exposure in the asbestos/cement industry (Ohlson & Hostedt, 1985;Thomas et al, 1982; Weill et al, 1979).

The Liddell, McDonald & McDonald report not only supports these previous findings, but it makes a significant new contribution to our understanding of the nature of the threshold level of exposure responsible for inducing chrysotile-related disease. In terms of its implications for industrial hygiene policy, the study provides compelling evidence that the controlled-use approach to chrysotile asbestos is not only feasible, but given that current exposure levels around the world are frequently 1 f/cc or less, it is the most logical regulatory option. ■

Previous Data on Chrysotile Exposure Support New Findings

Although the Liddell, McDonald & Mcdonald study is the largest and most thorough cohort study to date, a number of scientific antecedents support its conclusions.

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Churg, A. Lung. *Asbestos content in long-term residents of a chrysotile mining town.* American Review of Respiratory Disease, 1986, 134(1): 125-127.

Study comparing health effects in residents of chrysotile mining towns, where levels are from 200 to 500 times higher than in most North American cities. In spite of higher levels, no evidence of higher asbestos-related disease was found.

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Newhouse, M.L. and Sullivan, K.R. *A mortality study of workers manufacturing friction materials :1941-86.* British Journal of Industrial Medicine, 1989, 46(3): 176-179

The authors confirm that there was no excess mortality from lung cancer, other asbestos-related tumours or chronic respiratory disease.

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Ohlson, C.G. and Hogstedt,C. *Lung cancer among asbestos cement workers; ASwedish cohort study and review.* British Journal of Industrial Medicine, 1985, 42(6): 397-402.

A cohort study of 1176 asbestos-cement workers in a Swedish plant using chrysotile asbestos found no excess mortality at exposures of between 10-20 f/ml.

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Thomas, H.F., Benjamin, I.T.,Elwood, P.C. and Sweetnam, P.M.. *Further follow-up study of workers from an asbestos cement factory.* British Journal of Industrial Medicine, 1982, 39(3): 273-276.

A follow-up study of 1,970 workers in an asbestos-cement factory using chrysotile only showed no significant Standard Mortality Ratio (SMR) excesses. The causes of death investigated included neoplasms and cancers of the lung, pleura and gastrointestinal tract.

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Weill,H., Hughes, J. and Waggespack, C.. *Influence of dose and fibre type on respiratory malignancy risk in asbesos cement manufacturing.* American Review of Respiratory Disease, 1979, 120(2): 345-354.

An investigation of 5,645 asbestos-cement manufacturing workers found no increased mortality resulting from chrysotile exposures of approximately 15f/ml . years.

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A/C Pipe Makes a Resurgence in the U.S.

After several years of uncertainty, the overturn of the ban on asbestos products in the U.S. is beginning to revitalize its asbestos cement pipe industry.

Following the reversal of the U.S. Environmental Protection Agency's (EPA) ban rule many water authorities are considering returning asbestos cement (a/c) pipe to their specifications. Although it has long been recognized for its superior durability, performance and relatively low cost, the introduction of any new a/c pipe systems had been all but eliminated by the EPA ban rule.

In its ruling striking down the ban and phase-out of most asbestos products, the Fifth Circuit Court of Appeals concluded that no substantial evidence was presented to support a ban of asbestos pipe. In fact the proceedings did more to raise concerns regarding the health risks of competing products such as PVC or ductile iron pipe. With the reputation of A/C pipe clearly restored, so too are the prospects for its manufacturers.

In June of 1992, the West San Bernadino Water District officially announced that because of the reversal of the EPA ban, it will henceforth return A/C pipe to its specifications and sanction its installation. Several other city water agencies have followed suit with similar announcements, and many more are considering returning a/c pipe to their specifications.

In addition, the Bureau of Reclamation, a long-time user of a/c pipe and a U.S. Government agency has revoked its moratorium on its installation and has returned it to its material specification list. The Bureau explained that changes in technology and controlling regulations have made it possible to work safely with A/C pipe and have minimized the environmental concerns once thought to be presented by its use.

Prior to the EPA's ban, A/C pipe's technical and cost advantages resulted in more 500,000 km's being installed throughout the U.S.. Although the process of rebuilding the A/C pipe market will be a lengthy one, these latest developments are an encouraging sign for the industry. ■

An in-depth Special Report on the advantages of A/C pipe is available through the Asbestos Cement Pipe Producers Association (ACPPA) or the Asbestos Institute.

EPA's Science Advisory Board Critical of Agency's Asbestos Program

In a letter to EPA Administrator William K. Reilly dated April 21, 1992, the U.S. Environmental Protection Agency's Science Advisory Board (SAB) was critical of the agency's regulatory approach on asbestos.

The comments of the SAB followed a public meeting held on Feb. 24-25, 1992 of SAB's Indoor Air Quality and Total Human Exposure Committee which included several presentations by EPA officials.

Amongst other things, the SAB questioned the scientific basis for past EPA regulatory action regarding asbestos and criticized its research programs which appear to be based on outmoded notions of which fibres need to be measured and controlled...".

In terms of the risks of substitute fibres, the SAB had this to say; " It is possible that replacement fibres for asbestos in products and buildings may be as hazardous or more hazardous than the asbestos products they replace. Such research [on the critical issue of fibre properties] is needed if the Agency is to make scientifically sound policy decisions regarding asbestos and substitute products." ■

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" stringent regulation and frightening publicity have led to public anxiety and chemophobia... the cost of cleaning up phantom hazards will be in the hundreds of billions of dollars with minimal benefit to human health. In the meantime, real hazards are not receiving adequate attention."

P. Abelson
Associate Editor, Science

Policy considerations ...

which there are no detrimental health effects, many scientists are recommending that we rethink our approach to risk assessment. As such, legislators are asked to recognize the limitations of the linear model as a basis for regulatory policy.

Scientific Limitations of the Linear Model

There are a number of serious problems which can arise from applying the linear model of risk assessment which extrapolates from high dose exposures to much lower ones. Any of a number of experimental flaws can alter the slope of the dose-response curve and result in an inaccurate estimate of risks at the low end of the exposure scale. Experimental errors, and the effects of insufficiently large data pools or slight variations in chemical composition are magnified many times over as data from very high doses is extrapolated to very low doses. The end result is that predictions based on the linear model have resulted in gross exaggerations of the actual health risks and carcinogenicity of many substances at low levels of exposure. This has clearly been the case for asbestos. The actual number of asbestos-related cancers observed in the U.S. is more than 20 times less than the original estimates based on the linear extrapolations of Dr. Irving Selikoff and the U.S. Department of Health Education and Welfare (HEW).

Despite these and other serious limitations as well as the existence of other more realistic interpretations of the data, extrapolations from high dose exposures have frequently been used as the principal instrument for determining chrysotile exposure limits and regulatory policy. The reality is that once a risk estimate is calculated and published, regardless of its validity or accuracy, it can be used as a platform to justify unwarranted and extreme action.

All Substances are Potential Toxins

Supporters maintain that it is prudent to err on the side of caution. They believe that although at low doses no carcinogenic effect may be observed, it is possible that these effects exist, but are undetectable with current data and methodology. In theory, this is true. Zero risk for any substance cannot be proven with absolute certainty, nor will it ever be. Clearly **all** substances are potential toxins and can never be proven to be without risk. This includes exposures to common and essential substances such as salt, water or even oxygen. At very high doses any substance can be carcinogenic and the risk factor will always decline as the dose declines. Conversely, even the most toxic substances such as arsenic are not only safe at low doses, but necessary to our survival. The challenge for regulators, with the assistance of scientists, is to determine what level of safety is acceptable. In the case of chrysotile asbestos and many other substances, the linear model of extrapolations has proven ineffective. The high level of uncertainty in extrapolating from high doses to much lower ones is beyond that which is acceptable. It has led to misinformation, unrealistic risk estimates and ultimately to ill conceived and unrealistic regulations.

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Redefining the Basis for Regulatory Action

Today many scientists believe that extrapolations should be restricted to one order of magnitude outside the observable range (see article on National Toxicology Program). As the faulty risk estimates for chrysotile have demonstrated, extrapolations below this range are not reliable, accurate or useful. In addition, the notion of a threshold level of cancer induction is gaining acceptance in the scientific community as well as in the regulatory arena. Research such as the Liddell, McDonald and McDonald study provide compelling evidence for the existence of a threshold for chrysotile related disease which is many times higher than currently acceptable exposure limits. Critics may say that in theory, even though no increased cancers were observed below 50 f/cc, it is possible that chrysotile has a carcinogenic effect that is not detectable. If there is no observable carcinogenicity and no increased incidence of cancers, and this has been shown time and again through numerous studies across different populations, perhaps the issue of theoretical risk is a moot one. Regulators must look at the observed threshold, consider an adequate safety factor and determine exposure limits based on the strength of human epidemiological data. ■

Sources:

Tubiana, M., *The Carcinogenic Effect of Low Doses of Carcinogens.* British Journal of Industrial Medicine, 1992; 49:601-605

Harris, W.E., *Low-Dose Risks and Authoritative Misinformation.* Department of Chemistry, University of Alberta, 1991

Abelson, P.A., *Testing for Carcinogens with Rodents.* Science, 1990, 249:258.

Overturning the Verdict on Carcinogens

Review Board Says Methodology for Classifying Carcinogens is Flawed; Questions validity of existing procedures.

In a surprising announcement, an Advisory Review Board established by the U.S. National Toxicology Program (NTP) has questioned the scientific basis for applying the concept of *Maximum Tolerated Dose* (MTD) in identifying and classifying human carcinogens. The review board concluded that two thirds of NTP carcinogens would no longer be identified as such if the MTD was not used. "The implicit assumptions underlying extrapolations from the MTD ... do not appear to be valid."

As its name implies, the MTD method involves injecting laboratory animals with the highest dose compatible with bare survival. Based on their response and the level of cancerous effect produced, predictions are made regarding the carcinogenicity of vastly lower exposures in humans.

The NTP Review Board noted several major concerns with the MTD methodology employed. In particular it questioned assumptions about the rate at which substances are absorbed at different doses; the linearity of the dose-response relationship; the rate at which the body repairs genetic damage at different doses; and the generalizability of data from animals to humans. G.B. Gori, the former deputy director of the Cancer Cause and Prevention Division of the National Cancer Institute commented that "some of these assumptions are intuitively questionable and, as the report makes clear, there is now ample evidence and widespread consensus that they are scientifically untenable."

Mr. Gori goes on to say that despite fundamental flaws in the MTD methodology, these studies " have been the basis of far-reaching regulatory actions costing the U.S. economy billions of dollars." Moreover, he believes that these mistaken assumptions have created and sustained many of the myths associated with the pervasive fear of cancer in our society.

" Most regulatory policy in the U.S. has been based on the twin dogmas that animal and human susceptibilities to carcinogens are equivalent, and that 'no-effect thresholds' at low doses do not exist. Both have been the philosophical underpinnings of most health and safety regulations regarding carcinogens for more than 30 years. Both are faulty assumptions that the Advisory Review Report now questions." concluded Mr. Gori. ■

Source: The Wall Street Journal, Aug 27, 1992.

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U.S. Study Links Fiberglass to Lung Disease

Does prolonged exposure to fiberglass adversely affect pulmonary functions or produce radiographic abnormalities in humans ?

A recent study by researchers at the University of Southern California (USC) School of Medicine concluded that commercial rotary spun fiberglass appears to produce human disease that is similar to asbestosis. The study, conducted by K. Kilburn, D. Powers and R.H. Warshaw was published in the October issue of *The British Journal of Industrial Medicine*. It examined 284 workers at an appliance factory where refrigerator doors and cabinets were insulated with fiberglass sheeting and loose rotary spun fiberglass.Workers with exposures of twenty years or more were evaluated on a number of tests of respiratory functioning including lung volumes, chest x-rays and physical examination.

The researchers found that in addition to eye and throat irritation in about 20% of the population studied, expiratory flows, which indicate pulmonary dysfunction, were significantly impaired. 43 workers also had evidence of pneumoconiosis on chest radiographs. The authors believe that 36 (13%) of these pulmonary opacities or plural abnormalities were due to fiberglass exposure.

A postmortem analysis of one worker who died just prior to the study showed a substantial accumulation of glass fibres in the lungs. A transmission electron microscopy examination showed that each lung contained approximately 178,000 fibres.

Charles Rossiter, former professor at the London School of Hygiene and Tropical Medicine who currently acts as a consultant to the insulation industry disputes the study's conclusions. He argues that the study does not adequately recognize the compounding effects of smoking and that the control group was not representative. Mr. Rossiter does nonetheless urge the Man Made Mineral Fibre industry to undertake further study into the health effects on users.

Jim Merchant, a leading American authority and director of the Occupational and Environmental Health Department at the University of Iowa believes that this study is " in line with what we know about fiberglass". Mr. Merchant warns that "this may have a lot of implications for people who work in building and construction." Other major American and European cohort studies of the occupational health risks for workers in the Man Made Mineral Fibre (MMMF) manufacturing sector have found lung, trachea and bronchus cancer rates in excess of those expected. ■

Sources:

Marsh, G.M., Enterline, P., Stone, R. & Henderson, V.L., *Mortality among a Cohort of USD Man-Made Mineral Fibre Workers: 1985 Follow-up.* J. Occ. Med. 32, 594- 604, 1990.

Simonato, L. et al. *The man-made mineral fibre European Historical Cohort study: Extension of the Follow-up.* Scand. J. Work, Env. Hlth, 12, Suppl 1, 34-47, 1986

Code of Practice for Synthetic Mineral Fibres

In response to recent human and animal data, representatives from the Quebec Federation of Labour (QFL), with the support of the Canadian Labour Congress have written a draft Code of Practice for the use of Synthetic Mineral Fibres (SMF). The code would include descriptions of SMF, summaries of their health effects, as well as recommendations for proper monitoring, safe work practices and exposure limits. The code would detail work practices based on the different risk factors accorded to various fibres.

A number of recent studies (see article *U.S. Study...*) have found evidence that exposures to some types of SMFs can have serious health effects, including eye and throat irritation, pulmonary dysfunction, non-malignant disease and cancer. Despite the growing concerns of scientists, regulators and the labour movement, some industry representatives such as Frank Cereghini, manager of Occupational Health and Safety at Owens-Corning/Fiberglass Canada maintain that insulation fibres are not carcinogenic.

A new Code of Practice is intended to eliminate the inter-provincial inconsistencies which exist in worker protection policies across Canada and provide guidelines for government policy and industry practices. ■

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