UNITED STATES DEPARTMENT OF LABOR

WASHINGTON, D.C.

In the Matter of:	
STANDARD FOR EXPOSURE TO ASBESTOS DUST, PROPOSED RULE MAKING	PUBLIC HEARING

Conference Room B
Interdepartmental Auditorium
12th & Constitution Ave., N.W.
Washington, D.C.
Thursday, March 16, 1972

The above-entitled matter came on for further hearing, pursuant to recess, at 9:00 o'clock, a.m., Thursday, March 16, 1972.

BEFORE:

ARTHUR M. GOLDBERG, Hearing Examiner

APPEARNCES:

(As heretofore noted.)

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Are there any questions of Mr. Nobel? You are excused, sir.

MR. FUNDBACK: Dr. George W. Wright will be our next testifier.

STATEMENT OF MR. GEORGE W. WRIGHT, M. D., HEAD OF THE DIVISION OF MEDICAL RESEARCH, DEPARTMENT OF MEDICINE, ST. LUKE'S HOSPITAL, CLEVELAND, OHIO

DR. WRIGHT: Mr.Goldburg, my name is George W. Wright. I am the Head of Medical Research in the Department of Medicine, of St. Luke's Hospital, Cleveland, Ohio.

In 1932 I received the MD degree from Indiana University School of Medicine. After five years of Post Graduate Training in Internal Medicine, with special training in pulmonary disease I spent two additional years in research training in the Department of Physiology at Case-Western Reserve University.

From 1939 to 1953 I was a member of the Saranac Laboratories of the Trudeau Foundation engaged in studies of the pneumoconiosis, including asbestosis. Since 1953, I've continued this general field of study in my current position.

My statement will be confined to consideration of a single primary question. This question is: What is the quantity or concentration of asbestos, in the air breathed by those engaged in the production, manufacture, or use of asbestos products, which can be tolerated for a normally expected work life without risk that such exposure will cause disease?

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The answer to this question goes to the heart of these hearings. While the question is rather easy to formulate it is difficult though not impossible to answer.

The obligatory information required for developing an answer to the primary question on an acceptable scientific basis is of two categories. One of these essential categories concerns the dose or quantity of asbestos inhaled and the other essential category concerns the biological response. What we need to learn is the dose-risk relationship.

The dose is estimated in terms of concentration of respirable asbestos in the air multiplied by the duration of the exposure. It is obligatory that we establish a dose, in measurable terms, at which the biological manifestations of disease occurs and then, by observing populations exposed to progressively smaller and smaller doses, determine the level at which the biological reaction to asbestos no longer occurs.

To make observations with regard to the various dose levels of different working populations without knowledge of the biological response of these same populations is of no use in answering the primary question. To make observations of the biological response in various working populations without valid knowledge of the different levels of asbestos exposure experienced by these same populations is equally of no use for finding an answer to the primary question.

Standards for a safe level of asbestos exposure

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proposed or set in the absence of reliable and valid data in both of these two categories must be considered empirical and to some degree arbitrary and should be recognized as such.

I wish to indicate some of the difficulties encountered in efforts to obtain the information essential for determining what the safe level of asbestos in the occupational environment truly is.

Asbestos is a generic term embracing four varieties that are in common commercial use. Of these, chrysotile is used in largest quantities followed by crocidolite, amosite and anthophylite. Each of these has different chemical and physical attributes. Some working populations are exposed to only one variety of asbestos while others are exposed to two or more simultaneously and in varying proportions.

Thus there are several kinds of populations each exposed in quite different ways to one or more kinds of asbes each of which might react biologically in a different manner. Moreover, workers exposed to asbestos are further exposed simultaneously to other airborne agents.

In production, manufacturing, and utilization processes these may differ greatly. For example, the asbestos producer is exposed to asbestos with minimal coexisting agents while, in contrast, the insulation manufacturer inhales asbestos plus silica plus other pneumoconiosis producing dusts.

Insulation applicators inhale these materials plus

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a variety of additional agents present in whatever the environment is in the place where he is working at that time.

Attention to such coexisting agents has been ignored in most studies, especially those of insulation workers. Variations of type of fiber and the circumstances surrounding their use must be taken into account in answering the primary question and would suggest the possibility that different standards might be rational in order to meet different conditions of use of asbestos.

There are four totally different biological phenomena or diseases thought to be related in some way to the inhalation of asbestos fiber. These are pulmonary fibrosis, bronchogenic cancer, thickening of the pleura, and mesothelioma. Not a single one of these diseases is peculiarly related to or caused solely by the inhalation of asbestos fiber.

Each of the four diseases occurs de novo or for other reasons in persons who have never been exposed occupationally to asbestos. The fact is, the biological reaction attributable to asbestos is not a specific kind of disease induced solely by asbestos.

Instead, the biological reaction to asbestos manifests itself by the fact that in some populations occupationally exposed to asbestos, there is, in contrast to non-exposed populations, an excess occurrence of one or more of the four previously mentioned diseases.

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To determine the safe level for the use of asbestos, we are required to demonstrate the level of exposure to asbestos at which no excess of disease develops when the exposed population is compared to a non-exposed population. In order to establish a safe level we must examine suitable control populations not exposed to asbestos, but age matched and residence matched, in which population one can learn the frequency of occurrence of the scentific specific diseases in question.

In addition, we must examine an exposed population, which can be ranked in various levels of exposure, in order to learn at what level an excess of these diseases occur in the exposed population. The observation of a biological abnormality in only one or two persons who have been exposed to the inhalation of asbestos fibers does not permit a comparison for suitable groups, control groups, or afford contrasting exposure values.

Such observations are of no use for determining a safe level standard. Isolated case reports of mesothelioma, bronchogenic cancer, or pulmonary fibrosis in individuals who may also have had an exposure to the inhalation of asbestos fibers are of no use in setting a safe standard for asbestos based upon sound scentific principles.

Larger populations in which only the frequency of occurrence of disease is reported without the necessary data indicating ranges of exposure and in which no attempt to relate variations of exposure to disease is made, fall into the same

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non-usable category of setting a valid safe level.

That is not to say that observations in such groups are of no value for other purposes, but the issue should not be confused by introducing data from such inadequate studies into considerations of safe levels of asbestos exposure. Suitable control populations made up of individuals in sufficient number who were never exposed to the occupational inhalation of asbestos fiber and occupational groups where exposures are demonstrated to have wide variation are difficult to obtain but absolutely essential for our purpose.

The absence of this kind of control data, excused or overlooked on the basis that it cannot be obtained, is an unacceptable condition if the safe level standard is alleged to be set on the basis of universally accepted scientific principles.

There is difficulty also with assessing the frequency of occurrence of the diseases thought to be related under some circumstances to the inhalation of asbestos fiber. There is disagreement as to the criteria for a valid diagnosis of "asbestosis", especially in its least severe manifestation, are not generally agreed upon.

The use of the chest x-ray for diagnosing the early manifestation of asbestosis is a case in point. A recent report by Murphy and his co-workers of a study of employees in a shipyard demonstrated that twenty percent of the control, or non-exposed population gave evidence of x-ray abnormalities which, if observed in the exposed population in the absence of controls, in

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all probability would have been interpreted as being evidence of the effect of the inhalation of asbestos fibers. In a population which has been exposed to asbestos inhalation, it is very tempting to ascribe any departure from a perfect appearance in the chest roentgenogram to the occupational exposure, and indeed, in some studies this has been done.

It is imperative to even recognize that some persons who have never had an occupational exposure to asbestos will show the same x-ray shadows that have been interpreted by some as evidence of asbestosis in populations exposed to the inhalations of asbestos fiber.

Studies such as those by Murphy exemplify the necessity bearing on the determination of a safe standard for asbestos.

There are still other difficulties having to do with establishing the dose risk relationship. The health effects of asbestos inhalation are both dose and lapse-time related.

Over evidences of asbestosis do not appear until years after the initiation of the exposure. The interval between onset of exposure and its effect is even greater for the development of bronchogenic cancer or mesothelioma. This interval ranges between twenty and forty years.

Because of the long time lapse between the initiation of exposure and the manifestation of injury, the incidence of disease occurring in populations now under study is the result of, and must be related to, exposures which took place twenty to forty years or more ago.

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To relate exposure measured only now in the past five or so years to the current frequency of development of disease which actually was induced by exposure occurring years earlier, is a serious error. During the past twenty-five or thirty years there have been many technological changes in the production, manufacture and use of asbestos containing material.

In many situations there is much less asbestos now being incorporated in the material than was true twenty or more years ago. In addition, there has been a progressive dust control effort to reduce the concentration of airborne asbestos in mines, mills and manufacturing establishments in a deliberate attempt to reduce and abolish asbestos related disease.

So much has been accomplished in this direction by technological change and systematic asbestos control efforts, that contemporary measurements of occupational environments cannot be accepted as representative of conditions twenty to forty years ago.

To summarize this part of my statement I strongly urge that when data offered in support of setting a safe level stand... is being judged, one should ask the following questions:

1. What again were the different kinds and proportions of asbestos used and what were the coexisting agents to which workers were exposed in the different occupations?

2. What were the specific criteria and methods used and were they adequate for making a diagnosis

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of the biological reaction attributed to the inhalation of asbestos?

3. Were suitable controls in the sense of non-exposed populations and exposed populations whose exposure varied in the intensity and duration utilized?

4. Was the exposure actually responsible for the disease properly determined or were contemporary dust estimates inappropriately applied to disease which was in fact the result of exposure years ago?

The demands inherent in these questions pose formidable obstacles to arriving at a scientifically valid single number which will indicate the concentration of occupational airborne asbestos that can be tolerated with safety for the customary duration of employment.

In spite of this, as I will show later, there are substantial data which will satisfy the requirements posed by these questions and which again can be used for the purpose of determining at least a first approximation to the safe level of occupational exposure to airborne asbestos.

We must now examine the various established and proposed standards for a safe level of asbestos in the occupational environment, in the light of the just discussed requirements as to data needed for setting a standard on a sound scientific basis.

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Systematic efforts to reduce here the amount of asbestos in the air of working places by governmental directive was made in the factories of Great Britain beginning in 1931. No numerical standard for this purpose was set, but Statutory Rules and Orders were promulgated. Later, on the basis of limited data relating impinger dust counts to x-ray abnormalities in several asbestos textile factories of the U.S.A. Sayers and Dreesen suggested a numerical standard of five million particles per cubic foot as a tentative safe level.

This was the limit adopted by the American Congress of Governmental Industries Hygienists in 1946. Utilizing the conversion data for textile mills published by Lynch and Ayers of the U. S. Public Health Service 5 million parts per cubic foot is the equivalent of approximately thirty fibers/cc.

In 1960 the British Occupational Hygiene Society suggested numerical guides aimed at reducing the risk of developing asbestosis.

The suggested guides indicate that those concentrations, averaged over a three month period below 2 fiber/cc ought to be considered low, and that over the course of 50 years of employment, 100 fiber years is the level below which there would be less than 1 percent change of developing asbestosis as defined chiefly by the presence of rales.

If asbestosis is defined by x-ray abnormality, the level becomes 150 fiber years. In 1960 the ACGIH changed its recommended standard to a time weighted average of 2 million

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particles per cubic foot or twelve fibers/cc. In 1970 this Committee decided to change the standard to 5 fibers/cc which is equivalent to less than 1 million particles per cubic foot.

Several months ago OSHA set an emergency standard of 5 fibers/cc, and within the past few days NIOSH now proposes a standard of 2 fibers/cc.

What is the scientific basis of these various standards? The standard proposed by Sayers and Dreeson did attempt to relate dose of dust containing asbestos, as measured by the midget impinger to the risk of developing pulmonary abnormalities in terms of abnormal x-ray patterns.

Their study showed a higher frequency of abnormal x-ray patterns in those most heavily exposed as contrasted to those less exposed. They found no excess of abnormal chest x-ray patterns than in those workers exposed to less than 5 million particles per cubic foot. Hence their suggested standard of 5 million particles per cubic foot. We now know, however, that the population studied was not observed long enough for the full range of disease to develop.

The authors appreciated this possibility and proposed the standard as being a tentative one. In retrospect we know that the standard, although it led to marked lessening of the dustiness in some occupations, was not adequately based and the passage of time has demonstrated it to be an inadequate standard.

The numbers proposed by the British Occupational

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Hygiene Society are based on a study of 230 male employees from a single asbestos textile mill.

Their employment began after 1933, all had worked for at least ten years, and the exposure period extended from 1933 until 1966. The indicator of disease was basal rales and x-ray changes. No measurements of dustiness in this bill were available prior to 1950.

Membrane filter fiber content counts done in the mo' manner were used only in the last year of the study and these served as the factor for converting previous counts using other methods to an expression in terms of fibers. To obtain an index of exposure for the period between 1933 and 1950 - a crucial period of exposure - the first measurements made in 1930 were raised by 40 percent.

No evidence was given for using this very slight augmentation. Studies in other textile factories such as those by Sayers and Dreesen indicated that when ventilation controls were first applied in their textile mills the dust counts dropped 1,000 percent or more.

One would assume that the same happened in this British textile mill. The seventeen years of exposure during that most crucial period between 1933 and 1950 would appear to have been substantially underestimated.

This study, in spite of its less than adequate scientific base is important because it was the first attempt

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after 1938 to set numerical guidelines for the prevention of asbestosis. The number of persons in the study is very small; the criteria for disease, especially basal rales, not universally accepted; and the estimate of dustiness seriously lacking in rigor. The estimate of dustiness was on the low side for the reasons that I have already mentioned and, in addition, because no attempt was made to further adjust for the longer working hours and hence of exposure during the war and earlier years.

In spite of all of this, the study is a first approximation to a solution of a problem for which there were essentially no other available data in 1968 upon which to attempt a dose-risk estimate.

It is my understanding that the enforcement agency of Great Britain looks upon these standards as guidelines and not as rigid requirements for all circumstances in which asbestos is used. Thus they recognize the incomplete nature of the data used in developing the numbers.

The lowering of the 1938 standard from 5, to 2 million particles per cubic foot and 12 fibers per cc, adopted by the in 1968 appears to have been based in part upon the data underlying the British proposal and also upon the fact that there was a growing awareness that the old standard of 1938 was not universally effective.

The further lowering of it to 5 fibers/cc was not based upon new scientific data, but appeared to have been made

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to establish a margin of or "factor of safety." In a personal communication from Dr. Herbert Stockinger, Head of the Division of Laboratory and Criteria Development of the National Institute of Occupational Safety and Health and Chairman of the Committee on Threshold Limit Values of the American Conference of Government Industrial Hygienists, I am informed that four months ago, in November 1971, the Committee of the ACGIH reviewed the standard of 5 fibers/cc and found no evidence to indicate that it should be changed. There are several relatively current studies which support this decision.

I would now like to discuss five of these supporting studies. Murphy et al, in December of 1971 published data on workers exposed over a period of approximately 35 years as pipe coverers in new ship construction. The authors demonstrated that no evidence of asbestosis was found until at least 60 million particles per cubic foot years of exposure had been exceeded.

This would indicate that for a forty year period of employment, 1.5 million particles per cubic foot would be the value below which no asbestosis occurred. The report indicated that the actual occurrence of asbestosis was restricted almost solely to those exposed to more than 75 million particles per cubic foot years, which would be close to a value of 2.0 million particles per cubic foot for those employed for forty years.

Utilizing a conservative number to convert particles

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to fibers per cc, but arrives at a level of 5 fibers or more as being that below which no asbestosis was observed.

If one utilizes their konimeter data, one can, by suitable calculations, estimate that the average exposure for these workmen was in the neighborhood of 8 fibers per cc, and this too would suggest that a number of 5 or more fibers pe... cc would have been the level below which no evidence of asbe... developed.

This study indicates not only that the old standard of five million particles per cubic foot is unsafe but also that a standard of 5 fibers/cc will prevent asbestosis in employees working for forty years or more.

An extensive and detailed study of a population comprising thousands of workers, in the mining and milling of chrysotile in eastern Canada conducted over the past few years by Dr. Corbett McDonald and his associates is of great importance in our considerations because this study has dust counts going back many years and chest roentgenograms available from approximately 1935 to date.

Dr. McDonald will report on those studies at these hearings. It is my understanding that these studies support the conclusion that those individuals exposed in these occupations for forty or more years would have to be exposed to higher than 6 fibers/cc in order to reveal any evidence of asbestosis.

Becklake and her co-workers, utilizing a segment of

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22 the population from McDonald's larger study, have demonstrated
that in those individuals who have been employed for long
periods of time in the mining and milling of chrysotile asbestos
and who do not even show evidence of x-ray changes, the accumulated
exposure must have been more than 100 million particles per cubic
foot years before the most sophisticated techniques can detect
evidence of those physiologic changes thought to develop in res-
ponse to inhalation of asbestos.

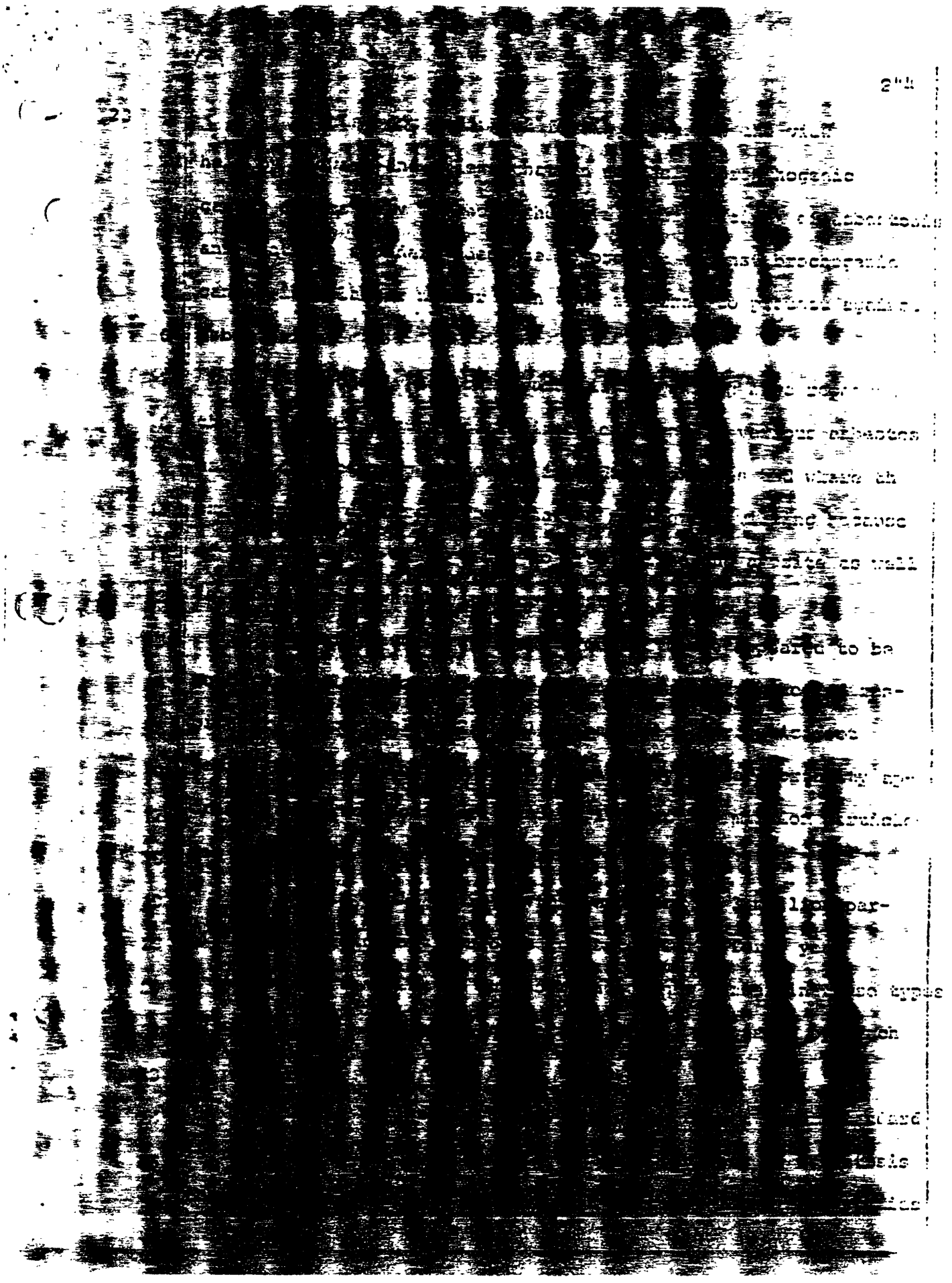
These data suggest that something larger than 2.5
million particles per cubic foot over a forty year period can be
tolerated without even the most subtle manifestations of asbestos
exposure. This number would translate into something between
five and ten fibers per cubic centimeter.

In the fall of 1971 at the Fourth International Con-
gress on Pneumoconiosis, held in Bucharest, Dr. McDonald updated
his previously reported large study and reaffirmed that an excess
of bronchogenic cancer did not occur in tthe workers in mining
and milling of chrysotile asbestos until an exposure equivalent
to 200 million particles per cubic foot years was exceeded.

This is equivalent to 5 million particles per cubic
foot for forty years. It indicates then in the mining and mill-
of chrysotile an excess of bronchogenic cancer would not be
demonstrable in those individuals who were exposed to less than
5 million particles per cubic foot.

This is equivalent to 10 or more fibers per cc.

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offer strong support for the position taken by the American Conference of Governmental Industrial Hygienists that there is no need to lower the standard below 5 fibers/cc in order to protect against pulmonary fibrosis or bronchogenic cancer.

In my judgment, we have no specific information of a suitable scientific nature expressing the dose risk relationship for mesothelioma. Isolated case reports of mesothelioma are of no value in establishing a dose risk relationship.

Equally useless for this purpose are the data offered in studies of insulation workers, asbestos workers, miners and millers, workers in asbestos using manufacturing, domestic exposures and neighborhood exposures.

Not a single one of these studies offers data comparing variable exposures to the incidence of mesothelioma and they are therefore of no use for establishing a safe level of asbestos in the occupational environment. These studies do indicate that in some circumstances the risk is present but none speak to the question of the safe level on scientifically acceptable grounds.

Nevertheless, these studies of a larger number of cases of mesothelioma suggest that, in some circumstances the exposure to asbestos which may be related to the development of mesothelioma might be less than that required to produce asbestosis or an excess of bronchogenic cancer.

One factor, which has been demonstrated which is with

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respect to the relationship between mesothelioma and inhalation of asbestos is of the utmost importance.

In all of these circumstances where a strong relationship between mesothelioma and the inhalation of asbestos is suspected, two varieties of asbestos, namely crocidolite and amosite, invariably have been implicated either alone or combined. This is the case in the excess occurrence of mesothelioma among crocidolite miners, asbestos using insulation workers, workers in asbestos textile and insulation manufacturing, and in a large multiproduct asbestos using manufacturing plant in the USA.

In most of these circumstances there has been a mixed exposure and chrysotile has also been present. In striking contrast, however, when exposure has been solely to chrysotile, as in mining and milling of chrysotile, the frequency of occurrence of mesothelioma has either not been increased or increased only to the very slightest degree.

The virtual absence of an excessof mesothelioma in populations exposed solely to chrysotile has been reported by Gilson, Vigliani, Wagner and McDonald on the basis of separate studies.

With respect to anthophylite, no excess of mesothelioma has ever been reported. On the basis of information currently in mind, therefore, mesothelioma appears to be predominantly linked with exposures to crocidolite or amosite but the

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dose relationships are unknown.

The studies referred to thus far are the only ones I am aware of which in my judgment have a meaningful bearing on the setting of a standard for control of asbestos exposure. Other data does exist but in my judgment, it does not conform to those criteria, universally agreed upon, for a sound scientific basis upon which to predicate a safe standard.

There is an abundant other body of data which indicates that the prolonged inhalation of asbestos fibers above some level is hazardous, that the biological effect is dose related but that many of the workers exposed for a lifetime never do develop asbestos related disease.

This data indicates clearly that past exposures in some occupations, as for example, the mining and milling of chrysotile, were far less hazardous than exposures in asbestos textile manufacture or the insulation worker's trade and possibly in other occupations as well.

The reasons for these differences are not entirely resolved at this time. Until recently the insulation trade used much more amosite than chrysotile and in some work, especially in England, large amounts of crocidolite have been used.

There are coexisting agents in the insulation trade which are not present in mining and milling of chrysotile. The peak exposures appear to be much higher in the insulation trades than in mining, milling, or manufacturing.

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Short term exposure may be much more hazardous than lower levels of prolonged exposure. Fiber counts in the insulation industry in Georgia which are contemplated to Finland, ranged from twenty to hundreds of fibers/cc depending upon the kind of work being done. Fiber counts in the construction industry in this country currently indicate somewhat lower time weighted averages, but the intermittent high peaks of exposure.

For example, during the mixing of asbestos cement, dust counts commonly as high as 75 fibers/cc during a 5 to 10 minute period are reached as often as 3 times or more a day. Unfortunately, there are no data in the insulation trades that compare degrees of exposure over a period of many years to the biological manifestations of chronic disease. Until this is available, there is no way of realistic data upon which to establish a standard for the control of asbestos inhalation.

There is every indication that the levels of exposure should be lowered, especially the peak levels, but whether or not a lower time weighted average standard is needed, in the insulation trade than in the other trades remains unsettled.

Where is reasonable to [illegible] that asbestos fiber and asbestos should be determined more judiciously than is chargeable. There is also reason to believe that [illegible] conformities as are likely in the mining and milling of asbestos fiber may be different from those likely encountered subsequently

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in manufacture and use of asbestos.

Moreover, the fibers of crocidolite and amosite even in mining have a different geometric configuration, as actually observed by Timbrell in airborne specimens, for that of some forms of chrysotile. For these reasons the pulmonary retention of chrysotile may be substantially less than for other varieties of asbestos or for the kinds of fibers generated in other occupations than mining and milling. Animal experiments have demonstrated this to be true.

On the basis of data now available and adequate for the purpose, I wish to indicate that in my judgment a standard of five fibers/cc time weighted average with peaks not to exceed 10 fibers/cc such as recommended by OSHA in its present standard and by ACGIH, constitutes a level which will protect against the development of asbestosis and bronchogenic cancer and includes a safety factor since it is a level substantially below that which has been demonstrated to be associated unequivocally with an excess of these two abnormalities.

There is evidence relating crocidolite and possibly amosite to excess mesothelioma which suggest that a more rigorous control of amosite or crocidolite would be justified. For this reason it may be rational to have different standards covering different occupations depending upon the variety of asbestos used.

Since I am in disagreement with the recommendation of

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the Criteria Development Document that two fibers/cc be established as the safe level of occupational airborne asbestos, it is incumbent upon me to indicate the important points of my disagreement.

In my opinion it is now incumbent upon the authors of the Criteria Document to present evidence, which will meet the requirements for scientific validity in support of their proposal to change the standard and to establish a new one.

In the entire document I do not find reference to a single study containing data which will, on the one hand meet the criteria of scientific validity for setting standards, and on the other, support the need to change the standard from 5 fibers/cc or to set it at 2 fibers/cc.

In fact, the Criteria Document explicitly says on page 10 of Section 5: "The number of studies that have collected both environmental and medical data and with a significant number of exposed workers, is not sufficient to establish a meaningful standard based upon firm scientific data."

In other words, the authors of the Criteria Document do not provide any scientific data upon which to base their proposal to change the standard from 5 to 2 fibers/cc or to support the choice of a standard of 2 fibers/cc. The failure to provide this support, in my judgment casts the most serious doubts upon the validity of the proposals.

I am in complete disagreement with the Criteria

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Document with respect to its expressed opinion that the data relating exposure to biological reaction is inadequate to establish a meaningful standard at this time. While the evidence may not be as far reaching as we would like, it is scientifically valid and adequate to support as a first approximation the opinion that the present standard, established by OSHA several months ago at 5 fibers/cc TWA and peaks not to exceed 10 fibers/cc should not be lowered but left as it is.

I have cited the studies supporting this opinion.

Lacking dose-risk relationship data adequate to support the proposal of 2 fibers/cc the Criteria Document appears to promote an aura of extreme toxicity of asbestos fibers in order to justify the new level. This is done chiefly by citing isolated case reports. In my judgment an inordinate amount of weight is given to isolated case reports, which, though of interest and some importance, have no possible utility in setting a numerical standard.

Their use in the Critical Document is doubly difficult to accept in view of the fact that on page 24 of Section III there is the following statement: "Isolated clinical case reports are difficult to interpret in terms of dose-time response relationship and can only be used to indicate other possible areas and to highlight what may prove to be practicable areas for further study."

An attempt to convey the implication of extreme

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toxicity of asbestos is again made on page 7 of Section 3 by reference to a study of 232 former employees in a plant that manufactured insulation.

This study, by Selikoff, is quoted as revealing four employees who developed x-ray evidence of asbestosis after only one day of exposure to asbestos. Observation of a control group for comparison to those who had been exposed, is totally absent from the Tables for this study that are shown in the Criteria Document.

Murphy's study of pipe-coverers, referred to earlier in this statement, demonstrates beyond doubt that in any adult population not exposed occupationally to asbestos there will be some individuals with x-ray shadows that could be interpreted as evidence of slight asbestosis.

In the absence of suitable controls, Selikoff's study cannot, on scientific grounds, be interpreted to prove that one day of exposure to asbestos causes asbestosis. To do so on the basis of the data shown is epidemiologically unsound and to cite this study as evidence of extreme toxicity of asbestos is completely unwarranted.

The manner in which reports and data of different investigators throughout the world are utilized and criticized does not appear to be uniform in this document. For example, the comprehensive review of the epidemiology of asbestos related cancers by Wagner, et al, published in 1971 is not referred to.

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The report by McDonald, et al, of an extensive epidemiologic study relating dose to risk in 11,780 workers employed in the Quebec chrysotile asbestos mining industry is not discussed in the Criteria Document . This study, published in June 1971 is the single most detailed and complete study of world's literature of the dose risk relationship of one kind of population exposed to airborne asbestos.

The only reference made in the Criteria Document to this study, pages 10 and 20 of Section 3, is a criticism of a "progress report" given by McDonald at the Bucharest meeting in September of 1971. One would think that a study of this magnitude would require discussion in a document intended to be a fully developed presentation of the evidence supporting recommendations of such great importance.

It is difficult to understand why McDonald's report is criticized, as stated at the top of page 20 of Section 3, because of the conversion of numbers of particles to numbers of fibers. Particles are converted to fibers by the British Occupational Hygiene Society in developing their standard and at no place in the Criteria Document, pertaining to the British recommendation, does one see a questioning of that procedure.

If it is acceptable in the one circumstance it should be acceptable in the other.

It is even more difficult to understand the criticism expressed in the last sentence of the 1st paragraph

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on page 20 of Section 1 of there to the effect that the McDonald study lacks the evidence necessary to make general comparisons with the data of other reported work.

The published paper by McDonald's group contains the complete biological data and the required exposure data expressed in millions of particles per cubic foot. This is substantially more data than that furnished by others since it relates exposure to biological effect in the same population whereas other studies such as those of insulation workers do not in any way provide this co-related data.

The index of dustiness used in the McDonald report is the same as in those of Murphy et al, Decouflé-Enterline and Williams, all of which are quoted in this document. The criticism that McDonald did not indicate the details of the method used for converting particles per cubic foot to fibers/cc could easily have been answered by a letter or a telephone call, if the authors of the Criteria Document had been desirous of making the comparisons.

Much weight is given to an unpublished paper by Williams, et al from the Pennsylvania Department of Health. One wonders why, in such an important document as the NIOSH Criteria Package, the crude data of the Williams' study was not shown in the tables of the Criteria Document.

That way in which the sixty-four cases of asbestosis referred to were related to what was undoubtedly a variable

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exposure is not shown. It is very probable that all of these 64 cases occurred in those who were most highly exposed, very possibly in the neighborhood of five million or more particles per cubic foot.

The failure to handle such data in the conventional dose risk relationships is a serious error. Inordinate and unwarranted attention is given to contemporary dust counts. The impression is given that these present day counts represent the conditions that existed over the past forty years. While this may not be intended, more care should be given to indicate that the counts were substantially higher in the past, especially in manufacturing places where effort toward controlling exposures by exhaust ventilation has been expended in the past 30 years.

In addition, the reduction of the amount of asbestos contained in manufactured materials has further reduced the exposures, particularly in asbestos insulation workers.

Most of the counts in the tables of this document are expressed as averages, for example, tables 13 and 14, pertaining to exposures of insulation workers. This is an inadequate way of displaying data, since it can give misleading information by making high exposures if there are a large number of low exposures to dilute the high ones.

Biological effects are much more likely to occur in those persons heavily exposed than in those with low exposure, thus, averages of all exposures have little meaning or use in determining the dose risk relationship.

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It is not possible to evaluate fully the exposure from the data shown in some of the Tables of this document. For this we need to know not only the time weighted averages but also the peaks, the number of observations and the conditions of the environment during the time of sampling.

This criticism is especially pertinent to the exposures of insulation workers shown in Table 14. The insulation worker experiences great variability with respect to job conditions, to a large degree dictated by the volume of the space in which he works and by natural ventilation as well as the kind of work he is doing at the time.

Dust counts under all sorts of conditions, and peak as well as TWA exposures must be measured before the insulation worker's exposure can be portrayed. With respect to Table 14, it is surprising that the job of "cement mixing", notoriously characterized by peaks of exposure as high as 75 fibers/cc for periods of 5 to 10 minutes several times a day, is omitted.

The summary, on page 16 of Section 5, describing the basis for the new standard recommended by the Criteria Document is confusing and inconsistent. I quote from the second paragraph, "evidence indicates that past and current standards for fiber concentrations in the working places where asbestos fibers occur, though undoubtedly contributing to reduction of the severity and frequency of asbestosis, have not provided complete protection from exposure to asbestos, necessitating development of a new

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standard."

There is evidence that asbestosis developed under some circumstances in places thought to have an average exposure of five million particles per cubic foot, or in modern parlance, thirty fibers/cc.

This was the standard set in 1938. The ACGIH created a new lower standard in 1968 and another still lower, introducing a safety factor in 1970. The British Occupational Hygiene Society suggested numbers that might serve as a standard in 1968.

The current standard in the USA set by OSHA is five fibers/cc and was set only a few months ago. If there is to be a new standard it will be one set since a few months ago, or at most, set since three years ago. The statement in the Criteria Document, to which I have just referred, indicates that the authors have evidence that the standard recommended by ACGIH in 1968 has been inadequate and has not provided complete protection and hence a new standard is needed.

The authors of the Criteria Document should be required to give that evidence and it is obvious that they have not. Could it be that they are referring to the fact that the standard set in 1938 is inadequate and that a better standard is needed?

If so, a lower standard was provided in 1968 and still lower in 1970, and it is this standard which was promulgated as an "emergency standard" by OSHA.

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37 It is this OSHA standard for which I believe there is substantial factual evidence for a suppressive nature.

An even more serious inconsistency is demonstrated on page 16 of Section 5. Close examination of items a, b, c, and d reveals in unequivocal terms that in the judgment of the authors of the Criteria Document there are no scientifically usable data on which to base a standard.

Nevertheless, without such data they decide that the current standard must be changed and moreover recommend precisely what the new one should be. There is a strong inference from the second paragraph of page 17, section 5 that one and perhaps the chief reason for setting the recommended standard at two fibers/cc, is that the British have recommended such a standard.

I disagree with the concept, if actually intended, that this represents a scientifically valid reason for recommending such a standard. Moreover, it is my understanding that the British did not set a standard in the same sense that it is intended to be used under the new Occupational Safety and Health Act.

The British standard is a series of numbers proposed to furnish a guideline with a wide range of personal judgment on the part of their inspectors as to the need for corrective measures when these numbers are exceeded. Under our act it is my interpretation that a standard is to be set which, if not complied with, places the operator under certain penalties. To my mind the two conditions are utterly different.

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I would like briefly to summarize. In this statement I have described the kind of data required for characterizing the dose risk relationship in such a manner, that it can be used for setting an occupational standard for airborne asbestos on a scientific rather than an arbitrary basis.

Because of the difficulties described, much of the new content, concerning asbestos associated disease, is of no use ofr setting a standard. Isolated case reports and data giving exposures or biological effects without relating the [illegible] in the same population are examples of this kind of unusable information.

Unfortunately, much of the data now available is competent only to say that asbestos is more or is less hazardous in different groups and that the exposure is varied. Nevertheless although not numerous, there are specific data competent to speak to dose risk relationship and these can be used for our purpose. I have cited these.

I have indicated the reasons for my opinion that the Criteria Document have failed to do what which is incumbent upon it, namely, to provide sound scientific evidence to support their or your case for a change from the OSHA emergency standard and for a new standard of 2 fibers/cc time weighted average with peaks not to exceed 10 fibers/cc.

I disagree with the view of the Criteria Document that there are no epidemiologically obtained data adequate for the

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purpose of setting a standard. I have cited the studies which I believe are scientifically valid and adequate for setting a first approximation to a standard or safe level of airborne asbestos in occupational environments.

In my opinion, these studies fully support the current OSHA temporary standard of 5 fibers/cc TWA with peaks not to exceed 10 fibers/cc and the recent decision of the ACGIH that there is no need to change from this standard.

It should be emphasized that prior to 1940 and for some years thereafter, when many of those persons now developing disease were actually being exposed, the dust counts in mining, milling, and manufacturing commonly were in the range of 10 to 100 million particles per cubic foot. This was likely most equivalent to 30 to 600 fibers/cc.

There is no evidence that exposures during that period for insulation workers was substantially lower, and, on the basis of British and Finnish data, it was in that range. It is clear then, that the current OSHA temporary standard represents a tremendous reduction from the dust levels of previous years, and in my opinion includes a substantial safety factor.

I believe this level will protect workers, using asbestos over a forty year or more span of employment, from developing asbestosis or experiencing an excess of bronchogenic cancer. If crocidolite and perhaps amosite are more stringently controlled, the liability of experiencing mesothelioma will

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be markedly reduced and probably abolished.

Thank you, Mr. Examiner.

EXAMINER GOLDBERG: Thank you, Dr. Wright. Dr. Nicholson

DR. NICHOLSON: I am William Nicholson. I appreciate very much Dr. Wright's description of what would be admirable scientific procedure to evaluate the standards to obtain doses over a 40 year period, but let me ask some specific questions with respect to his testimony.

One is with respect to the control -- first, a major question with respect to the needs for a controlled population which is indeed a good point.

Could you, Dr. Wright, tell me what the control population was in Dr. Murphy's study?

DR. WRIGHT: Dr. Murphy's study, his control population was a group of individuals employed in the same shipyard which he stated were not exposed to asbestos.

DR. NICHOLSON: Would that group be in the shipyard?

DR. WRIGHT: I am sure they were on the premises, but Dr. Murphy states they were not exposed.

DR. NICHOLSON: The concern for mesothelioma bears upon the question of the incidence in insulation workers. It has been documented that the disease incidence of insulation workers who work in shipyards and who work in construction sites and never worked in the shipyard are the same.

Could you give us some background as to the amount of

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crocidolite or amosite which was used in insulation work other than in shipyards?

DR. WRIGHT: Well, as you indicate or refer to, the British shipyards did use large amounts of crocidolite, and, in so far as I know the insulation workers, and not shipyard workers in this country, have been exposed primarily to amosite.

DR. NICHOLSON: The materials used by non-shipyard insulation workers is amosite?

DR. WRIGHT: That is right.

DR. NICHOLSON: I have been led to understand that it was predominantly crysotile, and that the total use in the United States of amosite was only about 3 percent, perhaps, and that was in shipyard work construction.

DR. WRIGHT: Mr. Goldburg, there are people in this audience who can answer the question better than I can. I can only do it by hearsay. I think others know exactly what was in insulation over the past 40 years.

EXAMINER GOLDBURG: Just testify to the knowledge you ha.

DR. WRIGHT: My knowledge is that it was predominantly amosite until recently.

DR. NICHOLSON: Perhaps we can have comment later by other members on that point.

The main point I would like to raise now is with respect to the discussion you made on the studies of Murphy, McDonald in the various ways reported, and of Enterline where

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[illegible] dust evaluation was in terms of million particles per cubic foot, and you have a conversion from that dust exposure to fibers per cc.

Could you tell me what the conversion factor was that you used?

DR. WRIGHT. The conversion factor for the McDonald study he will give in the ensuing presentation. I don't know what it reported.

In converting the number that were given in million of particles per cubic foot from the Murphy study, I utilized a factor of 2, which is about as low an estimate as anybody has given, 2 fibers per million particles per cubic foot. Most conversion factors are higher than that.

The one for Dutchline, since it involved textile workers, I used Dr. Lynch's conversion factor of 5.

DR. NICHOLSON: Were these conversion factors experimentally determined in either of the two studies?

DR. WRIGHT: I am sure you are familiar with Dr. Lynch's conversion factors. They have all been published. Dr. McDonald will tell you how his were done, by side sampling of impingers. I [illegible] by taking the pictures of fibers in the dust mask on the machine and making a conversion in that way.

Now the conversion I used in the Murphy study, as I indicated to you, I took the lowest one I knew of, which is two fibers per million, because we made no attempt to make a

conversion himself. The counts are immaterial, because it is accepted that the fibers were faithfully captured, and utilizing what was in Murphy's paper, namely an expression of the percent of the dust that was made up of fibers, I made the calculation and it comes to an average of 8.

Now that means there is a range on either side. Somewhere higher, in other words, and somewhere lower.

DR. NICHOLSON: Since the dust exposure, that of the mines, that of the insulation workers and that of the textile workers, are so completely different in the magnitude of all th other material as presented there, there certainly is a need for this in terms of fibers.

Moreover, I would suggest that there is a considerable difference in the fiber size, distribution of fibers in each of these separate operations.

Were any measurements done to indicate that the total fiber size was in these operations going to microscopic sizes, greater than five microns to the full range of sub-microscopic fibers present in the atmosphere?

DR. WRIGHT: So far as I know, this was not done, but I would submit we were talking about a standard set on light microscope studies. I am aware of the questions raised by the electron microscope mined fibers, but they have no bearing here.

DR. NICHOLSON: We are talking about a standard set in terms of the quantities of fibers measured longer than five microns.

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But in addition there are the fibers shorter. Do these fibers here not have potential biological effect also and should that fraction, if it is shorter than 5 microns, should that be acknowledged and related to other exposures?

DR. WRIGHT: Dr. Nicholson, if you are talking about those fibers seen in a microscope, you cannot recognize a fiber ---

DR. NICHOLSON: I am talking about all fibers.

DR. WRIGHT: I don't think that sine fiber enters into our discussion. We are setting a standard in terms of light microscope sizes, and if we are going to talk about the electron microscope size fibers we will have a long, long discussion.

I am prepared to have it now if you are prepared to embark upon that, Mr. Goldburg.

DR. NICHOLSON: What -- one makes a comparison of data contained in conditions in which the dust is so different, and is it not appropriate for a scientific study for a desirable criterion to use that total characterization of that dust cloud used for the dose to which you are attributing a response be completely characterized?

DR. WRIGHT: On the basis of science and a better understanding, I agree we need all this information, and there is some information, of course, on this point, but I can only say, again, that I don't see how it is germane to the subject we are talking about.

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OSHA has recommended standards in terms of the microscop

MR. DEGREGORIO: May I ask a question?

EXAMINER GOLDBURG: Go ahead.

MR. DEGREGORIO: May I suggest for the sake of a complete record that the witness answer as many questions as possible within the scope of his knowledge, and leave the questions of what is relevant to one who has to make a decision, so that extraneous information may be kept out of the record, merely on the basis of what the witness thinks is relevant or not? I think that would be a loss to the record.

EXAMINER GOLDBURG: All right.

MR. WOLFE: Dr. Wright, since you support the reduction from 12 to 5 of the allowable number of particals, this in itself is knowledge. That previous thoughts about what was safe, or modifications needed for them, were changed. You mentioned befo at the beginning of your testimony, that a number of workers could be exposed to asbestos without ever developing disease.

The law, as stated, would have no worker develop disease. What I am really wondering is, since the technical feasibility exists to lower levels in plants down to the 2 that has been recommended by the criteria package, why should not one opt now in a maximum direction of safety?

You alluded to the fact that the new 5 standard contai a substantial safety factor. The question I raise is, is it substantial enough?

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In other words, if any possibility exists for any worker to develop disease at that level, why should it not be lowered to 2 until proven otherwise?

You would have the burden of proof be placed on workers or on people developing data to show that it is unsafe, and I think the burden of proof really in the face of something as disastrous as asbestos needs to be to show that it is safe, and if there is any possibility existing, which I think there is, for the development of disease at 2, why can we not go down to there until it can be proven or shown that 2 is too low, and then perhaps it could be built back up?

DR. WRIGHT: I thought I made it as clear as I could that I believed 5 fibers is safe. I think the evidence clearly supports this, in terms of either fibrosis, which we call asbestosis, or bronchogenic cancer. I don't know what the number should be for mesothelioma, but since it is related to a crocidolite and amosite, if we control those two more stringently we would all probability get rid of any mesothelioma.

MR. WOLFF: What would you estimate the substantial safety factor is?

Or obviously one gets diseases at a certain level, and one says, "We want to really insure protection for the worker." On what basis do you agree or disagree with a close substantial safety factor?

DR. WRIGHT: I think the evidence as I interpret it is

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that every worker would be protected. 100 percent, in my judgment, would be protected from asbestosis or bronchogenic cancer in terms of this being zoned at a level of 5 fibers.

You have to bear in mind that bronchogenic cancer is a common kind of cancer. Some workers will still get it, but it will not be in excess, and therefore there is no greater risk for them to get it at the 2 level than if they had never walked into an asbestos-using factory.

MR. WOLFF: Since we are dealing with measurement of fibers over 5 microns, and since we are not dealing with the fibers or fibrilles which some people think are related to other sorts of disease, are we not assume at least in a number of instances that there is, particularly when there are other forms of asbestosis mixed with the chrysotile, that going down, again, below 5, down to 2, would not increase the possibility of protectio of workers in some of these other areas?

I agree with your idea that it would probably be more adequate to set other standards for these smaller particles, but at this point we have not, and in a sense going down from 5 to 2 for greater than 5 micron fibers is also going to reduce the exposure to some other carcinogens.

Could you comment on that?

DR. WRIGHT: Would you rephrase your question so I can get it more clearly?

MR. WOLFF: We are dealing only with the greater than

five micron fibers. By lowering this number to 2, for instance, or ultimately even to unit, are we not also measuring exposure to an ever increased count of particles and fibers?

MR. WRIGHT: I think you have to look at that in this way, that that is, however particles you may have in mind, which we are not now measuring, have been there over this past 40 years in that environment while we have been measuring 5 microns and over particles.

There are two ways of looking at this. We do have some documented evidence that the electron microscope size fibers are there in very large numbers in the environment that we now know at the five micron level is a safe level, so far as asbestos is concerned and bronchogenic cancer are concerned. We know that the fibers have been there since asbestos has been in use.

I think this is my way of answering your question, that when we use the light microscope size of 5 microns as being the one that we will look at, we are automatically taking care of the EM size fibers, because they have been there all the time.

What you would like to know is, is there a direct relationship between the light sized fibers and the EM sized fibers. That is a piece of information we do not have.

CHAIRMAN GOLDSTEIN: Dr. Wright, let me ask you one question. I am asking questions to establish the record. Do I understand you, then, that the measurement of the 5 micron through the light microscope does not establish the consent of the

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smaller fiber which would be discovered by the electron microscope

DR. WRIGHT: You are correct. It does not.

EXAMINER GOLDBURG: There is no established correlation in content?

DR. WRIGHT: Not as yet.

MR. SIEGEL: My name is Edward Siegel. I am a member of the American Council of Governmental Industrial Hygienists and I have a question in regard to Dr. Wright's statement that the ACGIH has said there is no need to lower the standard below 5.

I am somewhat puzzled by this. I am well familiar with the publication of the TLV's, but in the preamble to this, it states that these are only to be used as guidelines. There is no statement that you are not to lower it below this, or raise it above that, for that matter, and I am just wondering if you have received any other pronouncement or letter from ACGIH or on what you base that rather firm figure.

DR. WRIGHT: I don't think that what I said is in conflict with what you are saying. You are absolutely correct that the principal underlying the TLV's is that if you want to go below them you can.

The suggestion is that you not go above them. The evidence that I had is by personal telephone call, speaking with Dr. Stokinger, and I have a letter in my possession sent from Dr. Stokinger saying that the meeting was held, and they

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had considered and saw no reason to change the TLV as it currently stands at 5.

MR. SIDEL: I would say I agree with that, but the preamble to the TLV is not a statement that it should not be above or below.

DR. WRIGHT: I have no disagreement with that; if somebody wants to go below it, we are in the business of setting something here which is a TLV.

MR. DEGREGORIO: At the very beginning of your presentation you set up certain data of scientific methodology. You expressed a view that in order for a study to be correct, in your judgment the study would have to show an accurate relationship between accurate measurements of exposure and the onset of disease.

DR. WRIGHT: The level at which the excess begins to occur, yes.

MR. DEGREGORIO: You mentioned, also, the possibility that a mixture of asbestos fibers and dust with other agents could affect the study. On that point, am I correct in assuming that you mean that the mixture could either increase or decrease the carcinogenic nature of asbestos fiber?

DR. WRIGHT: "you", is the quickest way to answer that.

MR. DEGREGORIO: Fine. Keep it that way. Now in the light of those criteria or methodologies you have considered as of no value, or no use, and I think these are your words, some

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51 studies made on the relationship of asbestos and disease. You
2 have particularly referred, particularly and repeatedly referred
3 to studies made on inhalation workers.
4 Could you please name some of those studies?
5 DR. WRIGHT: Well, I would say that the studies by
6 Cooper, by Selikoff, by Hames, those come to my mind most
7 quickly. All of them speak of the frequency of occurrence of
8 a biological abnormality, whether it be fibrosis, or whatever.
9 They speak of the frequency of occurrence in the population and
10 study.
11 What is one side of the thing. Not a single one of them
12 rank the severity of the exposure and indicate by such a ranking
13 a comparison to the level at which an excess of these diseases
14 occurs. Not one of them does that.
15 Therefore, they are of no use for the purposes we
16 are sitting here for, namely, setting such a level. That does
17 not mean they are not useful for other things.
18 MR. DEGNAN: What are the things for which they
19 are useful?
20 DR. WRIGHT: To indicate that asbestos is a hazard.
21 MR. DEGNAN: I hope it has not. use them that,
22 surely. Those physicians do not waste time proving what I assume
23 a lot of people have already conceded long, long ago, that there
24 is a relationship between certain exposures and diseases, so
25 presumably these researchers have tried to prove something more

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concrete, more definite than that.

Do you know them personally?

DR. WRIGHT: I don't know Hanes personally.

MR. DEGREGORIO: Do you know what they are trying to prove?

DR. WRIGHT: I can only react to that in terms of what they write, which I can examine with my own eyes, and my interpretation of what they write is what I have said.

MR. DEGREGORIO: Do you know what they think the studies prove? I will be more specific. Do you know that these authors you have mentioned, Selnikoff, and Cooper and the others, do you know if any of them believes that his studies or anybody's studies offer good reason to believe that we need a standard lower than 5 fibers to assure the protection of the health of the workers from either asbestosis or lung cancer, or whatever?

DR. WRIGHT: I can only assume from what I have heard Dr. Selnikoff say that he believes this should be below 5. There are times when he says it should be below 2. This I have heard him say. That is a long way from saying he has the evidence to demonstrate that that is necessary.

MR. DEGREGORIO: Do you think Dr. Selnikoff is a competent worker in the field?

EXAMINER GOLDBERG: I will sustain my own objection to that question.

MR. DEGREGORIO: Would you say, then, on the basis

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53 of your last answer, would you say there is a difference of opinion among the experts in the area, a difference of opinion as to whether something less than five fibers standard is necessary to protect the health of workers?

DR. WRIGHT: I would like you to leave out the term "expert", because that requires me to say who is expert, and I don't intend to do that. But there is a difference of opinion. That is quite clear.

MR. DEGREGORIO: Dr. Wright, you have stressed the importance of peaks. During two days of hearings, cumulative experience has also been stressed as important in producing certain diseases.

Could you tell us if the cumulative experience is also an important factor to consider?

DR. WRIGHT: There is a very scant evidence on this. There is some to suggest, and perhaps Dr. McDonald will refer to this, that if you take dose only, and no time, and this would be what you are talking about, an accumulated dose, that there is a relationship between the excess of all pulmonary fibrosis and dose, but it appears at times equally important, and perhaps it even overshadows this in some circumstances.

Now, my own belief would be that you must have at least some dose. It is hard to believe that you could operate without having some quantity accumulating, but to say that the quantity in the lung of necessity is the controlling factor as to what

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would happen later on, I don't think one could say that and substantiate it.

It is one of the factors. It takes that, plus time. I don't know whether I answered your question. You see, peaks, you have mentioned something about peaks, and they enter into the dose.

MR. DEGREGORIO: Yes, of course.

DR. WRIGHT: Because, as you know, you take any amount of material and you, within the next hour or two, you get rid of a large amount of it. It does not stay in the lung. There is a cleansing mechanism in the lung. Now, the peak doses, and I use the word "may" very advisedly, because I don't know this, but it is possible the peak doses may overwhelm the cleansing mechanism and therefore you might retain more from peak doses than from lower sustaining doses.

It is for this reason that I think peak doses may even be more important than the time weighted averages.

MR. DEGREGORIO: I have heard said, in fact I have seen it written, that there are differences, observable, in the health experience of workers in mining and milling and workers in other occupations.

I think you mentioned more or less the same thing when you referred to insulation. Do you believe that?

DR. WRIGHT: Yes, I believe it. The evidence indicates that.

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MR. DEGREGORIO: Do you know why it happens?

55 DR. WRIGHT: Well, I touched on that in my testimony. I said it was a matter that was unresolved. I think that in mining and milling you have less opportunity for exposure to other things simultaneously, and furthermore, the geometry of the fibers may be different, because fibers bundles, as you handle them, tend to break lengthwise and split longitudinally. So the more the fiber is handled, the more opportunity there is in the handling of the fiber to have it become smaller and smaller.

The chrysotile fiber in many instances is a curly fiber, which, although its diameter let's say is of a certain dimension, by the time you put the curl in it, it is much broader and therefore it gets intercepted on the mucociliary cleansing mechanism and then comes out.

There are animal experiments that show that if you expose animals to curly chrysotile, the fibers retained are less than if you exposed them to straight crocidolite.

So there are reasons you might use to explain the differences between the miner and the insulation worker.

MR. DEGREGORIO: We have made a distinction, then, between mining and milling and the insulation workers. Do you know of any other differences observed by yourself or others among insulation workers and workers, say, engaged in manufacturing

DR. WRIGHT: The data that is in the literature would suggest that the bundle workers, at least, as reported by Dr. Newhouse, have about the same biological experiences as the

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insulation workers have.

The textile workers that have been reported thus far by Dr. Knox I don't think would have quite the same. They would be a little less severe. When you look at these, that is about all there is in the literature to look at in terms of published data that you can examine and make your own mind up about.

In contrast are the mining and milling experiences, the experiences in Italy, the Cyprus experience reported by Gilleson, and so forth.

The chrysotile experiences of these people are quite concordant, and all speak to the finding that the biological effects have been far less severe in mining than in manufacturing.

MR. DEGREGORIO: That seems to me a very important thing to consider because that seems to caution, at least, to caution us in applying results of studies in mining and milling to workers engaged in other occupations, doesn't it?

DR. WRIGHT: I would agree with you whole heartedly. The only study that, to my mind, would go against this is the underlying data which suggests that at least so far as bronchogenic cancer is concerned, the requirement to develop it is that the exposures are quite heavy, and the studies in England which have led them to believe that the exposure must be heavy enough to have at least produced asbestosis before there is an excess of bronchogenic cancer.

This does not apply at all to mesothelioma, to that

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question.

MR. DEGREGORIO: I won't even keep you long. There is one think you said which is very important before these proceedings, and I want to ask you questions about that.

You have said that there is evidence, to your mind, that we need not go below 5 in order to protect the health of workers. In support of that conclusion, you have mentioned the study by McDonald in Canada, which I understood was made on mining workers.

DR. WRIGHT: Mines and mills.

MR. DEGREGORIO: But your conclusion applies across the board, because we are considering a standard to all workers across the board.

DR. WRIGHT: I included Dr. Hesterdine's study, which is on manufacturing.

MR. DEGREGORIO: Right, yes.

Now, what I would like to find out is this: Do those studies which you mentioned prove that somehow that certain type of groups under observation, that no adverse effect has been shown to result from certain exposures, or do they really prove, to your mind, that such exposures, or similar exposures, will not result in adverse biological effects in other groups in general?

In other words, what I am driving at is this: Can we generalize from these results and apply those results to other groups apart from the question of the differences we have seen?

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DR. WRIGHT: Well, your question is an extremely important one, and a very searching unprecedented one. I used the term "first approximation" and I used that advisedly. It should imply very strongly that we don't have all of the evidence necessary to be adamant about all circumstances.

What I am saying is that we are here faced with the problem of having to do something, and we must therefore deal with what we have available to do something with, and the evidence that I have cited includes mining and milling, it includes at least one study of manufacturing, and the data seem strong enough so that in my mind I believe, well, when taken in conjunction with one thing that you may not think is very scientific, and I hope you will permit me one lapse, when you think of the exposures these people operated under in the years when they were having exposures that caused the disease they are now evidencing -- you see, we have no information on people exposed only in the last ten years, and we won't have it for some period of time, because it takes time to develop whatever is going to happen -- if you put these studies together with the fact that we have an enormous reduction, and I think I am as compassionate as m In my judgment we don't need to go below 5 until we have more evidence to suggest that we should.

That is what is meant by "first approximation."

Well, when any evidence comes to bear, I think any open minded person would be perfectly willing to accept new

evidence, but on the basis of the evidence we currently have, and there is one other thing I say that in my mind is so important, and I think we are not subjecting individuals who will work under those circumstances to an excess risk of getting pulmonary fibrosis or bronchogenic cancer.

I made it clear that I am not in a position at this moment to express an opinion in terms of numbers with respect to mesothelioma. The route I have gone here is that I would suggest a more stringent control of crocidolite and amosite, because this seems to be the kind of asbestos that is associated most strongly with excess mesothelioma.

I would recommend a more stringent control, of those two items.

MR. DEGREGORIO: What about chrysotile?

DR. WRIGHT: I would not include chrysotile, because we have evidence that the increase in mesotheliomas is very, very low, and in some studies non-existent, with chrysotile. When you come to pure chrysotile manufacturing exposures, I would have to say we have essentially no numbers, no data. They will be coming within the next two or three years, because there are studies underway at the present moment that should develop that kind of information.

It is hard to find a pure chrysotile exposure, as in mining and milling. I have sought diligently for a pure chrysotile exposure in manufacturing. I know of only four in the

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amosite world. I have not been able to persuade one to undertake studies in those plants. That would be extremely important.

Most amosite, I think perhaps Dr. Selikoff's study at the Paterson plant, and I could be corrected on that, but I think it was essentially pure amosite, and that should bring out some very useful information, provided he can construct something about the intensity of past exposure.

That is essential. It can be the intensity of the exposure or the nature of the material, and you must know both of those factors before you can incriminate one or the other.

If you want to say that it is amosite that is the harmful material, you must also prove then that it occurred in an exposure which was low enough not to do it with other materials. So it gets to be very complicated. I don't know whether I answered your question.

MR. DEGREGORIO: Yes, you did, and I thank you very much.

MR. DAHM: I have a few short questions. You did recommend the 5 fiber standard.

DR. WRIGHT: Yes.

MR. DAHM: While you did not go into engineering controls, is that the method you would suggest to control to the 5 fiber level?

Generally speaking, I mean?

DR. WRIGHT: Yes. I think that -- I am trying to think back.

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I don't know of any other way to do it.

MR. BARAB: Are the engineering controls currently in use designed specifically to lower the exposure level to 5 fibers, and not less?

DR. WRIGHT: Well, I can tell you that in some there are circumstances where the engineering and the purification gets the fiber count below 5. It has gotten it down to 2, and I use the same occupations and circumstances where I think it is under 5. But there are still many places where it has been -- it has not even achieved 5 -- and serious efforts will have to be made to get it to 5.

The other thing that I think should be pointed out is that when we set numbers, and this is, I think, comparable to the spirit which the British regulations run in, when we give a number, let's say, of 5, it means that an operator will have to work at 3.

Otherwise, he is going to be out of compliance very frequently, because you never stay right at 3. You go either side of 3. Some of it will fall in 5 or 3 and 6 ranges, and maybe a month later if the weather is somewhat different or if some other factor is different, he could be back in again.

If you set it at 2, he has to operate at 1, or even lower. It has been designed that to give him his margin of safety so he won't be out of compliance.

The British standards do a little difference, I think.

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[illegible] ... I don't know how you would, based on what is going [illegible] ... To get back to your question, I [illegible] ... the way to get there, and I also think that [illegible] ... where it is below 5, and I don't know [illegible] ... encourage people to go below 5. This is many [illegible] ... The problem is that if you put a limit that is unnecessary, you will run the risk of making some parts of the industry not [illegible] ... comply, and you will be asking them to comply unnecessarily, which I don't think anyone wants to do.

MR. BARKA: You also mentioned earlier in your statement that perhaps there was some element of mix of other substances in the exposure factor, and I am sure you are aware [illegible] ... attempting to deal with other exposures.

In light of this fact that even this we deal with a [illegible] ... substance, or a harmful substance we are going to bear [illegible] ... of other substances perhaps leads to the toxicity [illegible] ... this particular substance, do you propose that we defer, then, taking anything in each instance? Do you see this as an illogical [illegible] ... on our part?

DR. WRIGHT: No, I think that what would be logical would be to make every effort to learn the true culprits, in [illegible] ... the biological effect is. This is done this would in [illegible] ... circumstances.

You cannot ignore the concept that it is mixed

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exposures that do things, especially in carcinogenesis. When you use a pure agent, sometimes nothing happens, when you combine agents, something does happen.

This is the real world. What you strive to do, of course, is that you know the agents that are involved, and these are the ones you try to control. When you don't know the agents, you are not in a position really to do the control.

MR. EARLE: But you would agree to attempt to learn as much as possible about all of them as -- and approach them one at a time so interested parties such as yourself have an opportunity to speak to their particular interest.

DR. WRIGHT: Of course, that is a logical approach, and a very logical and long, hard and tedious one.

MR. EARLE: Agreed.

EXAMINER GOLDBURG: Is there any evidence at this time as to the effect of any other substances combined with asbestos

DR. WRIGHT: Well, yes, if you will permit me, I will do it briefly. There are the striking data that Dr. Selnikoff has, in which, if he excludes the cigarettse smokers, the excessive bronchogenic cancer virtually vanishes. This can be thought to be a premature conclusion in the sense that the numbers involved in the non smoking group are really quite small.

Nevertheless, because the excess is quite high, in the then, I think the small number is significant. So that is one thing. Cigarette smoking, which is an -- accepted in the scientific

54 world mostly --- there are a few people who don't agree -- butmost of the people who look at the scientific data would say there is something which relates cigarette smoking to excessive lung cancer.

When you come to looking at trace material, you take asbestos out of the earth in its raw state and from that time on you handle it mechanically. You start with certain things that are present in the virgin fiber and then you keep adding things to it, and you add some things which are known carcinogens -- nickel, for example-- it takes a very hard steel to, especially with thecidolite, to make it into a form you can use.

So you have the problem of trace metals attached to fibers, and there is some scientific evidence to support the idea that these trace metals may indeed play almost, if not the controlling role, and if we learn that, then, of course you handle that situation by saying, "Don't process your fiber with a material such as nickel."

I am using this as an example only. There is even some evidence which has not been published as yet, but I have been privy to see it, in which it appears some trace metals act as suppressants. You ask are there mixed agents that make you have less chances of malignancy. There is some evidence that this is true, that there are suppressants.

There is the whole question of what do other hydrocarbons which could exist besides those that are in cigarette smoke.

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We know the hydrocarbons are carcinogenic in their own right, and when you begin to have incompletely burned materials, then you form some of these hydrocarbons, and they can be absorbed by asbestos. It is a fairly good absorber, and can be carried on and held inside the lungs.

So there are bits and pieces, the most dramatic, I think, is Dr. Selnikoff's experience.

EXAMINER GOLDBURG: I was thinking in products used in the industry processing. Let me ask you an elemental question which I don't think has been developed on the record. I guess it has been assumed by everyone who has appeared here. There seems to be a general consensus that a fiber level must be established in the asbestos industry. It appears that this is based on empirical study as to the effect of the ingestion of asbestos fibers over periods of time in quantity, and there is dispute as to how much of a period of time and the number of quantities.

Can you tell us what is the peculiar nature of asbestos, the asbestos fiber, as compared to other fibers which are present in the industrial establishments which are ingested by workers over a similar work life period in equal or greater quantity?

What is the peculiar property of asbestos which makes it carcinogenic when other fibers are not?

DR. WRIGHT: I was going to answer your question until the last word, and then I would have to say I don't know what

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makes it carcinogenic. For fibrogenesis, making scars in the lung, we have some observations which don't lead to a final definitive conclusion of the kind you would like. Just let me say that I don't know about the carcinogenesis end of it.

There are data including some going on at the present time in my own laboratory, because I am looking specifically at the question of what is the relationship between the geometry of a fiber and the biological reaction in terms of scar or fibrosis, and one thing that is clear, you have to have a fiber that can be inhaled, and retained.

Because something does not happen even very abruptly. It takes time, and it also takes some amount, that is, there has to be a volume of the material present. I have animal lungs that you could look at where you can see one fiber, and no reaction, and in another place in the lung if there are 15 or 20 fibers, there will be a reaction.

It looks as though one thing that has to happen is that you must have numbers. It must, of course, get there and stay there long enough for something to happen. There are some fibers that are curly that fall out high in the air tubes, and you swallow them or cough them up.

Let's say they get in. Fibers that are small enough to go inside a cell which we call a macrophage, which means a big eater. It is a cell which has the ability to engulf all kinds of things.

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67 If the fiber is short enough or flexible enough to be taken into this single cell, or into a complex of half dozen of these cells, it appears on the basis of what I know about it that such fibers are neutralized and don't do anything. They sit there surround by cells so to speak. That is quite in contrast with what happens with particles where the problem is the reverse.

The cell is killed by the free crystalline silica. This is not ture in the data that I know of with respect to asbestos fibers. When the asbestos fiber is long enough to not be totally engulfed, it appears that then this is the size fiber that does cause the fibrous tissue.

How does it do it? I haven't the answer. There are people who are looking at whether it is a chemical reaction between the surface of the fibers, or whetner it is the fact that you have a long structure sitting there which can act as a physical irritant.

I don't think we are in a position to begin to answer that. But I do think we have on the basis of experiments that others have done, on the basis of experiments that I know of that are going on now, short fibers, less than 5 microns long, they do not cause fibrosis in the lung.

The fibers must be longer than that, and that is of importance to us. Our standards are expressed in terms of fibers longer than 5. That only goes to fibrosis. I have no comment about carcinogenesis.

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EXAMINER GOLDBURG: Thank you very much.

MR. BRODNEUR: Dr. Wright, you stated that a standard of 5 fibers per cubic centimeter would be sufficient and it would not be necessary to go lower than that. In describing standards that existed previous to that, you mentioned that the recent standard which had been in effect for about 30 years previous to 1968 was the equivalent of 30 fibers cubic centimeter.

You have told us during that time you worked on asbestos disease and related pneumoconiosis at Saranac Lake, and since 1953 in a Department of Saint Luke's Hospital.

I wanted to ask you, in these 30 years in which there was a standard in effect, did you at any time publish recommendations in any reports to lower that standard?

DR. WRIGHT: No.

MR. BRODNEUR: Subsequent to 1968 when a standard was an inadequate standard and was lowered to 12 fibers per cubic centimeter, did you between 1968 and the present time, or say last December when OSHA took up the emergency standard of five fibers, did you at any time publish recommendations that the 12 fibers per cubic centimeter be lowered?

DR. WRIGHT: No.

MR. BRODNEUR: What I would like to know is, do you feel the 5 fibers per cubic centimeter is exactly the right level, or would you revise it upwards, or downwards, sir? I would -- I know you wouldn't revise it downward, but where are

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you as far as what you feel would be safe?

DR. WRIGHT: I am right on the 5.

MR. BRODNEUR: Thank you, sir.

MR. ST. LAURANT: My name is Yves St. Laurant. Dr. Wright, you were at Saranac way back in the 1930's, am I right?

DR. WRIGHT: Well, the late 1930's.

MR. ST. LAURANT: The director, the most important director of research work then was Dr. Garten?

DR WRIGHT: He was director, and I considered him an important man.

MR. ST. LAURANT: His first works were published in 1931 with comments on inhalation of asbestos dust and the experimental studies on pneumoconiosis -- 1931.

DR. WRIGHT: You have reviewed it more recently than I have. I will accept your 1931 date.

MR. ST. LAURANT: And in the years up to his death he was very closely assigned, to your personal knowledge I ask, to the problem relating to dust in our mines of Quebec Provin-- where I am from?

DR. WRIGHT: Yes, he was.

MR. ST. LAURANT: These are the same mines which were the object of the studies of Professor McDonald of McGill University, who was here today, am I right?

DR. WRIGHT: Yes.

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MR. ST. LAURANT: Do these mines constitute, according to your knowledge, a reservoir that has been supplying the free world up to 85 or 90 percent of the crystals for the last 40 or 50 years, although mining started up there a century ago?

DR. WRIGHT: I understand that the proportion of the free world supply of asbestos is mined there.

MR. ST. LAURANT: Did I understand you rightly when you stressed it seemed to be a paramount, if not the paramount study, at least as to mining, in connection with pure chrysotile asbestos?

DR. WRIGHT: Yes.

MR. ST.LAURANT: Did I hear you say that Mr. McDonald reported that the incidence of bronchogenic cancer there did not seem to be in excess of the rate affecting the population at large?

DR. WRIGHT: I did not say that, but I understand that the study showed that.

MR. ST. LAURANT: Are you aware, Dr. Wright, that you are considered to be the top consultant in the field in my opinion? Are you aware that there were studies at Saranac from time to time such as the Trurin and Brown study? Brown is at Pittsburgh now, I think. These dealt with the incidence of cancer in the asbestos belt, I would call it, across Quebec, and that this study did also point -- that was in 1954 or 1955 -- did point out that the incidence of cancer did not seem to be in

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excess, maybe not in a substantial portion anyhow, to that existing in the general population?

DR. WRIGHT: That is the substance of the Brown report.

MR. ST. LAURANT: Are you aware of the Metropolitan Life ---

MR. EARLE: May he answer?

DR. WRIGHT: I don't believe the Brown-Truran study is the Saranac Lake study. I gather from what you said that you were inferring that it was.

MR. ST. LAURANT: No, it was an Industrial Hygiene Foundation study. I am sorry, sir. I should like to respectfully ask you if you are aware, also, that the Metropolitan Laboratory conducted an independent study under George Levy, who is now vice president, and I am speaking about in the 1940's, the same asbestos belt of Quebec, as to the incidence of tuberculosis or pulmonary conditions in Quebec and they found as to tuberculosis that the incidence was that of about the general population at large?

MR. EARLE: Mr. Examiner, with all due respect to our visitor from Canada, if he does wish to testify, we would like him to take the stand so that we may have an opportunity to question him about these studies.

MR. ST. LAURANT: I don't think I should testify, but maybe I would be allowed to put one or two more questions just to underscore the importance of the names, because we spoke the

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name of Professor Gilson, and Wagner, who have reported as to important data in connection with the problem now under consideration.

Gilson, is that the Gilson that I know, that you know, who is in charge of the pneumoconiosis research bureau in Great Britain?

DR. WRIGHT: Yes.

EXAMINER GOLDBURG: I am going to cut you off on this, sir. You are testifying, not asking questions.

MR. ST. LAURANT: I am guilty.

EXAMINER GOLDBURG: I would seek to save you from sin, sir.

(Laughter)

EXAMINER GOLDBURG: Is there anything further of this witness? Thank you, Dr. Wright. You have been very helpful.

Off the record.

(Discussion off the record)

EXAMINER GOLDBURG: We will recess.

(Whereupon, a brief recess was taken.)

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