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PLAINTIFF'S EXHIBIT

UC-2214

MEDICAL SURVEILLANCE OF ASBESTOS WORKERS AND THE REQUIREMENTS OF THE NEW OSHA STANDARD.

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Introduction.

The Occupational Safety and Health Administration published Final Rules in the Federal Register on Friday June 20, 1986, entitled "Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite", setting standards amending the existing regulations (29CFR 1910.1001).The new standard reduces employee exposure to asbestos to 0.2 fibers per cubic centimeter of air (f/cc) averaged over an 8-hour day. A departure from the previous standard is the establishment of an action level of 0.1 f/cc TWA-8. If this level is exceeded employers must begin compliance activities such as air monitoring, employee training and medical surveillance. Separate standards have been developed to apply to general industry (including maritime industries) and to the construction industry.

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This paper will discuss medical surveillance as required by the two standards and attempt to determine the rationale for the various techniques which are incorporated in this regulation. The historical facts which need to be considered will be reviewed and used to develop the critique of the medical surveillance requirements of the amended standards.

Historical Background.

It is stated in the literature that the asbestiform minerals have long been used by man and that their use can be traced back to the ancient Greeks. The Greek geographer Pausanias discussed lamps of gold with incombustible wicks of "Carpathian flax" made in approximately 430 BC.. The Romans used woven asbestos cremation cloths and the French Emperor, Charlemagne, is reputed to have impressed his enemies by passing an asbestos tablecloth through fire to cleanse it.

"The fact that asbestos is a hazard to man's health was recognized quite early. In the first century,

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both Pliny the Elder, the Roman naturalist, and Strabo, the Greek geographer, wrote of a sickness of the lungs in slaves whose occupation was the weaving of asbestos into cloth."

The modern asbestos industry dates from the discovery in the 1870's of large deposits of chrysotile fibre in Canada and Russia. Chrysotile is the fibrous form of serpentine. This fibre is white in colour and is long and flexible making it ideally suited for textile uses. Shorter varieties of chrysotile are used in cement products, brake-lining and friction materials manufacture and in composite products which have a multitude of uses. Shortly after the introduction of chrysotile into industrial use three other fibres derived from amphibole minerals were commercially exploited, namely crocidolite, amosite and anthophyllite. Perhaps the most important application of the asbestiform minerals was fire-proofing of buildings and ships.

The first recorded health effects from exposure to asbestos dust in the English medical literature appeared in 1900. Asbestosis is a twentieth

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ACL Doc 17224 · Page 4 of 24 asbestosclaims.law/library/17224/4

century disease. It was Dr.Montague Murray who drew attention to the death of an asbestos exposed worker from pulmonary fibrosis in the absence of any evidence of tuberculosis and who subsequently recorded that a number of the deceased's colleagues had died from a similar condition. Cases continued to be reported in the medical literature, the first comprehensive report on the pulmonary fibrotic effects of asbestos being published in Great Britain by Merewether and Price in 1930. As a result of their recommendations the Asbestos Industry Regulations,1931, were promulgated and the medical surveillance of asbestos workers was required to be carried out by the Silicosis Medical Boards, now known as the Pneumoconiosis Medical Panels. Asbestosis became a compensable illness in the United Kingdom in 1931. The first report of asbestosis cases in the United States of America was made by Pancoast et al. in 1917. Further cases were reported into the 1930's. North Carolina industries figure prominently in the U.S. epidemiologic literature on the subject with reports by Shull in 1936 and Dressen et al in 1938 These investigators reported cases of respiratory impairment and various degrees of "asbestosis" among the groups of workers investigated. Dressen's study was conducted on

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ACL Doc 17224 · Page 5 of 24 **asbestosclaims.law/library/17224/5**

behalf of the U.S. Public Health Service and the permissible exposure limit of 5 million particles per cubic foot of air was based on their conclusions.. This limit remained in effect until 1971 when the newly established Occupational Safety and Health Administration promulgated a 12fibers/cc temporaryStandard. A permissible exposure limit of 5 fibres per cubic centimetre of air averaged over an 8-hour period was permanently established in 1972.This standard reduced to 2 fibres per cubic centimetre of air 8-hour TWA in 1976. Medical surveillance was required by this standard for persons exposed to airborne concentrations of asbestos dust. An action level to trigger the medical surveillance requirements was not incorporated in the standard but was unofficially regarded by OSHA as 0.1 f/cc TWA8.

About fifty years after the commercial exploitation of asbestos started the first suspicions arose that lung cancer deaths in asbestos workers might be attributable to their occupation. Case reports in the USA and UK in 1935 sparked the interest in this subject. It was the same Dr. Merewether in the UK who found that lung cancer deaths occurred in 13% of certified cases of

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ACL Doc 17224 · Page 6 of 24 **asbestosclaims.law/library/17224/6**

asbestosis diagnosed by the Silicosis Medical Boards, whereas none were associated with silicosis cases cases. In 1955 the landmark study of asbestos textile factory workers in Rochdale, Lancashire, England was published by Doll and demonstrated a definite excess of lung cancer deaths in male workers exposed for more than ten years prior to the introduction of the Asbestos Industry Regulations, an excess in men employed for twenty years or more since that time and no excess in others with briefer lengths of employment. The findings of Merewether in 1945 were confirmed by Buchanan in the UK in 1964 when he found that approximately 60% of certified asbestosis cases died of lung cancer. It is unfortunate that smoking histories were not obtained for these cases and that no attempt was made to compare the cases with a control population.

Dr. Selikoff's studies of various exposed worker populations in the United States drew the world's attention to a number of previously neglected facts. Until the publication of his findings in asbestos insulation workers in New Jersey the risk to other than factory workers had not been demonstrated and the disastrous effects of cigarette smoking combined with exposure to airborne asbestos fibres had not been

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DRAFT

realized to its full extent. Table 1 illustrates the overwhelming effect of smoking in combination with asbestos exposure in the etiology of lung cancer.

In 1960 Wagner et al. published their findings which associated diffuse malignant mesothelioma of the pleura with exposure to asbestos. Although the first case of malignant mesothelioma in an asbestos worker is said to have been observed by Leicher in 1954, Wagner was the first to conclusively demonstrate an association between exposure to asbestos and this invariably fatal tumour. Wagner also introduced a new concept into the developing understanding of the asbestos-related diseases, namely that of indirect exposure. He found cases of mesothelioma in young persons whose exposure was to fibers which they inhaled when strapped to their mothers backs while they hand-cobbed pieces of asbestos bearing rock. Cases also developed in the nearby mining town where people were exposed to fibers from the roads which were made from asbestos mine tailings or from the school playing area which was made from the same material. Wagner's work also led to the worldwide development of an interest in determining whether different fibre types produced differences in the

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observed effects of exposure to them. There is a considerable body of evidence that in the crocidolite mining areas which Wagner studied, in shipyards in the UK which used substantial quantities of crocidolite from World War I until the early 1960's, and in people who manufactured crocodolite containing gas-masks during World War II in Britain, this tumour appears more commonly than in mining areas or manufacturing operations involving the use of chrysotile asbestos.

Amosite asbestos (the fibrous variety of the cummingtonite-grunerite mineral series) may be largely responsible for the cases of malignant mesothelioma which have developed in shipyard workers and factory workers in the United States.

Other forms of cancer have been said to be associated with asbestos exposure. Selikoff has demonstrated a slight excess incidence of gastro-intestinal cancers in his study population. Elmes in Belfast also reported an excess of deaths from G-I cancers in insulation workers and so did Newhouse in London. The original cohorts of asbestos textile workers studied in Britain by Merewether and others, exposed mainly to chrysotile fibers, have not shown a similar excess. As Elmes' follow-up of his population progressed

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the excess of deaths from G-I cancers declined over time, possibly indicating the effect of improving controls.

Because the 2f/cc standard was designed to protect workers from developing the "earliest signs" of asbestosis and did not take into account the development of lung cancer, mesothelioma and other asbestos-related conditions, it came under progressively increasing criticism from many quarters. In 1975 OSHA published a notice of proposed rule-making to revise the standard because the agency believed that "sufficient medical and scientific evidence has been accumulated to warrant the designation of asbestos as a human carcinigen." The proposal would have reduced the 8-hour time-weighted average to 0.5f/cc and imposed a ceiling limit of 5f/cc for 15 minutes. OSHA based it's arguments very heavily on the theory that there was no safe threshold level demonstrable for a carcinogen and that the OSHAct therefore required that the PEL be set at a level as low as technologically and economically feasible. This philosophy was rejected by the Supreme Court in the benzene decision in 1980 and resulted in a further delay in the revision of the 1972 Asbestos Standard.

In 1983 OSHA issued an Emergency Temporary

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ACL Doc 17224 · Page 10 of 24 **asbestosclaims.law/library/17224/10**

Standard for Asbestos but it was invalidated by the US Circuit Court of Appeals for the Fifth Circuit in 1974.

Before concluding these remarks about the historical background of the asbestos-related diseases it is necessary to define and briefly discuss two findings which are frequently referred to in reports about asbestos exposed subjects. Lung tissue from asbestos workers contains unusual beaded, dumb-bell shaped or rod-like particles which were originally mistakenly called asbestosis bodies because they were thought to occur only in asbestosis cases. They can be found in sputum and in lung tissue of the general population, larger numbers being present in persons with known occupational exposure and decreasing in number as asbestos exposure possibilities decline. The name asbestosis bodies gave way to asbestos bodies when this was realized. These particles owe their golden colour to the fact that they contain iron and for this reason and because some authorities believe that the fibre core may be made up of materials other than asbestos in some instances they prefer to call them "ferruginous bodies". There is considerable evidence that most ferruginous bodies are in fact asbestos bodies. Asbestos bodies are the "tombstones" of asbestos fibers and are found in the

A04505

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ACL Doc 17224 · Page 11 of 24 **asbestosclaims.law/library/17224/11**

absence of disease thus providing an index to exposure but not having any other diagnostic significance.

The second finding commonly discussed in the literature and probably reported as the most frequent radiographic abnormality in asbestos exposed workers in the United States today is involvement of the pleura manifesting itself as localized pleural plaques or as diffuse thickening (pleural fibrosis). Pleural plaques have been associated with non-occupational exposure as well as occupational exposure to asbestos. When pleural plaques are seen on both sides of the chest the clinician's suspicion should be aroused to the possibility that they are asbestos-related. Plaques are another indicator of past exposure. They used to be regarded merely as an index to past exposure and not of significance in producing impairment of lung function, but it has become clear from studies conducted over many years on workers in British Naval Dockyards that persons with these radiographic findings may be more prone to subsequently developing asbestosis or may even be at increased risk of developing malignant mesothelioma.

MEDICAL SURVEILLANCE

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ACL Doc 17224 · Page 12 of 24 asbestosclaims.law/library/17224/12

DRAFT

In the UK the Silicosis and Asbestosis (Medical Arrangements) Scheme, 1931, made initial and periodic medical examinations obligatory for workers employed in the process of breaking, crushing, disintegrating, opening or grinding of asbestos, and the mixing or sieving of asbestos or any admixture of asbestos, and in the making of asbestos textiles and insulating mattresses. It was believed that these examinations "may be of great value as a means of preventing or arresting the development of asbestosis. Asbestosis was made a compensable disease under the Asbestos Industry (Asbestosis) Scheme, 1931.

In their 1930 Report Merewether and Price recommended "the control of the disease by periodical medical examinations of the workers by which those unfitted by health reasons are prevented from entering the industry, and cases of fibrosis and pulmonary tuberculosis are detected at the earliest possible moment. The ultimate and only reliable test of the effectiveness of the preventive measures adopted in the industry will be found in the statistics derived from the records of periodical medical examinations of workers.....". These words of Merewether and Price

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ACL Doc 17224 · Page 13 of 24 asbestosclaims.law/library/17224/13

remain true today but unfortunately their hopes for the establishment of a statistical data base were never realized and nowhere in the world is it possible to find information of a standardized nature on the incidence of asbestos-related disease in an entire national population.

In the examination of asbestos exposed workers the following has been the traditional approach:

Medical history with emphasis on the respiratory system;

Chest x-ray pre-placement and annually thereafter;

Physical examination with emphasis on the respiratory system.

The introduction of pulmonary function tests did not occur routinely until the late 1950's and proved most

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ACL Doc 17224 · Page 14 of 24 asbestosclaims.law/library/17224/14

valuable in assessing fitness for work and also in determining disability for compensation purposes. Assuming that lung function is normal at the time of pre-employment evaluation the continued follow-up of a worker by means of pulmonary function testing should allow any deterioration to be measured and steps to be taken to remove the worker from any further exposure. There is no adequately documented evidence to indicate that impairment of lung function can regress on removal from exposure to asbestos although some such claims have been made.

Lung function impairment may take one of two forms in the early stages of asbestosis, either reduction in breathing ability, that is to say ventilatory capacity, or impairment of the process of gas exchange in the lungs.In either case the condition may progress to include the other at a later stage or it may become complicated by the changes in function which are associated with bronchitis or emphysema. The impaired ventilatory capacity may be due to diminished lung expansion (restrictive syndrome) related to the fibrotic scarring of the lungs which is the basic pathological process occurring in asbestosis or it may be due to obstruction or narrowing of the

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ACL Doc 17224 · Page 15 of 24 **asbestosclaims.law/library/17224/15**

airways (obstructive syndrome). The latter is not usually the presenting lung function abnormality associated with pulmonary fibrosis but may be present if it is complicated by bronchitis or emphysema.

Impairment of gas exchange when it occurs in asbestos workers may be the result of the thickening of the walls of the air sacs (alveolae) in the lungs and destruction of the pulmonary blood vessels associated with diffuse interstitial fibrotic changes. The ability of oxygen to diffuse into the venous blood and thus re-oxygenate it is impaired by the alveolar wall thickening , and may be further impaired in the presence of tissue destruction and abnormal distribution of pulmonary ventilation. The capacity to transfer gas across the alveolar-capillary membrane is known as the diffusing capacity or gas transfer factor. This can be measured by means of a test known as the carbon monoxide diffusing capacity obtained by the single-breath method. Measurement of the carbon monoxide diffusing capacity (T_L or D_L) requires sophisticated equipment and is not suitable for use in the routine medical surveillance of asbestos workers.

OSHA'S 1972 Asbestos Standard: Medical Surveillance

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ACL Doc 17224 · Page 16 of 24 **asbestosclaims.law/library/17224/16**

DRAFT

When the first OSHA Asbestos Standard was implemented in 1972 the requirements for medical surveillance were based on the traditional methods previously mentioned. The Standard required that every employer "shall provide, or make available, at least annually, comprehensive medical examinations to each employee engaged in an occupation exposed to airborne concentrations of asbestos fibers." The minimum requirement was for :

- a chest roentgenogram (Postero-anterior view 14" x 17")
- a history to elicit symptomatology of respiratory disease
- pulmonary function tests to include measurement of forced vital capacity (FVC) and forced expiratory volume at 1 second ($FEV_{1.0}$).

The 1972 Standard required the employer to provide or make available within 30 calendar days before or after termination of employment, a comprehensive medical examination. No medical examination was required of any employee if adequate records showed that the

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ACL Doc 17224 · Page 17 of 24 **asbestosclaims.law/library/17224/17**

DRAFT

physicians' findings and that employers provide the examining physicians with the necessary information to enable them to carry out their duties.

There is still a lack of good data on the dose-response relationship between asbestos and the various conditions said to be caused by it. The medical surveillance requirements of the new standards go part of the way towards improving the data that can ultimately be studied. In 20 years time some of the unresolved issues may be resolved and some of the uncertainty surrounding the asbestos dose-response be more readily understood.

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ACL Doc 17224 · Page 18 of 24 **asbestosclaims.law/library/17224/18**

employee had been examined in accordance with the requirements of the OSHA Asbestos Standard (29CFR ss1910.1001(j)(2)-(5) within the previous one year.

In general, medical surveillance of worker populations exposed to known health risks is undertaken for two main reasons, namely:

- to record a base-line state of health and follow the population prospectively by means of a designed epidemiological approach which is capable of linking medical and exposure records and evaluating dose-response relationships;

- to provide a tool for the detection of the earliest and least harmful effects of exposure at a stage when cessation of such exposure would be of benefit to the exposed person's continued health and well-being or when active intervention could restore the person to a "normal" state of health.

The second of these objectives can not be met in full since the asbestos-related diseases are not readily amenable to therapy and early effects may not be recognizable at a stage when removal from further occupational exposure could possibly arrest or

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ACL Doc 17224 · Page 19 of 24 asbestosclaims.law/library/17224/19

significantly delay the progress of asbestosis or prevent the occurrence of other asbestos-related conditions.

Because of its increased and widespread use in the U.S.A. in many sectors of industry during the past 50 years and until recent times, it has been estimated that millions of people have been exposed in various ways to the different commercial forms of asbestos. Most of these people have experienced low levels of exposure in comparison to asbestos miners and millers, asbestos insulation workers, asbestos textile workers, workers in the asbestos cement industry, and employees of the friction materials manufacturers.

Pleural plaques without evidence of underlying pulmonary fibrosis on x-ray, lung function testing or clinical examination, are probably an important index to conditions in the work-place where such low concentrations of fibers were encountered. Some observers believe that plaques are related to duration of exposure rather than to level of exposure and that they are a sensitive marker in a population of long-term low-level exposure conditions.

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ACL Doc 17224 · Page 20 of 24 asbestosclaims.law/library/17224/20

Unfortunately the evidence necessary to prove this point conclusively from the study of well-documented medical surveillance records is lacking.

The radiological diagnosis of asbestos-related effects requires special training and skill on the part of the x-ray reader in order to differentiate them from similar appearances due to a number of other fibrotic lung diseases. The 1972 Standard did not make reference to any standardized reading technique or reader qualifications. This defficiency has obviously led to both under and over-diagnosis of asbestosis and other radiological abnormalities associated with asbestos exposure.

Although the 1972 Standard required that a history of respiratory symptoms be elicited, it did not specify the use of a standardized questionnaire. This defficiency has detracted from much of the available medical surveillance data obtained since it is not possible to carry out epidemiological studies on the morbidity of asbestos exposed populations comparing radiologic appearances, pulmonary function changes and clinical findings in the determination of dose-response relationships.

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ACL Doc 17224 · Page 21 of 24 **asbestosclaims.law/library/17224/21**

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1986 OSHA ASBESTOS STANDARDS:MEDICAL SURVEILLANCE.

Once OSHA had made the determination that the 1972 Standard required amendment consideration was given to the revision of the medical surveillance needs. It was determined that two Standards would be promulgated, one for General Industry and one for the Construction Industry. The General Industry Standard applies to manufacturers of asbestos products and workers employed in the primary or secondary manufacturing of such products have to be kept under medical surveillance if exposure is at or above the Action Level of 0.1 fibers per cubic centimeter TWA8. Exceptions to this definition by "process" include service industries such as automotive brake and clutch repair and replacement and the shipbuilding industry which fall under the General Industry Standard.

The Construction Standard applies where workers are potentially exposed to asbestos as a result of removal, demolition, new installation, maintenanceor new construction. The medical

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ACL Doc 17224 · Page 22 of 24 **asbestosclaims.law/library/17224/22**

surveillance requirements of the two standards differ in a number of respects and will be discussed later after the changes which have been made to this section of the new standards have been considered and the rationale for them explained. The new medical surveillance requirements have introduced some modifications to the "traditional approach" but have nevertheless not satisfied all the criticisms of the old standard.

(a) General Industry Standard and Medical Surveillance:

The employer must establish a medical surveillance program for all employees who are exposed to airborne concentrations of asbestos at or above the action level (0.1f/cc TWA_8).

All examinations must be performed under the supervision of a licensed physician and shall be provided without cost to the employee and at a reasonable time and place.

Examinations must include a complete physical examination with emphasis on the respiratory

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ACL Doc 17224 · Page 23 of 24 asbestosclaims.law/library/17224/23

system, cardiovascular system and digestive tract. A comprehensive medical examination as defined by OSHA would encompass

- a medical history and work history
- a complete physical examination of all systems with emphasis on the respiratory, cardiovascular and gastro-intestinal systems
- completion of the respiratory disease standardized questionnaire Appendix D
- a chest x-ray (14" x 17")
- pulmonary function tests to include forced vital capacity(FVC), forced expiratory volume at 1 second(FEV1),
- and any additional tests deemed appropriate by the examining physician.

Examinations are required as folows:

- Preplacement;
- Termination of employment;
- Periodic examinations.

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ACL Doc 17224 · Page 24 of 24 **asbestosclaims.law/library/17224/24**